Experts bring clarity to end-of-life difficulties

Understanding family perspective is an important factor

By Thomas R. Collins

A Vietnam veteran steered clear of the health care system for years, then showed up at the hospital with pneumonia and respiratory failure. He was whisked to the intensive care unit, and cancerous masses were found.

The situation— as described by Jeffrey Frank, MD, director of quality and performance at Vituity, a physician group in Emeryville, Calif.—then got worse.

“No one was there for him,” Dr. Frank said. “He’s laying in the ICU; he does not have the capacity to make decisions, let alone communicate. So the care team needs guidance.”

Too often, hospitalists find themselves in confusing situations involving patients near the end of their lives, having to determine how to go about treating a patient or withholding treatment when patients are not in a position to announce their wishes. When family is present, the health care team thinks the most sensible course of treatment is at odds with what the family wants to be done.

At the Society of Hospital Medicine 2019 Annual Conference, hospitalists with palliative care training offered advice on how to go about handling these difficult situations, which can sometimes become more manageable with certain strategies.

For situations in which there is no designated representative to speak for a patient who is unresponsive—the so-called “unbefriended patient” or

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The QI pipeline supported by SHM Student Scholar Grants

By Emily Gottenborg, MD, and Ashley Duckettd, MD, FHM

As fall arrives, new interns are rapidly gaining clinical confidence, and residency recruitment season is ramping up. It’s also time to announce the opening of the Society of Hospital Medicine’s Student Hospitalist Scholar Grant Program applications. We are now recruiting our sixth group of scholars for both the Summer and Longitudinal Programs.

Since its creation in 2015, the grant has supported 23 students in this incredible opportunity to allow trainees to engage in scholarly work with guidance from a mentor to better understand the practice of hospital medicine and to further grow our robust pipeline.

The 2018-2019 cohort of scholars, Matthew Fallon, Philip Huang, and Erin Rainosek, have just recently concluded their projects and are currently preparing their abstracts for submission for Hospital Medicine 2020, where there is a track for Early-Career Hospitalists.

The projects targeted a diverse set of domains, including improving upon the patient experience, readmission quality metrics, geographic cohorting, and clinical documentation integrity – all highly relevant topics for a practicing hospitalist.

Matthew Fallon collaborated with his mentor, Venkata Andukuri, MD, at Creighton University School of Medicine in Omaha, Neb., to reduce the rate of hospital readmission for patients with heart failure, by analyzing retrospective data in a root-cause analysis to identify factors that influence readmission rate, then targeting those directly. They also integrated the patient experience by seeking out patient input as to the challenges they face in the management of their heart failure.

Philip Huang worked with his mentor, Ethan Kuperman, MD, at the Carver College of Medicine, University of Iowa, to improve geographic localization for hospitalized patients to improve care efficiency. They worked closely with an industrial engineering team to create a workflow model integrated into the hospital EHR to designate patient location and were able to better understand the role that other professionals play in improving the healthcare delivery.

Finally, Erin Rainosek teamed up with her mentor, Luci Leykum, MD, at the University of Texas Health Science Center at San Antonio, to apply a design thinking strategy to redesign the healthcare experience for hospitalized patients. She engaged in over 120 hours of patient interviews and ultimately identified key themes that impact the experience of care, which will serve as target areas moving forward.

The student scholars in this cohort garnered significant insight into the patient experience and quality issues relevant to the field of hospital medicine. We are proud of their accomplishments and look forward to their future successes and careers in hospital medicine.

If you would like to learn more about the experience of our scholars this past summer, they have posted full write-ups on the Future Hospitalist RoundUp blog in HMX, SHM’s online community.

For students interested in becoming scholars, SHM offers two options to eligible medical students – the Summer Program and the Longitudinal Program. Both programs allow students to participate in projects related to quality improvement, patient safety, clinical research, or hospital operations, in order to learn more about career paths in hospital medicine. Students will have the opportunity to conduct scholarly work with a mentor in these domains, with the option of participating over the summer during a 6- to 10-week period or longitudinally throughout the course of a year.

Discover additional benefits and how to apply on the SHM website. Applications will close in late January 2020.

Dr. Gottenborg is director of the Hospitalist Training Program within the Internal Medicine Residency Program at the University of Colorado. Dr. Ducketted is assistant professor of medicine at the Medical University of South Carolina.
Unit-based rounding in the real world

Balance and flexibility are essential

By Tresa Muir McNeal, MD, FACP, SFHM

Many hospitalists agree that their most productive and least productive work can happen in the setting of interdisciplinary rounds. How can this paradox be true?

Most hospitals strive to assemble the health care team every day for a brief discussion of each patient’s needs as well as barriers to a safe/successful discharge. On most floors this requires a well-choreographed “dance” of nurses, case managers, social workers, physicians, and advanced practice providers coming together at agreed-upon times. All team members commit to efficient synchronized swimming through the most high-yield details for each patient in order to benefit the patients and families being served.

Of course, there are always challenges to this process in the unpredictable world of patients with acute needs. One variable that is at least partially controllable and tends to promote a more cohesive interdisciplinary experience is that of hospitalist unit-based rounding.

The 2018 State of Hospital Medicine (SoHM) survey reveals that 68% of hospital medicine groups serving adults with greater than 30 physicians employ some degree of unit-based rounding; this trend decreases with smaller group size. About 56% of academic hospital medicine groups use some amount of unit-based rounding. Not surprisingly, smaller hospital medicine groups are less likely to have this routine, likely because they cover fewer total nursing units.

One of the most obvious benefits to unit-based rounding is that the physician or advanced practice provider is more reliably able to participate in the interdisciplinary discussions that day. When more of the team members are at the table each day, patients and families have the best chance of hearing a consistent message around the treatment and discharge plans.

There are challenges to unit-based rounding as well. If patients transfer to different floors for any variety of reasons, strict unit-based rounding may increase handoffs in care. If a hospital has times when it isn’t completely full and nursing units have a varying percentage of being occupied, strict unit-based rounding can cause significant workload inequities among physicians on different units, depending on numbers of patients on each unit.

If there is no attempt at unit-based rounding in larger hospitals, some physicians may be running among five or more units. They work to find different care managers, nurses, and pharmacists — not to mention the challenges of catching patients in their rooms between their departures for diagnostic studies and procedures.

It is often good to balance the benefit of promoting unit-based rounds with the reality of everyday patient care. Some groups maintain that the physician/patient relationship trumps the idea of perfect unit-based rounding. In other words, if a physician establishes a relationship with a patient while they are in the ED being admitted or boarding from overnight, that physician will continue seeing the patient regardless of the patient being assigned to a different unit. It can help for groups to agree that the pursuit of unit-based rounding may create some inequity in the numbers of patients seen each day because of these issues.

In a larger hospital, certain units are often dedicated to specialty care. While most hospitalists want to maintain general medical knowledge, there are some who may enjoy having portions of their practice devoted to perioperative medicine or cardiac care, for instance. This promotes familiarity among hospitalists and groups of consultant physicians and nurse practitioners/physician assistants. Over time this allows for enhanced teamwork among those physicians, the nursing team, and the specialty physicians.

Depending on the group’s schedule, patients can be reassigned coinciding with the primary change of service day. This resets the physicians’ patients in the most ideal unit-based way on the evening prior to the first day of rounding for that week or group of shifts.

No matter how you do it, the goal of unit-based rounding is time efficiency for the care team and care coordination benefits for patients and families. If you have other suggestions or questions, go online to SHM HMX to join the discussion.

Take-home message: Unit-based rounding likely has its benefits. Don’t let the inability to achieve perfection in patient distribution to the physicians each day lead to abandonment of attempting these processes.

Choosing Wisely® and its impact on low-value care

Focus energy on ‘low-hanging fruit’

By Moises Auron, MD, SFHM

It is a well-known fact that health care expenditure in the United States occupies a large proportion of its gross domestic product. In fact, it was 17.8% in 2016, almost twice what is expended in other advanced countries. However, this expenditure does not necessarily translate into optimal patient outcomes.

In 2012, the Institute of Medicine reported that the U.S. health care system wastes $750 billion per year in spending that does not provide any meaningful outcome to patients or the system; and patients can also suffer a financial impact from the delivery of low-value care.

In 2013, the Pediatrics Committee of the Society of Hospital Medicine published five recommendations through the Choosing Wisely® campaign aimed to decrease the use of low-value interventions. These recommendations were:
1. Do not order chest radiographs (CXR) in children with asthma or bronchiolitis.
2. Do not use systemic corticosteroids in children aged under 2 years with a lower respiratory tract infection.
3. Do not use bronchodilators in children with bronchiolitis.
4. Do not treat gastroesophageal reflux in infants routinely with acid suppression therapy.
5. Do not use continuous pulse oximetry routinely in children with acute respiratory illness unless they are on supplemental oxygen.

This publication led to the implementation of quality improvement initiatives across different hospitals and institutions nationally. Eventually, a team of hospitalists developed a report card that could help measure the utilization of these interventions in hospitals that were part of the Children’s Hospital Association (CHA). The data stemming from the report card analysis would allow for benchmarking and comparing performance, as well as determining the secular trend in utilization of these procedures across the different institutions of the CHA.

Reyes et al. recently published the impact of utilization of these scorescards among all hospital members of the CHA in the Journal of Hospital Medicine, noting a positive impact of the SHM Choosing Wisely® recommendation in decreasing the utilization of low-value interventions.

Continued on following page
Have lower readmission rates led to higher mortality for patients with COPD?

By Christopher Moriates, MD, SFHM

There is at least one aspect of “ObamaCare” that my mother-in-law and I can agree on: Hospitals should not get paid for frequent readmissions. The Hospital Readmission Reduction Program (HRRP), enacted by the Centers for Medicare and Medicaid Services in 2012 with the goal of penalizing hospitals for excessive readmissions, has greater face validity and noble intentions. Does it also have a potentially disastrous downside?

The HRRP has been a remarkable success. It moved the national needle significantly on readmission rates. There are some caveats about increases in observation status patients and other shifts that could account for some of the difference, but it is fairly uncontroversial that, overall, there are fewer 30-day readmissions across the country following initiation of HRRP. That is encouraging evidence of the positive impact that policy can make to drive changes for specific targets.

However, there is also a more controversial side. A number of studies have suggested reductions in readmission rates may have been associated with an increase in mortality in some patient groups. You discharge a patient and hope they won’t return to the hospital, but perhaps you should be more careful what you actually wish for. Overall, the evidence of an association between readmissions and mortality has been conflicting. Headlines have alternately raised alarm about increased deaths and then reassured that there has been no change or perhaps even some concordant improvements in mortality. Not necessarily surprising: These studies are all of observational design and use different criteria, datasets, and analytic models, which drive their seemingly conflicting results.

An article published recently in the Journal of Hospital Medicine examined the potential association between changes in rates of chronic obstructive pulmonary disease (COPD) readmissions and 30-day mortality following HRRP introduction. While the initial HRRP program and subsequent analyses included patients with heart failure, acute MI, and pneumonia, the program was extended in 2014 to include patients with COPD. So, what happened in this patient group?

The researchers seem to have found some important insights:

- The all-cause 30-day risk-standardized readmission rate declined from 2010 to 2017.
- The all-cause 30-day risk-standardized mortality rate increased from 2010 to 2017, and the rate of increase in mortality appears to be accelerating.
- Hospitals with higher readmission rates prior to COPD readmission penalties had a lower rate of increase in mortalities.
- Hospitals that had a larger decrease in readmission rates had a larger rate of increase in mortality. These researchers could not evaluate data at the patient level and could not adjust for changes in disease severity. However, taken together, these findings suggest something bad may be happening here.

The authors note that the associations with increased mortality have largely been seen in patients with heart failure – and now COPD – which are chronic diseases characterized by exacerbations, as opposed to acute MI and pneumonia, which are episodic and treatable. Perhaps in those types of disease, efforts to avoid readmissions may be more universally helpful. Maybe.

I find it concerning that there is “biological plausibility” for this association. Hospitalists know exactly how this might have happened. Have you heard of pop-up alerts that fire in the ED to let physicians know that this patient was discharged within the past 30 days? That alert is not meant to tell you what to do, but you might want to consider trying to discharge them or place them in observation – use your clinical judgment, if you know what I mean.

Within the past decade, observation units quickly cropped up all over the country, often not staffed by hospitalists nor cardiologists, where patients with decompensated heart failure, chest pain, and/or COPD, can be given Lasix and/or nebulizer treatments – at least just enough to let them walk back out that door without an admission.

As Ashish Jha, MD, wrote in 2018, “Right now, a high-readmission, low-mortality hospital will be penalized at 6-10 times the rate of a low-readmission, high-mortality hospital. The signal from policy makers is clear – readmissions matter a lot more than mortality – and this signal needs to stop.”

Dr. Moriates is the assistant dean for health care value at Dell Medical School at the University of Texas, Austin. This article first appeared on the Hospital Leader, SHM’s official blog, at hospitalleader.org.
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“unrepresented patient” – any source of information can be valuable. And health care providers should seek out this input, Dr. Frank said. “When there is a visitor at the bedside, and as long as they know the person, and they can start giving the medical providers some information about what the patient would have wanted, most of us will talk with that person and that’s actually a good habit,” he said.

Thirty-nine states and the District of Columbia have regulations on whom health care providers should talk to when there is no obvious representative, Dr. Frank said, noting that most of these regulations follow a classic family-tree order. But in the discouraging results of many surveys of health care providers on the subject, most clinicians say that they do not know the regulations in their state, Dr. Frank said.

But he said such results betray a silver lining because clinicians say that they would be inclined to use a family tree–style hierarchy in deciding with whom they should speak about end-of-life decisions. Hospitalists should at least know whether their hospital has a policy on unrepresented patients, Dr. Frank said. “That’s your roadmap on how to get through consenting this patient – what am I going to do with Mr. Smith?” he said. “You may ask yourself, ‘Do I just keep treating him and treating him? If you have a policy at your hospital, it will protect you from liability, as well as give you a sense of process.”

Conflicts in communication
An even worse situation, perhaps, is one that many hospitalists have seen: A patient is teetering at the edge of life, and a spouse arrives, along with two daughters from out of state who have not seen their father in a year, said Elizabeth Gundersen, MD, director of the ethics curriculum at Florida Atlantic University, Boca Raton.

“The family requests that the medical team do everything, including intubation and attempts at resuscitation if needed,” she said. “The family says he was fine prior to this admission. Another thing I hear a lot is, ‘He was even sicker than this last year, and he got better.’” Meanwhile, “the medical team consensus is that he is not going to survive this illness,” Dr. Gundersen said.

The situation is so common and problematic that it has a name – the “Daughter from California Syndrome.” (According to medical literature, it’s called the “Daughter from Chicago Syndrome” in California.) “This is one of the most agonizing things that happens to us in medicine,” Dr. Gundersen said. “It affects us, it affects our nurses, it affects the entire medical team. It’s agonizing when we feel like treatment has somehow turned to torture.”

Dr. Gundersen said the medical staff should avoid using the word “futile,” or similar language, with families. “Words matter,” she said. “Inappropriate language can inadvertently convey the feeling that, ‘They’re giving up on my dad – they think it’s hopeless.’ That can make families and the medical team dig in their heels further.”

—Dr. Gundersen

“Words matter. Inappropriate language can inadvertently convey the feeling that, ‘They’re giving up on my dad – they think it’s hopeless.’ That can make families and the medical team dig in their heels further.”

Dr. Gundersen strongly advised getting at the root causes of a family’s apprehension. They might not have been informed early enough about the dire nature of an illness to feel they can make a decision comfortably. They also may be receiving information in a piecemeal manner or information that is inconsistent. Another common fear expressed by families is a concern over abandonment by the medical team if a decision is made to forgo a certain treatment. Also, sometimes the goals of care might not be properly detailed and discussed, she said.

But better communication can help overcome these snags, Dr. Gundersen said.

She suggested that sometimes it’s helpful to clarify things with the family, for example, what do they mean by ‘Do everything’?

“Does it mean ‘I want you to do everything to prolong their life even if they suffer,’ or does it mean ‘I want you to do everything that’s reasonable to try to prolong their life but not at the risk of increased suffering,’ or anywhere in between. Really just having these clarifying conversations is helpful.”

She also emphasized the importance of talking about interests, such as not wanting a patient to suffer, instead of taking positions, such as flatly recommending the withdrawal of treatment.

“It’s easy for both sides to kind of dig in their heels and not communicate effectively,” Dr. Gundersen said.

‘Emotional torture’
There are times when, no matter how skillfully the medical team communicates, they stand at an impasse with the family.
“Emotional torture’

“This is emotional torture for us,” Dr. Gundersen said. “It’s moral distress. We kind of dread these situations. In these cases, trying to support yourself and your team emotionally is the most important thing.”
Ami Doshi, MD, director of palliative care inpatient services at Rady Children’s Hospital in San Diego, described the case of a baby girl that touched on the especially painful issues that can arise in pediatric cases. The 2-month-old girl had been born after a pregnancy affected by polyhydramnios and had an abnormal neurological exam and brain MRI, as well as congenital abnormalities. She’d been intubated for respiratory failure and was now on high-flow nasal cannula therapy. The girl was intolerant to feeding and was put on a nasojejunal feeding tube and then a gastrostomy-jejunostomy tube.

But the baby’s vomiting continued, and she had bradycardia and hypoxia so severe she needed bag mask ventilation to recover. The mother started to feel like she was “torturing” the baby.

The family decided to stop respiratory support but to continue artificial nutrition and hydration, which Dr. Doshi said, has an elevated status in the human psyche. Mentioning discontinuing feeding is fraught with complexity, she said.

“The notion of feeding is such a basic instinct, especially with a baby, that tackling the notion of discontinuing any sort of feeds, orally or tube feeds, is fraught with emotion and angst at times,” Dr. Doshi said.

The girl had respiratory events but recovered from them on her own, but the vomiting and retching continued. Eventually the artificial nutrition and hydration was stopped. But after 5 days, the medical staff began feeling uncomfortable, Dr. Doshi said. “We’re starting to hear from nurses, doctors, other first place,” she said.

According to Dr. Doshi, there is a consensus among medical societies that artificial nutrition and hydration is a medical intervention just like any other and that it should be evaluated within the same framework: Is it overly burdensome? Are the chances of success, and still without clarity about how to proceed, a good option might be considering a “time-limited trial” in which the medical team sits with the family and agrees on a time frame for an intervention and chooses predetermined endpoints for assessing success or failure.

“This can be very powerful to help us understand whether it is beneficial, but also – from the family’s perspective – to know everything was tried,” Dr. Doshi said.

Hospitalists should emphasize what is being added to treatment so that families don’t think only of what is being taken away, she said.

“Usually we are adding a lot – symptom management, a lot of psychosocial support. So what are all the other ways that we’re going to continue to care for the patient, even when we are withdrawing or withholding a specific intervention?” Dr. Doshi noted.

Sometimes, the best healer of distress in the midst of end-of-life decision making is time itself, Dr. Gundersen said.

In a condolence call, she once spoke with a family member involved in an agonizing case in which the medical team and family were at odds. Yet the man told her: “I know that you all were telling us the entire time that this was going to happen, but I guess we just had to go through our own process.”

“When there is a visitor at the bedside, and as long as they know the person, and they can start giving the medical providers some information about what the patient would have wanted, most of us will talk with that person.”

—Dr. Frank
The branching tree of hospital medicine

Diversity of training backgrounds

By Alan M. Hall, MD; Pallabi Sanyal-Dey, MD; Dennis Chang, MD, FHM; Brian Kwan, MD, FHM; Patricia Seymour, MD, MS, FAAFP, FHM

You've probably heard of a “nocturnist,” but have you ever heard of a “weekendist?”

The field of hospital medicine (HM) has evolved dramatically since the term “hospitalist” was introduced in the literature in 1996.1 There is a saying in HM that, “if you know one HM program, you know one HM program,” alluding to the fact that every HM program is unique. The diversity of individual HM programs combined with the overall evolution of the field has expanded the range of jobs available in HM.

The nomenclature of adding an -ist to the end of the specific roles (e.g., nocturnist, weekendist) has become commonplace. These roles have developed with the increasing need for day and night staffing at many hospitals secondary to increased and more complex patients, less availability of residents because of work hour restrictions, and the Accreditation Council for Graduate Medical Education (ACGME) rules that require overnight supervision of residents.

Additionally, the field of HM increasingly includes physicians trained in internal medicine, family medicine, pediatrics, and medicine-pediatrics (med-peds). In this article, we describe the variety of roles available to trainees joining HM and the multitude of different training backgrounds hospitalists come from.

Nocturnists

The 2018 State of Hospital Medicine Report notes that 76.1% of adult-only HM groups have nocturnists, hospitalists who work primarily at night to admit and to provide coverage for admitted patients.2 Nocturnists often provide benefit to the rest of their hospitalist group by allowing fewer required night shifts for those that prefer to work during the day.

Nocturnists may choose a night-time schedule for several reasons, including the ability to be home more during the day. They also have the potential to work fewer total hours or shifts while still earning a similar or increased income, compared with predominantly daytime hospitalists, increasing their flexibility to pursue other interests. These nocturnists become experts in navigating the admission process and responding to inpatient emergencies often with less support when compared with daytime hospitalists.

In addition to career nocturnist work, nocturnist jobs can be a great fit for those residency graduates who are undecided about fellowship and enjoy the acuity of inpatient medicine. It provides an opportunity to hone their clinical skill set prior to specialized training while earning an attending salary, and offers flexible hours which may allow for research or other endeavors. In academic centers, nocturnist educational roles take on a different character as well and may involve more educational experiences. The role of nocturnists as educators is expanding as ACGME rules call for more oversight and educational opportunities for residents who are working at night.

However, challenges exist for nocturnists, including keeping abreast of new changes in their HM groups and hospital systems and engaging in quality initiatives, given that most meetings occur during the day. Additionally, nocturnists must adapt to sleeping during the day, potentially getting less sleep then they would otherwise and being “off cycle” with family and friends.

Weekendists

Similar to nocturnists, weekendists preferentially working weekends.

Weekendists must balance having potential challenges of needing to work while being “off cycle” with family and friends. For nocturnists raising children, being off cycle may be advantageous as it can allow them to be home with their children after school.

Weekendists may prefer working weekends because of fewer total shifts or hours and/or higher compensation per shift. Additionally, weekendists have the flexibility to do other work on weekdays, such as research or another hospitalist job.

SNFists

With increasing emphasis on transitions of care and the desire to avoid readmission penalties, some hospitalists have transitioned to work partly or primarily in skilled nursing facilities (SNF) and have been referred to as “SNFists.” Some of these hospitalists have split their clinical time between SNFs and acute care hospitals, while others may work exclusively at SNFs.

SNFists have the potential to be invaluable in improving transitions of care after discharge to post-acute care facilities because of increased provider presence in these facilities, comfort with medically complex patients, and appreciation of government regulations.3 SNFists may face potential challenges of needing to staff more than one post-acute care hospital and of having less resourc-
es available, compared with an acute care hospital.

**Specific specialty hospitalists**
For a variety of reasons including clinical interest, many hospitalists have become specialized with regards to their primary inpatient population. Some hospitalists spend the majority of their clinical time on a specific service in the hospital, often working closely with the subspecialist caring for that patient. These hospitalists may focus on hematology, oncology, bone-marrow transplant, neurology, cardiology, surgery services, or critical care, among others. Hospitalists focused on a specific service often become knowledge experts in that specialty. Conversely, by focusing on a specific service, certain pathologies may be less commonly seen, which may narrow the breadth of the hospital medicine job.

**Hospitalist training**
Internal medicine hospitalists may be the most common hospitalists encountered in many hospitals and at each Society of Hospital Medicine annual conference, but there has also been rapid growth in hospitalists from other specialties and backgrounds.

- **Family medicine hospitalists** are a part of 64.9% of HM groups and about 9% of family medicine graduates are choosing HM as a career path. Most family medicine hospitalists work in adult HM groups, but some, particularly in rural or academic settings, care for pediatric, newborn, and/or maternity patients. Similar to pediatric hospitalists, pediatric hospitalists have become entrenched at many hospitals where children are admitted. These pediatric hospitalists, like adult hospitalists, may work in a variety of different clinical roles including in EDs, newborn nurseries, and inpatient wards or ICUs; they may also provide consult, sedation, or procedural services.

- **Med-peds hospitalists** that split time between internal medicine and pediatrics are becoming more commonplace in the field. Many work at academic centers where they often work on each side separately, doing the same work as their internal medicine or pediatrics colleagues, and then switching to the other side after a period of time. Some centers offer unique roles for med-peds hospitalists including working on adult consult teams in children’s hospitals, where they provide consult care to older patients that may still receive their care at a children’s hospital. There are also nonacademic hosp-
Key Clinical Question

A novel communication framework for inpatient pain management

By Sarah Horman, MD, and Sarah Richards, MD

Case
A 55-year-old male with a history of diabetes mellitus, lumbar degenerative disc disease, and chronic low back pain was admitted overnight with right lower extremity cellulitis. He reported taking oral hydromorphone for chronic pain, but review of the Prescription Drug Monitoring Program (PDMP) revealed multiple short-term prescriptions from various ED providers, as well as monthly prescriptions from a variety of primary care providers. Throughout the ED, he is described as manipulative and narcotic-seeking with notation of multiple ED visits for pain. Multiple discharges against medical advice were noted. He was given two doses of IV hydromorphone in the ED and requested that this be continued. He was admitted for IV antibiotics for severe leg pain that he rated 15/10.

Background
The Society of Hospital Medicine published a consensus statement in the Journal of Hospital Medicine in 2018 that included 16 clinical recommendations on the safe use of opioids for the treatment of acute pain in hospitalized adults. In regard to communication about pain, clinicians are encouraged to set realistic goals and expectations of opioid therapy, closely monitor response to opioid therapy, and provide education about the side effects and potential risks of opioid therapy for patients and their families.

However, even when these strategies are employed, the social and behavioral complexities of individual patients can contribute to unsatisfactory interactions with health care staff. Because difficult encounters have been linked to provider burnout, enhanced communication strategies can benefit both the patient and physician.

SHM’s Patient Experience Committee saw an opportunity to provide complementary evidence-based best-practice tips for communication about pain. Specifically, the committee worked collectively to develop a framework that can be applied to more challenging encounters.

The VIEW Framework

VISIT the patient’s chart and your own mental state.

First, visit the patient’s chart to review information relevant to the patient’s pain history. The EHR can be leveraged through filters and search functions to identify encounters, consultations, and notes relevant to pain management.

Look at the prior to admission medication list and active medication list and see if there are discrepancies. The medication administration record (MAR) can help identify adjunctive medications that the patient may be refusing. PDMP data should be screened for signs of aberrant use, including multiple pharmacies, multiple prescribers, short intervals between prescriptions, and serially prescribed, multiple, low-quantity prescriptions.

While documented pain scores can be a marker of patient distress, objective aspects of the patient’s functional status can shed light on how much his/her discomfort impacts day-to-day living. Examples of these measures include nutritional intake, sleep cycle, out of bed activity, and participation with therapy. Lastly, assess for opioid-related side effects including constipation, decreased respiratory rate, and any notation of over sedation in narrative documentation from ancillary services.

Once this information has been accrued, it is important to take a moment of mindfulness before meeting with the patient. Take steps to minimize interruptions with electronic devices by silencing your pager/cell phone and disengaging from computers/tablets. Some examples of mindfulness-based practices include taking cycles of deep breathing, going for a short walk to appreciate hospital artwork or view points, or focusing on the sensory aspects of washing your hands prior to seeing the patient. Self-reflection on prior meaningful encounters can also help reset your state of mind.

These activities can help clear prior subconscious thoughts and frustrations and prepare for the task ahead of you.

Intense focus and awareness can enhance your recognition of patient distress, increase your ability to engage in active listening, and enable you to be more receptive to verbal and nonverbal cues. Additionally, mindful behaviors have been shown to contribute to decreased burnout and improved empathy.

INTERVIEW the patient.

Once you enter the room, introduce yourself to the patient and others who are present. Interview the patient by eliciting subjective information. Use open-ended and nonjudgmental language, and take moments to summarize the patient’s perspective.

Inquire about the patient’s home baseline pain scores and past levels of acceptable function. Further explore the patient’s performance goals related to activities of daily living and quality of life. Ask about any prior history of addiction to any substance, and if needed, discuss your specific concerns related to substance misuse and abuse.

EMPATHIZE with the patient.

Integrate empathy into your interview by validating any frustrations and experience of pain. Identifying with loss of function and quality of life can help you connect with the patient and initiate a therapeutic relationship. Observe both verbal and nonverbal behaviors that reveal signs of emotional discomfort. Use open-ended questions to create space and trust for patients to share their feelings.

Pause to summarize the patient’s perspective while acknowledging and validating emotions that he or she may be experiencing such as anxiety, fear, frustration, and anger. Statements such as “I know it is frustrating to...” or “I can’t imagine what it must feel like to...” can help convey empathy. Multiple studies have suggested that enhanced provider empathy and positive messaging can also reduce patient pain and anxiety and increase quality of life.

Empathic responses to negative emotional expressions from patients have also been associated with higher ratings of communication.

Finally, WRAP UP by aligning expectations with the patient for

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pain control and summarize your management recommendations. Educate the patient and his/her family on the risks and benefits of recommended therapy as well as the expected course of recovery. Setting shared goals for functionality relevant to the patient’s personal values and quality of life can build connection between you and your patient.

While handing over the patient to the next provider, refrain from using stereotypical language such as “narcotic-seeking patient.” Clearly communicate the management plan and milestones to other team members, such as nurses, physical therapists, and oncoming hospitalists, to maintain consistency.

This will help align patients and their care team and may stave off maladaptive patient behaviors such as splitting.

The VIEW framework as it applies to the case

Visit

Upon visiting the medical chart, the physician realized that the patient’s opioid use began in his 20s when he injured his back in a traumatic motor vehicle accident. His successful athletic career came to a halt after this injury and opioid dependence ensued.

While reviewing past notes and prescription data via the PDMP, the physician noted that the patient had been visiting many different providers in order to get more pain medications. The most recent prescription was for oral hydromorphone 4 mg every 4 hours as needed, filled 1 week prior to this presentation.

She reviewed his vital signs and found that he had been persistently hypertensive and tachycardic. His nurse mentioned that the patient appeared to be in severe pain because of facial grimacing with standing and walking.

Prior to entering the patient’s room, the physician took a moment of mindfulness to become aware of her emotional state because she recognized that she was worried this could be a difficult encounter. She considered how hard his life has been and how much emotional and physical pain he might be experiencing. She took a deep breath, silenced her mobile phone, and entered the room.

Interview

The physician sat at the bedside and interviewed the patient using a calm and nonjudgmental tone. It was quickly obvious to her that he was experiencing real pain. His cellulitis appeared severe and was tender to even minimal palpation. She learned that the pain in his leg had been worsening over the past week to the point that it was becoming difficult to ambulate, sleep, and perform his daily hygiene routine.

The patient was taking 4 mg tablets of hydromorphone every 2 hours, and he had run out a few days ago. He added that his mood was increasingly depressed, and he had even admitted to occasional suicidal thoughts because the pain was so unbearable. When asked directly, he admitted that he was worried he was addicted to hydromorphone. He had first received it for low back pain after the motor vehicle accident, and it been refilled multiple times for ongoing pain over the course of a year. Importantly, she also learned that he felt he was often treated as an addict by medical professionals and felt that doctors no longer listened to him or believed him.

Continued on following page
The patient was on chronic baseline opioids and also had objective signs of acute pain, she started an initial regimen of hydromorphone 6 mg tablets every 4 hours as needed (a 50% increase over his home dose) and added acetaminophen 1000 mg every 6 hours and ibuprofen 600 mg every 8 hours.

She informed the patient that she would check on him in the afternoon and that the ultimate plan would be to taper down on his hydromorphone dose each day as his cellulitis improved. She also communicated that bidirectional respect between the patient and care team members was critical to a successful pain management.

Finally, she explained that there was going to be a different doctor covering at night and major changes to the prescription regimen would be deferred to daytime hours.

When she left the room, the physician summarized the plan with the patient’s nurse and shared a few details about the patient’s difficult past. At the end of the shift, the physician signed out to the overnight team.

During his hospital stay, she monitored the patient’s nonverbal responses to movement, participation in physical therapy, and ability to sleep. She tapered the hydromorphone down each day as the patient’s cellulitis improved.

At discharge, the patient was prescribed a 3-day supply of his home dose of hydromorphone and the same acetaminophen and ibuprofen regimen he had been on in the hospital with instructions for tapering. Finally, after coming to an agreement with the patient, the physician arranged for follow-up in the opioid taper clinic and communicated the plan with the patient’s primary care provider.

References
Previously healthy patients hospitalized for sepsis show increased mortality

By Mitchel L. Zoler
MDEdge News

WASHINGTON / Although severe, community-acquired sepsis in previously healthy U.S. adults is relatively uncommon, it occurs often enough to strike about 40,000 people annually, and when previously healthy people are hospitalized for severe sepsis, their rate of in-hospital mortality was double the rate in people with one or more comorbidities who have severe, community-acquired sepsis, based on a review of almost 7 million Americans hospitalized for sepsis.

The findings underscore the importance of improving public awareness of sepsis and emphasizing early sepsis recognition and treatment in all patients, including those without comorbidities, Chanu Rhee, MD, said at an annual scientific meeting on infectious diseases. He hypothesized that the increased sepsis mortality among previously healthy patients may have stemmed from factors such as delayed sepsis recognition resulting in hospitalization at a more advanced stage and less aggressive management.

In addition, the findings provide context for high-profile reports about sepsis death in previously healthy people, said Dr. Rhee, an infectious diseases and critical care physician at Brigham and Women’s Hospital in Boston. Dr. Rhee and associates found that, among patients hospitalized with what the researchers defined as “community-acquired” sepsis, 3% were judged previously healthy by having no identified major or minor comorbidity or pregnancy at the time of hospitalization, a percentage that—while small—still translates into roughly 40,000 such cases annually in the United States. That helps explain why every so often a headline appears about a famous person who died suddenly and unexpectedly from sepsis, he noted.

The study used data collected on hospitalized U.S. patients in the Cerner Health Facts, HCA Healthcare, and Institute for Health Metrics and Evaluation databases, which included about 6.7 million people total including 337,983 identified as having community-acquired sepsis, defined as patients who met the criteria for adult sepsis advanced by the Centers for Disease Control and Prevention within 2 days of their hospital admission. The researchers looked further into the hospital records of these patients and divided them into patients with one or more major comorbidities (96% of the cohort), patients who were pregnant or had a “minor” comorbidity such as a lipid disorder, benign neoplasm, or obesity (1% of the study group), or those with no chronic comorbidity (3%; the subgroup the researchers deemed previously healthy).

In a multivariate analysis that adjusted for patients’ age, sex, race, infection site, and illness severity at the time of hospital admission, the researchers found that the rate of in-hospital death among the previously healthy patients was exactly twice the rate of those who had at least one major chronic comorbidity. Dr. Rhee reported.

Differences in the treatment received by the previously healthy patients or in their medical status compared with patients with a major comorbidity suggested that the previously healthy patients were sicker. They had a higher rate of mechanical ventilation, 30%, compared with about 18% for those with a comorbidity; a higher rate of acute kidney injury, about 43% in those previously healthy and 28% in those with a comorbidity; and a higher percentage had an elevated lactate level, about 41% among the previously healthy patients and about 22% among those with a comorbidity.

Fewer bloodstream infections with FMT for C. difficile

By Bianca Nogrady
MDEdge News

Treating Clostridioides difficile infection with fecal microbiota transplantation is associated with a lower risk of bloodstream infection and recurrence than treatment with antibiotics, new research has found.

A paper published in Annals of Internal Medicine presents outcomes of a prospective cohort study in 290 inpatients with recurrent C. difficile infection, 109 of whom were treated with fecal microbiota transplantation (FMT); the remaining patients in the study were treated with antibiotics including metronidazole, vancomycin, and fidaxomicin.

While the FMT group had a higher mean number of previous C. difficile infections than the antibiotics group (2.82 vs. 1.23, respectively), a sustained cure was achieved in 97% of the FMT group, compared with 38% in the antibiotics group.

Blood cultures were done if patients developed a temperature above 30° C or showed symptoms that might be attributable to sepsis. Bloodstream infections were diagnosed in 5% (5 patients) of those treated with FMT, and 22% (40 patients) in the antibiotics group.

The patients in the FMT group with bloodstream infections all had bacterial infections—one of which was polymicrobial—and there were no cases of fungal bloodstream infections. In the antibiotics group, 28 patients (15%) had bacterial bloodstream infections—11 of which were polymicrobial and 12 (7%) had fungal bloodstream infections. Bloodstream infections were particularly evident among the 11 inpatients whose C. difficile infection was treated with fidaxomycin, 4 of whom developed a bloodstream infection.

Overall, 27% of patients died during the 90-day follow-up, with 7% dying because of bloodstream infections, all of whom were in the antibiotic-treated cohort. Three patients in the FMT group died because of overwhelming C. difficile infection, compared with 12 in the antibiotic cohort.

Nearly three-quarters of deaths occurred within 30 days of the end of treatment; 5 of these deaths were in the FMT group, and 53 were in the antibiotics group.

“These findings suggest that the longer 90-day [overall survival] of patients in the FMT group is attributable to cure of C. difficile infection, leading to an improvement in clinical condition,” wrote Gianluca Ianiro, MD, from the Catholic University of the Sacred Heart in Rome, and coauthors.

The 90-day overall survival rate was 92% in the FMT group and 61% in the antibiotic group. Patients treated with FMT also showed significantly shorter mean duration of hospital stay at 13.3 days, compared with 29.7 days in patients treated with antibiotics.

The authors noted the results should be interpreted with caution because of baseline differences between the two groups that were not entirely accounted for by using propensity matching.

However, even in the propensity-matched cohort of 57 patients from each group, there was still a significantly higher overall survival at 90 days among patients treated with FMT.

One author declared grants from the pharmaceutical sector outside the submitted work. No funding or other conflicts of interest were reported by the coauthors.
Aligning scheduling and satisfaction

Research reveals counterintuitive results

Hospitalist work schedules have been the subject of much reporting – and recent research. Studies have shown that control over work hours and schedule flexibility are predictors of clinicians’ career satisfaction and burnout, factors linked to quality of patient care and retention.

Starting in January 2017, an academic hospital medicine group at the University of Colorado at Denver, Aurora, undertook a scheduling redesign using improvement methodology, combined with purchased scheduling software. Tyler Anstett, DO, a hospitalist and assistant professor at the university, and colleagues presented the results in an abstract published during the SHM 2019 annual conference last March.

“We wrote this abstract as a report of the work that we did over several years in our hospital medicine group to improve hospitalist satisfaction with their schedules,” said Dr. Anstett. “We identified that, despite not following the traditional 7-on, 7-off model and 100% fulfillment of individual schedule requests, the majority of clinicians were dissatisfied with the scheduling process and their overall clinical schedules. Further, building these complex, individualized schedules resulted in a heavy administrative burden. We strove to provide better alignment of schedule satisfaction and the administrative burden of incorporating individualized schedule requests.”

Prior to January 2017, service stretches had ranged from 5 to 9 days, and there were few limits on time-off requests.

“Through sequential interventions, we standardized service stretches to 7 days (Tuesday-Monday), introduced a limited number of guaranteed 7-day time-off requests (Tuesday-Monday), and added a limited number of nonguaranteed 3-day flexible time-off requests,” according to the authors. “This simplification improved the automation of the scheduling software, which increased the schedule release lead time to an average of 16 weeks. Further, despite standardizing service stretches to 7 days and limiting time-off requests, physicians surveyed reported improved satisfaction with both their scheduling process (94% of participants ‘satisfied’ in 2017 to 67% in 2018) and their overall clinical schedules (50% of participants ‘satisfied’ in 2017 to 75% in 2018).”

Cultivating patient activation through tech

Tech alone is not enough

Patient activation refers to an individual’s knowledge, skill, and confidence in managing their health and healthcare, according to a recent BMJ editorial. It’s recognized as a critical aspect of high-quality, patient-centered health care – patient activation has the potential to improve patient outcomes while reducing costs.

Total knee replacement offers a great opportunity to study patient activation, said editorial lead author Jesse I. Wolfstadt, MD, MS, FRCSC, of the University of Toronto. “It may help address the one in five patients who are unsatisfied with their knee replacement despite an otherwise technically sound procedure.”

The authors considered some patient activation studies that have shown positive results for cultivating activation through technology. In one, patients engaging with a bedside multimedia intervention on a tablet after undergoing knee replacement reported better pain scores, length of stay, knee function, and satisfaction with care. Another study showed patients who received automated text messages after joint replacement improved time spent on home exercises, decreased their use of narcotics, and had fewer calls to the surgeon’s office.

But “negative mobile app studies may not result in improved satisfaction and likely results in heavy administrative burden,” according to the authors. “This simplification improved the automation of the scheduling software, which increased the schedule release lead time to an average of 16 weeks. Further, despite standardizing service stretches to 7 days and limiting time-off requests, physicians surveyed reported improved satisfaction with both their scheduling process (94% of participants ‘satisfied’ in 2017 to 67% in 2018) and their overall clinical schedules (50% of participants ‘satisfied’ in 2017 to 75% in 2018).”

So counterintuitively, creating individualized schedules may not result in improved satisfaction and likely results in heavy administrative burden. Dr. Anstett said, “Standardization of schedule creation with allowance of a ‘free-market’ system, allowing clinicians to self-individuate their schedules may also result in less administrative burden and improved satisfaction.”

Reference


Reference

Improving sepsis-related outcomes
Performance data provided a key goal

Sepsis is a leading cause of death and disease among patients in hospitals, and it’s the subject of a recent quality improvement study in the Journal for Healthcare Quality.

“The number of cases per year has been increasing in the U.S., and it is the most expensive condition treated in U.S. hospitals,” said lead author M. Courtney Hughes, PhD, of Northern Illinois University.

But early identification of symptoms can be difficult for clinicians, meaning there’s a continuing need for studies examining sepsis identification and prevention. “The purpose of this study was to examine a QI project that consisted of clinical alerts, audit and feedback, and staff education,” she said.

In a retrospective analysis, the researchers examined data from three health systems to determine the impact of a 10-month sepsis QI program that consisted of clinical alerts, audit and feedback, and staff education. The results showed that, compared with the control group, the intervention group significantly decreased length of stay and costs per stay.

“One way to improve sepsis health outcomes and decrease costs may be for hospitals to implement a sepsis quality improvement program,” Dr. Hughes said. “Providing sepsis performance data and education to hospital providers and administrators can arm staff with the knowledge and tools necessary for improving processes and performance related to sepsis.”

Reference

Treating pain with virtual reality
Pilot studies are underway

Physicians may soon have another tool to help patients deal with pain: virtual reality (VR) therapy. A New York Times article earlier this year described the way immersive VR experiences seem to crowd pain sensations out of the brain.

Jeffrey I. Gold, PhD, director of the Children’s Outcomes, Research, and Evaluation program at Children’s Hospital Los Angeles, told the newspaper that VR was “like an endogenous narcotic providing a physiological and chemical burst that causes you to feel good.”

So far, VR has been most successfully used in cases of acute pain. “But it can also enhance the effectiveness of established techniques like physical therapy, hypnosis and cognitive behavioral therapy to treat debilitating chronic pain,” the New York Times reported.

“Using VR as an adjunct, we can teach coping skills, techniques patients can use on their own that will help diminish chronic pain,” said Hunter Hoffman, PhD, principal investigator at the Human Photonics Laboratory of the University of Washington, Seattle. “Learning changes the brain and gives patients something that continues to work when they take the helmet off. When patients realize their pain isn’t inevitable, they’re more receptive to physical therapy.”

Others with experience in VR say the technique can foster mindfulness, which teaches the mind how to quiet the body and nervous system through breathing.

Pilot studies of VR and pain management are underway, and software companies are developing programs that create therapeutic VR environments.

Reference
Complications and death within 30 days after noncardiac surgery

CLINICAL QUESTION: What is the frequency and timing of perioperative complications associated with death after noncardiac surgery? BACKGROUND: There have been advances in perioperative care and technology for adults, but at the same time the patient population is increasingly medically complex. We do not know the current mortality risk of noncardiac surgery in adults.

STUDY DESIGN: Prospective cohort study.

SETTING: Twenty-eight academic centers in 14 countries in North America, South America, Asia, Europe, Africa, and Australia. At least four academic centers represented each of these continents, except Africa, with one center reporting there.

SYNOPSIS: The VISION study included 40.004 inpatients, aged 45 years and older, followed for 30-day mortality after noncardiac surgery. One-third of surgeries were considered low risk. A startling 99.1% of patients completed the study. Mortality rate was 1.8%, with 71% of patients dying during the index admission and 29% dying after discharge.

Nine events were independently associated with postoperative death, but the top three – major bleeding, myocardial injury after noncardiac surgery (MINS), and sepsis – accounted for 45% of the attributable fraction. These, on average, occurred within 1-6 days after surgery. The other events (infection, kidney injury with dialysis, stroke, venous thromboembolism, new atrial fibrillation, and congestive heart failure) constituted less than 3% of the attributable fraction. Findings suggest that closer monitoring in the hospital and post discharge might improve survival after noncardiac surgery.

Limitations for hospitalists include that patients were younger and less medically complex than our typically comanaged patients: More than half of patients were aged 45-64, less than 10% had chronic kidney disease stage 3b or greater, and only 20% had diabetes mellitus.

BOTTOM LINE: Postoperative and postdischarge bleeding, myocardial injury after noncardiac surgery, and sepsis are major risk factors for 30-day mortality in adults undergoing noncardiac surgery. Closer postoperative monitoring for these conditions should be explored.


By Kathryn Brouillette, MDCM

Eosinophilia-guided treatment cuts corticosteroid exposure in COPD exacerbations

CLINICAL QUESTION: Is eosinophilia-guided therapy in the setting of a chronic obstructive pulmonary disease (COPD) exacerbation a safe way to reduce total systemic steroid exposure?

BACKGROUND: Corticosteroids in the setting of an acute exacerbation of COPD symptoms but do not affect the decline in lung function, rate of repeat exacerbations after a month, or mortality. There is concern regarding the cumulative adverse effects over time. Limited prior research suggests that a patient’s blood eosinophil count may be useful for determining the necessity of steroids for treatment of exacerbation.

STUDY DESIGN: Randomized, controlled, open-label trial.

SETTING: Respiratory departments of three university hospitals in Denmark.

SYNOPSIS: A total of 318 patients admitted for COPD exacerbation were randomized to standard or eosinophilia-guided therapy. On day 1, all patients received 80 mg of IV methylprednisolone. The standard-therapy group then received 37.5 mg of oral prednisolone for 4 more days. In contrast, the eosinophilia-guided therapy in the setting of three university hospitals in Denmark.

Although not statistically significant, a trend was noted toward increased readmission for COPD exacerbations or death at 30 days in the eosinophilia-guided group (25% vs. 17% of control; P > .01). Future work will need to further study this trend.

BOTTOM LINE: Eosinophilia-guided treatment of COPD exacerbations reduced the cumulative exposure of steroid therapy, thereby decreasing side effects, although further study of safety profile is warranted.


By Nicholas Dupuis, DO

A standardized approach to postop management of DOACs in AFib

CLINICAL QUESTION: Is it safe to adopt a standardized approach to direct oral anticoagulant (DOAC) interruption for patients with atrial fibrillation (AFib) who are undergoing elective surgeries/procedures?

BACKGROUND: At present, perioperative management of DOACs for patients with AFib has significant variation, and robust data are absent. Points of controversy include: The length of time to hold DOACs before and after the procedure, whether to bridge with heparin, and whether to measure coagulation function studies prior to the procedure.

STUDY DESIGN: Prospective cohort study.

SETTING: Conducted in Canada, the United States, and Europe.

SYNOPSIS: The PAUSE study in...
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Continued from page 16

cluded adults with atrial fibrillation who were long-term users of either apixaban, dabigatran, or rivaroxaban and were scheduled for an elective procedure (n = 3,007). Patients were placed on a standardized DOAC interruption schedule based on whether their procedure had high bleeding risk (held for 2 days prior; resumed 2-3 days after) or low bleeding risk (held for 1 day prior; resumed 1 day after).

The primary clinical outcomes were major bleeding and arterial thromboembolism. Authors determined safety by comparing to expected outcome rates derived from research on perioperative warfarin management.

They found that all three drugs were associated with acceptable rates of arterial thromboembolism (apixaban 0.2%, dabigatran 0.6%, and rivaroxaban 0.4%). The rates of major bleeding observed with each drug (apixaban 0.6% low-risk procedures, 3% high-risk procedures; dabigatran 0.9% both low- and high-risk procedures; and rivaroxaban 1.3% low-risk procedures, 3% high-risk procedures) were similar to those in the BRIDGE trial (patients on warfarin who were not bridged perioperatively). However, it must still be noted that only dabigatran met the authors’ predetermined definition of safety for major bleeding.

Limitations include the lack of true control rates for major bleeding and stroke, the relatively low mean CHADS2-VaSc of 2.3-2.5, and that greater than 95% of patients were white.

**BOTTOM LINE:** For patients with moderate-risk atrial fibrillation, a standardized approach to DOAC interruption in the perioperative period that omits bridging along with coagulation function testing appears safe in this preliminary study.


**4 Overdiagnosis and overtreatment of COPD appears rampant**

**CLINICAL QUESTION:** How frequently is chronic obstructive pulmonary disease (COPD) overdiagnosed and overtreated in the general population?

**BACKGROUND:** COPD is a highly morbid disease, and there is a need for a better understanding of the true prevalence. Little is known regarding overdiagnosis of COPD. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), airflow limitation by spirometry is a key criteria for diagnosis.

**STUDY DESIGN:** Population-based survey.

**SETTING:** Altogether, 23 sites in 20 countries worldwide were included.

**SYNOPSIS:** The Burden of Obstructive Lung Disease (BOLD) study recruited community-dwelling adults who underwent questionnaires, as well as spirometry. Of the 16,717 participants, 919 self-reported a COPD diagnosis. Of these, more than half were found to not meet obstructive lung disease criteria on spirometry, and therefore were misdiagnosed: 62% when defined as forced expiratory volume in 1 second to forced vital capacity (FEV1/FVC) ratio less than the lower limit of normal and 55% when using the GOLD definition of FEV1/FVC less than 0.7. After patients with reported asthma were excluded, 34% of participants with false-positive COPD were found to be treated with respiratory medications as outpatients.

Overdiagnosis of COPD was noted to be more prevalent in high-income countries than they were in low-middle-income countries (4.9% versus 1.9% of the participants sampled).

The self-reporting of the diagnosis of COPD is a limitation of the study because it may have artificially inflated the rate of false positives.

**BOTTOM LINE:** Patient-reported diagnoses of COPD should be taken with a degree of caution because of high rates of overdiagnosis and overtreatment.


**By Elizabeth Herrle, MD**

**5 DOACs show safety benefit in early stages of CKD**

**CLINICAL QUESTION:** In terms of efficacy and bleeding risk, what is known about anticoagulation in patients with chronically impaired renal function?

**BACKGROUND:** Chronic kidney disease (CKD) is both a prothrombotic state and a condition with an elevated bleeding risk that increases in a linear fashion as estimated glomerular filtration rate (eGFR) decreases. These features of the disease along with the exclusion of patients with CKD from most anticoagulation trials have resulted in uncertainty about overall risks and benefits of anticoagulant use in this population.

**STUDY DESIGN:** Systematic review and meta-analysis.

**SETTING:** Variable across included trials.

**SYNOPSIS:** Forty-five randomized, controlled trials of anticoagulation covering a broad range of anticoagulants, doses, indications, and methodologies were included in this meta-analysis, representing 34,082 patients with CKD or end-stage kidney disease.

The most compelling data were seen in the management of atrial fibrillation in early-stage CKD (five studies representing 11,332 patients) in which high-dose DOACs were associated with a lower risk for stroke or systemic embolism (risk ratio, 0.79; 95% confidence interval, 0.66-0.92), hemorrhagic stroke (RR, 0.48; 95% CI, 0.30-0.76), and all-cause death (RR, 0.88; 95% CI, 0.78-0.99). Overall stroke reduction was primarily hemorrhagic, and DOACs were equivalent to vitamin K antagonists (VKAs) for ischemic stroke risk.

The analysis also suggests that, in CKD, DOACs may reduce major bleeding when compared with VKAs across a variety of indications, though that finding was not statistically significant.

Efficacy of DOACs, compared with VKAs, in treatment of venous thromboembolism was uncertain, and patients with end-stage kidney disease and advanced CKD (creatinine clearance, less than 25 mL/min) were excluded from all trials comparing DOACs with VKAs, with limited overlap in all data in these populations.

**BOTTOM LINE:** For patients with atrial fibrillation and early-stage CKD, direct oral anticoagulants offer a promising risk-benefit profile when compared with vitamin K antagonists. Very few data are available on the safety and efficacy of anticoagulants in patients with advanced CKD and end-stage kidney disease.


**6 Covert stroke after noncardiac surgery linked with cognitive decline**

**CLINICAL QUESTION:** Does covert stroke increase the risk of cognitive decline after noncardiac surgery in patients older than 65 years?

**BACKGROUND:** Prior studies have established an increased risk of overt stroke after noncardiac surgery, with significant associated morbidity and mortality. Similarly, covert stroke in the nonsurgical population is well described and has been shown to be associated with cognitive decline.

**STUDY DESIGN:** Prospective cohort study.

**SETTING:** Academic centers in nine countries.

**SYNOPSIS:** This study evaluated 1,114 patients older than 65 years who were hospitalized for noncardiac surgery, excluding patients with carotid and neurosurgical procedures. All enrolled participants completed diffusion-weight MRI of the brain within 9 days of surgery. Follow-up rates for clinical outcomes (1,112; greater than 99%) were excellent, and the primary outcome measure, follow-up Montreal Cognitive Assessment (MOCA) at 1 year, was defined in 1,001 (90%) of the study subjects.

Covert stroke was detected in 78 (7%) of the study participants. Those with covert stroke had a higher incidence of cognitive decline at 1 year (adjusted odds ratio, 1.98; 95% confidence interval, 1.22-3.3) with an absolute risk increase of 13%. Patients with covert stroke also had a higher rate of delirium within 3 days of surgery (hazard ratio, 2.24; 95% CI, 1.06-4.73) and a higher rate of overt stroke and transient ischemic attack at 1 year (HR, 6.13; 95% CI, 1.14-34.9).

This study helps to establish the incidence of covert stroke after noncardiac surgery and provides support for covert stroke as a risk factor for cognitive impairment.

**BOTTOM LINE:** Covert stroke following noncardiac surgery is common, affecting 1 in 14 patients in this study, and it is associated with an increased risk of cognitive decline, perioperative delirium, and subsequent overt stroke.

**CITATION:** The NeuroVISION Investigators (Mrkobrada M et al.). Perioperative covert stroke in patients undergoing noncar-

Dr. Herle is a hospitalist at Maine Medical Center in Portland and at Stephens Memorial Hospital in Norway, Maine.

By Emily Zarookian, MD

7 Think twice before intensifying BP regimen in older hospitalized patients

**CLINICAL QUESTION:** Does intensifying antihypertensive regimens in older patients hospitalized for noncardiac conditions lead to better long-term blood pressure control or does this practice potentially cause harm?

**BACKGROUND:** It is common practice for providers to intensify antihypertensive regimen during admission for noncardiac conditions even if a patient has a history of well-controlled blood pressure as an outpatient. Many providers have assumed that these changes will benefit patients; however, this outcome had never been studied.

**STUDY DESIGN:** Retrospective cohort study.

**SETTING:** Veterans Affairs hospitals.

**SYNOPSIS:** The authors analyzed a well-matched retrospective cohort of 4,056 adults aged 65 years or older with hypertension who were admitted for noncardiac conditions including pneumonia, urinary tract infection, and venous thromboembolism. Half of the cohort was discharged with intensification of their antihypertensives, defined as a new antihypertensive medication or an increase of 20% of a prior medication.

Patients discharged with regimen intensification were more likely to be readmitted (hazard ratio, 1.23; 95% confidence interval, 1.07-1.42; number needed to harm = 27), experience a medication-related serious adverse event (HR, 1.42; 95% CI, 1.06-1.88; NNH = 63), and have a cardiovascular event (HR, 1.65; 95% CI, 1.13-2.4) within 30 days of discharge. At 1 year, no significant difference in mortality, cardiovascular events, or systolic BP were noted between the two groups. A subgroup analysis of patients with poorly controlled blood pressure as outpatients (defined as systolic blood pressure greater than 140 mm Hg) who had their antihypertensive medications intensified did not show significant difference in 30-day readmission, severe adverse events, or cardiovascular events.

Limitations of the study include observational design and majority male sex (97.5%) of the study population.

**BOTTOM LINE:** Intensification of antihypertensive regimen among older adults hospitalized for noncardiac conditions with well-controlled blood pressure as an outpatient can potentially cause harm.

**CITATION:** Anderson TS et al. Clinical outcomes after intensifying antihypertensive medication regimens among older adults at hospital discharge. JAMA Intern Med. 2019;

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**SHORT TAKES**

**Dose of ibuprofen may not affect analgesia**

A randomized, double-blind, equivalency trial of 225 patients found no difference in analgesic effect among ibuprofen doses of 400 mg, 600 mg, and 800 mg within 1 hour of administration. The study did not examine anti-inflammatory effect and did not examine effect after 1 hour.


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**Staying alive: Compression rate and depth affects survival**

Employing 107 compressions per minute with a depth of 4.7 cm is associated with improved outcomes for out-of-hospital cardiac arrest. A cohort study of 3,643 patients with out-of-hospital cardiac arrest showed that survival was higher when CPR was performed within 20% of the above values (6% vs 4.3% outside of range; \( P = .02 \)).

**CITATION:** Duval S et al. Optimal combination of compression rate and depth during cardiopulmonary resuscitation for functionally favorable survival. JAMA Cardiol. 2019;4(9):900-8.

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**Bottom line:** Intensification of antihypertensive regimen among older adults hospitalized for noncardiac conditions with well-controlled blood pressure as an outpatient can potentially cause harm.

**CITATION:** Anderson TS et al. Clinical outcomes after intensifying antihypertensive medication regimens among older adults at hospital discharge. JAMA Intern Med.

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**Short takes**

**Dose of ibuprofen may not affect analgesia**

A randomized, double-blind, equivalency trial of 225 patients found no difference in analgesic effect among ibuprofen doses of 400 mg, 600 mg, and 800 mg within 1 hour of administration. The study did not examine anti-inflammatory effect and did not examine effect after 1 hour.

The most frequent pathogen was `Staphylococcus aureus` (31%) with no methicillin-resistant strains. There was a low incidence of patients with bacteremia (4%) and chronic immune compromise (10%). Antibiotic regimen varied with 13 different initial intravenous regimens and 11 different oral regimens.

The primary study outcome was rate of recurrent infection within 2 years, which was low with only one recurrence in the 2-week arm and two recurrences in the 4-week arm. This difference was well within the 10% noninferiority margin selected by the authors.

The study was underpowered for nonhand and nonwrist cases, limiting generalizability.

**BOTTOM LINE:** Consider a shorter duration of antibiotic therapy after surgical drainage for native joint bacterial arthritis of the hand and wrist in an otherwise healthy patient.


Dr. Zarookian is a hospitalist at Maine Medical Center in Portland and Stephens Memorial Hospital in Norway, Maine.
By Kerry Dooley Young

WASHINGTON / The practice of medicine needs a major reset to address the stresses that lead to clinician burnout, a condition now estimated to affect a third to a half of clinicians in the United States, according to a report from an influential federal panel.


There must be a concerted effort by leaders of many fields of health care to create less stressful workplaces for clinicians. Pascale Carayon, PhD, cochair of the NAM committee that produced the report, said during the NAM press event.

“This is not an easy process,” said Dr. Carayon, a researcher into patient safety issues at the University of Wisconsin–Madison. “There is no single solution.”

The NAM report assigns specific tasks to many different participants in health care through a six-goal approach, as described below.

• Improve usability and relevance of health information technology (IT). Medical organizations should develop and buy systems that are as user-friendly and easy to operate as possible. They also should look to use IT to reduce documentation demands and automate nonessential tasks.

• Reduce stigma and improve burnout recovery services. State officials and legislative bodies should make it easier for clinicians to use employee assistance programs, peer support programs, and mental health providers without the information being admissible in malpractice litigation. The report notes the recommendations from the Federation of State Medical Boards, American Medical Association, and the American Psychiatric Association on limiting inquiries in licensing applications about a clinician’s mental health. Questions should focus on current impairment rather than reach well into a clinician’s past.

• Create national research agenda on clinician well-being. By the end of 2020, federal agencies – including the Agency for Healthcare Research and Quality, the National Institute for Occupational Safety and Health, the Health Resources and Services Administration, and the U.S. Department of Veterans Affairs – should develop a coordinated research agenda on clinician burnout, the report said.

• Create positive workplaces. Leaders of care systems should consider how their business and management decisions will affect clinicians’ jobs, taking into account the potential to add to their levels of burnout. Executives need to continuously monitor and evaluate the extent of burnout in their organizations, and report on this at least annually.

• Address burnout in training and in clinicians’ early years. Medical, nursing, and pharmacy schools should consider steps such as monitoring workload, implementing pass-fail grading, improving access to scholarships and affordable loans, and creating new loan repayment systems.

• Reduce administrative burden. Federal and state bodies and organizations such as the National Quality Forum should reconsider how their regulations and recommendations contribute to burnout. Organizations should seek to eliminate tasks that do not improve the care of patients.

Then called the Institute of Medicine (IOM), NAM in 1999 issued a report, “To Err Is Human,” which is broadly seen as a key catalyst in efforts in the ensuing decades to improve the quality of care. IOM then followed up with a 2001 report, “Crossing the Quality Chasm.”

Those papers over a period of time really did change the way we do health care,” said Dr. Rotella, who was not involved with the NAM report.

In Dr. Rotella’s view, the NAM report provides a solid framework for what remains a daunting task, addressing the many factors involved in burnout.

“The most exciting thing about this is that they don’t have 500 recommendations. They had six and that’s something people can organize around,” he said. “They are not small goals. I’m not saying they are simple.”

The NAM report delves into the factors that contribute to burnout. These include a maze of government and commercial insurance plans that create “a confusing and onerous environment for clinicians,” with many of them juggling “multiple payment systems with complex rules, processes, metrics, and incentives that may frequently change.”

Clinicians face a growing field of measurements intended to judge the quality of their performance. While some of these are useful, others are duplicative and some are not relevant to patient care, the NAM report said.

The report also noted that many clinicians describe electronic health records as taking a toll on their work and private lives. Previously published research has found that, for every hour spent with a patient, physicians spend an additional 1-2 hours on the EHR at work, with additional time needed to complete this data entry at home after work hours, the report said.

In an interview, Cynda Rushton, RN, PhD, a Johns Hopkins University researcher and a member of the NAM committee that produced the report, said this new publication will support efforts to overhaul many aspects of current medical practice. She hopes it will be a “catalyst for bold and fundamental reform.”

“It’s taking a deep dive into the evidence to see how we can begin to dismantle the system’s contributions to burnout,” she said. “No longer can we put Band-Aids on a gaping wound.”

Dr. Washington

The NAM report instead defines burnout as a “work-related phenomenon studied since at least the 1970s,” in which an individual may experience exhaustion and detachment. Depression and other mental health issues such as anxiety disorders and addiction can follow burnout.

Burnout ranging between 45% and 60% for medical students and residents, the NAM report said.

Leaders of health organizations must consider how the policies they set will add stress for clinicians and make them less effective in caring for patients, said Vindell Washington, MD, chief medical officer of Blue Cross Blue Shield of Louisiana, and a member of the NAM committee that wrote the report.

“Those linkages should be incentives and motivations for boards and leaders more broadly to act on the problem,” Dr. Washington said at the NAM event.

Dr. Kirch said he experienced burnout as a first-year medical student. He said a “brilliant aspect” of the NAM report is its emphasis on burnout as a response to the conditions under which medicine is practiced. In the past, burnout has been viewed as being the fault of the physician or nurse experiencing it, with the response then being to try to ‘fix’ this individual, Dr. Kirch said at the event.

The NAM report instead defines burnout as a “work-related phenomenon studied since at least the 1970s,” in which an individual may experience exhaustion and detachment. Depression and other mental health issues such as anxiety disorders and addiction can follow burnout, he said. “That involves a real human toll.”

Joe Ruelas, MD, MBA, chief medical officer at American Academy of Hospice and Palliative Medicine, said in an interview that this NAM paper has the potential to spark the kind of transformation that its earlier research did for the quality of care.

To Err Is Human, which is broadly seen as a key catalyst in efforts in the ensuing decades to improve the quality of care.
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DEPARTMENT OF MEDICINE
Hershey, Pennsylvania

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The Division of Hospital Medicine at Penn State Health is made up of five teaching teams, five attending teams, two nocturnists, one consult team and one triage team. Together they provide inpatient care to 140+ hospitalized patients per day. The discipline of hospital medicine grew out of the increasing complexity of patients requiring hospital care and the need for dedicated clinicians to oversee their care. There are plans to further expand the number of providers, presenting a tremendous opportunity for a visionary leader to establish a national presence.

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**Please Contact:**
Tina McLaughlin, CMSR
Ballad Health Senior Physician Recruiter
O) 276-258-4580
tina.mclaughlin@balladhealth.org

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Dr. Joanna Bonsall, Director
c/o Tomeika Forde’, Program Coordinator
Phone: 404-727-4145
tforde@emory.edu

www.medicine.emory.edu/hospital-medicine
Ochsner Health System is seeking physicians to join our hospitalist team. BC/BE Internal Medicine and Family Medicine physicians are welcomed to apply. Highlights of our opportunities are:

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- We are a medical school in partnership with the University of Queensland providing clinical training to third and fourth year students
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Interested physicians should click here to apply online.

Visit ochsner.org/physician Job Number 00022186

Sorry, no opportunities for J1 applications.

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NOW INTERVIEWING COMPETITIVE APPLICANTS

Penn State Health is a multi-hospital health system serving patients and communities across central Pennsylvania. We are seeking IM/FM trained physicians interested in joining the Penn State Health family in various settings within our system.

What We're Offering:
- Opportunities for both Community based and Academic settings
- We’ll foster your passion for patient care and cultivate a collaborative environment rich with diversity
- Commitment to patient safety in a team approach model
- Experienced hospital colleagues and collaborative leadership
- Salary commensurate with qualifications
- Relocation Assistance

What We're Seeking:
- IM/FM trained physicians interested in joining the Penn State Health family in various settings within our system.

What the Area Offers:
- Penn State Health is located in Central Pennsylvania. Our local neighborhoods boast a reasonable cost of living whether you prefer a more suburban setting or thriving city rich in theater, arts, and culture. Our surrounding communities are rich in history and offer an abundant range of outdoor activities, arts, and diverse experiences.
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For more information please contact:
Heather J. Peffley, PHR FASPR, Penn State Health Physician Recruiter
hpeffley@pennstatehealth.psu.edu

http://go.osu.edu/hospitalmedicine

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The Ohio State University Wexner Medical Center

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Leadership

Envisioning the future of hospital medicine

By Leslie Flores, MHA, SFHM

I have written frequently over the last few years on topics related to the sustainability of the hospital medicine practice model. I continue to be concerned by what I see as a confluence of significant trends that are conspiring to challenge hospital medicine’s status quo.

On one hand, the financial pressures on U.S. hospitals are unremitting, and their willingness or even ability to continue providing significant funding to support their hospital medicine groups is in question. Combine this with hospitalists’ rapidly evolving clinical scope and the ever-increasing demands of physicians in other specialties for hospitalist support, and the result is hospital medicine groups that will continue to grow in size, complexity, and the demand for ever more financial support.

On the other hand, the hospitalists I interact with in my work all over the country seem more stressed out than ever, and many are questioning whether this is a job that can be satisfying and sustainable for a career. Increasing patient complexity, productivity pressures, a lack of resources to address patients’ social issues, a systole-diastole schedule, the frustration of EHRs and other documentation responsibilities, and feeling ‘dumped on’ by physicians in other specialties all contribute to hospitalist job stress.

As you leave the auditorium, you overhear a group of mid-career staff hospitalists talking. They are saying that they didn’t originally believe the specialty would actually change, and they weren’t sure if they could do this job for a career – but that it did change. They begin talking about what it feels like to work as a hospitalist, and how they have improved their lives. Listen to what she is saying. What is it that this group has accomplished?

Up on a huge screen beside the stage, a video starts. In it, there are several hospital and physician executives in a focus group, and one executive says, ‘The thing that is great about what these leaders have accomplished in the field of hospital medicine is...’ Fill it in – what did that executive say?

The video then moves on to show a focus group of recent hospital patients. One patient says, ‘10 years ago when my mom was in the hospital, the poor hospitalists caring for her seemed completely overwhelmed and burnt out, and the whole care system seemed fragmented and inefficient; but my own recent hospital experience was so different because...’ Additional patients chime in, talking about how confident they felt about the care they received in the hospital and the reasons for that. What is it these patients are describing?

SHM’s CEO gets up to accept the award and explains that 10 years ago, a group of multi-site hospital medicine leaders from across the country came together to begin addressing the issue of sustainability; this led to a formal process for developing a vision and plan for the future of hospital medicine, and the execution of that plan eventually resulted in the outcomes recognized by this award. She acknowledges this group of leaders deserving. Listen to what she is saying. What is it that this group has accomplished?

When the applause finally dies down, the President goes on to list all the accomplishments that made this group of leaders deserving. Listen to what she is saying. What is it that this group has accomplished?

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INDICATIONS AND USAGE

Prophylaxis of Venous Thromboembolism

XARELTO® is indicated for the reduction in the risk of recurrence of DVT and PE in patients with nonvalvular atrial fibrillation.

XARELTO is indicated to reduce the risk of thrombotic events. If anticoagulation with XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider the anticoagulation effect of rivaroxaban in patients who develop acute renal failure while on XARELTO.

The following clinically significant adverse reactions are also discussed in other sections of the labeling:

• Increased Risk of Thrombosis in Patients with Triple-Positive Antiphospholipid Syndrome

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 the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During clinical development for the approved indications, 31,881 patients were exposed to XARELTO. The most common adverse reactions across the clinical trials are listed below:

• Major bleeding
• Hemorrhage
• Nausea
• Intraparenchymal hemorrhage

Table 1: Bleeding Events in ROCKET AF® - On Treatment Plus 2 Days

<table>
<thead>
<tr>
<th>Parameter</th>
<th>XARELTO N=10,114</th>
<th>Warfarin N=9,018</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>395 (3.0)</td>
<td>386 (3.5)</td>
<td>1.04 (0.90, 1.20)</td>
</tr>
<tr>
<td>Intraparenchymal hemorrhage (ICH)</td>
<td>50 (0.5)</td>
<td>84 (0.9)</td>
<td>0.57 (0.47, 0.73)</td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>36 (0.3)</td>
<td>58 (0.6)</td>
<td>0.63 (0.42, 0.96)</td>
</tr>
<tr>
<td>Gastrointestinal bleed</td>
<td>221 (2.2)</td>
<td>140 (1.5)</td>
<td>1.61 (1.39, 1.89)</td>
</tr>
<tr>
<td>Fatal bleeding</td>
<td>27 (0.3)</td>
<td>55 (0.6)</td>
<td>0.50 (0.31, 0.80)</td>
</tr>
<tr>
<td>Non-intracranial</td>
<td>39 (0.3)</td>
<td>131 (0.1)</td>
<td>0.23 (0.17, 0.32)</td>
</tr>
</tbody>
</table>

For a comprehensive list of adverse reactions, please see the Summary of Prescribing Information for XARELTO® (rivaroxaban) tablets.

Risk of Bleeding

Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. Use of procoagulant reversal agents, such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa, may be considered but has not been evaluated in clinical efficacy and safety studies for the anticoagulant effect of rivaroxaban when using clotting test (PT, INR or APTT) or anti-factor Xa (FXa) activity is not recommended when using procoagulant reversal agents.

If neurological compromise is noted, urgent treatment is recommended in patients who develop acute renal failure while on XARELTO.

The safety and efficacy of XARELTO® have not been studied in patients with triple-positive antiphospholipid syndrome (APS).

In pregnant women, XARELTO should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO cannot be reversed with standard anticoagulants. Prompt evaluation of any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress) [see Warnings and Precautions].

Patients with Prosthetic Heart Valves

Safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in patients with prosthetic heart valves.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy

Thrombolysis or pulmonary embolectomy is recommended only as an alternative to unfractured heparin in patients with pulmonary embolism who present with hemodynamic instability or who may require thrombolysis or pulmonary embolectomy.

Increased Risk of Thrombosis in Patients with Triple-Positive Antiphospholipid Syndrome

In patients with APS (especially those who are triple-positive [positive for lupus anticoagulant, anticardiolipin, and anti-beta 2-glycoprotein I antibodies]), treatment with DOACs has been associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy.

The following clinically significant adverse reactions are also discussed in other sections of the labeling:

• Increased Risk of Thrombosis after Premature Discontinuation of Xarelto

Abbreviations: HR = Hazard Ratio, CI = Confidence interval, CRNM = Clinical Risk-Network Model

* Major bleeding events in each subcategory were counted once per patient, but patients may have contributed events to multiple subcategories. These events occurred during treatment or within 2 days of stopping treatment.

** Defined as any overt bleeding associated with a decrease in hemoglobin of >2 g/dL, a transfusion of >12 units of packed red blood cells or platelets, the need for surgery, need for transfusion of >1 unit of packed red blood cells, or with a fatal outcome.

† Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid and/or epidural hematoma.

‡ Hemorrhage is used in this text as a general term and refers to non-traumatic intracranial and/or intraventricular hematoma in patients on rivaroxaban who have a focal neurological deficit.

§ Gastrointestinal bleeding events included upper GI, lower GI, and rectal bleeding.

¶ Fatal bleeding is adjudicated death with the primary cause of death from bleeding.
Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were pre-specified (diabetic status was not pre-specified in the subgroup but was a criterion for the CHADS2 score). The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

**Table 5: Major Bleeding Events** in COMPASS - On Treatment Plus 2 days

<table>
<thead>
<tr>
<th>Parameter</th>
<th>XARELTO† plus aspirin†</th>
<th>Enoxaparin/VKA‡</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major GI bleeding</td>
<td>117 (3.7)</td>
<td>49 (2.5)</td>
<td>2.40 (1.72, 3.35)</td>
</tr>
<tr>
<td>Major blood loss</td>
<td>60 (2.9)</td>
<td>60 (3.1)</td>
<td>1.17 (0.39, 3.48)</td>
</tr>
</tbody>
</table>

**Table 6: Bleeding Events in MAGELLAN** in EINSTEIN DVT and EINSTEIN PE Studies

<table>
<thead>
<tr>
<th>Bleeding Event</th>
<th>Number of Patients (n)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>65 (2.3)</td>
<td>1.09 (0.61, 1.98)</td>
</tr>
<tr>
<td>Non-fatal critical organ bleeding</td>
<td>39 (1.3)</td>
<td>1.36 (0.91, 2.01)</td>
</tr>
<tr>
<td>Extra-surgical site bleeding requiring reoperation</td>
<td>29 (1.0)</td>
<td>1.09 (0.61, 1.98)</td>
</tr>
<tr>
<td>Total treated patients</td>
<td>261 (8.5)</td>
<td>251 (7.8)</td>
</tr>
</tbody>
</table>

**Table 7: Other Adverse Reactions** Reported by ≥1% of XARELTO-Treated Patients in the EINSTEIN DVT and EINSTEIN PE Studies

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>N=3298</th>
<th>N=3218</th>
<th>N=3218</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Abdominal pain</td>
<td>46 (2.8)</td>
<td>24 (0.8)</td>
<td></td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>30 (2.9)</td>
<td>31 (1.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2: Risk of Modified ISTH Major Bleeding Events by Baseline Characteristics in COMPASS – On Treatment Plus 2 Days**
Table 7: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN DVT and EINSTEIN PE Studies (continued)

<table>
<thead>
<tr>
<th>System</th>
<th>XARELTO® (6 mg [N=2000] n (%)</th>
<th>XARELTO® (20 mg [N=2000] n (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>38 (2.2)</td>
<td>21 (1.1)</td>
<td></td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>24 (1.6)</td>
<td>11 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>20 (1.3)</td>
<td>10 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td>28 (1.8)</td>
<td>18 (1.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>55 (2.2)</td>
<td>27 (1.1)</td>
<td></td>
</tr>
</tbody>
</table>

* Adverse reaction with Relative Risk ≥5 for XARELTO versus comparator

Table 8: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

<table>
<thead>
<tr>
<th>Body System</th>
<th>XARELTO® (10 mg [N=2405] n= (%)</th>
<th>XARELTO® (15 mg [N=2405] n= (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound secretion</td>
<td>125 (2.8)</td>
<td>89 (2.0)</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>74 (1.7)</td>
<td>55 (1.2)</td>
<td></td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>52 (1.2)</td>
<td>32 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>55 (1.2)</td>
<td>32 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>96 (2.1)</td>
<td>79 (1.8)</td>
<td></td>
</tr>
</tbody>
</table>

* Adverse reaction occurring any time following the first dose of double-blind medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind medication study

Adverse reaction occurring any time following any dose of double-blind medication study

Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Notes:
The following adverse reactions have been identified during post-approval use of XARELTO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis, thrombocytopenia

Gastrointestinal disorders: anorexia, diarrhea, gastritis, gastroenteritis, gastroesophageal reflux disease, hematemesis, ileus, nausea, pancreatitis, pyloric stenosis, proctitis, toxic megacolon, vomiting

Hepatobiliary disorders: anorexia, jaundice, cholestasis, hepatitis (including hepatocellular injury)

Immune system disorders: hypersensitivity, anaphylaxis, allergic drug reaction, angioedema, shock, angina, vasculitis

Nervous system disorders: cerebellar, hemispheric, subdural hematoma, intracranial pressure increase, myasthenia, encephalopathy, peripheral neuropathy

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS)

DUG INTERACTIONS

General Inhibition and Induction Properties

Rivaroxaban is a substrate of CYP3A4, CYP2C9, and the P-gp and ATP-binding cassette (ABC) transporters. Combined or high dosage of P-gp and strong CYP3A inhibitors may increase exposure to rivaroxaban and may increase the risk of bleeding. Combined P-gp and strong CYP3A inhibitors may increase rivaroxaban exposure and may increase the risk of thromboembolic events.

Drugs that Inhibit Cytochrome P450 3A Enzymes and Drug Transport Systems

Interaction with Combined P-gp and Strong CYP3A Inhibitors

Avoid concomitant administration of XARELTO with known combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole and ritonavir) (see Warnings and Precautions and Clinical Pharmacology (12.3) in Full Prescribing Information).

Although clarithromycin is a combined P-gp and strong CYP3A inhibitor, pharmacodynamic studies have shown that no pharmacodynamic interaction occurs with concomitant administration with XARELTO as the change in exposure is unlikely to affect the bleeding risk (see Clinical Pharmacology (12.3) in Full Prescribing Information).

Interaction with Combined P-gp and Moderate CYP3A Inhibitors in Patients with Renal Impairment

XARELTO should not be used in patients with CrCl 15 to <30 mL/min who are being concomitant combined moderate P-gp and moderate CYP3A inhibitors (e.g., erythromycin) unless the potential benefit justifies the potential risk (see Warnings and Precautions and Clinical Pharmacology (12.3) in Full Prescribing Information).

Drugs that Induce Cytochrome P450 3A Enzymes and Drug Transport Systems

Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A inducers (e.g., carbamazepine, phenytoin, buproprion, St. John's wort) (see Warnings and Precautions and Clinical Pharmacology (12.3) in Full Prescribing Information).

Anticoagulants and NSAIDs/Aspirin

Combination of antiplatelet agents (e.g., warfarin, aspirin, clopidogrel) and chronic NSAID use may increase the risk of bleeding (see Clinical Pharmacology (12.3) in Full Prescribing Information).
IMPORTANT SAFETY INFORMATION

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. Premature discontinuation of XARELTO® increases the risk of thrombotic events

Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO® who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- Use of indwelling epidural catheters
- Concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, see Drug Interactions
- A history of traumatic or repeated epidural or spinal punctures
- A history of spinal deformity or spinal surgery
- Optimal timing between the administration of XARELTO® and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

CONTRAINDICATIONS
- Active pathological bleeding
- Severe hypersensitivity reaction to XARELTO® (eg, anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

- Risk of Bleeding: XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue in patients with active pathological hemorrhage.

- An agent to reverse the anti-factor Xa activity of rivaroxaban is available. Because of high plasma protein binding, rivaroxaban is not dialyzable.

- Concomitant use of other drugs that impair hemostasis increases risk of bleeding. These include aspirin, P2Y12-platelet inhibitors, dual antiplatelet therapy, other antithrombotic agents, fibrinolytic therapy, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), and serotonin nonselective reuptake inhibitors (SNRIs).

- Risk of Hemorrhage in Acutely Ill Medical Patients at High Risk of Bleeding: Acutely ill medical patients with the following conditions are at increased risk of bleeding: use of the XARELTO® for primary VTE prophylaxis; history of bronchectasis, pulmonary cavitation, or pulmonary hemorrhage; active cancer (ie, undergoing acute, in-hospital cancer treatment); active gastroduodenal ulcer or history of bleeding in the three months prior to treatment; or dual antiplatelet therapy. XARELTO® is not for use for primary VTE prophylaxis in these hospitalized, acutely ill medical patients at high risk of bleeding.

- Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. To reduce the potential risk of bleeding associated with concurrent use of XARELTO® and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO®. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO® is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An indwelling epidural or intrathecal catheter should not be removed before at least 2 hours have elapsed (ie, 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO®. The next dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO® for 24 hours. Monitor frequently to detect signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate initial urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

- Use in Patients with Renal Impairment:

  - Nonvalvular Atrial Fibrillation: Periodically assess renal function as clinically indicated (ie, more frequently in situations in which renal function may decline) and adjust therapy accordingly. Consider dose adjustment or discontinuation in patients who develop acute renal failure while on XARELTO®. Clinical efficacy and safety studies with XARELTO® did not enroll patients with CrCl ≤30 mL/min or end-stage renal disease (ESRD) on dialysis.

  - Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and PE: Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamics in this patient population.

  - Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamics in this patient population. Observe closely and promptly evaluate signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue treatment.

  - Prophylaxis of Venous Thromboembolism in Acutely Ill Medical Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding: Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Consider discontinuation of XARELTO® in patients who develop acute renal failure while on XARELTO®.

  - Reduction of Risk of Major Cardiovascular Events in Patients with Chronic CAD or PAD: For patients with CrCl ≤15 mL/min, no data are available, and limited data are available for patients with a CrCl of 15-30 mL/min. In patients with CrCl ≤30 mL/min, a dose of 2.5 mg XARELTO® twice daily is expected to give an exposure similar to that in patients with moderate renal impairment, whose efficacy and safety outcomes were similar to those with preserved renal function. Clinical efficacy and safety studies with XARELTO® did not enroll patients with end-stage renal disease (ESRD) on dialysis.

  - Use in Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment. Avoid use in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.

  - Use with P-gp and Strong CYP3A Inhibitors or Inducers: Avoid concomitant use of XARELTO® with known combined P-gp and strong CYP3A inhibitors or inducers.

  - Risk of Pregnancy-Related Hemorrhage: In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing. Promptly evaluate signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

  - Patients with Prosthetic Heart Valves: Safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Use of XARELTO® is not recommended in these patients.

  - Acute PE in Hemodynamically Unstable Patients/Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

  - Increased Risk of Thrombosis in Patients with Antiphospholipid Syndrome: Direct-acting oral anticoagulants (DOACs), including XARELTO®, are not recommended for use in patients with a triple-positive antiphospholipid syndrome (APS). For patients with APS (especially those who are triple positive [positive for lupus anticoagulant, antiphospholipid, and anti-beta 2-glycoprotein I antibodies]), treatment with DOACs has been associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoFC.com/PI.
BECAUSE A THROMBOTIC EVENT DOESN’T ALWAYS COME WITH A WARNING

CHOOSE XARELTO® TO HELP PROTECT THEM FROM THE UNEXPECTED

The DOAC with the most FDA-approved indications to treat and help protect against thrombotic events

INDICATIONS

XARELTO® is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF).

There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled.

XARELTO® is indicated for the treatment of deep vein thrombosis (DVT). XARELTO® is indicated for the treatment of pulmonary embolism (PE). XARELTO® is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

XARELTO® is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

*XARELTO® is indicated for the prophylaxis of venous thromboembolism (VTE) and VTE-related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE, and not at high risk of bleeding.

XARELTO® is indicated, in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular [CV] death, myocardial infarction [MI], and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

IMPORTANT SAFETY INFORMATION (cont’d)

DRUG INTERACTIONS

• Combined P-gp and strong CYP3A inhibitors increase exposure to rivaroxaban and may increase risk of bleeding.

• Combined P-gp and strong CYP3A inducers decrease exposure to rivaroxaban and may increase risk of thromboembolic events.

• XARELTO® should not be used in patients with CrCl <15 mL/min who are receiving concomitant combined P-gp and moderate CYP3A inhibitors (eg, erythromycin) unless the potential benefit justifies the potential risk.

• Coadministration of enoxaparin, warfarin, aspirin, clopidogrel, and chronic NSAID use may increase risk of bleeding.

• Avoid concurrent use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

USE IN SPECIFIC POPULATIONS

• Pregnancy: The limited available data on XARELTO® in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO® for the mother and possible risks to the fetus when prescribing to a pregnant woman.

• Fetal/Neonatal adverse reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.

• Labor or delivery: The risk of bleeding should be balanced with the risk of thrombotic events when considering use in this setting.

• There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage.

• Lactation: Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. Consider the developmental and health benefits of breastfeeding along with the mother’s clinical need for XARELTO® and any potential adverse effects on the breastfed infant from XARELTO® or from the underlying maternal condition.

• Females and Males of Reproductive Potential: Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

• Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

OVERDOSE

• Overdose of XARELTO® may lead to hemorrhage. Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdose occur. An agent to reverse the anti-factor Xa activity of rivaroxaban is available.

ADVERSE REACTIONS IN CLINICAL STUDIES

• Most common adverse reactions with XARELTO® were bleeding complications.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS for XARELTO®.

Janssen Pharmaceuticals, Inc.