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15 Autumn CMEs

Two Keys to Connection in Healthcare: Presence and Reflective Listening
By William J. Maples, MD, Sandra Argenio, MD, and Jennifer Krippner

The single most important factor in creating an excellent patient experience is the patient’s interaction and relationship with his or her healthcare provider. In multiple studies over the past few decades, patients tell us what they desire most in their healthcare provider—someone who respects and listens to them. Traditional medical training has devoted little time to the development of communication skills. Through training and practice, healthcare providers can develop a culture of excellence where safety, efficiency, quality and experience of patients, families, and caregivers flourish.

43 Quality of Care of Patients with HIV Infection
By Mobeen Rathore, MD, CPE, FAAP, FPIDS, FIDSA, FACPE, FSHEA

The management of HIV infection has improved significantly over the last three decades of the epidemic. The treatment of HIV/AIDS infection has benefited significantly from the progress. National targets and benchmarks are used to determine the quality and extent of HIV care that patients are given in a particular program. In addition, quality of a program can also be gauged by the recognition of a program as a patient centered medical home. Staff can be safe from the potential transmission of HIV if they carefully follow all standard precautions and take blood and body fluid precautions when needed. In addition, the use of safer devices can provide protection against transmission.

Features

Innovative, Data-driven Care for Sepsis: The UF Health Jacksonville Experience
By Faheem W. Guirgis, MD, Lisa M. Jones, MD, Rhemar Esma, MD, L. Kendall Webb, MD, and Kelly Gray-Eurom, MD, MMM

ERAS Implementation: Continuing the Quest for Better, Safer Care for Our Patients
By Patrice Vinsard, MD, Amit Merchea, MD, and Dorin T. Colibaseanu, MD

The Science of Patient Safety:

A Discipline Designed to Understand and Promote Delivery of High Quality Healthcare
By Cynthia L. Leaphart, MD

Surgical Outcomes of Diabetic versus Non-Diabetic Patients Undergoing Vascular Interventions: A Case Study
By Houssam Farres, MD, Dorin Colibaseanu, MD, Tariq Almerey, MD, January Moore, BA, Mahmoud Selim, MD, David Lee, MD, Warner A. Oldenburg, MD, and Albert G. Hakaim, MD

Also in this Issue

Inflammatory Bowel Disease & Pregnancy: Top Ten Questions (Part Two)
By Mark R. Fleisher, MD

In vitro maturation (IVM): a kinder, gentler, more natural, and less expensive way to undertake IVF
By Bruce I. Rose MD, PhD and Samuel Brown MD
H and P: Then, Now and Tomorrow

Since the days of Hippocrates, the history and physical exam (H and P) has been the bedrock of the physician and patient encounter. The face to face interaction, multiple queries of symptoms and problems, past medical history, family history, and the meticulous physical exam provided clues and answers to the ailments of patients. Medical school education focused on time, accuracy, exam skills, and the cerebral process of developing a differential diagnosis. The H and P was to serve as the guide for diagnostic testing, the thoughts and opinion of fellow physicians, and a model of ideal patient care.

However, with the advent of Medicare, billing, insurance, and now the EMR, the history and physical has lost its way. Almost every physician views the H and P as a checklist to get enough points to justify a code in order to get paid. Instead of being valued for years of training, time spent with patients, and doing an appropriate exam, physicians continue to become “check the box” professionals. Leave it up to the bureaucrats at CMS/Medicare to decide that four types of histories and exams exist: problem focus, expanded problem focuses, detailed, and comprehensive. In my mind, any new patient is comprehensive, no matter “how simple” or “complex” of a medical problem they may have. Medicare then dictates to physicians what is a chief complaint, a history of present illness, a review of systems, past medical history, past surgical history, and even what is considered a good/complete physical exam. If that is not enough, Medicare also dictates what it considers an appropriate level of decision making and level of risk. What is considered “simple and low risk” in the eyes of Medicare, is very likely complex and time consuming for the physician. Nowhere in the world of Medicare do the years spent learning anatomy and physiology or training as an intern/resident/fellow factor into physician interactions with patients. “Simple hypertension” is easy to diagnose and treat because we all spent years of education and training to make it “simple.”

The last guidance/update to H and P Medicare regulations was in 1997. In the age of the EMR and more pointing and clicking, it is time to modernize the H and P. Unfortunately, physicians no longer have the time to spend 45-60 minutes with new patients. The H and P needs to be adapted to patient age, physician specialty, and for the EMR. In patients over 65, there is less relevance to the family history. The Review of Systems is redundant and inherently covered by a good history of present illness. The focus on billing and coding should be in the assessment and plan, not in whether a doctor did a 12-point review of systems or documented the lymphatic system on exam. In the era of “cost effective medicine,” a focus on a clear diagnosis and plan is better than the laundry list of medical histories and problems that add nothing to the contemporaneous care of a patient. In order to get paid for our time, work, and expertise, physicians pile on medical diagnosis in a hope that “medical complexity and decision making” is high enough to justify the CPT code for payment. In the era of the EMR, the H and P is often auto populated and parts of the review of system and exam just add to document length rather than substance. In a time where technology and modernization are supposed to make medicine more efficient, the H and P has not been modernized. Physicians need to lead the way of making the H and P a true medical document of thought and idea, rather than a tool for billing and coding.

Maybe it is time, like every other profession (lawyers, dentist, etc.), for physicians to start charging by the hour or a flat fee. This way physicians can be truly valued for their time and services without wasting time meeting the arbitrary 1997 coding and billing guidelines. We can save time, money, and improve patient care and outcomes with this simple but long overdue concept. Time spent talking and examining patients will replace the clicks and endless pages of documentation. ♦
From the President’s Desk

Tackling the Opioid Crisis

The founding of the Duval County Medical Society was rooted in the idea that the epidemics affecting Northeast Florida needed to be addressed. The physicians in our community knew it was of grave importance for them to tackle the diseases that had the potential to cause mass death and devastation. In their time, the primary assailants were infections like malaria, smallpox, and dengue fever. As the years have passed, other conditions have arisen such as polio, HIV and AIDS, various strains of influenza and tuberculosis. We have endured great loss from these diseases and ailments, but none of them has destroyed us. Every time we have been faced with these immense challenges, we have come together and found a way to overcome. While we have almost eliminated conditions like polio and smallpox, and we have made great strides against tuberculosis and HIV, it has always been clear that our fight would continue against these aggressors and that there would be new goons waiting in the shadows, threatening our great community. The latest menace is not bloodborne, airborne or passed on by skin-to-skin contact. In fact, it is not an infection at all. It is an enemy that has attacked populations’ worldwide for thousands of years. It has lurked in the background and quietly pulled at the fibers of our civilizations and now we are beginning to unravel rapidly. This is what drug abuse - specifically opioid addiction - is doing to our society.

The National Institute for Drug Addiction (NIDA) defines addiction as a “chronic, relapsing brain disease that is characterized by compulsive drug seeking and use, despite harmful consequences. It is considered a brain disease because drugs change the brain both in terms of its structure and how it works.” We have records supporting the use of narcotics since 4000 B.C. So, for as long as these substances have existed, so has the ability to abuse them. We began extracting the active ingredients of psychoactive drugs in the 19th Century. This is what led to the emergence of unregulated and freely prescribed drugs such as Morphine, Laudanum and cocaine. Ultimately, this laid the foundation for modern addiction. Those who were wounded in the American Civil War returned home with Morphine kits which led to the development of opium dens or drug houses. It was estimated that over 250,000 morphine addicts were living in the U.S. in the early 1900’s. This was the start of opioid addiction in America. Since 1875, there has been national and local legislation presented, as well as drug education which helped curtail the progression of addiction. Unfortunately, in the 1960’s there was a drastic increase in drug use and the introduction of hallucinogenic narcotics. This trend did eventually change and there was a decrease in the use of most drugs during the 1980’s. Unfortunately, the increase in the use of prescribed opiates has led to an increase in substance abuse and addiction. In response, six states including Florida have declared this opioid epidemic a Public Health State of Emergency. In Duval County, the number of overdoses from heroin and synthetic fentanyl has sky rocketed in every zip code. This has put financial strains on our City budget, as well as strains on morgues and the foster care system. This epidemic is touching us all.

As physicians, we have an opportunity to play a crucial role in putting the reigns on this widespread problem. President Trump has now declared this is a National Emergency. This may assist us in developing programs and interventions that can ultimately eliminate this problem. My goal is to establish a task force that will bring to the table every health system and other stake holders who are ready to think critically and collaboratively on ways to improve the role of the physician in this problem. I recognize that this is not an easy fight and will take long-term commitment and effort from all parties involved. But just as we have fought vigorously against and made strides towards expunging many other great contagions, we will fight this fight and we will win. ✱
In this issue of Northeast Florida Medicine, Duval County Medical Society physicians tackle the tough issue of patient safety and quality. The subject can be a difficult one to broach. No physician wants to cause harm for a patient, and every physician wants the best outcomes for their patients. The movement to tie quality measures to reimbursement is well-intentioned, but adds another layer of complexity to the already cumbersome reporting system.

In fact, the burden of too many bureaucratic tasks was rated as the #1 cause of burnout among physicians according to the 2017 Medscape Lifestyle Report*. That was followed closely by long hours, the feeling of being a cog in a wheel, and EHRs.

Notice that none of those reasons directly relate to doing what physicians do best: caring for patients.

More than 51 percent of physicians report feeling burned out. That’s up 11 percent from a report just three years ago. Emergency physicians have the highest rate at 59 percent, but OB/GYN, Family Medicine, Infectious Disease and Internal Medicine are all close behind with rates over 55 percent.

Physician Wellness is a patient safety issue. A physician who is struggling with depression, burnout, or other stress factors is not operating at 100 percent. That is why the Duval County Medical Society Foundation has joined a growing number of County Medical Societies around the country in creating a Physician Wellness Program.

The Physician Wellness Program is a free and confidential resource for DCMS Members who are dealing with issues of stress or burnout. If a physician feels that they are in need of someone to talk to, they can call our wellness line at (904) 631-1446 and receive up to six free counseling sessions per calendar year. These sessions are considered pre-clinical, or coaching, in nature. That means that there is no medical record retained. That means that there is nothing to report on a medical license renewal.

The DCMS has worked with the Florida Board of Medicine and several other County Medical Societies in Florida to make this resource available for physicians who may not have access to an Employee Assistance Program, or who choose not to utilize one for any reason.

This resource is available for all DCMS Members, whether in private practice or employed by a health system. It is open to Residents and Retired members as well. The goal of the Foundation in creating this program is simple: the DCMS and Foundation are here to help physicians in Jacksonville deliver the best possible care.

Now, it’s time for us to provide that same level of care to our physician members.

I hope that you will remember our program when a friend or colleague might need a little help or encouragement. Or if you, yourself, feel that you’d just like someone to help you deal with the mounting pressures of practicing medicine today, that’s what the Physician Wellness Program is here to help with.

To learn more about the Physician Wellness Program, you can check out our website at dcmsonline.org/Physician_Wellness. There you will find information about our counselors, as well as resources to help you deal with stress and burnout.

Almost two decades have passed since the Institute of Medicine published *To Err is Human: Building a Safer Health System.* This publication presented the startling statistic that 98,000 Americans die annually from preventable medical harm. Many physicians, including myself, were in disbelief that such an enormous number could be correct. Eventually, the skeptics were partially vindicated. The number was incorrect—but not because it was too high. Medical errors may, in fact, account for between 200,000 to 400,000 fatalities every year in the U.S.

Last year, Dr. Martin Makary, a surgical oncologist at Johns Hopkins, made international headlines with his article “Medical error—the third leading cause of death in the U.S.,” which attributed more than 250,000 deaths to preventable harm. This article rekindled the widespread sense of disbelief over the scope of iatrogenic injuries, and inspired an international debate on the methodology used by Dr. Makary and his team to arrive at its conclusions.

Setting aside the debate over the precise number of patients harmed unnecessarily by healthcare, clinicians can agree that we have a long way to go before we can achieve the same degree of safety and reliability of other industries. For example, I fly on commercial aircraft every week without a moment’s concern for my personal safety. I wish I felt the same confidence about the prospect of undergoing a minor outpatient procedure.

Achieving high reliability in healthcare remains an aspirational goal, and the solutions will be not only technical, but also cultural and social. This edition of *Northeast Florida Medicine* highlights some of the important work being performed in our region to advance the science of patient safety as well as improve provider effectiveness and patient experience.

Late recognition contributes to the enormous death toll of sepsis. Drs. Faheem Guirgis, Lisa Jones, Rhemar Esma, L. Kendall Webb, and Kelly Gray-Eurom, of University of Florida Health Jacksonville, describe their development of an approach to early sepsis recognition and treatment that leverages evidence based care along with automation and information technology. As a result of this initiative, UF Health has demonstrated decreased mortality and length of stay in this patient population.

One of this issue’s CME articles is written by Drs. William Maples and Sandra Argenio from the Institute for Healthcare Excellence, along with Chief Experience Officer Jennifer Krippner. They discuss the role of mindfulness and reflective listening in healthcare. The role of communication in safety and quality, as well as patient and provider experience, cannot be overemphasized. The authors define these strategies as well as their impact on patient perception of care and provider resilience.

Drs. Patrice Vinsard, Amit Merchea, and Dorin Colibaseanu, from Mayo Clinic Jacksonville, review their implementation of Enhanced Recovery after Surgery (ERAS). ERAS is an innovative approach which requires providers to rethink some of the conventional wisdom relating to perioperative management as well as engage in multidisciplinary collaboration. The ERAS program at Mayo has proved to decrease length of stay and readmissions.

Dr. Cynthia Leaphart, Assistant Professor of Surgery and Anesthesiology at UF Health Jacksonville, outlines the organization’s Patient Safety Fellowship. This program, initiated in 2010, trains future healthcare leaders and provides a unique resource for our region.

The final article comes from Mayo Clinic Jacksonville. Drs. Houssam Farres, Dorin Colibaseanu, Tariq Almerey, Mahmoud Selim, David Lee, Warner Oldenburg, and Albert Hakaim, and team member January Moore, report on the impact of the concomitant diagnosis of diabetes on outcomes in vascular surgery. Although mortality was not negatively impacted by diabetes, these researchers observed increases in complications and readmissions in patients, prompting the need for further research to identify effective strategies to address the diabetic vascular surgery patient.

I am grateful to the authors, not only for their contributions to this issue of *Northeast Florida Medicine*, but also for their relentless commitment to improving the art and science of medicine for the benefit of those we serve. It has been a distinct honor to work with these physicians on this edition, and I hope that the articles will inspire others to innovate with the goal of eliminating preventable patient harm.

**References**

Overview of Training Program

Mayo Clinic School of Graduate Medical Education was one of the first medical specialty teaching programs in the world, now with more than 24,000 graduates of residency and fellowship programs across all medical and surgical specialties. Mayo Clinic opened for business in Jacksonville, Florida in 1986 with an outpatient clinic. Since then, there has been significant expansion to the current campus at Mayo Clinic Florida hospital which operates at an expanded capacity of over 304 beds, 22 operating rooms, 20 medical and 15 surgical specialties, and an emergency department. There are presently more than 200 residents and fellows in training in over 45 programs, and the clinic is staffed by 511 physicians and scientists and a total of 5,046 allied health staff in the clinic and hospital. Mayo Clinic Florida welcomed its 23rd class of residents this year in July since the initial class of residents in Internal Medicine in 1994. Residents and fellows experience further clinical opportunities at nearby institutions including the Mission House of Jacksonville, Nemours Children's Clinic, Wolfson Children's Hospital, University of North Florida, the University of Florida Health Jacksonville, and the Jacksonville Naval Hospital. Mayo Clinic residents routinely participate in clinical rotations in Arizona and Minnesota, as well as the very unique opportunity to venture internationally as part of the Mayo International Health Scholars Program. In addition to postgraduate training, the Mayo Clinic educates many medical students through their specialty rotations. The goal of training at Mayo Clinic is to be a physician that encompasses the three shields: patient care, research, and education.

This past year, the Internal Medicine program started a new multidisciplinary longitudinal point of care ultrasonography course. This course brought together Internal Medicine, Critical Care Medicine, and Emergency Medicine physicians to teach the residents. This course utilized the simulation center at Mayo Clinic, where participants were able to use the state-of-the-art simulation models, simulation ultrasound equipment, and live models.

Mayo Clinic J. Wayne and Delores Barr Weaver Simulation Center: A Nationally Recognized Training Tool

Dr. William J. Mayo noted the need for alternative methods of learning when in 1927 he stated: “There is no excuse today for the surgeon to learn on the patient.” Indeed, Mayo Clinic has stayed at the leading edge of medical education in Florida.
with the opening of the Mayo Clinic simulation center, which opened on the Florida campus in 2013. This 9,600-square foot state-of-the-art center provides a wide array of resources in a high fidelity environment that provides residents and fellows at Mayo Clinic the skills they need to interact with patients and to perform lifesaving procedures. The center allows residents and fellows to explore the boundaries of modern medicine and to practice their skills in a controlled environment. Some of the notable technology and applications that learners have access to include:

- State-of-the-art robotic surgery simulation to develop unique surgical skills
- Virtual dissection table to demonstrate anatomy and clinical applications
- Endoscopy simulation with varied scenarios
- Complex laparoscopic surgery simulation
- Ultrasound simulation to assess the thoracic, abdominal, and pelvic cavities
- A radiographic table and lead shielding to practice fluoroscopy and other imaging techniques
- Multiple control rooms with video recording, task training rooms, debrief rooms, and a learning center

Simulation experiences typically involve medical mannequins that can be remotely controlled to enact a variety of clinical situations. The center offers a complete scenario library for planning and developing training curricula, which can be recorded and then assessed in debriefing. The simulation center further employs actors who play the role of patients and engage the learners in a variety of ways. Because the actors portray many roles and set up different clinical situations during the scenarios, the learners are exposed to the human factor as a part of their training.

**Resident Elective Program**

New in 2017 is the resident elective program which aims to expose residents to adult learning theory and experiential learning. During this rotation, the resident is required to design a new clinical scenario to teach other residents, physicians, nurses, and other allied health professionals. At the end of this rotation, the resident will submit their project to MedEd Portal for publication.

**Mayo Clinic Simulation Fellowship**

Mayo Clinic began accepting graduates for a one-year fellowship program currently in the third year of training fellows. This fellowship teaches physicians how to develop curricula and teach procedural techniques to residents. Participants learn how to design, implement, manage, and assess simulated educational programs. After graduation, the fellow is prepared to be a leader and innovator in medical education.

**Conclusion**

The simulation center allows Mayo Clinic residents to develop into competent, confident, reflective, and ethical healthcare providers through the use of clinical simulation to enhance healthcare education, research, and practice. The exemplary center fosters a highly experiential and contextual learning environment for students, faculty, staff, community health professionals, and researchers to promote patient safety and quality patient care. New programs such as the resident elective program and the Mayo Clinic simulation fellowship further increase the availability of this great resource and encourage increased collaboration between local residents and fellows throughout Jacksonville.
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Innovative, Data-driven Care for Sepsis: The UF Health Jacksonville Experience

By Faheem W. Guirgis, MD,1 Lisa M. Jones, MD,2 Rhemar Esma, MD,3 L. Kendall Webb, MD,1 and Kelly Gray-Eurom, MD, MMM1

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3UF Health Jacksonville, Quality Management

Source of Funding: W. Martin Smith Interdisciplinary Patient Safety and Quality Award

Abstract: Sepsis is a disease with a high mortality which can be difficult to recognize. However, when recognized early and treated appropriately, outcomes can be improved. In January of 2014, the Sepsis Committee was assembled in an effort to systematically address sepsis recognition, early management, and continued care at UF Health Jacksonville. After analyzing data from hospital patients, an electronic sepsis recognition tool (Azrael) that was based on an adjusted Modified Early Warning Signs - Sepsis Recognition Score was chosen for sepsis recognition and integrated into the background of the electronic health record. Standardized order sets for sepsis care delivery were created and hospital wide education was undertaken with teams assigned to respond to different areas of the hospital. A particularly novel approach was the use of the rapid response team nurses for sepsis recognition and care delivery on the general wards. The UF Health Jacksonville Sepsis Committee recently published a study that demonstrated significant reductions in odds of death, mean intensive care unit (ICU) length of stay, mean overall hospital length of stay, odds of mechanical ventilation use, and total charges per admission after implementing the Sepsis Alert Program.

Data-driven, Evidence-based Care

In general, patient care should be data-driven, and sepsis is no different. It has been the authors’ experience that institutions can use data to drive their own care and improve care for patients.8 It simply requires an approach in which hospitals take data from their own patients, evaluate it for trends, and institute changes specific to their population. In addition, committees seeking to improve care may offer opportunities for innovative ideas and programs that can improve patient outcomes and serve to create an even playing field by standardizing care across an institution. In this way, something very complex can be simplified and successfully applied in any area of the hospital.

When the UF Health Jacksonville Sepsis Committee gathered for its first meeting in January of 2014, there was no standardized approach to sepsis care as was currently recommended by the Surviving Sepsis Campaign, a national effort aimed at improving care for sepsis across the world.10 Therefore, a team of leaders from different clinical areas and departments of the institution was developed and roles were assigned. Five initial teams were constructed: 1) process improvement, 2) clinical protocol development, 3) electronic-health record and information technology, 4) sepsis prevention, and 5) research. The Committee also realized that clinical care for the septic patient fit into three categories: 1) sepsis recognition, 2) initial management and stabilization, and 3) continued care.

Sepsis Recognition

The committee leadership realized that for effective sepsis recognition, a screening tool would be needed. After an extensive literature search, the Modified Early Warning Signs - Sepsis Recognition Score (MEWS-SRS) was chosen, which had proven accuracy for sepsis recognition and had
demonstrated improved outcomes in a surgical intensive care population. The score included basic elements such as temperature, heart rate, respiratory rate, systolic blood pressure, mental status, and white blood cell (WBC) count but needed to be more inclusive to capture patients from the emergency department (ED), the general wards, and the ICUs as well. Therefore, to fit the diverse UF Health Jacksonville patient population across all areas of the hospital, the score was modified and tested using seven different algorithms with differing cut-offs, with ≥ 5 points considered positive. The testing included surveying the patient population for 48 hour periods of time and then performing focused chart reviews to adjudicate the sepsis diagnosis. The goal was to achieve a positive predictive value of > 50 percent, meaning that for every two alerts, one of the patients would be confirmed septic. The chosen algorithm had a positive predictive value of 70 percent (Figure 1).

**Automation and Information Technology**

Once the committee had settled on a particular algorithm, implementation was the next step. The committee leadership was aware of the shortcomings of having bedside nurses calculate the score on a shift by shift basis. This was far too laborious and infrequent to be effective and would not work in the emergency department due to the flux of patients. However, the solution to this problem arrived with the help of a computer-wizard, physician, and co-author (RE) working in the Quality Department who created a program that applied the adjusted MEWS-SRS score to the electronic chart of every patient at UF Health Jacksonville on an hourly basis. For patients with a score ≥ 5, it would send an electronic page to providers taking care of the patient, the rapid response team (RRT) for general ward patients, and the ICU teams depending on the patient’s location. This system, code-named Azrael, provides hourly surveillance of all patients in the hospital. At the end of each day, Azrael sends a list of all patients with a positive score from the day before to all sepsis core team members. Moving forward, the Sepsis Committee hopes to make the Azrael alert system as real-time as possible so that providers and nurses can have immediate awareness of patients with potential sepsis. Having both IT leadership (KW) and Quality Leadership (KGE) integrated within the team has been advantageous and will undoubtedly result in this dream becoming a reality. Due to the Azrael efforts and protocol thus far, UF Health Jacksonville was one of two institutions out of 350 to recently be awarded the Vizient Innovation Excellence Award in 2016.

**Sepsis Management**

A sepsis alert order set was created for hospital-wide use. The order set was constructed using both the National Quality Forum and Centers for Medicare and Medicaid Services SEP-1 quality measures and mirrored the three-hour bundle. The order set includes point-of-care serum lactic acid, antibiotic recommendations, two sets of blood cultures, and a 30 mL/kg initial fluid bolus. Options for further infectious workup and closer vital sign monitoring and nursing care are also included. Initiation of this order set also triggers a sepsis alert notification to be paged out to providers and responders after which, primary providers, nurses, clinical pharmacists, and technicians administer the sepsis protocol by delivering the care bundle. For general ward patients, the patient’s primary

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**Figure 1.** Adjusted MEWS-SRS Score for identifying all patients with sepsis via automated, Azrael system.

<table>
<thead>
<tr>
<th>Score</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>0</th>
<th>1</th>
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<td>&lt;36</td>
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<td>38.5 - 38.9</td>
<td>39 - 40.9</td>
<td>≥41</td>
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<tr>
<td>HR</td>
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<td>40 - 44</td>
<td>45 - 50</td>
<td>51 - 100</td>
<td>101 - 110</td>
<td>111 - 129</td>
<td>&gt;130</td>
</tr>
<tr>
<td>RR</td>
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<td>8</td>
<td>9</td>
<td>10 - 14</td>
<td>15 - 20</td>
<td>21 - 29</td>
<td>≥30</td>
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<tr>
<td>SBP</td>
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<td>71 - 80</td>
<td>81 - 100</td>
<td>≥101</td>
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</tr>
<tr>
<td>Latest WBC</td>
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<td>1 - 2.9</td>
<td>3 - 12.9</td>
<td>13 - 17.9</td>
<td>18 - 37.9</td>
<td>≥38</td>
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</tbody>
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hospital physician and nurse with the assistance of an RRT nurse, clinical pharmacist, and a respiratory technician initiate treatment for sepsis in consult with medical or surgical ICU services. When available, clinical pharmacists review each patient’s microbiologic history at bedside for requirement of alternative antimicrobials or reasons in which standard agents would be inappropriate. A sepsis continued care order set, with more comprehensive choices of antibiotics, fluids, and monitoring, was also created for continued care.

**Innovation:**

**Rapid Response Teams for Sepsis Care**

Perhaps the most challenging area of the hospital to recognize and deliver care for a septic patient is the general wards. The committee was aware of this fact at the beginning and knew that the expert team of rapid response nurses would be integral to this process. Under the direction of the Code Blue Committee and leadership by Dr. Cynthia Gerdik DNP, MBA, and Dr. Andy Godwin MD, the RRT had already improved care in numerous areas through an innovative idea termed proactive rounding. Proactive rounding consists of the RRT nurse rounding through the general wards, identifying high risk patients, and intervening preemptively. Previous improvements in outcomes had been seen at UF Health Jacksonville in other high-risk populations including tracheostomy patients, patients with tube thoracostomies, halos, heparin infusions, chemotherapy, recent ICU discharges (within 24 hours), patients with fraction of inspired oxygen requirements > 50 percent, altered mental status, patients with specific cardiac or respiratory conditions, patients with volatile blood glucose levels, and patients receiving opioids for pain. The Rapid Response Team members assisted as they had already been dealing with sepsis on a daily basis but did not have a systematic approach to caring for a septic patient. With the implementation of the sepsis alert system, the RRT became an integral part of sepsis screening and care delivery on the general wards. RRT nurses receive pages for all possible sepsis cases on the general wards through the Azrael system, provide a bedside evaluation, and directly contact the responsible providers.

Through education and open discourse, providers have been encouraged to trust the RRT nurses in the bedside evaluation. Moreover, when a possible sepsis page is received, providers are required to perform a bedside evaluation of a potential sepsis patient within one hour. If the provider agrees with the sepsis diagnosis, RRT is already there to deliver care and facilitate transfer to a higher level of care when needed.

**Improvements in Safety and Quality Outcomes**

It is important to demonstrate improved outcomes after a quality improvement program is instituted whenever feasible. The UF Health Jacksonville Sepsis Committee recently published a before and after study of nearly 4,000 sepsis admissions, comparing outcomes after the implementation of the Sepsis Alert program in November of 2014. The study demonstrated that after controlling for other factors, significant reductions in odds of death, mean ICU length of stay, mean overall hospital length of stay, odds of mechanical ventilation use, and total charges per admission (with a savings of over $7,000 per admission) were observed. The study did not demonstrate a significant reduction in need for vasopressors after implementation. This study clearly demonstrates that an innovative, data-driven effort to improve sepsis care can improve outcomes and reduce hospital charges.

**Moving Forward**

The UF Health Jacksonville Sepsis Committee has seen several challenges including changes in policy and sepsis definitions which have been confusing to providers and nurses. Even experts have the challenge of reconciling the latest science to current practice and policy. The future undoubtedly holds changes to sepsis policy, but as these changes are enacted, it is even more important to remain up-to-date and innovative. The committee must be educated, persistent, and have its hand on the pulse of its own patient population. Providing quality care is a privilege, and the UF Health Jacksonville Sepsis Committee members are thankful to its patients for the opportunity to serve and be taught by them.
References

Two Keys to Connection in Healthcare: Presence and Reflective Listening

Background:

The Duval County Medical Society (DCMS) is proud to provide its members with free continuing medical education (CME) opportunities in subject areas mandated and suggested by the State of Florida Board of Medicine to obtain and retain medical licensure. The DCMS would like to thank the St. Vincent’s Healthcare Committee on CME for reviewing and accrediting this activity in compliance with the Accreditation Council on Continuing Medical Education (ACCME).

This issue of Northeast Florida Medicine includes an article, “Two Keys to Connection in Healthcare: Presence and Reflective Listening” authored by William J. Maples, MD, Sandra Argenio, MD and Jennifer Krippner, which has been approved for 1 AMA PRA Category 1 credit. TM For a full description of CME requirements for Florida physicians, please visit www.dcmsonline.org.

Faculty/Credentials:

William J. Maples, MD, Sandra Argenio, MD and Jennifer Krippner are with The Institute for Healthcare Excellence in Jacksonville, FL. Dr. Maples serves as Executive Director, Dr. Argenio serves as physician faculty, and Krippner is the Chief Experience Officer.

Objectives:

1. Understand the importance of effective physician and caregiver communication in creating a culture of excellence for our patients and fellow caregivers.
2. Understand the benefits and practice art of reflective listening in clinical and non-clinical encounters.
3. Demonstrate communication techniques useful in building patient and team-based relationships.
4. Learn, understand, and practice mindfulness/presence and its application in a healthcare setting.

Date of release: September 1, 2017 Date Credit Expires: September 1, 2019 Estimated Completion Time: 1 hour

How to Earn this CME Credit:

1) Read the “Two Keys to Connection in Healthcare: Presence and Reflective Listening” article.
2) Complete the posttest. Scan and email your test to Kristy Williford at kristy@dcmsonline.org or mail it to 1301 Riverplace Blvd., Suite 1638, Jacksonville, FL 32207.
3) You can also go to www.dcmsonline.org/NEFM CME to read the article and take the CME test online.
4) All non-members must submit payment for their CME before their test can be graded.

CME Credit Eligibility:

A minimum passing grade of 70% must be achieved. Only one re-take opportunity will be granted. If you take your test online, a certificate of credit/completion will be automatically downloaded to your DCMS member profile. If you submit your test by mail, a certificate of credit/completion will be emailed within four weeks of submission. If you have any questions, please contact Kristy Williford at 904.355.6561 or kristy@dcmsonline.org.

Faculty Disclosure:

William J. Maples, MD, Sandra Argenio, MD and Jennifer Krippner report no significant relations to disclose, financial or otherwise with any commercial supporter or product manufacturer associated with this activity.

Disclosure of Conflicts of Interest:

St. Vincent’s Healthcare (SVHC) requires speakers, faculty, CME Committee and other individuals who are in a position to control the content of this educations activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly evaluated by SVHC for fair balance, scientific objectivity of studies mentioned in the presentation and educational materials used as basis for content, and appropriateness of patient care recommendations.

Joint Sponsorship Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of St. Vincent’s Healthcare and the Duval County Medical Society. St. Vincent’s Healthcare designates this educational activity for a maximum of 1 AMA PRA Category 1 credit. TM Physicians should only claim credit commensurate with the extent of their participation in the activity.
**Two Keys to Connection in Healthcare: Presence and Reflective Listening**

By William J. Maples, MD, Sandra Argenio, MD, and Jennifer Krippner

*The Institute for Healthcare Excellence*

**Abstract:** The single most important factor in creating an excellent patient experience is the patient’s interaction and relationship with his or her healthcare provider. In multiple studies over the past few decades, patients tell us what they desire most in their healthcare provider—someone who respects and listens to them. Traditional medical training has devoted little time to the development of communication skills. Through training and practice, healthcare providers can develop a culture of excellence where safety, efficiency, quality and experience of patients, families, and caregivers flourish.

**Introduction**

The single most important factor in creating an excellent patient experience is the patient’s interaction and relationship with his or her healthcare provider. The experience culture, safety and healthcare outcomes are influenced by multiple factors. The Institute for Healthcare Excellence (IHE) was founded to help healthcare organizations, physicians, and caregivers implement proven solutions to deliver the best possible care to every patient every day, including optimal outcomes, safety, experience, and efficiency.

At the core of IHE’s RELATIONS™ program are six essential communication skills which include presence, reflective listening, efficient and accurate information gathering, joint agenda setting, connecting with all members of the team, and appreciation. Through nurturing these skills, a culture of respect, compassion, trust, and teamwork is created with the patient at the center of the team. This article focuses on two of these skills: presence and reflective listening.

**Communication and Healthcare**

American healthcare is in the midst of a transformation to address the rising costs of healthcare and sub-optimal access of healthcare for United States citizens. At the cornerstone of this transformation is a shift from the traditional fee-for-service payment structure to a value-based payment system which is rooted in providing desired outcomes, without harm, without waste, and with an excellent patient experience for the patients being served. Although re-engineering of healthcare via the electronic medical record and processes such as lean and six-sigma have been robustly pursued over the past decade, physicians have had significant challenges to eliminating harm, removing waste and improving efficiency, and creating an excellent experience for patients and fellow caregivers. As reimbursement/payment models increasingly shift to reward individual providers and institutions for the value they deliver, the external pressures have increased to answer the question of how best to accomplish this transformation.

Healthcare organizations have worked diligently at creating a culture which generates an excellent experience for their patients and caregivers. However, most organizations have not engaged physicians to partner in leadership of this work. The Institute for Healthcare Excellence has recognized the importance of physicians, who by definition lead American healthcare, to be at the forefront of leading this cultural transformation in partnership with nursing and administration leadership. By creating a program that is relevant to the practicing physician and clinical team and also reconnects caregivers to their purpose, physicians and clinical leaders readily and willingly step forward to become internal faculty for this work. As healthcare organizations witness their leaders cohesively moving this work forward, a magical catalyst surfaces for all of the mission critical work of the organization.
Communication in Healthcare Curriculum

**Presence**

The first skill introduced in the RELATIONS™ curriculum is Presence. Presence is the basis of good communication. Many errors happen due to lack of presence or attention to the task at hand. Mindfulness is the tool that can help healthcare providers develop a better ability to be present in their everyday interactions and tasks with patients, families, and colleagues. Mindfulness is defined as “present moment attention without judgment.”1 Being present without judgment in every conversation and patient interaction is key to patient satisfaction, outcomes, safety, and efficiency. Due to the complexities of delivering healthcare, mindfulness can frequently be challenged, contributing to serious safety events. On November 29, 1999, the Institute of Medicine released a report “To Err Is Human: Building a Safer Health System.”2 The report aimed to eliminate preventable harm in healthcare by 2010; unfortunately, there is still much to be done to reach that goal. Physicians and caregivers make errors for a variety of reasons which have little to do with lack of good intention or knowledge. As stated by Hughes, “Humans have many intellectual strengths (e.g. large memory capacity and an ability to react creatively and effectively to the unexpected) and limitations (e.g. difficulty attending carefully to several things at once and generally poor computational ability, especially when tired).”3 Improving safety requires recognizing and respecting human abilities, strengths and limitations. Effective communication cannot occur when one or both parties are not paying attention to each other or to details required for care. A review of The Joint Commission reports found that communication failure (rather than a provider’s lack of technical skill) was at the root of over 70 percent of serious adverse health outcomes.4

Being present through mindfulness is a skill that can be taught and learned. A study in 2014 from the Warfighter Performance Department, Naval Health Research Center and University of California San Diego followed eight marine infantry platoons (n=181).5 One half of the marines were trained in mindfulness while the control group received “standard” training. After stressful combat simulation, the marines trained in mindfulness showed:

- “Elite performer” brain pattern on functional MRI (showing increased grey matter density in areas of the brain associated with executive function—specifically, attention, and emotion)6
- Enhanced recovery after stressful situations (heart rate, respiratory rate, plasma neuropeptide Y concentration)
- More efficient deployment of neural processing and autonomic responses

The marines who were trained in mindfulness could reach peak performance compared to the control group.5 Reaching peak performance when delivering healthcare can be critical given the highly complex nature of medicine.

Working with healthcare organizations across the country, IHE’s direct observations have found that less than 20 percent of physicians and caregivers have developed a formal practice of mindfulness. As busy professionals, many physicians and caregivers feel that the development of this skill requires a significant investment of time. Mindfulness can occur in brief moments. Examples include taking a breath before entering each exam room and allowing a moment to clear other thoughts. Surgeons often describe using the few moments while scrubbing to focus on the patient and the procedure at hand. One military physician described his mindfulness moment as “I leave ‘me’ outside of the room before I enter a patient exam room.” Moments of mindfulness can be found in offices, chapels, closets, or even restrooms—a place to take a moment to quiet multiple thoughts and focus on the task at hand.

Mindfulness is practiced formally and informally. Formal practice refers to finding a regularly scheduled time to purposefully cultivate present moment attention. An example of formal mindfulness is as follows:

“When I press start on my coffee maker in the morning I sit down and practice mindfulness for five minutes; I notice what it feels like to breathe and let go of any distractions that take me away from the breath during the five minutes of practice.”

Informal mindfulness refers to finding moments during daily tasks/activities to be mindful. An example of informal mindfulness is as follows:

“When I wash my hands in-between patients I practice mindfulness for a few seconds; I notice what it feels like to have my feet on the ground as I wash my hands and let go of the thoughts about the future or the past that take me away from the awareness of my feet on the ground in this present moment.”
The practice of mindfulness has resulted in multiple benefits, including:

- Improvement in mood disturbance, depression, anxiety, and stress
- A decrease in caregiver burnout (emotional exhaustion and personal accomplishment subscales)
- Improvement in caregiver empathy
- Finding meaning in work
- Empowerment and engagement at work
- Emotional stability
- Conscientiousness

Aetna evaluated the effectiveness of mindfulness training in a cohort of 50,000 employees. Twenty-five percent of the employees participated in mindfulness training and the remainder served as the control group. Individuals who participated in mindfulness training had a 20 percent increase in sleep quality, 28 percent reduction in stress, 19 percent reduction in pain, 3-5 percent savings in employee health costs, a $3,000 per employee per year decrease in healthcare costs, and a 62-minute increase in productivity per week.

**Reflective Listening**

The second skill introduced in the IHE RELATIONS™ curriculum is reflective listening. Sir William Osler counseled his fellow physicians at the dawn of the 20th century with the following words of wisdom:

"Listen to the patient: He is telling you the diagnosis."

Patients commonly reflect that physicians and caregivers are too busy to listen to their concerns. Approximately one-third of hospitalized patients state nurses or aides were too busy to address an immediate concern. Patients perceive healthcare workers as rushed and hurried. Physicians must find a way to change these perceptions while dealing with the complexity of healthcare and the many demands placed on the healthcare team.

Multiple studies have examined what patients most desire from their healthcare team over the past few decades. The results have consistently found “Having a doctor or healthcare provider who listens to me” at the top of the list. A recent study illustrated the top three attributes that people rated as “extremely important” contributing factors for a successful healthcare visit (Table 1).

The skill of reflective listening is an excellent starting point for beginning a dialogue. With reflective listening, the listener’s attitude is curious, non-judgmental, and seeks to understand the patient’s perspective. Use of open-ended questions is critical to reflective listening. Listening is critical to gaining the trust of the person in front of you. A doctor’s ability to listen, reflect back and explain in an empathetic manner has a profound impact on a patient’s care. However, on average, physicians interrupt their patients’ narratives in 18 seconds to “take control” of the situation. During approximately one-third of primary care visits and one-third of subspecialty visits, patients report they never were able to talk about the primary reason they came for the visit. Healthcare providers cannot expect patients to be compliant with care plans if they have not been listened to and do not feel they are part of the plan.

**Training in Reflective Listening: A Case Study**

The skill of reflective listening can be taught and implemented into physicians’ and caregivers’ daily routines as outlined in Figures 1-3. Following implementation of communication skills within the RELATIONS™ program, a healthcare organization demonstrated improvement of patient’s perceptions of their physicians listening to them.

<table>
<thead>
<tr>
<th>Major Contributors to Patient’s Health Care Experience</th>
<th>Percentage of Patients Rating Attribute as Extremely Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Having a doctor who listens to them</td>
<td>85%</td>
</tr>
<tr>
<td>Having a doctor who is caring and compassionate</td>
<td>71%</td>
</tr>
<tr>
<td>Having a doctor who explains well</td>
<td>69%</td>
</tr>
</tbody>
</table>
and being understanding and caring. The national percentile rankings are from approximately 800 surveys over eight quarters of patient experience surveys conducted within the large healthcare organization.

Following initiation of the Institute for Healthcare Excellence Communication curriculum, the skills were gradually diffused to the entire active physician, nursing and allied healthcare team over a two-year period. The steady improvement of listening and communication skills is clearly demonstrated as the program was implemented.

Conclusion

The skills of presence and reflective listening are an excellent starting point for developing a culture rooted in teamwork, trust, respect, and compassion with the patient at the center of the team. These skills, in conjunction with four additional core skills introduced in the IHE RELATIONS™ for Healthcare Transformation program including 1) efficient and accurate information gathering, 2) joint agenda setting, 3) connecting with all members of the team, and 4) appreciation, provide the tools necessary for caregivers to navigate the healthcare transformation upon us. In working with healthcare organizations across the nation who have successfully introduced the skills in the RELATIONS™ for Healthcare Transformation program, IHE has directly observed significant and sustainable improvement in HCAHPS (with improvement to top decile in the communication associated metrics), patient experience metrics, employee engagement metrics, culture of safety metrics, multiple safety and outcomes metrics, and empathy and burnout metrics.

Significant and sustained improvement in the heretofore elusive journey to create an excellent experience culture for patients and caregivers can finally be achieved through focusing on these behavioral skills in contrast to a lengthy list of tactical solutions. In addition, by nurturing skills which reconnect caregivers to their purpose, it is possible to restore joy and resiliency for all caregivers practicing medicine.
References


Presence & Reflective Listening

CME Questions & Answers (circle one answer)/Free to DCMS Members/$55.00 charge non-members*
(Retrieve by June 15, 2019  BY MAIL: 1301 Riverplace Blvd. Suite 1638, Jacksonville, FL 32207 or ONLINE: www.dcmsonline.org/NEFMCME)

1. According to the RELATIONSTM program, there are six skills that are important in creating a culture of respect, compassion, trust, and teamwork. Which of the following is not one of those skills?
a. Presence
b. Reflective Listening
c. Time Management
d. Joint Agenda Setting
e. Appreciation

2. A recent study illustrated the top three attributes that people rated as "extremely important" contributing factors for a successful healthcare visit. Which of the following is not one of those attributes?
a. Having a doctor who listens to them.
b. Having a doctor who is caring and compassionate.
c. Having a doctor with extensive experience and training.
d. Having a doctor who explains well.

3. According to The Institute for Healthcare Excellence, who should be leading the work of cultural transformation in partnership with nursing and administration leadership?
a. Patients
b. Legislators
c. Patient families
d. Physicians

4. True or False: Mindfulness is defined as "present moment attention without judgment."
a. True
b. False

5. A review of The Joint Commission reports found that communication failure (rather than a provider's lack of technical skill) was at the root of what percent of serious adverse health outcomes.
a. 40 percent
b. 50 percent
c. 60 percent
d. 70 percent

6. What skill is an excellent starting point for beginning a dialogue with a patient?
a. Storytelling
b. Reflective Listening
c. Critical-Thinking
d. Problem Solving

7. Practicing Mindfulness can result in all of the following, except:
a. Improvement in mood disturbance, depression, anxiety, and stress
b. A decrease in caregiver burnout (emotional exhaustion and personal accomplishment subscales)
c. Improvement in caregiver empathy
d. A decrease in the need for time-off from work
e. Finding meaning in work

8. Sir William Osler provided the following words of wisdom for physicians:
a. "Question the patient: Be sure the diagnosis is accurate."
b. "Provide the patient with all of the necessary information about the diagnosis."
c. "Listen to the patient: He is telling you the diagnosis."
d. "Be cautious of what the patient reports. Make your diagnosis based on your exam."

9. According to results from the 2014 NHS Inpatient Survey, how many hospitalized patients stated nurses or aides were too busy to address an immediate concern?
a. Approximately one-third
b. Approximately one-half
c. Approximately two-thirds
d. None

10. On average, how soon do physicians interrupt their patients' narratives to "take control" of the situation?
a. 12 seconds after the patient begins speaking
b. 18 seconds after the patient begins speaking
c. 34 seconds after the patient begins speaking
d. 46 seconds after the patient begins speaking

Evaluation questions & CME Credit Information
(Please evaluate this article. Circle one number using this scale: 1= Strongly Agree to 5= Strongly Disagree)
The article met the stated objectives: 1 2 3 4 5
The article was appropriate to my practice: 1 2 3 4 5
The topic was current and well presented: 1 2 3 4 5
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Account # ________________ Expiration date ____________ Security Code ____________
Signature __________________________

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ERAS Implementation: 
Continuing the Quest for Better, Safer Care for Our Patients

By Patrice Vinsard, MD, Amit Merchea, MD, and Dorin T. Colibaseanu, MD

Abstract: Enhanced Recovery after Surgery (ERAS) has become the standard of care for patients undergoing elective colorectal surgery. It has been shown to decrease length of stay and postoperative complications in multiple studies. Mayo Clinic Florida (MCF) initiated an ERAS protocol in 2013, modeled after the ERAS protocol implemented at Mayo Clinic Rochester. It is important to look at the implementation process and outcomes associated with the initiation of ERAS. The measured outcomes for this study were length of stay and readmission rates before and after ERAS implementation. Shorter hospital stay and fewer readmissions were associated with ERAS implementation.

Introduction

Conventionally, ambulation and diet advancement after bowel surgery follows the patient’s progress. In recent years, Enhanced Recovery after Surgery (ERAS) was introduced.¹ This evidence-based pathway is based on the principle that reducing the body’s stress response after surgery facilitates recuperation. In the colorectal patient population, ERAS was implemented with the scope of reducing postoperative physiological stress, complications, and organ dysfunction. It also improves outcomes and decreases hospital length of stay, while expediting recovery following elective procedures.²,³ Recovery is facilitated by multimodal and optimized analgesia techniques, improved oral intake, avoidance of fluid overload, and early ambulation.⁴,⁵,⁶ Other critical components are the technical aspects of the surgery, standardized nursing care, dedicated teams caring for and motivating patients, and objective, standardized discharge criteria.⁷

Methods

The clinical pathway was initiated at MCF in 2013. Unlike Mayo Clinic Rochester, the Florida campus did not proceed through a fast track recovery protocol, rather, a direct change to ERAS was applied across all colorectal surgical patients undergoing elective colorectal surgery. ERAS is now the standard of care for colorectal surgery patients and is well described by multiple centers in various iterations.⁸-¹⁷ The colorectal surgery section at MCF has uniformly adopted the protocol described herein.

Preoperative Elements

Bowel Preparation

Studies investigating the effects of conventional care have been performed and show that many of the traditional approaches to surgical care, such as preoperative bowel clearance, is unnecessary or even harmful.²,¹⁸ On the other hand, a recent Cochrane analysis¹⁹ determined that there was no statistically significant evidence that patients benefit from mechanical bowel preparation or the use of rectal enemas. The few studies focused in rectal surgery suggested that mechanical bowel preparation could be used selectively, even though no significant effect was found.

All patients undergoing an elective surgery at MCF expected to need a diverting ileostomy, or a low (distal) anastomosis, are more likely to undergo a bowel preparation, while patients having surgery on the right colon are less likely.

 Fluids / Carbohydrate Loading

Preoperative fasting has been shown to increase metabolic stress, hyperglycemia, and insulin resistance, which the body is already prone to during the surgical process.²⁰ Avoiding fasting attenuates postoperative insulin resistance, reduces nitrogen and protein losses, preserves skeletal muscle mass, and reduces preoperative thirst, hunger, and anxiety.²¹

Within this protocol, patients are encouraged to consume a general diet and avoid preoperative fasting. The patient is encouraged to maintain an oral intake of at least 800 mL of fluid, but no more than 2000 mL by midnight. The day of surgery, one box of clear liquid oral nutritional supplement is provided, acting as the carbohydrate supplement. Patients
are initiated on an immediate low-fiber diet post-operatively, and this is continued throughout their hospitalization.

Nondiabetic patients are encouraged to drink 400 mL of a carbohydrate rich drink (such as apple juice) the night before surgery and 3-4 hours in the morning before the surgery.

**Multi-modal Analgesia**

Preemptive pain control is achieved by providing the patient with a number of multimodal pain adjuncts preoperatively. Upon admission, patients are given Celecoxib, Gabapentin, and Acetaminophen (Table 1).

Contraindications for Celecoxib use are true sulfonamide allergy, acute gastrointestinal bleeding or a history of gastrointestinal bleeding within the past six months, nonsteroidal anti-inflammatory drug (NSAID) contraindication, and acute or chronic renal failure with an estimated creatinine clearance below 50 mL/min. Patients weighting less than 50 kg or older than 65 years of age are not candidates for this analgesic. Gabapentin is not administered by consensus to patients over 70 years of age.

Multimodal analgesia has been shown to spare opioid use and side effects by 30 percent. Also, Cyclo-oxygenase (Cox)-2 inhibitors can be used safely in conjunction with epidural anesthesia. No studies have established whether administration of ketamine, gabapentin, or tramadol in the postoperative period have a positive impact on postoperative outcomes after colorectal surgery.22

**Intrathecal Injection**

Intrathecal analgesia has been shown to reduce postoperative pain, ileus, and postoperative nausea and vomiting compared with other analgesic techniques after colorectal surgical procedures.23

| Table 1. Analgesia Used Preoperatively |

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celecoxib P.O.</td>
<td>400 mg</td>
<td>Weight ≥ 50 kg, Creatinine clearance ≥ 50 mL/minute, 18-64 years old</td>
</tr>
<tr>
<td>Gabapentin P.O.</td>
<td>600 mg</td>
<td>18-59 years old</td>
</tr>
<tr>
<td></td>
<td>300 mg</td>
<td>60-69 years old</td>
</tr>
<tr>
<td>Preprocedure unit</td>
<td>Acetaminophen P.O.</td>
<td>1000 mg</td>
</tr>
</tbody>
</table>

Prior to induction of anesthesia, 100 micrograms of intrathecal hydromorphone is administered. Relative contraindications are prior spinal surgery and scoliosis, and absolute contraindications include an International Normalized Ratio (INR) of 1.4 or greater, active infection in the spinal area, or systemically.

**Intraoperative Elements**

Intraoperatively, I.V. Fentanyl is used at the discretion of the anesthesiologist. Fluid management is goal directed with the objective of administering I.V. fluids judiciously, using vasoconstrictor medication when necessary. In general, the goals are 500 mL or less per hour of I.V. saline administration for laparoscopic cases and 800 mL or less per hour for open cases. Unless contraindicated, prophylactic postoperative nausea and vomiting prophylaxis consists on Dexamethasone 4 mg I.V. and Granisetron 0.1 mg I.V. For three or more postoperative nausea and vomiting risk factors (PONV), such as female gender or history of PONV/Motion sickness, Droperidol 0.625 mg I.V. is added.

**Postoperative Elements**

**Pain Control**

Postoperative pain prophylaxis includes scheduled Acetaminophen, Ketorolac, and Ibuprofen (Table 2). Variation in doses and interval depends on the patient’s condition.

| Table 2. Pain control in the postoperative period. |

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>1000 mg P.O.</td>
<td>BID or QID</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>15-30mg I.V.</td>
<td>Four doses</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>200-600 mg P.O.</td>
<td>QID, start after last Ketorolac dose</td>
</tr>
</tbody>
</table>
Patient Quality & Safety

comorbidities. If the patient is not a candidate for NSAIDs, Tramadol 100 mg P.O. BID or QID is administered.

Additionally, Oxycodone 5-10 mg P.O. every four hours is used if the Visual Analogue Scale (VAS) for pain is higher than 4, starting 24 hours after the use of intrathecal opioid dose. Intravenous fentanyl is available PRN for breakthrough pain.

For the first 24 hours after intrathecal administration, close monitoring is performed by anesthesia and the primary team, who have in-house members overnight. The patient is assessed, and Fentanyl is administrated as a 50 mcg I.V. bolus, repeated after 10 minutes if VAS pain score remains over 4.

Efforts are made to minimize I.V. opioids and, if possible at all, avoid patient controlled administration pump (PCA). Nonetheless, if pain persists, a Fentanyl PCA is started.

Venous Thromboembolism (VTE) Prophylaxis

Heparin sodium 5000 units is administered subcutaneously every eight hours for patients weighing 50 kg or greater, and every 12 hours for patients weighing less than 50 kg. In both cases, sequential compression devices are also utilized.

Diet and Fluids

On the day of surgery and until discharge two boxes of clear liquid oral nutritional supplement are given, and a daily oral intake of 1500–2500 mL of fluids is encouraged.

Diet starts the day of surgery. All meals are taken in the chair.

After surgery, Lactated Ringer’s is maintained at 40 mL per hour until postoperative day (POD) one at 8 AM, and then discontinued. Postoperative antibiotics are not routinely required. To improve bowel function, Magnesium oxide 400 mg orally two times per day for three days is used.

Activity

Patients start ambulating the day or evening of surgery, and are required to be out of bed for more than two hours, including one or more walks and sitting in chair. Starting the day after surgery and until discharge, the patient should be out of bed for more than eight hours, including four or more walks and sitting in chair.

Pulmonary Therapy

The evening following surgery, oxygen is weaned off to room air while maintaining an oxygen saturation level of at least 90 percent. The patient is admitted to general care, deep breathing exercises every hour while awake is encouraged.

Additional Orders

The protocol requires strict records of intakes and outputs as well as daily weights.

The wound is washed daily with Chlorhexidine four percent liquid soap or Chlorhexidine wipes (if the patient is unable to take a shower).

The indwelling urinary catheter is discontinued on POD1 at 8 AM. If the patient complains of urinary pain, fullness or bladder distention, and/or has not been able to void for six hours, or has voiding frequency with less than 100 mL per void, in and out catheterization every six hours as needed is implemented. If catheterization has been performed more than twice, an indwelling urinary catheter is inserted. The patient is followed in clinic in 10 days, at which time a voiding trial is performed, and the urinary catheter is discontinued.

Laboratory

The day after surgery, a CBC, creatinine, potassium, and glucose level are assessed.

Outcomes/Discussion

Data from observational studies and randomized trials show that ERAS protocols are characterized by reduced hospital length of stay (LOS), earlier return of bowel function, and earlier ambulation. Contemporary LOS in ERAS protocols range from three to five days. While previous studies suggested an increased readmission rate compared with traditional practice, a systematic review of later reports identified no significant differences. These protocols have also been effective in patients undergoing complex procedures.

Factors that have been shown to lead to failure of ERAS include open surgery, intraoperative nasogastric tube placement, substantial blood loss, stoma formation and insertion of more than one intraabdominal drain during surgery, failure to ambulate on POD1, and using a PCA. Postoperative continuation of intravenous fluids, reinserter of urinary catheter, non-compliance with diet, and postoperative ileus are also strongly associated with delayed discharge. Open surgery tends to have higher usage of fluids and opioid usage, hence a potentially greater failure rate.
Greater than 85 percent of the elective colorectal resections at MCF are performed in a minimally invasive fashion, and this is shown to be a factor in postoperative pain and the ability of the patient to remain on ERAS through their hospital stay. In addition, this is associated with a shorter hospital stay and a lower rate of infection.

Data from ERAS implementation at Mayo Clinic Rochester suggests that there is a significant decrease in LOS in patients under ERAS protocol from 5 to 3 days ($P < 0.001$). In the ERAS group, 44 percent of patients had a two-day hospital stay compared with 8 percent in the control group ($P < 0.001$). Earlier return of gastrointestinal function is seen in ERAS patients compared to those with standard treatment: one day versus two days. ($P < 0.001$). Even though the readmission rate is found to be higher in the ERAS patients, the difference is not statistically significant.

Another important outcome is that pain management goals are achieved at a higher rate in the ERAS group (74–94 percent versus 44–88 percent with control group), with differences on return to the postoperative patient care unit, and 4 and 8 h thereafter. There was a significant difference in pain score profiles over time between the groups ($P = 0.001$).

This correlates with similar findings in other programs that have implemented ERAS. In fact, a systematic review and meta-analysis of randomized trials found that patients managed with ERAS had a significantly reduced length of stay (standard mean difference -1.14 days, 95 percent CI -1.45 to -0.85) and reduced risk for perioperative complications (risk ratio 0.71, 95 percent CI 0.60-0.86). ERAS was associated with a 16 percent (95 percent, CI 9 to 23) reduction in LOS ($P <0.001$). MCF has 85 percent compliance with the pathway.

It is worth mentioning that data is conflicting regarding the potential benefits and adverse effect of bowel preparation, with some studies demonstrating decreased infectious complications, while others do not.

### The Patient’s Perspective

Patients’ perspective about surgery can drastically change if they are informed about the benefits of the ERAS program. The Royal Berkshire NHS Foundation Trust (RBHFT) in the UK implemented a program for patients to discuss expectations perioperatively and postoperatively, as well as a practical demonstration of stoma care. They received written information about the ERAS benefits of regional anesthesia and postoperative physiotherapy leading to an 85 percent satisfaction and a positive impact on their hospital stay. The practice at MCF is to discuss ERAS with patients preoperatively, receiving teaching directly from the surgeon as well as the preoperative nurse. Expectations are set in the clinic, and the patients are generally very open to the pathway and very happy to be active participants in their own care.

### ERAS Implementation in Other Centers

As stated by Aditya et al, ERAS implementation in an institution requires a multidisciplinary team. Surgery, nursing, and anesthesia play a major role and are the key to success of the protocol. Other important members include nutritionists, physical and occupational therapists, and social workers.

The most critical component of implementation is continuous feedback, including all providers that interact with the patient. Any issue should be addressed and discussed in scheduled team meetings to optimize program implementation. External reviews or audits can also be helpful, and once changes have been made, the entire cycle must be re-initiated.

### Conclusion

ERAS implementation requires a focused, organized multidisciplinary effort. Nurses, doctors, social workers, trainees - all patient care team members - must understand the philosophy behind ERAS and their role in its implementation. Most importantly, through education, the patient should understand its value, and that ultimately, they will be the beneficiaries of ERAS, receiving better, safer care.
References


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The Science of Patient Safety: A Discipline Designed to Understand and Promote Delivery of High Quality Healthcare

By Cynthia L. Leaphart, MD
University of Florida College of Medicine, Jacksonville, FL

Abstract: Patient safety is an emerging discipline within the health care profession. The methods used in patient safety draw upon the collaborative fields of cognitive psychology, human factors and ergonomics, and organizational management. This approach emphasizes a recognition of systems-based challenges that contribute to the presence of hazards within a healthcare system. Adaptation to the complexities of the healthcare system enable healthcare providers to adjust performance within the unique positions that they work. The adaptation of behaviors enables risk modifications and proactive changes to prevent systems-failures. These adaptations within a complex system create resilience and are the sine qua non of high performing organizations. This article contains a brief overview of the science of Patient Safety and highlights the training program at the University of Florida College of Medicine in Jacksonville.

The Evolution of Patient Safety Science

Patient Safety is a relatively new formal discipline within the health care profession. The methods evolved from disciplines outside of medicine, including cognitive psychology, human factors and ergonomics, and organizational management. Cognitive psychology is the study of mental processes, problem solving, perception, and thought processes where greatest emphasis is placed on the mental processes that affect human behavior. Human factors and ergonomics is the practice of designing systems, processes, or products to accommodate users and their environments. Organizational management involves monitoring of the work environment to anticipate necessary changes to induce adaptive responses required for the success of an institution. Within the discipline of patient safety, the intersection of these three fields to positively affect and motivate a complex environment requires tools and techniques such as communication training, effective teamwork skills, and simulation training to study and change behavior. This discipline, highly regarded for the ability to understand healthcare systems and effect positive change, has only recently been instituted into curriculum for medical, nursing, and other hospital providers.

The rapid evolution of patient safety within healthcare stems partially from the Institute of Medicine’s report To Err Is Human, which emphasized that safety of care is a property of a system of care where well-designed processes prevent, recognize, and quickly recover from hazards so that patients are not harmed. This November 1999 publication and additional prominent news reports of deaths due to medical errors, wrong-site surgery, and similar unthinkable events from systems of healthcare, accelerated the need to educate the healthcare workforce in Patient Safety. Conventional wisdom regards To Err Is Human as a sentinel historical event defining the field of patient safety, but experts understand this as only one of three publications which galvanized patient safety as a socially accepted movement.
The historical development of the field dates back to the ancient Greeks in 4 BCE with Hippocrates’s admonition to physicians to “First, do no harm.” This time period, known as The Sporadic Era (4 BCE – 1958) saw the introduction of improvements in healthcare that reduced infection, such as Semmelweis’s insights into the origin and prevention of puerperal sepsis based on empirical observations. In the early 1900’s, Earnest Amory Codman, a surgeon, advocated for the routine recording of outcomes in surgery and public reporting of results. For this, he was ostracized, but his work was adopted partially by professional organizations. His attempts at standardization of hospitals ultimately led to the development of the accrediting body currently known as The Joint Commission.

As evidence and data took shape, the patient safety movement evolved into the second period, “The Cult Era,” where groups of people coalesced to advocate for safety in healthcare. In this era, spanning 1959 – 1997, evidence supporting the science of patient safety evolved from studies regarding risk and responsibility related to managing modern disease without unnecessary harm. This group of researchers was little known outside of their own circles, which is why and how the Institute of Medicine’s publication To Err is Human advanced the science of patient safety through an organized social movement.

The third period (1998 – current), referred to as the “Breakout Era,” was influenced by the publication of To Err is Human, in addition to the British Medical Journal special issue on safety, and the National Health Service Report, An Organization with a Memory. These publications occurred within months of each other, thus amplifying knowledge and providing legitimacy to the patient safety movement derived from the reputation of each of the publishers. Public awareness was increased, and patient safety became a socially organized movement working towards the improvement of healthcare.

The relationship of patient safety to human factors and ergonomics stems from a common interest of interactions of people with environments and the technology and machinery they use to ensure the highest level of safety and performance. Human Factors as a field emerged around the end of World War II when technological advances outpaced the ability of pilots to adapt and compensate in high stakes environments. More specifically, highly-trained pilots flew technologically advanced aircraft and machinery, yet crashes still occurred. Due to loss of life and machinery, it was realized that design of equipment had to account for limitations of human capabilities and the decision-making, situational awareness, attention, and hand-eye coordination of the pilot to ensure that tasks performed in highly stressful situations could be successfully accomplished. One example of human factors is found in the research of Fitts and Jones (1947) who reported that “pilot error” occurred because knobs and gears within the cockpit typically looked or felt identical, were often co-located, and were easily mixed up while working across different cockpits. So-called “pilot error” was connected to the features of tools and tasks within a complex environment, rather than attributed to personal skill or ability. Strikingly, the same findings are applicable in healthcare organizations where tradeoffs by people at the sharp end (clinicians) are influenced by organizational resources and constraints that influence decision-making and action. Improving overall understanding of the resources and constraints that influence decisions and actions provides insight that ultimately improves the delivery of healthcare.

The Public’s Attention is Drawn to Patient Safety

On December 13, 1995, Ben Kolb’s parents took him to Martin Memorial Medical Center in Stuart, Florida for an outpatient procedure to remove scar tissue from his ears after multiple procedures to unblock his Eustachian tubes. The surgeon ordered two medications for injection, a local anesthetic and a medication to control bleeding. On the surgical field, both substances look like water and the syringes were confused. The medication to control bleeding was injected first, rather than the local anesthetic. As a result, the injection caused this 7-year-old’s heart to race and his blood pressure skyrocketed. The child left the operating room in a coma and died shortly thereafter. The story of Ben Kolb is one of many publicized events that drew the public’s attention to the safety of patients in the healthcare system.

Other notable stories include Betsy Lehman, an award-winning health columnist for the Boston Globe, whose death was attributed to an overdose of chemotherapy drugs and Lewis Blackman, a South Carolina teenager whose untimely passing in a teaching hospital was attributed to systems failure and poor communication amongst interprofessional teams. Throughout the United States, it is estimated that medical errors like these occur at a rate between 44,000 to
98,000 per year.\(^1\) In patient safety, an emphasis is placed on designing infrastructure that makes a system safer, rather than using the traditional “shame and blame” methodology to find and punish people who are responsible for mistakes. This practice is consistent with the conclusions drawn in the Institute of Medicine’s study which emphasized that the majority of errors do not result from individual recklessness or actions of a particular group, but rather occur due to faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.\(^1\)

To enhance the systems-based approach of patient safety, educational emphasis has been placed on training healthcare providers in the science of patient safety and recognition of systems-processes that contribute to factors leading to mistakes in healthcare delivery. Specialized training programs may occur as components of the curriculum for medical students, nursing students, or in residency training programs with additional CME for practicing providers. Some medical providers choose to continue with intensive training in fellowships which are evolving across the nation. There are many fellowship training opportunities across the nation, most of which emphasize quality improvement training rooted in manufacturing techniques such as Lean and Six Sigma. Lean is a systematic method to minimize waste within a system without sacrificing productivity. This quality improvement methodology adds value by reducing everything in a system that does not add value to production. Six Sigma is a disciplined, data-driven approach to process improvement that eliminates problems within a system that prevent reaching near perfect functioning states.

It should be emphasized that quality improvement is different from patient safety, in that quality improvement tools and techniques assess processes that occur in a linear fashion with improvements made at points along the flow of work. This approach emphasizes management without recognition of interdigitated networks that do not conform to standardized rules or control. By contrast, patient safety focuses on complex adaptive systems that review and assess multiple components of a process and the opportunities within to correct or enhance the infrastructure of the healthcare system.\(^2\) The patient safety approach uses leadership techniques to reinforce system integration and create feedback loops and learning organizations for complex systems.\(^11\)

**Literature on Patient Safety**

Literature and didactic curriculum focused on the importance of team training, assessment of latent and overt factors contributing to systems based errors, and communication that provides a foundation to understand how large organizations are impacted by decision making that is focused on reduction of risks within a complex system. The healthcare system is a multidimensional integration of culture, technology, and the ability to complete tasks by working across multiple integrated departments. Attention to the works of Rene Amalberti, Mary Dixon-Woods, Charles Bosk, Charles Vincent, and other contributors to the discipline of patient safety provides a framework to understand systems design and the contribution of design to error development and risk mitigation.

Rene Amalberti is a thought-leader in Resilience Engineering, a new way of thinking about safety. While conventional risk management approaches focus on hindsight and emphasize error tabulation and failure probabilities, Resilience Engineering looks for ways to enhance the ability of all organizations to create processes that are robust yet flexible. Failures represent the ability to adapt and conform to real world complexity because individuals must constantly adjust their performance to the unique situations in which they work. Resources and time are considered finite, and success depends on the ability of a group, individual, or organization to anticipate changes and modify risks before systems-failures occur.\(^12\) A resilient organization is a proactive and adaptive organization that achieves ultra-high levels of safety to manage the unexpected, disruptive, and constant changes facing organizations with high pressures to perform.\(^13\) A key diagnostic signal for a resilient system is understanding how an organization or group of people make sacrificial judgments in trade-off situations between acute production or efficiency-related goals when risk reduction is necessary as safety boundaries are approached.\(^12\) In surgery, the sacrificial judgment indicative of resilience is exemplified when a surgeon decides to convert from a laparoscopic to an open surgical procedure for visualization and technical purposes. Similarly, sacrificial judgements are made in the airline industry when aircraft approaches may be aborted due to weather that increases the risks of wind shear.
Mary Dixon-Woods and Charles Bosk are sociologists whose respective careers have focused on the culture of medicine with an emphasis in how providers make decisions in uncertain situations. Amongst a multitude of publications, the two co-authored a paper explaining the behavior and theory behind the noted success of the state of Michigan’s ability to drive central line infection rates to zero using interprofessional teamwork, peer competition, and a vertical core of leadership.14

Charles Vincent is an Emeritus Professor of Clinical Safety at Imperial College in London. He is a pioneer of patient safety whose publications provide practical guidance on the implementation of safer practices in healthcare.15,16

Patient Safety Fellowship Training at UF College of Medicine - Jacksonville

In North America, the number of true patient safety training programs providing an emphasis on systems-based engineering, cognitive psychology, and organizational management number less than ten. The University of Florida College of Medicine – Jacksonville offers a one-year formal training program in patient safety. The Patient Safety Fellowship began in 2010 under the direction of Constance K. Haan, MD, cardiothoracic surgeon and former Designated Institutional Official for Graduate Medical Education Programs. The training program immerses fellows in a year of study using a systems-based approach to evaluate clinical errors, principles of patient safety, and human factors. More specifically, modules are designed to provide training in measurement of safety indicators, an introduction to accident investigation, hazard and risk assessment in healthcare, human-device interaction/usability testing and safety design. Hands-on opportunities are provided through event tracers and initiatives within various departments within the hospital and ambulatory settings. Using this approach, the fellow gains an understanding of measures of hospital-wide quality and safety while engaging in improvement and innovations across the system. There is broad exposure to physician engagement in system initiatives while working closely with pharmacists on medication safety teams, nursing personnel in hospital and ambulatory settings, and key hospital leaders engaged in quality improvement initiatives. Additional opportunities to understand risk mitigation and interaction of system-design are provided by working with the institution’s Patient Safety Officer and Risk Management Personnel.

Framework of the Patient Safety Fellowship

By focusing on the evaluation of systems design, the Patient Safety Fellow learns how design of a system leads to the results that are obtained. To change unfavorable results, system redesign is required. However, this is rarely achieved without a thorough evaluation of all the integrated components.

The Patient Safety Fellow works closely with undergraduate training programs to design and lead simulation scenarios for team training and patient safety improvement. Simulation Training and assessment models are resources used for patient safety. The Center for Simulation Education Safety and Research (CSESaR) at the University of Florida in Jacksonville provides the setting for didactic training and simulation instruction within a former hospital emergency department and operating room areas. There is a wide variety of training scenarios, including mass casualty simulation, patient encounters, and a range of simple task trainers through high fidelity simulators. The CSESaR is actively used for graduate and undergraduate medical education, nursing student education, active hospital personnel, special operations medics, emergency responders, and local and regional health care providers. The Assistant Dean of Simulation Education, Andy Godwin, MD, serves as Program Director for the Patient Safety Fellowship and is nationally and internationally known for co-creation of the Simulation Team Competition known as SimWars. Through these activities, the Patient Safety Fellow becomes a resource to graduate medical education leadership and faculty for clinical outcomes and performance improvement initiatives.

Cynthia Leaphart, MD is the Associate Program Director for the fellowship and uses simulation training to educate residents and fellows enrolled in the College of Medicine in patient safety principles and concepts. More recently, the training evolved to incorporate interprofessional hospital teams and frequently involves in situ (bedside) training using high fidelity simulation. Her background includes formal training in the science of patient safety with additional emphasis in quality improvement as a senior member of the American Society of Quality, as well as formal training in Lean and Six Sigma methodology.

Since its inception, the engagement of the Patient Safety Fellow in institutional activities has provided additional valuable insights for daily operations. All residents and fellows attend an annual patient safety training simulation
that emphasizes basic knowledge for safe physician-patient interactions while maintaining effective communication with staff. This activity serves as a building block for additional requirements from the Accreditation Council for Graduate Medical Education (ACGME) to ensure that residents and fellows in accredited specialty and subspecialty programs obtain fundamentals of quality care and safety that enable tomorrow’s physician workforce to meet the challenges of a rapidly evolving healthcare system. Fellows frequently serve as an additional resource to provide education and training or analytical skills for initiatives to improve quality, such as the reduction of acquired infections or implementation of barcode scanning medical administration. To enhance interprofessional team performance, in situ models of simulation have been developed to promote effective team communication in emergent situations such as perioperative fire drills and disaster drills and training.

Conclusion

Formally-trained fellows with a deep understanding of human factors, cognitive psychology, and organizational management enhance the organization through a distinctive knowledge base and assessment skill set that promotes safer delivery of healthcare within the system while demonstrating decision making from an organizational standpoint. Formally trained experts in Patient Safety provides healthcare systems with highly sought-after skills to improve the delivery of high quality and safer medical care.

References:

Surgical Outcomes of Diabetic versus Non-Diabetic Patients Undergoing Vascular Interventions: A Case Study

By Houssam Farres, MD ¹, Dorin Colibaseanu, MD ², Tariq Almerey, MD ¹, January Moore, BA ¹, Mahmoud Selim, MD ¹, David Lee, MD ³, Warner A. Oldenburg, MD ¹, and Albert G. Hakaim, MD ¹

Mayo Clinic Florida, Division of Vascular Surgery ¹ and Colorectal Surgery ²

Abstract:
Objective: The purpose of this study is to highlight the effect of diabetes mellitus (DM) on vascular interventions outcomes.

Methods: A retrospective analysis was conducted of 245 patients who underwent vascular interventions at Mayo Clinic Florida. The patient sample represents a compilation of all the vascular patients who were reported in institutional NSQIP reports between 2013 and 2015 and in our institutional surgical site infection registry from 2013 and 2015.

Results: In this sample, 56.7 percent of patients had diabetes at the time of their vascular intervention. There was no statistically significant difference in thirty-day mortality rate between diabetics and non-diabetic patients (2.2 percent versus 0.9 percent respectively, p=0.632). Readmission occurred in 20.6 percent of diabetic patients versus 6.7 percent in non-diabetic patients (p=0.002). The need for reoperation between the two groups was 22.6 percent in diabetics versus 12.3 percent in non-diabetics, p=0.037.

There was no statistically significant difference in surgical site infection between diabetics and non-diabetic patients (19.4 percent versus 13.2 percent, p=0.201, respectively). Graft thrombosis occurred in 2.2 percent in diabetics versus 0.9 percent in non-diabetic patients, however, this was not statistically significant (p=0.632).

Conclusion: Diabetes mellitus plays an important role in increasing morbidity following vascular interventions. In addition, the increase in readmission and reoperation rate in diabetic patients will, inadvertently, result in a considerable increase in national health care cost. Therefore, further studies are necessary to outline the impact of adequate diabetes mellitus control on decreasing morbidity and patient health care cost.

Introduction

The prevalence of diabetes mellitus (DM) in the United States continues to increase significantly with changes in population growth, aging, urbanization and obesity.¹,² DM leads to macrovascular complications earlier than those seen in nondiabetic patients.³ DM is of special concern in vascular surgical patients, as diabetic patients have been shown to experience higher perioperative morbidity and long-term cardiovascular events than patients without diabetes.⁴,⁵ Vascular surgical patients with peripheral arterial disease and DM were found to have more advanced peripheral arterial disease (PAD) than non-diabetic patients⁶ and higher length of stay and higher patient costs than non-diabetic patients.⁷ Chronically impaired glucose metabolism can also weaken the immune system and may play a role in post-operative infections.⁸

The increase in glucagon and cortisol levels resulting from surgery can alter metabolism, leading to gluconeogenesis.⁹,¹⁰ High glucose levels also interfere with the inflammatory cascade and can increase early pro-inflammatory cytokine levels.¹¹ These cytokines interfere with insulin signaling and trigger insulin resistance.¹²,¹³,¹⁴ High glucose concentrations can cause vascular dysfunction due to the imbalance between nitric oxide and reactive oxygen species.¹⁵ Endothelial dysfunction caused by hyperglycemia leads to a weakened vasodilation in response to acetylcholine and endothelium-derived nitric oxide.¹⁶–¹⁹

In this study, the outcomes between diabetic and non-diabetic patients who had undergone vascular interventions were analyzed and compared. Post-operative complications analyzed included mortality, readmission, reoperation, surgical site infection (SSI), and graft thrombosis.
Patient Quality & Safety

**Consider delaying surgery until sugar is under better control**

- Process with surgery
- Refer pt for ENDO consult in hospital post op

**Provide pt w/ DM Med instructions pre-op**

---

**Surgical pt evaluated in POE**

- A1C>8
- BS<71
- **BS>/=140**
- **BS>/=140, po meds & basal insulin**
- **BS>/=140 and on home basal insulin**

- **BS>/=140, stable pt, good perfusion, procedure <2 hrs**
- **BS>/=140, unstable pt w/ poor perfusion, procedure >2 hrs, unable to administer SQ insulin due to surgical factors**

- **BS<71**

- **BS>/=140, stable pt, good perfusion, procedure <2 hrs**

**Initiate IV insulin gtt w/BS checks Q1 hour**

**BS>/=140, unstable pt w/ poor perfusion, procedure >2 hrs, unable to administer SQ insulin due to surgical factors**

**BS>/=140, stable pt, good perfusion, procedure <2 hrs**

**Initiate the Peri-Anesthesia Power Plan & Select**
- mild correction scale
- moderate correction scale

- **BS>/=140, po meds & basal insulin**
- **BS>/=140 and on home basal insulin**

**BS<71**

**BS>/=140, stable pt, good perfusion, procedure <2 hrs**

**BS>/=140, unstable pt w/ poor perfusion, procedure >2 hrs, unable to administer SQ insulin due to surgical factors**

**Preform Time Out to include: “Is the patient a diabetic? What was the most recent blood sugar?”**

**Pre-Operative Holding**

**Pre-OP Nurse to assess meds then prior to arrival & document in Peri-Operative Nursing Ad Hoc Form**

**Intra-Op**

**Continue BG checks as previously ordered (Q1 hour vs. Q2 hours)**

**Intra-Op**

**Continue BG checks as previously ordered (Q1 hour vs. Q2 hours)**

**PACU**

**Meet PACU d/c criteria**

**Transition glucose management from anesthesia to surgery team, ensure that correction scale has been ordered.**

**Is pt on Insulin drip? Must have a plan for transitioning off drip.**

- No Dextrose IVF Except:
  - Prolonged NPO status
  - Blood sugars <70
  - Required for Medication Mixing

- Oral DM only requiring 2 unit/hr or less from IV gtt, with a BS consistently <140

- Oral DM only requiring > 2 unit/hr and BS consistently >140

- DM using home basal insulin

- DM not using home basal insulin at home

**D/C gtt w/out SQ Basal**

**New order for BGM QID and correction scale**

**D/C gtt w/out SQ Basal**

**New order for BGM QID and correction scale**

**Report to receiving unit time/dose of last insulin & time/result of BS check**

**Initiate Insulin SQ Transition FL Power Plan**

**Order Home basal**

**New order for BGM QID and correction scale**

**Initiate Insulin SQ Transition FL Power Plan**

---

**Figure 1.**
Methods

This was a retrospective analysis conducted at Mayo Clinic Florida of 245 patients undergoing vascular interventions between 2013 and 2015. Thirty percent of the patients underwent outpatient intervention versus 70 percent who required in-hospital stay. After Institutional Review Board approval, the patient sample was compiled from the vascular patient populations reported in NSQIP and institutional glycemic and surgical site infection dashboards.

Patient characteristics and outcomes were recorded and analyzed using the appropriate statistical tests.

Results

Demographics and comorbidities.

Of the patient sample, the median age was 71.5 years for non-diabetic patients and 70 years for diabetic patients (Table 1). 56.6 percent of non-DM patients and 69.1 percent of DM patients were male. Of the total 245 patient sample, 56.7 percent had diabetes at the time of vascular intervention. 217 patients (91.2 percent) of the total patient population had American Society of Anesthesiologists (ASA) physical status scores of 3 (74.4 percent) or above (16.8 percent), showing that these patients had severe systemic disease. Surgical patients with DM were optimized through an algorithm adopted by the enterprise (Figure 1).

Postoperative outcomes.

There was no statistically significant difference in thirty-day mortality rate between DM and non-DM patients (2.2 percent versus 0.9 percent respectively, \(p=0.632\) (Table 2). Readmission was required for 20.6 percent of DM patients versus 6.7 percent in non-DM patients \(p=0.002\). The need for reoperation between the two groups was 22.6 percent in DM patients versus 12.3 percent in non-DM \(p=0.037\).

There was no statistically significant difference in surgical site infection between DM and non-DM patients (19.4 percent versus 13.2 percent, \(p=0.201\), respectively). Graft thrombosis occurred in 2.2 percent of DM patients compared to 0.9

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Non-DM</th>
<th>DM</th>
<th>Total</th>
<th>(p)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age</td>
<td>71.5 (61.0, 78.0)</td>
<td>70 (63, 77)</td>
<td>71 (63, 77)</td>
<td>0.736 †</td>
</tr>
<tr>
<td>Median (Q1, Q3)</td>
<td>30, 93</td>
<td>35, 92</td>
<td>30, 93</td>
<td>0.045 ‡</td>
</tr>
<tr>
<td>Male</td>
<td>60 (56.6%)</td>
<td>96 (69.1%)</td>
<td>156 (63.7%)</td>
<td>&lt;0.001 §</td>
</tr>
<tr>
<td>ASA Score</td>
<td>Missing</td>
<td>2</td>
<td>18 (17.3%)</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>5</td>
<td>73 (70.2%)</td>
<td>104 (77.6%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>7</td>
<td>13 (12.5%)</td>
<td>27 (20.1%)</td>
</tr>
</tbody>
</table>

† Wilcoxon | ‡ Chi-square | § Fisher exact
percent in non-DM patients; however, this was not statistically significant ($p=0.632$). No statistical significance was seen between the two groups regarding length of stay at the hospital, myocardial infarction, pulmonary embolism, urinary tract infection, limb loss, bleeding, sepsis, acute kidney injury, deep vein thrombosis, pneumoniae and cerebrovascular incident.

**Discussion**

There was no statistically significant difference in mortality rate between diabetic and non-diabetic patients, which is similar to results seen in other studies. One retrospective study of 177,430 general surgery and 34,006 vascular surgery patients found that insulin-dependent diabetics undergoing general and vascular surgery were at increased risk for 30-day morbidity but did not find increased risk for postoperative mortality versus non-DM patients. The study found that vascular surgery itself was predictive of mortality. A 2012 study showed that diabetic patients undergoing carotid endarterectomy were at higher risk of perioperative morbidity and mortality but that diabetic patients undergoing carotid artery stenting were not. Accordingly, one limitation of this study is that the type of vascular intervention was not distinguished. It is therefore recommended that future studies take into account various procedure types, even within the same surgical specialty.

Readmission and reoperation were significantly higher in patients with DM. Endara et al. found that reoperation was significantly associated with glycemic variability perioperatively, suggesting that tight glycemic control should be in place throughout surgery.

In the current study, although there was a higher percentage of a surgical site infection in patients with DM, the finding was nonsignificant. This corresponds with results seen by Blankush et al., although that study showed a significantly increased risk of infection in patients older than 81 years or with dirty wounds. While it is believed that increased glucose levels impair the immune system, making the body more vulnerable to infection, other studies show that high blood glucose also increases the pathogenicity of bacteria in vitro through higher biofilm formation. These findings suggest that high glucose levels play a multifaceted role in SSI, and further study into the various mechanisms of interaction is warranted.

**Table 2.** Postoperative outcomes of patient population by diabetes mellitus

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Non-DM</th>
<th>N=106</th>
<th>DM</th>
<th>N=139</th>
<th>Total</th>
<th>N=245</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td>1 (0.9%)</td>
<td>3 (2.2%)</td>
<td>4 (1.7%)</td>
<td>0.632 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmission</td>
<td>7 (6.7%)</td>
<td>28 (20.6%)</td>
<td>35 (14.5%)</td>
<td>0.002 ‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td>13 (12.3%)</td>
<td>31 (22.6%)</td>
<td>44 (18.1%)</td>
<td>0.037 ‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Site Infection</td>
<td>14 (13.2%)</td>
<td>26 (19.4%)</td>
<td>40 (16.7%)</td>
<td>0.201 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graft Thrombosis</td>
<td>1 (0.9%)</td>
<td>3 (2.2%)</td>
<td>4 (1.7%)</td>
<td>0.632 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of Stay (days)</td>
<td>1 (0, 2)</td>
<td>1 (0, 4)</td>
<td>1 (0, 3)</td>
<td>0.240 †</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (Q1, Q3)</td>
<td>0, 21</td>
<td>0, 26</td>
<td>0, 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0 (0.0%)</td>
<td>4 (3.0%)</td>
<td>4 (1.7%)</td>
<td>0.132 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary Embolism</td>
<td>1 (0.9%)</td>
<td>0 (0.0%)</td>
<td>1 (0.4%)</td>
<td>0.442 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>0 (0.0%)</td>
<td>2 (1.5%)</td>
<td>2 (0.8%)</td>
<td>0.505 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limb Loss</td>
<td>3 (2.8%)</td>
<td>6 (4.5%)</td>
<td>9 (3.8%)</td>
<td>0.735 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 (1.9%)</td>
<td>2 (1.5%)</td>
<td>4 (1.7%)</td>
<td>1.000 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sepsis</td>
<td>1 (0.9%)</td>
<td>2 (1.5%)</td>
<td>3 (1.3%)</td>
<td>1.000 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Kidney Injury</td>
<td>3 (2.8%)</td>
<td>4 (3.2%)</td>
<td>7 (3.0%)</td>
<td>1.000 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep Venous Thrombosis</td>
<td>1 (0.9%)</td>
<td>2 (1.5%)</td>
<td>3 (1.3%)</td>
<td>1.000 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumoniae</td>
<td>2 (1.9%)</td>
<td>2 (1.5%)</td>
<td>4 (1.7%)</td>
<td>1.000 §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular Incident</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† Wilcoxon  | ‡ Chi-square  | § Fisher exact
Selection bias was another limitation of this study, as the patient sample was collected from specific institutional surgical site infection, glycemic, and NSQIP dashboards.

**Conclusion**

This study shows that diabetes mellitus negatively affects outcomes in patients undergoing vascular surgery by increased morbidity, readmission, and reoperation. This leads to an increase in healthcare cost. Future investigation is recommended for perioperative and long-term glycemic control in this particular population, subdivided by type of intervention. ♦

**References**

For adult patients with moderately to severely active UC or CD

Envyvio
vedolizumab

FASTEST GROWING BIOLOGIC ACROSS
UC & CD

*Based on an analysis of all products available in SHA database comparing patient counts from Jan-Dec 2015 to Jan-Dec 2016.

INDICATIONS
Adult Ulcerative Colitis (UC)
ENTYVIO (vedolizumab) is indicated in adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids for inducing and maintaining clinical response, inducing and maintaining clinical remission, improving endoscopic appearance of the mucosa, and achieving corticosteroid-free remission.

Adult Crohn’s Disease (CD)
ENTYVIO (vedolizumab) is indicated in adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids for achieving clinical response, achieving clinical remission, and achieving corticosteroid-free remission.

IMPORTANT SAFETY INFORMATION
• ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
• Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
• Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is
• Provides remission at 52 weeks for patients with moderately to severely active ulcerative colitis (UC) or Crohn’s disease (CD)\(^2\)
  - Studied in patients who have failed conventional therapies or a biologic
  - Individual results may vary

• Clinical trials evaluated safety in more than 3300 adults on Entyvio\(^2\)
  - Including more than 800 patients who received Entyvio for more than 2 years

• A distinct mechanism of action that specifically blocks lymphocyte migration, a key contributor to inflammation in the gut\(^2\)

• Entyvio specifically binds to \(\alpha_4\beta_7\) integrin, blocking its interaction with MAdCAM-1, which is mainly expressed on gut endothelial cells\(^2\)

• 300-mg dose for adult patients\(^2\)

IMPORTANT SAFETY INFORMATION (continued)

not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

• Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.

• There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

• Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines.

Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

• Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

See brief summary of Prescribing Information on adjacent pages.


To learn more, visit EntyvioHCP.com
BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

ENTVIO (vedolizumab) for injection, for intravenous use

INDICATIONS AND USAGE

Adult Ulcerative Colitis (UC)
ENTVIO (vedolizumab) is indicated for:
- inducing and maintaining clinical response,
- inducing and maintaining remission,
- improving the endoscopic appearance of the mucosa, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Adult Crohn’s Disease (CD)
ENTVIO (vedolizumab) is indicated for:
- achieving clinical response,
- achieving clinical remission, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

CONTRAINDICATIONS

ENTVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTVIO or any of its excipients (such as dyes, bronchospasm, urticaria, flushing, rash and increased heart rate) [see Warnings and Precautions and Adverse Reactions].

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions and Hypersensitivity Reactions
In UC Trials I and II and CD Trials I and III, hypersensitivity reactions occurred including a case of anaphylaxis (one out of 1434 patients [0.07%]) [see Adverse Reactions]. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. The majority were mild to moderate in severity as assessed by the investigator. Experience with other biologic medications suggests that hypersensitivity reactions and anaphylaxis to ENTVIO may vary in their time of onset from during infusion or immediately post-infusion to occurring up to several hours post-infusion.

If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTVIO immediately and initiate appropriate treatment (e.g., epinephrine and antihistamines).

Infections
Patients treated with ENTVIO are at increased risk for developing infections [see Adverse Reactions]. The most commonly reported infections in clinical trials occurring at a rate greater on ENTVIO than placebo involved the upper respiratory and nasal mucosa (e.g., nasopharyngitis, upper respiratory tract infection). Serious infections have also been reported in patients treated with ENTVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis and cytomegaloviral colitis.

ENTVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding treatment in patients who develop a severe infection while on treatment with ENTVIO. Exercise caution when considering the use of ENTVIO in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice. For progressive multifocal leukoencephalopathy (PML) [see Warnings and Precautions].

Progressive Multifocal Leukoencephalopathy
Another integrin receptor antagonist has been associated with progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system (CNS). PML is caused by the John Cunningham (JC) virus and typically occurs in patients who are immunocompromised.

In ENTVIO clinical trials, patients were actively monitored for PML with frequent and regular screenings, and evaluations of any new, unexplained neurological symptoms, as necessary. While zero cases of PML were identified among patients with at least 24 months of exposure, a risk of PML cannot be ruled out. No claims of comparative safety to other integrin receptor antagonists can be made based on this data.

Monitor patients on ENTVIO for any new onset, or worsening, of neurological signs and symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. The progression of deficits usually leads to death or severe disability over weeks or months. If PML is suspected, withhold dosing with ENTVIO and refer to a neurologist; if confirmed, discontinue dosing permanently.

Liver Injury
There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTVIO. In general, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. ENTVIO should be discontinued in patients with jaundice or other evidence of significant liver injury [see Adverse Reactions].

Live and Oral Vaccines
Prior to initiating treatment with ENTVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTVIO may receive non-live vaccines (e.g., influenza vaccine injection) and may receive live vaccines if the benefits outweigh the risks. There are no data on the secondary transmission of infection by live vaccines in patients receiving ENTVIO [see Adverse Reactions].

ADVERSE REACTIONS

The following topics are also discussed in detail in the Warnings and Precautions section:
- Infusion-Related Reactions and Hypersensitivity Reactions [see Warnings and Precautions]
- Infections [see Warnings and Precautions]
- Progressive Multifocal Leukoencephalopathy [see Warnings and Precautions]
- Liver Injury [see Warnings and Precautions]

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to ENTVIO in 3,326 patients and healthy volunteers in clinical trials, including 1,986 exposed for greater than one year, and 835 exposed for greater than two years. The safety data described in Table 1 are derived from four controlled Phase 3 trials (UC Trials I and II, and CD Trials I and II); data from patients receiving open-label ENTVIO treatment at Weeks 0 and 2 (prior to entry into UC Trial II and CD Trial III) and from Weeks 6 to 52 (non-responders at Week 6 of UC Trial I and CD Trial I) are included.

In these trials, 1,434 patients received ENTVIO 300 mg for up to 52 weeks, and 297 patients received placebo for up to 52 weeks. Of these, 769 patients had ulcerative colitis and 962 patients had Crohn’s disease. Patients were exposed for a mean duration of 259 days (UC Trials I and II) and 247 days (CD Trials I and III).

Adverse reactions were reported in 52% of patients treated with ENTVIO and 45% of patients treated with placebo (UC Trials I and II: 49% with ENTVIO and 37% with placebo; CD Trials I and II: 55% with ENTVIO and 47% with placebo). Serious adverse reactions were reported in 7% of patients treated with ENTVIO compared to 4% of patients treated with placebo (UC Trials I and II: 8% with ENTVIO and 7% with placebo; CD Trials I and III: 12% with ENTVIO and 9%, with placebo).

The most common adverse reactions (reported by ≥3% of patients treated with ENTVIO in the UC Trials I and II and CD Trials I and III combined group and ≥1% higher than in combined placebo group) were nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain and pain in extremities (Table 1).
<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ENTVYIO(^1) (N=1434)</th>
<th>Placebo(^2) (N=297)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>13%</td>
<td>7%</td>
</tr>
<tr>
<td>Headache</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12%</td>
<td>10%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>6%</td>
<td>3%</td>
</tr>
<tr>
<td>Cough</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Influenza</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Back pain</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Rash</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Pain in extremities</td>
<td>3%</td>
<td>1%</td>
</tr>
</tbody>
</table>

\(^1\)Data from patients receiving open-label ENTVYIO treatment at Weeks 0 and 2 (prior to entry into UC Trials I and II and CD Trials III and IV) and from Weeks 5 to 52 (non-respondents at Week 6 of UC Trial I and CD Trial I) are included.

\(^2\)Patients who received ENTVYIO for up to 52 weeks.

There were reports of elevations in transaminase and/or bilirubin in patients receiving ENTVYIO [see Warnings and Precautions]. In UC Trials I and II and CD Trials I and III, three patients reported serious adverse reactions of hepatitis, manifested as elevated transaminases with or without elevated bilirubin and symptoms consistent with hepatitis (e.g., malaise, nausea, vomiting, abdominal pain, anorexia). These adverse reactions occurred following two to five ENTVYIO doses; however, based on case report information it is unclear if the reactions indicated drug-induced hepatitis etiology. All patients recovered following discontinuation of therapy with some requiring corticosteroid treatment. In controlled trials, the incidence of ALT and AST elevations >3 x ULN was <2% in patients treated with ENTVYIO and in patients treated with placebo. In the open-label trial, one additional case of serious hepatitis was observed.

**Malignancies**

In UC Trials I and II and CD Trials I and III, malignancies (excluding dysplasia and basal cell carcinoma) were reported in six of 1434 (0.4%) patients treated with ENTVYIO, including colon cancer (n=2), transitional cell carcinoma (n=1), breast cancer (n=1), carcinoid tumor of the appendix (n=1), and squamous cell carcinoma (n=1). Malignancy was reported in one of 297 (0.3%) patients treated with placebo (squamous cell carcinoma).

**Immunogenicity**

As with all therapeutic proteins, there is potential for immunogenicity. In UC Trials I and II and CD Trials I and III, in patients who received ENTVYIO, the frequency of antibodies detected in patients was 13% at 24 weeks after the last dose of study drug (greater than five half-lives after last dose). During treatment, 56 of 1434 (4%) of patients treated with ENTVYIO had detectable anti-velozoalumab antibody at any time during the 52 weeks of continuous treatment. Nine of 56 patients were persistently positive (at two or more study visits) for anti-velozoalumab antibody and 33 of 56 patients developed neutralizing antibodies to velozoalumab. Among eight of these nine subjects, there was persistently positive anti-velozoalumab antibody and available velozoalumab concentration data, six had undetectable and two had reduced velozoalumab concentrations. None of the nine subjects with persistently positive anti-velozoalumab antibody achieved clinical remission at Weeks 6 or 52 in the controlled trials.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced...
by several factors, including sample handling, timing of sample collection, concomitant medications, presence of vedolizumab, and underlying disease. For these reasons, comparison of the incidence of antibodies to ENTYVIO with the incidence of antibodies to other products may be misleading.

**DRUG INTERACTIONS**

**Natalizumab**
Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab.

**TNF Blockers**
Because of the potential for increased risk of infections, avoid the concomitant use of ENTYVIO with TNF blockers.

**Live Vaccines**
Live vaccines may be administered concurrently with ENTYVIO only if the benefits outweigh the risks [see Warnings and Precautions].

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

*Pregnancy Exposure Registry*
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ENTYVIO during pregnancy. Information about the registry can be obtained by calling 1-877-TAKEDA7 (1-877-825-3327).

*Pregnancy Category B*

*Risk Summary*
There are no studies with ENTYVIO in pregnant women. No fetal harm was observed in animal reproduction studies with intravenous administration of vedolizumab to rabbits and monkeys at dose levels 20 times the recommended human dosage. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the benefits to the mother outweigh the risk to the unborn child.

*Clinical Considerations*
Any adverse pregnancy effect from ENTYVIO would likely be greater during the second and third trimesters of pregnancy. Monoclonal antibodies are transported across the placenta in a linear fashion as pregnancy progresses, with the largest amount transferred during the third trimester.

*Animal Data*
A reproduction study has been performed in pregnant rabbits at single intravenous doses up to 100 mg/kg administered on gestation Day 7 (about 20 times the recommended human dosage) and has revealed no evidence of impaired fertility or harm to the fetus due to vedolizumab. A pre- and post-natal development study in monkeys showed no evidence of any adverse effect on pre- and post-natal development at intravenous doses up to 100 mg/kg (about 20 times the recommended human dosage).

*Nursing Mothers*
It is unknown whether vedolizumab is present in human milk. Vedolizumab was detected in the milk of lactating monkeys. Exercise caution when administering vedolizumab to a nursing woman.

*Pediatric Use*
Safety and effectiveness of ENTYVIO in pediatric patients have not been established.

*Geriatric Use*
Clinical trials of ENTYVIO did not include sufficient numbers of subjects aged 65 and over (46 Crohn’s and ulcerative colitis patients aged 65 and over were treated with ENTYVIO during controlled Phase 3 trials) to determine whether they respond differently from younger subjects. However, no overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

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VM8245 R1_BrF L-BZV-0514-7
Quality of Care of Patients with HIV Infection

Background:
The Duval County Medical Society (DCMS) is proud to provide its members with free continuing medical education (CME) opportunities in subject areas mandated and suggested by the State of Florida Board of Medicine to obtain and retain medical licensure. The DCMS would like to thank the St. Vincent's Healthcare Committee on CME for reviewing and accrediting this activity in compliance with the Accreditation Council on Continuing Medical Education (ACCME).

This issue of Northeast Florida Medicine includes an article, “Quality of Care of Patients with HIV Infection” authored by Mobeen Rathore, MD, CPE, FAAP, FPIDS, FIDSA, FACPE, FSHEA, which has been approved for 1 AMA PRA Category 1 credit.™ For a full description of CME requirements for Florida physicians, please visit www.dcmsonline.org.

Faculty/Credentials:
Mobeen Rathore, MD, CPE, FAAP, FPIDS, FIDSA, FACPE, FSHEA is the Professor/Director at the University of Florida Center for HIV/AIDS Research, Education and Service (UF CARES) and Chief, Pediatric Infectious Diseases at Wolfson Children's Hospital in Jacksonville, FL.

Objectives:
1. Understand the epidemiology of HIV.
2. Understand prevention of transmission of HIV.
3. Understand principles of infection control in HIV.

Date of release: September 1, 2017  Date Credit Expires: September 1, 2019  Estimated Completion Time: 1 hour

How to Earn this CME Credit:
1. Read the “Quality of Care of Patients with HIV Infection” article.
2. Complete the posttest. Scan and email your test to Kristy Williford at kristy@dcmsonline.org or mail it to 1301 Riverplace Blvd., Suite 1638, Jacksonville, FL 32207.
3. You can also go to www.dcmsonline.org/NEFMCME to read the article and take the CME test online.
4. All non-members must submit payment for their CME before their test can be graded.

CME Credit Eligibility:
A minimum passing grade of 70% must be achieved. Only one re-take opportunity will be granted. If you take your test online, a certificate of credit/completion will be automatically downloaded to your DCMS member profile. If you submit your test by mail, a certificate of credit/completion will be emailed within four weeks of submission. If you have any questions, please contact Kristy Williford at 904.355.6561 or kristy@dcmsonline.org.

Faculty Disclosure:
Mobeen Rathore, MD, CPE, FAAP, FPIDS, FIDSA, FACPE, FSHEA reports no significant relations to disclose, financial or otherwise with any commercial supporter or product manufacturer associated with this activity.

Disclosure of Conflicts of Interest:
St. Vincent’s Healthcare (SVHC) requires speakers, faculty, CME Committee and other individuals who are in a position to control the content of this educations activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly evaluated by SVHC for fair balance, scientific objectivity of studies mentioned in the presentation and educational materials used as basis for content, and appropriateness of patient care recommendations.
Quality of Care of Patients with HIV Infection

By Mobeen Rathore, MD, CPE, FAAP, FPIDS, FIDSA, FACPE, FSHEA

Professor and Director
University of Florida Center for HIV/AIDS Research, Education and Service (UF CARES)
Chief, Pediatric Infectious Diseases, Wolfson Children’s Hospital

Abstract: The management of HIV infection has improved significantly over the last three decades of the epidemic. The treatment of HIV/AIDS infection has benefited significantly from the progress. National targets and benchmarks are used to determine the quality and extent of HIV care that patients are given in a particular program. In addition, quality of a program can also be gauged by the recognition of a program as a patient centered medical home. Staff can be safe from the potential transmission of HIV if they carefully follow all standard precautions and take blood and body fluid precautions when needed. In addition, the use of safer devices can provide protection against transmission.

Introduction

Significant advances have been made in the past three decades in diagnosis and management of HIV infection. The newer, fourth generation HIV screening tests are more sensitive and can diagnose HIV infection as early as one to two weeks after an individual is infected. A lot of effort is still needed to reach populations at risk for HIV infection. Outreach programs need to be tailored to specific populations and HIV testing needs to be easy for the tester and individuals wanting to get tested.

Transmission

HIV can be transmitted by several mechanisms including sexual contact, intravenous drug abuse, exposure to blood and body fluids (including needles), transfusion of infected blood and blood products (a route that no longer occurs in the United States of America) and MTCT (also referred to as perinatal transmission).

HIV/AIDS in Florida

Since 2010, almost 5000 cases of HIV infections have been diagnosed in Florida.¹ According to the Florida Department of Health, the HIV/AIDS surveillance program "plays a vital role in how Florida determines HIV/AIDS resource needs, program planning and evaluation." Data from each calendar year is finalized on June 30. Figure 1 shows a summary of newly diagnosed HIV infection cases over the last six years. The Department of Health also points out that there is a difference between year of diagnosis and year of report. Year of diagnosis indicates when a person was first diagnosed with HIV/AIDS, while year of report is the year the patient’s case was first reported to the Florida Department of Health and entered into the enhanced HIV/AIDS Reporting System.¹

Of all the reported cases in Florida of HIV infection in 1987, 11 percent were in women (ages 13+). This number grew to 29 percent in 2005. In 2014, this figure decreased to 20 percent.² According to the Florida Department of Health, women are more likely to be infected through high risk heterosexual contact, followed by injection drug use.³ In 2014, Florida statistics showed that HIV was the 5th leading cause of death among women between the ages of 25-44.

It is also important to look at racial statistics regarding HIV/AIDS. National and Florida data show that the survival time from AIDS diagnosis to death is significantly shorter for blacks than other racial/ethnic groups.³ Survival rates for AIDS cases in Florida also

Figure 1. (Reprinted with permission from the Florida Department of Health)
differs by race. According to data from 2007-2014, blacks had a median survival rate of 66 months, compared to 67 months for Hispanics, 75 months for American Indians, and 90 months for whites.4

When it comes to states with the highest number of pediatric AIDS cases, the state of Florida, with 1,571 pediatric AIDS cases in 2013, ranks second, after New York, in the number of pediatric AIDS cases.5,6 Through 2013, Florida has reported 2,561 cases of pediatric HIV infection, of which 74 percent were in African Americans and 95 percent were the result of MTCT.5,6 The number of perinatally acquired HIV-infected babies born in Florida (N=1,208 through 2013) has steadily declined (91 percent) from a peak of 110 cases in 1993 to 10 cases in 2013.5,6 Of the 503 babies known to be born to an HIV-infected mother in Florida in 2013, 10 (2 percent) were infected.5,6

The risk factors for these transmissions include:

1. Mothers who do NOT know their HIV status prior to birth
2. Inadequate prenatal care (adequate care is defined as: 5 or more visits, starting by month 4 or earlier),
3. No prenatal antiretroviral therapies (ART)
4. No ART at delivery, and/or
5. Non-caesarean birth
6. No neonatal ART (within the first 6 weeks of the infant’s life)
7. Breast feeding
8. A mother who is a substance abuser during pregnancy
9. A mother who acquired a STD during pregnancy
10. Issues associated with poverty and limited access to health care

In Florida, state law requires that healthcare providers must offer HIV testing to all pregnant patients early and late in pregnancy. HIV testing should be offered at the initial visit and then at 36 weeks gestation or after. The use of an “opt-out” HIV testing strategy in Florida has increased HIV testing in pregnant women by making it easier. In Florida, there are many sites where HIV testing can be obtained free of charge. Testing is always confidential and has the same protection under HIPPA laws as any other medical condition.

Tuberculosis

Tuberculosis (TB) remains a major public health concern in the HIV-infected population. Routine annual screening of all HIV-infected individuals is a quality outcome that must be a major target. Although tuberculin skin testing (TST) has traditionally been the gold standard, interferon gamma release assays (IGRAs) are more specific and a better option to screen for TB in the HIV-infected population. IGRA is now the preferred test for TB screening.

According to the Centers for Diseases Control and Prevention (CDC), people living with HIV are more likely to become infected with tuberculosis.7 Worldwide, TB is a leading cause of death among those with HIV. 2011 statistics from the World Health Organization estimate that of the 8.7 million people who developed incident tuberculosis, 13 percent were co-infected with HIV.8

Physicians can treat both HIV and tuberculosis but there are some challenges including overlapping side effects, drug-drug interactions and immune reconstitution inflammatory syndrome. Despite the challenges, the CDC reports that "providing antiretroviral therapy to HIV-infected adults during tuberculosis treatment, rather than waiting until completion of tuberculosis therapy, reduces mortality, particularly among those with advanced HIV disease."9

HIV/AIDS Research, Education and Service in Jacksonville

In Jacksonville, there is a system of care for HIV-infected women and children led by the University of Florida Center for HIV/AIDS Research, Education and Service, in collaboration with many community and healthcare partners. As a result, MTCT of HIV remains a rare occurrence and is considered a sentinel event for which UF CARES conducts an intensive route cause analysis.

One of the measures of high quality of care is recognition as a Patient Centered Medical Home (PCMH) by the National Committee on Quality Assurance (NCQA). Level 3 recognition by NCQA is the highest level of recognition and assures that a program offers care that is accessible, coordinated, culturally appropriate and patient and family-centered. UF CARES has NCQA recognition as a Level 3 PCMH.

Quality of care regionally, statewide or nationally can be determined by the percent of HIV-infected individuals diagnosed, engaged in care, prescribed antiretroviral medications and virally suppressed. A November 2014 study by the Centers for Disease Control and Prevention noted that only one-third of 1.2 million Americans living with HIV
Treatment of Infants

Infants born to HIV-infected mothers need antiretroviral therapy for at least six weeks. It is imperative the mother leaves the hospital with the necessary prescriptions. Follow-up at appropriate intervals is necessary so that diagnosis of HIV infection can be detected as soon as possible. Early treatment with antiretrovirals and prophylaxis for PCP infection in the infant is critical to decrease the morbidity and mortality associated with MTCT of HIV infection. Other opportunistic infections, such as tuberculosis, are fortunately rare in children in the United States, but are still a huge problem in the underresourced parts of the world. Nevertheless, HIV-infected children are at increased risk for tuberculosis and require appropriate screening for tuberculosis on a regular basis. Early diagnosis of HIV infection in the newborn period and the first 18-24 months of age requires molecular tests, such as HIV DNA or RNA PCR and, in some cases, a NAAT test. The routinely-used antibody-based HIV testing for adults is not accurate in infants, because of the presence of transplacentally acquired maternal HIV antibody.

Treatment of Children

Although many antiretroviral treatment options are available for children, the management of HIV-infected children is highly specialized. Such children should be managed by pediatric infectious diseases specialists who are experienced and knowledgeable about the latest treatment guidelines for pediatric HIV infection. Management of HIV is quite fluid and dynamic as the field burgeons and evolves. The latest information can be obtained from living documents at AIDSinfo.org.

All healthcare providers have a critical role in the prevention of MTCT of HIV. First and foremost, all healthcare providers and institutions should offer HIV testing to their patients annually, as recommended by the CDC in 2006.11 This will identify HIV-infected individuals so that they can receive appropriate treatment. Such treatment would decrease the chance of MTCT if a woman gets pregnant. Testing of HIV-infected men would identify potentially infected women. When appropriately treated and educated, HIV-infected men would be less likely to transmit the infection to their uninfected partners. As a result, a female partner would be less likely to transmit to their infants.
Treatment of Adolescents and Adults

HIV-infected adolescents and adults should be cared for by HIV specialists. At UF CARES, special programs for adolescents (13-18 years old) and emerging adults (19-24 years old) focus on their specific needs phased on their maturity and psychosocial development. Perhaps the most challenging group in this age group are those with alternate lifestyles, including the lesbian, gay, bisexual, transgender and questioning (LGBTQ) communities, who are at heightened risk for many life problems, including HIV. Young men who have sex with men are particularly at risk for HIV and especially vulnerable and difficult to reach.

Florida statistics show that in 2014, 16 percent of all new HIV infections occurred in individuals less than 25 years of age. Between 2012 and 2014, 548 new cases of HIV infection were reported among those between 13 to 19 years of age and 2,117 cases among those between 20 and 24 years of age. As of June 30, 2014, a total of 3,768 adolescents between the ages of 13 and 24 years old were infected.

The quality of care in a region, state or nationally is best defined by quality indicators and good outcomes. The CDC tracks the “HIV care continuum” to gauge progress towards national goals. The HIV care continuum tracks the following:

- **Diagnosed**: The number of people diagnosed with HIV, regardless of AIDS status.
- **Linked to care**: The number of people diagnosed with HIV in a given calendar year that had one or more documented medical visits, viral load or CD4 tests within three months after diagnosis.
- **Retained in care**: The number of diagnosed people who had two or more documented medical visits, viral load tests, or CD4 tests, performed at least three months apart in the measurement year.
- **Antiretroviral use**: The number of people receiving medical care and who have a documented antiretroviral therapy prescription in their medical records in the measurement year.
- **Viral load suppression**: Number of people whose most recent HIV viral load within the measurement year was less than 20 copies/ml.

The National HIV/AIDS Strategy (NHAS) 2020 has set up a five-year plan with annual targets for responding to the HIV epidemic. The ten indicators, plus three that considered developmental, are listed in Figure 3.
Preventing Transmission to Health Care Personnel

Prevention of transmission to health care personnel (HCP) is critically important. Following the recommended infection control policies is key. HCP should follow standard universal precautions for all patients. All blood and body fluids should be considered infectious and handled accordingly. All exposures must be reported and documented. This is important for protection of the HCP who may benefit from preventive antiretroviral protocols.

The most critical factor in patient and HCP safety is the use of standard precautions at all times and blood and body fluid precautions whenever necessary. In addition, the use of safer devices can also increase safety. It is important to remember that there are no completely safe devices, only safer devices. HCP must still use all medical devices especially sharps with utmost care.

Conclusion

High quality HIV care requires developing a system of care with strong processes and aiming for PCMH recognition. Using accepted standard outcome targets, such as those set by NHAS, assures the highest quality care. Every HIV program must have a quality improvement program that establishes a process to reach the desired outcomes. The use of infection prevention and control procedures and safer devices protects HCP from potential exposure to HIV.

Figure 4: Annual Targets for Indicator 6 of the National HIV/AIDS Strategy (adapted from Reference 14)

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<tr>
<td>Value</td>
<td>51.1%</td>
<td>54.5%</td>
<td>57.9%</td>
<td>61.3%</td>
<td>64.7%</td>
<td>69.8%</td>
<td>74.9%</td>
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For example, for Indicator 6 the target is to increase the percentage of persons diagnosed HIV infection who are virally suppressed to at least 80 percent. This target was expected to be reached progressively over a period of years. The annual targets for year 2010 through year 2020 are shown in Figure 4.15

Prevention of HIV/AIDS

The solution to the HIV epidemic worldwide is a safe and effective vaccine. Unfortunately, the field of HIV vaccinology has been fraught with more failures than successes. Although, each of these failures has guided the path to developing a safe and effective vaccine, progress has been slow and a vaccine remains elusive. Other prevention modalities such as condoms, diaphragms and microbicides have been available for years and offer significant protection for preventing HIV transmission, but they have not been very easy to implement. More recently, there has been success with the use of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) in the prevention of HIV transmission. None of the discussed modalities are perfect and require the at-risk person to proactively seek these modalities of prevention before or after an at-risk encounter making them less than optimum. A vaccine remains the best hope.
References:


Quality of Care of Patients with HIV Infection

CME Questions & Answers (circle one answer)/Free to DCMS Members/$55.00 charge non-members*

(Return by June 15, 2019 BY MAIL: 1301 Riverplace Blvd. Suite 1638, Jacksonville, FL 32207 or ONLINE: www.dcmsonline.org/NEFMCME)

1. Approximately how many new HIV infections have been reported in Florida since 2010?
   a. 20,000
   b. 10,000
   c. 5,000
   d. 1,000

2. The survival time from AIDS diagnosis to death is significantly shorter for which racial group?
   a. Whites
   b. Blacks
   c. Hispanics
   d. American Indians

3. When it comes to pediatric AIDS cases, which two states had the highest number of cases according to 2013 data?
   a. Florida and California
   b. California and New York
   c. Florida and New York
   d. Texas and Florida

4. Which of the following organizations determine whether a program is a Patient Centered Medical Home:
   a. HRSA
   b. NCQA
   c. CDC
   d. NIH

5. A November 2014 study by the Centers for Disease Control and Prevention noted that Americans living with HIV had their virus under control.
   a. One-third
   b. Fifty percent
   c. Two-thirds
   d. Seventy-five percent

6. In Florida, HIV testing:
   a. Does not have the same protection under HIPPA laws as any other medical condition.
   b. Mandatory every five years.
   c. Is confidential at most facilities.
   d. None of the above.

7. True or False: Infants born to HIV-infected mothers need antiretroviral therapy for at least six weeks.
   a. True
   b. False

8. NHSA target for percent of HIV infected individuals with viral load suppression for 2017 is:
   a. 57.9%
   b. 61.3%
   c. 64.7%
   d. 69.8%
   e. 74.9%

9. True or false: All blood and body fluids should be considered infectious.
   a. True
   b. False

10. Infection control procedures for the prevention of HIV include:
    a. Red Precautions
    b. Level 10 Precautions
    c. Standard Precautions
    d. No Precautions

Evaluation questions & CME Credit Information

(Please evaluate this article. Circle one number using this scale: 1= Strongly Agree to 5= Strongly Disagree)

The article met the stated objectives: 1 2 3 4 5
The article was appropriate to my practice: 1 2 3 4 5
The topic was current and well presented: 1 2 3 4 5
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**GI Corner**

**Inflammatory Bowel Disease and Pregnancy: Top Ten Questions (Part Two)**

By Mark R. Fleisher, MD

The previous issue of Northeast Florida Medicine addressed five questions often posed by patients and families regarding pregnancy and Inflammatory Bowel Disease (IBD). Here are five more that are often encountered in practice.

**Question 6: Can a Cesarean section (C-section) cause IBD in my child?**

Although a seemingly innocuous question, it really does confront the crux of IBD: how does IBD start? There is a plethora of research concerning the human microbiome. Moreover, since this milieu is forming in the neonate and C-sections disrupt this natural evolution, the question is a natural extension of these facts. The most recent study points out that a C-section does not predispose the fetus to developing IBD. Obstetrical data was obtained spanning 1984 through 2010 from over 12,000 patients in Manitoba. Interestingly, there was no difference in the number of patients who developed IBD born via cesarean section than those who did not develop IBD yet delivered in the same manner. Although the mode of birth affects the development of the intestinal microbiota, it did not play a role in the development of IBD in this study. These findings indicate that events of the immediate post-partum period that shape the developing intestinal microbiome do not affect the risk for eventually developing IBD.1 Older studies were equivocal. For example, one study from Denmark spanning 1973 to 2008 noted that rates of IBD with onset in childhood are modestly increased after birth by cesarean section.2 Older studies were equivocal. For example, one study from Denmark spanning 1973 to 2008 noted that rates of IBD with onset in childhood are modestly increased after birth by cesarean section.2 Once again, the question was whether or not disturbing the normal bacterial colonization of the newborn's intestine by delivering via C-section will increase the risk of developing IBD. Another meta-analysis study of nine studies supported the hypothesis that C-section delivery was associated with the risk of Crohn's disease but not ulcerative colitis.3 In essence, the etiology of IBD is still quite murky, but the most recent data points to cesarean sections not being a risk factor for a child to develop IBD. Although the microbiome is still quite nascent and evolving in the newborn, the mode of delivery is doubtfully a major factor in developing IBD, if at all.

**Question 7: Can I get a C-section safely?**

The patient is probably more interested in whether it is safe, in general, to have a C-section rather than whether the mode of delivery causes IBD in the child. One recent study showed that C-section rates are higher in patients with IBD. No increase in new or recurrent disease was noted in patients with quiescent disease who gave birth via spontaneous vaginal delivery as opposed to those who had a C-section. The authors noted that systematic C-section in patients with IBD should be limited to women at risk for perineal tears, those with active perineal Crohn's disease, and those with an ileal pouch anal anastomosis (IPAA).4 Another study notes that the mode of delivery did not influence the natural course of IBD. Vaginal delivery was not associated with an increased risk of developing perianal disease in women with IBD.5

Now you can tell your patient the following: a C-section is unlikely to cause IBD in your child. Moreover, vaginal delivery is safe as long as you do not have active IBD or have an IPAA at the time of delivery. However, if prenatal testing points to the possibility of a tear or episiotomy in a patient with a history of perineal IBD, get the C-section to be safe.

**Question 8: What is the likelihood that I will flare during my pregnancy?**

Certainly, if medications are stopped, your likelihood to flare is increased. As addressed in the previous journal issue, the manipulation of 5 aminosalicylates, as well as immunotherapy and biologic therapies, is tricky, but stopping all medications during pregnancy is just asking for trouble.6 In fact, studies show that women with IBD may have incorrect beliefs about...
their illness and their medications. Simple patient education and awareness prior to conception leads to fewer patient relapses during pregnancy and higher birth weight babies. These studies from Rotterdam, The Netherlands, and Jerusalem, Israel reveal that simple conversation and education about continuing medications and stopping smoking dramatically decreased hospitalizations and led to healthier children. Moreover, conception during an IBD flare results in or worsens disease activity in two-thirds of women. Lastly, exacerbation of the disease in pregnancy leads to an increased risk of fetal and maternal complications.\textsuperscript{7,8}

The old dogma of “a third, a third, a third” is a tad simplistic and outdated. Physicians will recall being taught in medical school that upon becoming pregnant, a third of women get better, a third get worse, and a third stay the same. However, this was before the advent of the biologic era. In fact, those physicians who espoused saving biologics as their “big gun” are akin to those people who refused to give up their horse when cars were invented. In essence, the earlier application of appropriate therapy will lead to more durable and sustainable remission.\textsuperscript{9} This will lead to safer pregnancies and healthier children. The heart of the matter was addressed by Drs. Gaidos and Kane when they wrote, "One of the main concerns these women have is whether these medications will have adverse effects on their growing fetus. Aminosalicylates, antibiotics, and steroids are all relatively low risk for use during pregnancy and breastfeeding. Recent studies also support the safety of continuing immunomodulators and anti-tumor necrosis factor agents during pregnancy and with breastfeeding."\textsuperscript{10}

**Question 9: Are there any tests available to predict if my child will get IBD?**

Loving parents are always on high alert. Loving parents with IBD are always on high alert for IBD in their children. These parents are all too aware of the typical delay in diagnosis and recognition of IBD. In fact, one study points to no improvement in diagnostic delay over the past 60 years in Italy!\textsuperscript{11} As of now, there are four genome wide loci that are associated with the prognosis and course of IBD. There are 170 loci that have been associated with susceptibility to IBD. Thus far, it appears that the genetic contribution to prognosis is independent of the genes associated with whether or not the patient is at risk for developing IBD.\textsuperscript{12} Serologic blood markers such as anti-saccharomyces cerevisiae antibody and perinuclear antineutrophil cytoplasmic antibody have inadequate sensitivity and specificity for children to be used as screening tests.\textsuperscript{13}

**Question 10: Who exactly was Crohn?**

I can’t tell you the number of patients who ask this simple question. In fact, asking this question displays that the patient is just beginning to own their illness. It is no longer an abstraction. It is a good sign. The original study regarding regional ileitis was published in 1932.\textsuperscript{14} The authors were Drs. Leon Ginzberg, Gordon Oppenheimer and Burrill Crohn. Dr. Crohn was a graduate of the City College of New York, a public college. He became chief of gastroenterology at The Mount Sinai Hospital in New York City. He was consultant in the care of president Dwight D. Eisenhower, who was officially diagnosed with Crohn’s disease in 1956. It is unclear if General Eisenhower had symptoms far earlier than he let on. We can only wonder if the leader of Operation Overlord on June 4, 1944, commonly known as D-Day, would have been washed out of the service if anyone knew of his chronic illness. Dr. Crohn retired from practice at the age of 90. One of his junior colleagues, Dr. Burton Korelitz, became instrumental in the advent of immunotherapy and biologic therapy for patients with IBD. Interestingly, he recently retired as well from the practice of gastroenterology at the age of 90. I was and remain Dr. Korelitz’s fellow and hope to be in practice until the age of 90 as well. However, according to my contract with my employer, I am compelled to retire at age 75. I suspect that at some point I will be furtively looking for employment to fulfill this goal. In the meantime, I remain ever hopeful that a cure for IBD will allow me to retire a bit earlier. Moreover, a team approach between obstetricians, pediatricians and gastroenterologists under the keen and watchful eyes of family practitioners and internists as well as nurse practitioners will help guide our patients not from flare to flare but from initial diagnosis to lifelong remission.\textsuperscript{15}
References


**In vitro maturation (IVM): a kinder, gentler, more natural, and less expensive way to undertake IVF**

By Bruce I. Rose MD, PhD\(^1,2\) and Samuel Brown MD\(^1,2\)

*Brown Fertility,\(^1\) Baptist Health South\(^2\)*

**Abstract:** In vitro maturation or “IVM” is an advanced reproductive technology that enables patients to achieve pregnancy without the complex use of most gonadotropin medications for ovulation induction as in conventional in vitro fertilization (IVF). IVM significantly reduces the cost of IVF type treatments, reduces the exposure of women to non-physiological hormonal environments, eliminates the most significant IVF complications, and greatly simplifies the IVF experience for the patient.

**Introduction**

In 1939, Dr. George Pincus observed that if an oocyte was removed from a rabbit ovary, it would often spontaneously complete meiosis.\(^1\) The oocytes stored in an ovary contain four times too many chromosomes and must extrude the excess chromosomes (as polar bodies) before fertilization can take place. Oocytes with the correct number of chromosomes for fertilization are termed mature. Over time, reproductive biologists foresaw the possibility of simply removing immature oocytes stored in the ovaries to help women with severe infertility problems achieve pregnancy. However, the details of how to accomplish this task eluded physicians and scientists for some time.

In 1978, after 102 laparoscopic oocyte retrievals, Edwards and Steptoe succeeded in achieving the first live birth of a baby conceived from an oocyte fertilized outside the body and transferred back into the uterus (IVF).\(^2\) This success was repeated in the United States at Eastern Virginia Medical School (The Jones Institute for Reproductive Medicine) by Howard and Georgianna Jones in 1981.\(^3\) One of their innovations was to use gonadotropins (FSH and LH purified from the urine of postmenopausal women) to cause multiple follicles to grow in the ovaries. Oocytes removed from these pre-ovulatory follicles were mature and thus capable of being fertilized immediately after removal from the ovary. This approach to IVF is still the predominant approach used today. IVF treatment generally involves a 10 to 14-day gonadotropin treatment phase which causes women to develop an average of 8 to 14 large follicles. From these follicles, oocytes can be obtained which contain the correct number of chromosomes for fertilization. (These oocytes complete meiosis in response to a medication given 36 hours before harvest.) Over the years, the process of IVF has been greatly simplified, the indications for IVF have greatly expanded, and the success rate of IVF has slowly increased. In the United States alone, at least 200,000 such cycles are performed each year.\(^4\) The IVF procedure has become streamlined into an office based procedure with transvaginal ultrasound guided oocyte retrieval rather than a hospital based procedure using laparoscopic oocyte retrieval in an operating room adapted to cell culture. The average pregnancy rate after fresh transfer for women under age 35 was 54.6 percent in 2014. The live birth rate after fresh transfer was 47.5 percent.\(^4\)

**Barriers to IVF**

Although women and physicians are willing to undertake the difficulties intrinsic to IVF in order to achieve pregnancy, minimizing these “side-effects” should be an objective of those providing this therapy. The cost of therapy is a major barrier to IVF utilization. Infertility therapy is viewed by some as partly elective and insurance coverage varies widely. Approximately one half of the cost of IVF is due to the cost of the gonadotropins used and the cost of monitoring gonadotropin use.\(^2\) Eliminating this component of IVF would be of great benefit to many patients. The production of multiple mature follicles causes the production of high levels of many hormones and growth factors. Many worry about the impact of high estrogen levels on their moods and on their long-term health.\(^5\) However, some of the less well known factors produced by the ovary in the course of routine follicle development, such as vascular endothelial growth factor...
(VEG-F) are of greater concern to their physicians. These factors can cause third spacing of fluid in an unpredictable manner leading from post oocyte retrieval bloating to severe ovarian hyperstimulation syndrome (OHSS). Untreated, severe OHSS has resulted in rare fatalities in the early days of IVF. Avoiding severe OHSS is still a major management issue for high risk patients.

**IVM: Another Option**

During IVF’s rapid development, some reproductive scientists continued to pursue the details of how to make in vitro fertilization work using immature oocytes (IVM). In 1991, Cha achieved the first human pregnancy using a donated immature oocyte obtained from an ovary during a Cesarean section. Unlike IVF, IVM uses immature oocytes, which are matured in vitro before being fertilized and transferred into the uterus. However, progress in determining the best way to perform IVM has been slow. There are successful clinical programs performing IVM throughout the world e.g., England (Oxford), Canada (McGill), France, Belgium, Finland, Italy, Korea, China, and Australia. The approaches taken for IVM vary greatly, and there is no consensus on how best to perform IVM in a clinical setting. Success rates have varied significantly both over time and between programs. Anecdotal reports suggest that IVM is a difficult procedure for many IVF programs. The latest position paper by the American Society of Reproductive Medicine states that IVM should presently be viewed as an experimental procedure.

**IVM: Weighing the Pros and Cons**

Many programs that have tried IVM have not found it to be worth the effort required. It is much harder to harvest oocytes from follicles that are 8 mm in diameter for IVM rather than 20 mm in diameter as in traditional IVF. Aspirated oocytes are much more difficult to identify when they do not have many granulosa cells around them. This is because the oocyte complex used in IVM is approximately 150 microns in diameter as compared to 450 microns in diameter for IVF. The follicular fluid volume aspirated is approximately 0.3 ml for an 8 mm IVM follicle compared to 4 ml for a 20 mm IVF follicle. Since the needle and tubing traditionally used to harvest oocytes for IVF have a dead space of about 1.5 ml, changes have to be made when harvesting oocytes in IVM compared to standard approaches in IVF. For IVM, the needle and tubing dead space could contain the fluid from up to five follicles. Also, since there is always some bleeding into the follicle during aspiration, the impact of bleeding is much more significant with IVM than with IVF. Without the dilution of follicular fluid there is significant clot formation in the IVM aspirate which can capture or obscure finding an oocyte.

Using the traditional approaches from IVF to select the best embryos to transfer for IVM is less effective. There is a lower embryo implantation rate with IVM. This imposes the need to transfer more embryos back into the patient with IVM compared to IVF. Presumably, some normal appearing embryos have not had the time to produce the molecular products required for achieving implantation and early growth. Judging this oocyte “competence” is a new concept important for IVM, but of less importance for IVF. The success rate with IVM may not exceed that of IVF even when the procedure has been optimized.

Despite these limitations, IVM has compelling features that make it attractive to help selected patients achieve pregnancy. IVM eliminates the risk of severe OHSS, the theoretical concerns about the medications used in traditional IVF is straightforward. With IVM, oocyte aspiration takes place with the largest follicles being between 8 and 12 mm in diameter (depending on program protocols). With IVF, aspiration occurs when the largest follicle is 20 mm in diameter or greater. The granulosa cells surrounding the oocyte and follicle are the sources of most hormone and growth factor production. An 8 mm follicle contains about 3 million granulosa cells, a 12 mm follicle contains about 15 million granulosa cells, but a 18 mm follicle contains more than 50 million granulosa cells. This difference in the number of hormone producing granulosa cells (in multiple follicles) not only eliminates the primary medical risk associated with IVF, but it also eliminates the two week period of discomfort that patients developing mild OHSS experience. The ability to avoid ovulation inducing agents (or limit their use) avoids the production of abnormally high levels of estrogen or other hormones and growth factors.

The patients who benefit most from IVM are those with the largest number of resting follicles. Although IVM could theoretically work for anyone, most programs restrict the application of IVM to patients with polycystic-
like ovaries. Polycystic-like ovaries have at least a total of 20 follicular cysts with diameters between 4 and 12 mm by transvaginal ultrasound. In the author’s experience, approximately one-third of all patients under age 38 will meet this cutoff definition.

Patients with polycystic-like ovaries generally also produce more oocytes to work with during traditional IVF than other subgroups of patients. In terms of pregnancy rates, they do a bit better than other IVF patients but also experience more side-effects of IVF treatment than do other IVF patients.27

Most approaches to IVM are simply easier for patients to undertake than with conventional IVF. For example, Rose compared 22 cycles of IVM to 21 contemporaneous cycles of IVF.28 With IVM, there were three fewer office visits, five fewer blood draws, 49 percent fewer injections, and 11 fewer blood assays. Cost estimates were based on out-of-pocket costs for the procedural aspects of IVM and IVF and on the lowest specialty pharmacy cost for injectable medications. IVM reduced medication costs by 91 percent and overall procedure costs by 46 percent.28

At present, IVM is less successful within a given program than IVF. For example, a selected series of 13 IVM trials published since 2000 have reported clinical pregnancy rates ranging from 17.7 to 46.7 percent per transfer.29 The primary reason to develop IVM appears to be its more gentle impact (physically and economically) on patients. One way of viewing this is that with IVM, the difficulties intrinsic to the advanced reproductive technology treatments are assumed by the treatment provider, rather than by the patient. IVM posits a tradeoff between increased efficacy and improved patient experience. How that tradeoff is adjudicated depends much on the cultural values of the patient and physician. Some patients express a strong preference for the more natural environment in which IVM takes place.

IVM: A Look at Two Cases

The following examples from the author’s practice illustrate how IVM may be a particularly good choice for patients in some situations.

**Case 1:** A 30-year-old woman presents with the request to become an egg donor for her sister with premature ovarian failure. She is graduating as a nurse practitioner in six months and may be leaving the area. She is also getting married in one month. Although her periods are regular, she has a PCO pattern in her ovaries.

The physicians were concerned that an IVF cycle might alter this patient’s ability to fit into her wedding dress, but also wanted to facilitate her kind offer to donate eggs to her sister. The physicians ultimately gave her the option of donating using an IVM cycle. The woman found the IVM procedure minimally disruptive and even attended her bachelorette party the day after her oocyte retrieval. Pregnancy in her sister required a second IVM cycle performed about six weeks after the donor’s marriage.

**Case 2:** A 35-year-old who had achieved pregnancy on her third IVF cycle in the past presented with the request to work on achieving another pregnancy. She was breastfeeding and was torn between the desire to work on an additional pregnancy and to extend her son’s duration at breastfeeding. It is common practice to discontinue breastfeeding before starting the ovulation induction for IVF. Given the length of time it took this patient to achieve her first pregnancy, the physicians offered the option of undertaking IVM rather than IVF. In this case, the physicians used minimal doses of Follicle Stimulating Hormone since her ovaries were extremely suppressed and antral follicles were not visible. The patient continued to breastfeed during her IVM cycle, achieved pregnancy, and breastfed for about six months during the pregnancy.30

**Conclusion**

There are many patients who can benefit from IVM rather than IVF. Patients at high risk for uncomfortable or dangerous side-effects may want to undertake IVM and reserve IVF as a procedure to use only if IVM is not successful. Patients needing IVF for fertility preservation because of hormonally sensitive cancers can benefit both from avoiding high levels of estrogen and a procedure that can be done more quickly than IVF (and more frequently). Finally, many patients may prefer the move natural environment of IVM to that of IVF.
The other day, I walked into the endoscopy dictation area. There, I found my partner relaxing with the newspaper after his last case. I was shocked and aghast to see that his newspaper was entitled “IBD.” Hey, wait a minute! Inflammatory Bowel Disease is my field of interest. Could it be that there is now a daily publication dedicated to this exploding field? How come no one told me? Send in the drug reps! Round up the usual suspects! You know, Romark, Salix, Takeda, and Centocor. Where are P & G and J & J? This is no time for R & R; I need to get my subscription to this “IBD” paper. I was so relieved to see that IBD stood for Investor’s Business Daily and not Inflammatory Bowel Disease. I quickly cancelled those pages to all the drug reps and got down to my business. I can only imagine the number of orders for danishes that were cancelled at Starbucks throughout Jacksonville, Florida as the reps returned to their lairs.

My business is gastroenterology, but that Investor’s Business Daily really got to me. Whenever someone makes passing reference to The Market, my attention doesn’t turn to Wall Street, but rather to Fulton Street. It turns out that at the southern heel of Manhattan, just across from the New York Stock Exchange, is the Fulton Fish Market. The Market was a cramped cluster of wholesale fish distributors who worked furiously from midnight to sunrise receiving and supplying seafood and fish. The Market has moved to The Bronx, and I suppose this makes sense. It was probably time for prime real estate in lower Manhattan to be freed up from the traps of lobsters to make way for condos. I never worked at the Fulton Fish Market, but it is a part of me. My father worked there for over forty years. He sold a lot of fish. He worked hours that are insane. I was always amused when some house staff would moan about their travails. It’s not as if we worked outside in the winter snow. We never had to tiptoe around members of families that were allegedly associated with organized crime. Of course, those allegations were never made to their face, not if you wanted to live with an intact spleen, that is. My father still says that The Fulton Fish Market had nothing to do with me, but he is wrong. I live down South now, and everyone here seems to love to talk about their Daddy. “Daddy did this,” and “Daddy did that.” Nevertheless, I’m no different about my Daddy. He worked long and hard and paid more bills for me than I could ever imagine. Although my diplomas are sheepskin, they are lined with fish guts and his guts.

I went to a conference of gastroenterologists a few weeks ago. I had the opportunity to mingle with hundreds of my colleagues. I am always impressed with the level of knowledge and expertise throughout the United States of America. I am also amazed that few are from royalty. I am comforted that I am surrounded by thousands of classic American success stories. Most of my colleagues come from the middle and lower classes, whatever that means, from all over the globe. Their families have made great sacrifices in order to allow their child to succeed, to become a doctor. We live in the world of a $15 copay. In essence, my expertise is the price of a movie and a small drink. To the general admission, movie-going public, being a doctor may not be such a big deal anymore. But it still is to my parents, and I bet it still is to my colleagues’ parents, as well. We all worked pretty hard for the right to attend these conferences.

As I spied my partner’s newspaper, I realized that The Fulton Fish Market will always mean more to me than the Stock Market. As July 4th just passed and more holidays near, each of us will take stock of our personal and moral portfolios. Most of us are only first or second-generation Americans. We are pilgrims, here to make a better life for ourselves by improving the health of our neighbors. What a great opportunity! What a great life! What a great country! To those who helped us get to these national conferences, thank you. Enjoy America!
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