



The Hospitalist

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Are you getting the most out of your EHR?



Work with IT, early adopters, and vendors to maximize your electronic health record system

By Thomas R. Collins

Sparrow Health System in Lansing, Mich., went live with its electronic health record (EHR) system at its main hospital on Dec. 1, 2012. For a year and a half, the system was untapped, innovation-wise. Very few features were turned on, and it sat relatively idle with regard to quality improvement. Hospitalists and others used the EHR, but not ambitiously. Everyone, essentially, used the post-launch period to catch their breath. Some even decided it would be the perfect time to retire, rather than confront the new reality of the EHR.

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Set a goal, or two, or three

Hospitalists need to set goals on the job, as well as for their careers; HM groups should do the same

By Karen Appold

In today's health care space, tracking progress and achieving specified metrics are all part of the job. Most fast-paced physician groups incentivize clinicians for efficiency, consistency, quality, and loyalty. Setting and achieving goals, although it might sound somewhat cliché, can play an important role in daily performance, as well as have an impact on long-term satisfaction with an HM career, according to experts in the field.

"Health care insurers and individuals choosing where to obtain health care want evidence that hospitalists are delivering the best care possible," says Judith S. Treharne, consulting executive at Halley Consulting Group in Westerville, Ohio. "This requires goal setting, measuring performance related to those goals, and continually developing processes that enhance performance in order to achieve goals."

Hospitalists are at the forefront of health care transformations taking place both inside the hospital and when patients are discharged to different settings. The opportunities for setting goals – personal and group-wide – are endless.

"If hospitalists want to see their careers evolve with these changes, it's important for them to set goals for

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Q&A

SHM MEMBER SPOTLIGHT



Scholar grants help future hospitalists explore career pathways.

SEE PAGE 7



2016 Humanitarian Award

Medicare CMO Pat Conway, MD, MSc, SFHM, earns 2016 Humanitarian Award for patient safety efforts



Dr. Conway

The Patient Safety Movement Foundation presented pediatric hospitalist Patrick Conway, MD, MSc, SFHM, with one of its 2016 Humanitarian Awards. The honor recognizes “life-saving achievement” in patient safety and efforts to “improve quality, affordability, access,

and health outcomes,” according to a press release. Dr. Conway is acting principal deputy administrator and CMO for the Centers for Medicare & Medicaid Services. In receiving the award, he said he “looks forward to continuing to help improve patient safety across the nation.”

O’Neil Pike, MD, SFHM, has been promoted to chief medical officer with health care staffing company Medicus Healthcare Solutions (MHS) of Windham, N.H. Formerly a hospitalist consultant and chief practice adviser with MHS, Dr. Pike is a practicing hospitalist and serves as an assistant professor of medicine at Geisinger Commonwealth School of Medicine in Scranton, Pa.

Timothy D. Bode, MD, MBA, has been named appointed medical officer at Saint Thomas Rutherford Hospital in Murfreesboro, Tenn., as well as several regional hospitals in the Saint Thomas system. Previously, Dr. Bode served as senior vice president and CMO at Memorial Health in Jacksonville, Fla.

Ibe Mbanu, MD, has been named medical director for Downers Grove, Ill.–based Advocate Operating System and Advo-

cate Medical Group ambulatory and hospitalist services. Dr. Mbanu previously served as chief of the adult hospitalist department and director of medical affairs for St. Mary’s Hospital in Marriottsville, Md.

Joseph Perras, MD, has been named chief executive officer at Mt. Ascutney Hospital and Health Center (MAHHC) in Windsor, Vt. Dr. Perras will continue as the center’s CMO, as well. He previously held the role of MAHHC’s director of hospital medicine.

Alamjit Virk, MD, has been promoted to medical director of Emergency Medicine and Hospitalist Services at Martha’s Vineyard Hospital in Oak Bluffs, Mass. Dr. Virk was a MVH staff physician for a year and half prior to the elevation, and he previously served as an attending physician in emergency medicine at Emerson Hospital in Concord, Mass.



Dr. Mbanu

BUSINESS MOVES

► **Dearborn County Hospital (DCH)** in Lawrenceburg, Ind., has partnered with TriHealth to provide hospitalist services for its inpatients. TriHealth’s team of more than 30 hospitalists is led by chief of hospital medicine Bryan Strader, MD. TriHealth also provides care for patients at Ohio’s Bethesda North, Good Samaritan and Bethesda Butler Hospitals.

► **MidMichigan Medical Centers** in Alma, Gladwin, and Midland have been recognized with Five Star Excellence Awards by national health care research leader Professional Research Consultants. Awards were received for excellence in providing patients discharge information and pain management.

► **Pediatric Associates**, located in Broward County, Fla., has expanded its pediatric hospitalist program thanks to the success of a pilot program run at Palm Beach Children’s Hospital at St. Mary’s Medical Center (West Palm Beach). Jamilah Grant-Guimaraes, MD, FAAP, and Nina Phillips Bernstein, DO, FAAP, will provide care to Pediatrics Associates patients at Broward General Medical Center.

► **The University of Pennsylvania Health System** announced that it will add Princeton HealthCare System (PHCS) to the UPHS family. Located just 40 miles from Philadelphia, PHCS serves more than 1.3 million people in central New Jersey and includes the University Medical Center of Princeton, which opened in 2012 in Plainsboro, N.J.

► **Lehigh Valley Health Network**, based out of Allentown, Pa., has absorbed Pocono Health System (East Stroudsburg, Pa.) in a move Jan. 1. Under the deal’s terms, Pocono Medical Center (the system’s only hospital) now will be known as Lehigh Valley Hospital–Pocono. LVH also absorbs Pocono’s three health centers. LVH now operates 8 hospital campuses and 19 health centers.

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Q&A

Scholar grants help future hospitalists explore career pathways

Ernie L. Esquivel, MD, FACP, FHM's passion for education, research leads to development of SHM student-resident programming

Editor's note: Each month, SHM puts the spotlight on some of our most active members who are making substantial contributions to hospital medicine. Log on to www.hospitalmedicine.org/getinvolved for more information on how you can lend your expertise to help SHM improve the care of hospitalized patients.

By Felicia Steele

This month, *The Hospitalist* spotlights Ernie L. Esquivel, MD, FACP, FHM, the clerkship director, medicine, and assistant professor of clinical medicine in the Division of General Internal Medicine at the Weill Cornell Medical College in New York City. Dr. Esquivel is involved with SHM's Physicians in Training Committee, and has spearheaded the creation of the Student Hospitalist Scholar Grant program.

Question: What inspired you to become a hospitalist?

Answer: I became a hospitalist serendipitously. At a critical juncture in my life about 8 years ago (when a change in career direction became necessary), I chanced upon a locum tenens position in a small community hospital in Lansdale, Pa., as a hospitalist. Having been a primary care track resident who subsequently chose to specialize in nephrology, I rediscovered my generalist inclinations during this job. I fell in love with the fast pace of the hospitalist's work, the complexity of delivering care and the diversity of diseases, and of personal life stories on the general medicine wards and the ICU.

Subsequently, I worked as an intensivist in Philadelphia for a year before joining the Academic Hospital Medicine Division at Weill Cornell in New York City. At Cornell, I have managed to cultivate my passion for medical education, especially for working with and mentoring students and residents, while continuing to care for patients on the general medicine wards. As the medicine clerkship director, I have had the privilege of creating an innovative curriculum that I hope prepares medical students for the challenges in, and the richness of, encounters in the practice of inpatient medicine.

Q: How and why did you become a member of SHM and the Physicians in Training Committee (PIT)?

A: I joined SHM 6 years ago as I started to explore my career options more deeply. In 2010, I attended the Academic Hospitalist Academy, and that really offered me a closer look at the different ways in which SHM could help me advance. I went to my first SHM annual meeting 5 years ago; it motivated me to become involved in committee work. Because of my interest in medical education, I volunteered



The decision to pursue a career as a hospitalist will open up many more questions in the future, because there are so many opportunities available.

—Ernie L. Esquivel, MD, FACP, FHM

for the PIT Committee and it has given me the opportunity to work closely with other hospitalists around the country, and develop programming specifically targeted toward future hospitalists.

Q: What is the PIT Committee working on?

A: The committee has continued to find ways for increased engagement of residents and students in SHM. Dr. Brian Kwan, an academic hospitalist at UC San Diego, and I have been developing a travel grant program for resident trainees and hospital medicine fellows to attend the annual meeting. By offering them a stipend to defray the costs of travel if their quality improvement innovation or research project is accepted, we hope that the annual meeting can become a venue for them to highlight their work, while becoming exposed to the many activities and opportunities offered by our society. In addition, it could be a way for them to network with other future hospitalists and established future mentors.

Q: What prompted you to lead the creation of the Student Hospitalist Scholar Grant summer program?

A: Before I became a hospitalist, I spent about 7 years in research, studying renal genetics. I have always been fascinated by science and asked how I can help to advance our knowledge. As a hospitalist, it became

clear to me early on that there are many questions that one can pose about the clinical work we do, the way we practice medicine, or ways to innovate education, and that there are many academic hospitalists who engage in advancing the field. I spearheaded this program because I would like students to see the field of hospital medicine as one in which they can develop a future career in academic medicine, not

you can use for CME, etc. How are you going to use this money to improve your skills in any particular area?" The ability of candidates to answer this question reflects for me their preparedness to develop themselves as career hospitalists and their willingness to contribute to their group or division in an innovative manner.

The reality is that as one gets older, most will find it difficult to sustain a 26-week/

only by caring for patients, but also by involving themselves in research questions or QI (quality improvement) projects.

Q: Do you have any specific advice for students and residents interested in hospital medicine? In what ways can early-career hospitalists utilize SHM resources to leverage their careers?

A: The decision to pursue a career as a hospitalist will open up many more questions in the future, because there are so many opportunities available. I would suggest that trainees ask in which ways they see themselves growing in the future – clinical research, medical education, QI/patient safety, operations, and hospital leadership are the main avenues. When I interview future faculty, I always pose the same question to each of them: "Every year you are allocated X amount of money that

year schedule. So find ways for your energies, in whichever area, to be noticed and developed toward a position of leadership in the hospital or medical school.

As you take care of patients in the hospital or consider your education and training, identify ways in which things can be done better. Invariably, someone in the Society of Hospital Medicine is interested in the same issue(s). Explore your ideas, share them at the meeting, talk to people, go to the SHM website and identify what resources are already available.

If SHM will be your future academic home, volunteer to engage in activities at the chapter or national levels. Our society is really dedicated to identifying ways to welcome you into our exciting and continually evolving field. **TH**

Ms. Steele is SHM's communications coordinator.



Learn more about how you can benefit from the Practice Administrators' Mentor Program via the SHM website.

www.hospitalmedicine.org/pamentor

Hospitalists trained in family medicine seek critical care training pathway

SHM committee works on intensivist certification proposal to ABFM

By Claudia Stahl

A nationwide shortage of intensivists has more hospitalists stepping into the critical care arena, but not all with the level of preparation and comfort of David Aymond, MD, a Louisiana-based hospitalist trained in family medicine (HTFM).

Dr. Aymond gained his ICU experience in a fellowship with the University of Alabama, where hospitalists also “were responsible for ICU patients,” he says. Years later, as an employee of both small and large hospitals with busy ICU services, and a faculty member for a family medicine residency with a busy ICU, Dr. Aymond moves seamlessly between roles.

In August, SHM’s Family Medicine Committee surveyed HTFM members on their professional needs and interests. The respondents (127) ranked a certification pathway in critical care medicine from the American Board of Family Medicine (ABFM) as a top priority.

“It was eye-opening to learn how many [HTFM] are not only caring for patients in the ICU, but also are requesting additional training,” says Dr. Aymond, a member of the SHM Family Medicine Committee. “A critical care pathway would provide them with a level of expertise already available to physicians in internal medicine, emergency medicine, and surgery.”

With 71% of HTFM reporting that they round on ICU as the attending physician,

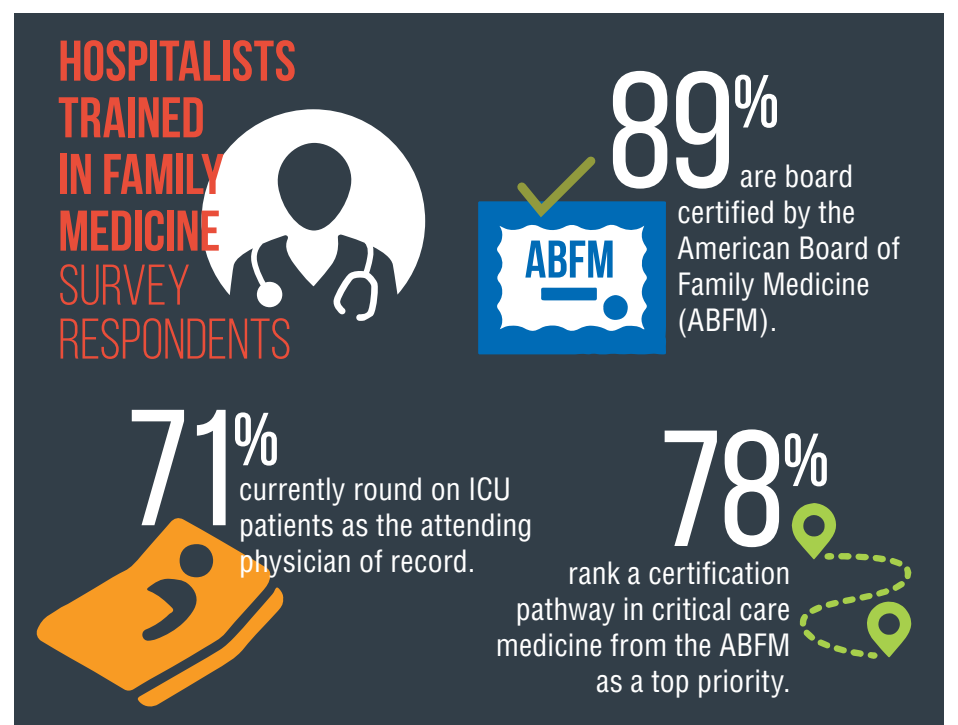
the strong endorsement (78%) for critical care certification is not surprising.

“I am currently practicing as a full time intensivist and take consults from other providers, yet I only have a certificate from fellowship, no formal board certification in critical care,” noted a survey respondent.

Other participants stated, “it makes perfect sense to have a pathway to critical care if both family medicine and internal medicine coexist as hospitalists,” that certification is “imperative at rural and underserved hospitals,” and also “helpful for those . . . who work in larger hospitals and take care of critically ill patients.” More than half of those surveyed want the Family Medicine Committee to work with ABFM to create the pathway.

The majority (89%) of the HTFM survey respondents are certified by the ABFM, and 8% have attained Recognition of Focused Practice in Hospital Medicine. Common pathways for additional credentialing include SHM’s Fellow of Hospital Medicine program (38%), a fellowship in hospital medicine (19%), and certification in hospice and palliative care (15%). More than 38% reported “other qualifications,” such as years of work experience, certification by the American Osteopathic Board of Family Physicians, and prior training in internal medicine.

The survey also found that certification differences in internal medicine and family medicine hospitalists, which may have posed employment obstacles in the past for HTFM, are not as much of an issue.



Survey data (N=127) collected July 2016 - October 2016. Society of Hospital Medicine Family Medicine Committee

“The critical care pathway is the bigger concern,” Dr. Aymond says.

SHM’s Family Medicine Committee will be working on a proposal to ABFM to create the training pathway in the coming months. Dr. Aymond wants intensivists to know that this not an attempt to encroach on their professional domain, “but an opportunity to fill the existing professional gap.

Family medicine physicians are already

providing critical care services, so a pathway to obtain formal training makes sense,” he adds. “If a family medicine doc completes the fellowship and takes it back to a residency program [the residents] will be more prepared for their potential careers in hospital and ICU medicine and much more comfortable with high-acuity patients.”

Ms. Stahl is SHM’s content manager.

NEWS & NOTES

The latest news, events, programs, and SHM initiatives.

By Brett Radler



Calling all pediatric hospitalists
 ▶ Register for Pediatric Hospital Medicine 2017 (PHM17), the premier educational conference for pediatric hospitalists and other clinicians who care for hospitalized children. Re-energize your practice with the latest research, best practices, innovations, and more.

The largest meeting of the year for pediatric hospitalists, the conference is cosponsored by the Ameri-

can Academy of Pediatrics (AAP), the AAP Section on Hospital Medicine, the Academic Pediatric Association (APA), and the Society of Hospital Medicine (SHM). The 2017 meeting will be July 20-23 at the Omni Nashville (Tenn.) Hotel.

Register before June 7 to receive the early-bird rates. Visit www.peds2017.org for more information.



SHM can prepare you for MACRA
 ▶ Reporting for Medicare’s Quality Payment Program (QPP), created by the Medicare Access and CHIP Reauthorization Act (MACRA), started with the new year. Two payment pathways under MACRA, the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), have varying requirements. Both pathways are complicat-

ed, and SHM has created resources to help hospitalists participate.

Visit www.macraforhm.org for general information and details in the MACRA FAQ and MIPS Tips links.

Don’t miss five new tracks at HM17

▶ HM17 will feature five new and engaging tracks at the annual meeting, May 1-4 at the Mandalay Bay Resort and Casino in Las Vegas.

- Learn how to avoid diagnostic and therapeutic overuse, and how to move toward the right care for every hospital medicine patient with the **High Value Care Track**.
- Don’t miss the **Clinical Updates Track**, which provides evidence-



based updates from recent literature published in medicine subspecialty fields and specific topic areas that all hospitalists need to know.

- Accurate and timely diagnosis are the two cornerstones of high-quality patient care. Find out what topics are in the **Diagnostic Reasoning Track**.
- Learn from experts during the **Health Policy Track** who will discuss the most current health care policy issues as they impact hospitalists and what we can expect from a new Presidential administration and changes in Congress.
- The Mini **Medical Education Track** is for hospitalists who are interested in improving their teaching skills. Learn more about the HM17 schedule and offerings at www.hospitalmedicine2017.org/schedule.

Mr. Radler is SHM’s communications specialist.

What PFACs reveal about patient experience



Dr. Moore is a hospitalist at Beth Israel Deaconess Medical Center, and instructor of medicine, Harvard Medical School, both in Boston.

Editor's note: "Everything We Say and Do" is an informational series developed by the Society of Hospital Medicine's Patient Experience Committee to provide readers with thoughtful and actionable tactics that have great potential to positively impact patients' experience of care.

By Amber Moore, MD, MPH

Patient and Family Advisory Councils (PFACs) provide a tool for understanding the patient perspective and are utilized nationwide. These councils, typically consisting of former and current patients and/or their family members, meet on a regular basis to advise provider communities on a wide range of care-related matters. At my institution, Beth Israel Deaconess Medical Center, our PFAC has weighed in on a wide range of issues, such as how to conduct effective nursing rounds and the best methods for supporting patients with disabilities.

Most recently, we have utilized an innovative approach to both understanding the patient experience and capitalizing on the expertise of our PFAC members. Modeled after a program developed at the Dartmouth-Hitchcock Medical Center, we have trained members of our PFAC to interview inpatients at the bedside about their experience.

Time-sensitive information is immediately reported back to the nurse manager, who responds with real-time solutions. Oftentimes, problems can be easily resolved using the right communication, or just providing the "listening ear" of someone to whom the patient relates.

In addition, the information is aggregated to provide us with a broad-based perspective of the patient experience at BIDMC. For example, we found that our patients often discuss issues with volunteers that they have not addressed with providers, suggesting they may at times feel more comfortable disclosing concerns to people outside of their medical team.

The Society of Hospital Medicine (SHM) also recognizes the central role of the patient's voice in quality medical care. Through the work of its Patient Experience Committee, SHM has convened a nationwide "virtual" PFAC consisting of leaders of PFACs from medical facilities across the country. Members of the SHM PFAC share questions posed by SHM's committees with their constituents, and the responses are reported back to the Patient Experience Committee.

What lessons have we learned from the SHM PFAC? Make no assumptions. While some of us have been patients ourselves and

all of us interact with patients, our ability to understand the patient perspective is blurred by the lenses of medical training, system constraints, and the pressures of the challenging work that we do.

It is often impossible to predict the response when you question a patient about his or her experience. For example, the first question we asked SHM's nationwide PFAC was: "What is one thing that a hospitalist could do to improve the patient experience?" The most common response we received was: "What is a hospitalist?" These responses suggest that we (hospitalists) need to redirect our efforts in a way that we had not anticipated, with a focus on clarifying who we are and what we do.

Other, more predictable themes emerged as well. Our patients want consistency and continuity throughout their hospitalization. They value a good bedside manner and want us to engage in sensitivity training. They ask us to work on minimizing errors and ensuring accountability both during hospitalization as well as pre- and post hospitalization.

Ultimately we hope that the SHM PFAC will be utilized by all of SHM's committees, allowing for the patient experience to be a common thread woven through all SHM initiatives. **TH**

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MACRA: What every hospitalist needs to know

Nearly every hospitalist will be affected, majority will use MIPS pathway in 2017



Dr. Afsar-Manesh



Dr. Dutta



Dr. Lenchus

By Nasim Afsar-Manesh, MD, SFHM, Suparna Dutta, MD, MS, MPH, Joshua Lenchus, DO, RPH, FACP, SFHM

In April 2015, President Obama signed the bipartisan Medicare Access and CHIP Reauthorization Act (MACRA) into law, effectively altering the future of the Medicare payment system for providers. MACRA not only removed the Sustainable Growth Rate, but also encouraged quality measure development, expanded the use of Medicare data, and locked provider payment rates to near zero growth.

For Medicare payments, MACRA created the Quality Payment Program, which breaks down clinical payments into two pathways: the Merit-Based Incentive Payment System (MIPS) combining current pay-for-performance programs into one consolidated payment system, and Alternative Payment Models (APMs), incentivizing payment models that move away from a fee-for-service system.

Starting in 2019, clinician Medicare payment adjustments will depend on which track the provider or the provider's hospitalist group chooses to participate in. The Centers for Medicare & Medicaid Services will use 2017 data to determine 2019 payment adjustments.

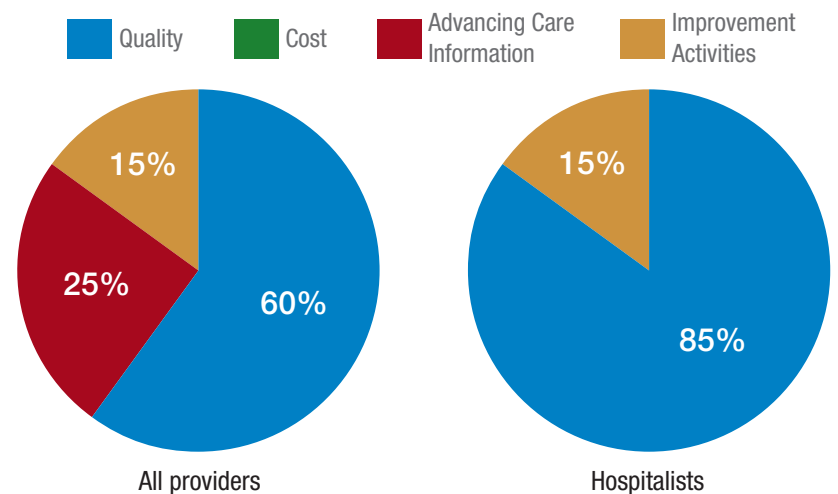
Both pathways incur risk, as well as rewards:

- **MIPS.** –4% penalty up to 12% positive adjustment in year 1 based on 2017 data reported and collected by the CMS, growing over time to include payment adjustments from –9% to +27% in future years.
- **APMs.** If the provider is eligible, a 5% payment increase from 2019 to 2024, with no reporting requirements, and exemption from MIPS.

Who is included in the program?

All clinicians who receive Medicare Physi-

Figure 1. 2017 MIPS category weights



Note: Based on regulations issued by the Centers for Medicare & Medicaid Services.

Source: Society of Hospital Medicine

cian Fee Schedule payments, including physicians, physician assistants, and nurse practitioners, will be affected by this program. The only providers who are exempt from the program are those who fall under low-volume thresholds (either less than \$30,000 in Medicare Part B charges or less than 101 Medicare patients) or those in their first year with Medicare.

The majority of hospitalists will fall into the MIPS pathway, at least for 2017.

What is MIPS?

MIPS requires reporting in four categories that determine a physician's payment adjustment:

- **Quality**, which replaces the Physician Quality Reporting System (PQRS).
- **Cost**, which replaces the value-based modifier.
- **Advancing Care Information (ACI)**, which replaces the meaningful use program.
- **Improvement activities**, a new category, but one in which hospitalists should excel, as they are already participating in many of the activities.

Each category is given relative weight, which the CMS will adjust in the first few years of the program.

Note that in the first year (2017), cost will be calculated, but not used to determine payment amount, hence this category gets a 0% weighting. Also, there are significant differences between how most providers' MIPS score will be calculated with respect to category weights, and how this will be done for hospitalists.

In addition to cost, the ACI will not play a role in the 2019 performance scores for hospitalists. However, hospitalists who practice in noninpatient settings, such as skilled nursing facilities or ambulatory clinics, will be subject to the ACI unless

they apply for exceptions.

The quality category requires physicians to report on 6 of the 271 measures available. Hospitalists can report from the hospitalist-specific specialty set for which the Society of Hospital Medicine (SHM) was successful in advocating. Although continued cooperation between the CMS and SHM is necessary to fine-tune the measures, below are those that the SHM believes are reportable by, and most relevant to, hospitalists.

The improvement activities category will determine 15% of hospitalists' performance in the MIPS. To receive full credit for this category, hospitalists must report on activities totaling 40 points. There are 92 available activities across eight different categories – 20 points for those that have a "high" weight determination and 10 points for those with medium weight.

In 2017, the CMS will calculate the cost category for providers, but it will not be counted toward the overall score. The data will still be collected based on Medicare Part A and Part B costs and will be reported to groups. Over time, this category will increase in scoring weight.

The Advancing Care Information category replaces the meaningful use program. This category will still promote EHR use, but hospitalists should be exempt from this category because of their "hospital-based" practice setting. This exemption is the reason why the quality category counts for 85% of the hospitalists' score.

What is the APM Track?

The Alternative Payment Model pathway will be difficult for hospitalists to participate in, given its current criteria. Only advanced APMs will qualify, and for an APM to qualify as advanced, its clinicians/groups must use certified EHR technology,

Figure 2. Quality measures most relevant to hospitalists

| PQRS # | Measure title | Reporting methodology |
|--------|---|-----------------------|
| 5 | Heart failure: ACE inhibitors/angiotensin-receptor blockers for left ventricular systolic dysfunction | R, EHR |
| 8 | Heart failure: Beta-blocker for LVSD | R, EHR, GPRO |
| 32 | Stroke: Discharged on antithrombotic therapy | C, R |
| 47 | Advance care plan | C, R |
| 76 | Prevention of catheter-related bloodstream infection: Central venous catheter insertion protocol | C, R |
| 130 | Documentation of current medications | C, R, EHR |
| 407 | Appropriate treatment of methicillin-susceptible <i>Staphylococcus aureus</i> bacteremia | C, R |

Notes: Based on regulations issued by the Centers for Medicare & Medicaid Services. C = claims; R = registry; EHR = electronic health records; GPRO = group practice reporting option.

Source: Society of Hospital Medicine

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CONTINUED FROM PAGE 10

tie clinician payments to quality measures, and bear greater than nominal financial risk for outcomes and expenses, or qualify as a medical home. A provider must also meet rather high patient or payment thresholds coming from the model (greater than 25% of Medicare payments or greater than 20% of patients as part of an APM) in order to qualify.

Nominal financial risk is defined as *either*

meeting revenue standards (at risk of losing 7% of its own revenues when Medicare expenditures are higher than expected) *or* benchmark-based standards (at risk of repaying the CMS up to a maximum of 3% of total Medicare expenditures).

Many hospitalists are participating in the Bundled Payments for Care Improvement (BPCI) model, but in its current form, it does not qualify as an APM for 2017 reporting.


The CMS has indicated that new volun-

tary bundled payment models that meet advanced APM criteria will be developed, but as of 2017, the list of APMs is slim, including only the Comprehensive ESRD Care, Comprehensive Primary Care Plus, Next Generation ACO, Shared Savings Program Tracks 2 and 3, and Oncology Care models.

Interested in learning more?

The SHM is working relentlessly in advocating on the behalf of hospitalists, and is constantly developing resources that will better prepare hospitalists for success within this program. If you are interested in learning more, check out the following resources:

- **The SHM’s MACRA for Hospitalists website.** Learn more about MACRA and its impact on hospitalists at www.macra-forhm.org.
- **The SHM’s annual meeting.** A health policy track has been approved for HM17, including two sessions May 4 from 7:45 a.m. to 8:35 a.m., “Hot Topics in Health Policy for Hospitalists,” and from 8:45 a.m. to 9:40 a.m., “The Impact of the New Administration on Health Care Reform.” A MACRA-specific session will be held May 4 from 9:50 a.m. to 10:45 a.m., “Tips for MIPS and Beyond,” as well as an Advocacy and Public Policy Special Interest Forum on May 2 from 4:30 p.m. to 5:25 p.m.

- **HMX.** Join the advocacy and public policy community on HMX to learn more about dynamic changes in public policy and be a part of the conversation.
- **Connect with SHM staff.** Email Josh Boswell, SHM’s director of government relations, at jboswell@hospitalmedicine.org.
- **The CMS website.** An easy to navigate site, the CMS’s MACRA-specific site, qpp.cms.gov, has additional resources and educational tools. 

Dr. Lenchus is associate professor of clinical medicine, anesthesiology, and radiology, University of Miami Miller School of Medicine, and associate director, University of Miami/Jackson Memorial Hospital Center for Patient Safety, Miami.

Dr. Dutta is interim division chief, division of hospital medicine; medical director, attending/APP directed services; and assistant professor, department of internal medicine, Rush Medical College in Chicago.

Dr. Afsar-Manesh is chief quality officer, department of medicine, UCLA Health in Los Angeles, and treasurer of SHM’s board of directors.

All three are members of SHM’s Public Policy Committee.

Figure 3. Examples of improvement activities

| Category | Activity | Weight |
|--|---|--------|
| Population management | Manage medications to maximize efficiency, effectiveness, and safety through one or more of the following: <ul style="list-style-type: none"> □ Reconcile and coordinate medications and provide medication management across transitions of care settings and eligible clinicians or groups □ Integrate a pharmacist into the care team. □ Conduct periodic, structured medication reviews. | Medium |
| Patient safety and practice assessment | Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs. | Medium |
| Patient safety and practice assessment | Clinicians would attest to consultation of prescription drug monitoring program prior to the issuance of a Controlled Substance Schedule II opioid prescription lasting longer than 3 days (60% for the first year, 75% for the second year). | High |

Frontline Medical News

Note: Based on regulations issued by the Centers for Medicare & Medicaid Services.

Source: Society of Hospital Medicine

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Journal of Hospital Medicine

The impact of bedside interdisciplinary rounds on LOS, complications

By Andrew S. Dunn, MD, MPH, Maria Reyna, MD, Brian Radbill, MD, Michael Parides, PhD, MS, MPhil, Claudia Colgan, Tobi Osio, Ari Benson, MD, Nicole Brown, MD, Joy Cambe, Margo Zwerling, MPH, Natalia Egorova, PhD, MPH, and Harold Kaplan, MD

BACKGROUND: Communication among team members within hospitals is typically fragmented. Bedside interdisciplinary rounds (IDR) have the potential to improve communication and outcomes through enhanced structure and patient engagement.

OBJECTIVE: To decrease length of stay (LOS) and complications through the transformation of daily IDR to a bedside model.

DESIGN: Controlled trial.

SETTING: Two geographic areas of a medical unit using a clinical microsystem structure.

PATIENTS: 2,005 hospitalizations over a 12-month period.

INTERVENTIONS: A bedside model (mobile interdisciplinary care rounds [MICRO]) was developed. MICRO featured a defined structure, scripting, patient engagement, and a patient safety checklist.

MEASUREMENTS: The primary

outcomes were clinical deterioration (composite of death, transfer to a higher level of care, or development of a hospital-acquired complication) and length of stay (LOS). Patient safety culture and perceptions of bedside interdisciplinary rounding were assessed pre- and post implementation.

RESULTS: There was no difference in LOS (6.6 vs. 7.0 days, $P = .17$, for the MICRO and control groups, respectively) or clinical deterioration (7.7% vs. 9.3%, $P = .46$). LOS was reduced for patients transferred to the study unit (10.4 vs. 14.0 days, $P = .02$, for the MICRO and control groups, respectively). Nurses and hospitalists gave significantly higher scores for patient safety climate and the efficiency of rounds after implementation of the MICRO model.

LIMITATIONS: The trial was performed at a single hospital.

CONCLUSIONS: Bedside IDR did not reduce overall LOS or clinical deterioration. Future studies should examine whether comprehensive transformation of medical units, including co-leadership, geographic cohorting of teams, and bedside interdisciplinary rounding, improves clinical outcomes compared to units without these features. **TM**

ALSO IN JHM THIS MONTH



Standardized Attending Rounds to Improve the Patient Experience: A Pragmatic Cluster Randomized Controlled Trial

AUTHORS: Bradley Monash, MD, Nader Najafi, MD, Michelle Mourad, MD, Alvin Rajkumar, MD, Sumant R. Ranji, MD, Margaret C. Fang, MD, MPH, Marcia Glass, MD, Dimiter Milev, MPH, Yile Ding, MD, Andy Shen, BA, Bradley A. Sharpe, MD, James D Harrison, MPH, PhD

All Together Now: Impact of a Regionalization and Bedside Rounding Initiative on the Efficiency and Inclusiveness of Clinical Rounds

AUTHORS: Kristin T.L. Huang, MD, Jacquelyn Minahan, Patricia Brita-Rossi, RN, MSN, MBA, Patricia Aylward, RN, MSN, Joel T. Katz, MD, Christopher Roy, MD, Jeffrey L. Schnipper, MD, MPH, Robert Boxer, MD, PhD

Family Report Compared to Clinician-Documented Diagnoses for Psychiatric Conditions Among Hospitalized Children

AUTHORS: Stephanie K. Douppnik, MD, Chris Feudtner, MD, PhD, MPH, Steven C. Marcus, PhD

Perceived Safety and Value of Inpatient 'Very Important Person' Services

AUTHORS: Joshua Allen-Dicker, MD, MPH, Andrew Auerbach, MD, MPH, Shoshana J. Herzig, MD, MPH

A Time and Motion Study of Pharmacists and Pharmacy Technicians Obtaining Admission Medication Histories

AUTHORS: Caroline B. Nguyen, PharmD, BCPS, Rita Shane, PharmD, FASHP, FCSHP, Douglas S. Bell, MD, PhD, Galen Cook-Wiens, MS, Joshua M. Pevnick, MD, MSHS



The Hospital Leader Blog

Equal time for hospital executives

By Leslie Flores, MHA

In December, I wrote a letter to hospital executives, urging them to deliberately invest their own personal time and effort in fostering hospitalist well-being. I suggested several actions that leaders can take to enhance hospitalist job satisfaction and reduce the risk of burnout and turnover.

Following publication of that post, I heard from several hospital executives and was pleasantly surprised that they all responded positively to my message. Several execs told me that they gained valuable new insights about their hospitalists' challenges and needs; others said they planned to take action on one or more of my suggestions that had never occurred to them before.

Especially useful to them was the idea of a hospitalist "hierarchy of needs," in which such basics as well-designed work (including adequate staffing), belonging, and esteem must be addressed before expecting hospitalists to undertake "self-actualizing" work, such as engagement in organizational performance improvement initiatives.

Their feedback reinforced my belief that most hospital leaders actually do care a lot about promoting healthy, stable, and

sustainable hospitalist programs, but the hospital leaders I talked with also had some messages for their hospitalist colleagues, and I think it's important to share them in the spirit of fostering a healthy exchange of perspectives. Your hospital's leaders would be delighted and encouraged if you engaged them in dialogue about these issues.

Help us help you

Several hospital leaders told me that their hospitalists grumble about being treated by the medical staff (and even nurses) like second-class citizens or glorified residents. Those same hospitalists, however, routinely show up for work dressed in scrubs and tennis shoes rather than professional attire. They rarely come in early when it's busy or invest more time than is absolutely needed to see the patients on their list, making it easy for others to dismiss them as shift workers.

Hospitalists, they say, are unwilling to come in on their own time to attend a medical staff meeting, something other doctors do as a matter of course. And instead of interacting as social peers with other physicians when opportunity arises (i.e., in the cafeteria or doctors' lounge), the hospitalists just grab food and head back to eat together in their work room.

The executives said they want to help enhance the stature of their hospitalists within the medical staff, but the hospitalists are "shooting themselves in the foot" by adopting resident-like behavior and isolating themselves from the broader medical community. Here's a typical comment:

"[Hospitalists] also need to be willing to participate in hospital and system committees. Although this may require them to interrupt their workflow and stay late on some days they

are working or come in on days off, they will never garner the respect of their colleagues if they are unwilling to do so." **TM**

Ms. Flores is a hospital medicine consultant and member of SHM's Practice Analysis Committee.

Read the full text of this blog post at <http://blogs.hospitalmedicine.org/Blog/equal-time-for-hospital-execs/>

ALSO ON "THE HOSPITAL LEADER" BLOG



POST: Creating Value through Crowdsourcing & Finding 'Value' in the New Year
By Vineet Arora, MD, MPP, FHM

POST: BREAKING NEWS: "Physicians Deemed Unnecessary"; Social Worker Promoted to Hospital CEO
By Jordan Messler, MD, SFHM

POST: ER Docs and Out-of-Network Billing: Are We in the Same Boat?
By Brad Flansbaum, DO, MPH, MHM

POST: The Best Way to Die?
David Brabeck, MD

Turnover rate for hospitalist groups trending downward



Dr. Vuong is a hospitalist at HealthPartners Medical Group in St Paul, Minn., and an assistant professor of medicine at the University of Minnesota. He is a member of SHM's Practice Analysis Committee.

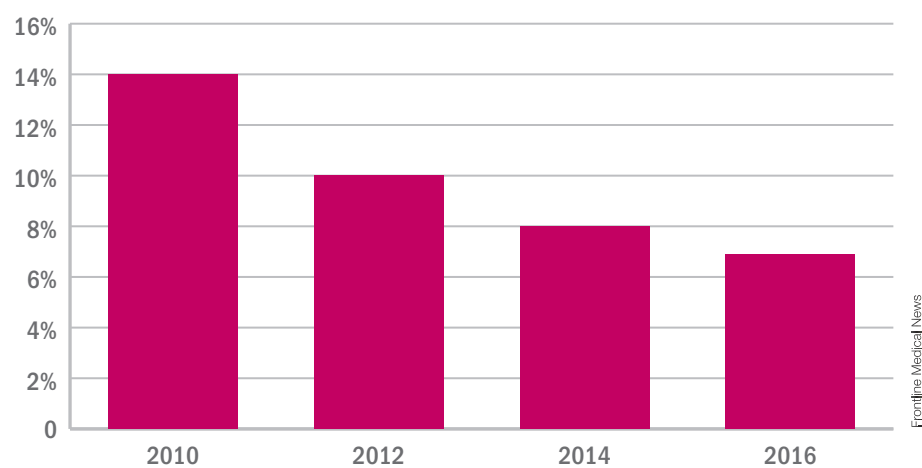
By Khuong Vuong, MD

According to the 2016 *State of Hospital Medicine* report based on 2015 data, the median physician turnover rate for hospital medicine groups (HMGs) serving adults only is 6.9%, lower compared with results from prior surveys. Particularly, turnover in 2010 was more than double the current rate (see Figure). This steady decline over the years is intriguing, yet encouraging, since hospital medicine is well known for its high turnover, compared with other specialties.

Similarly, results from *State of Hospital Medicine* surveys also reveal a consistent trend for groups with no turnover. As expected, a lower turnover rate usually parallels with higher percentage of groups with no turnover. This year, 40.2% of hospitalist groups reported no physician turnover at all, continuing the upward trend from 2014 (38.1%) and 2012 (36%). It is speculating that these groups are not just simply fortunate, but rather work zealously to build a strong internal culture within the group and proactively create a shared vision, values, accountability, and career goals.

Sources in search of why providers leave a practice and advice on specific strategies to retain them are abundant. To secure retention, at a minimum, employers, leaders, or administrators should pay close attention to such basic factors as work schedules, workload, and compensation – and even consider using national and regional data from the *State of Hospital Medicine* report for benchmarking to remain attractive and competitive in the market. Low or no turn-

Figure: Turnover rate for HM groups serving adults only



Note: Based on data collected from 595 hospital medicine groups representing 8,614 providers.
Source: Society of Hospital Medicine's 2016 *State of Hospital Medicine* report

over rate indicates workforce stability and program credibility and allows cost saving as the overall estimated cost of turnover (losing a provider and hiring another one) ranges from \$400,000 to \$600,000 per provider.¹

The turnover data further delineates differences based on academic status, Medicare Indirect Medical Education program status, and geographic region. For instance, the academic groups consistently report a higher turnover rate, compared with the nonacademic groups. The latter mirrors the overall decreasing trend of physician turnover. Nonteaching hospitals also score significantly higher on the number of groups with no turnover (42% as opposed to 24%-27% for teaching hospitals). Geographically,

HMGs in the South and Midwest regions of the United States are the winners this year, with more than 50% of the groups reporting no turnover at all.

Specific information regarding turnover for nurse practitioners and physician assistants (NPs/PAs) can also be found in the report. This rate has been increasing slightly compared with the past, with a subsequent drop in the percentage of groups reporting no turnover. Yet, the overall percentage with no turnover for NPs/PAs remains impressively high at 62%.

The turnover rates for HMGs serving both adults and children, and groups serving children only, appear somewhat similar to those of groups serving adults only, though we cannot reliably analyze the data, elucidate significant differences, or detect any meaningful trends from these two groups because of insufficient numbers of responders.

The downward trend of hospitalist turnover found in SHM's 2016 *State of Hospital Medicine* report is reassuring, indicative of a higher retention rate and an extended stability for many programs. Although some hospitalists continue to shop around, most leaders and employers of HMGs work endlessly to strengthen their programs in hope to minimize turnover. The promising data likely reflect such effort. Hopefully, this trend will continue when the next *State of Hospital Medicine* report comes out. **TH**

Reference

1. Frenz, D (2016). The staggering costs of physician turnover. *Today's Hospitalist*.



This steady decline over the years is intriguing, yet encouraging, since hospital medicine is well known for its high turnover, compared with other specialties.

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Improve your treatment of VTE during Blood Clot Awareness Month

► March is Blood Clot Awareness

Month, and SHM recently introduced a new toolkit and guide surrounding treatment of venous thromboembolism (VTE) in the hospital setting. SHM has a history of providing cutting-edge resources in this space, and Steven B. Deitelzweig, MD, MMM, SFHM, FACP, FACC, system chairman of hospital medicine at Oschner Health System in New Orleans, was integral in editing SHM's VTE treat-

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ment mentored implementation guide and online toolkit.

“SHM has an established track record of implementing evidence-based and guideline-driven learnings successfully, and we continue to see improvement across multiple facilities based on this work with this disease,” Dr. Deitelzweig says. “Whenever possible, I would strongly recommend taking full advantage of SHM’s outstanding programs as they are intensely developed by experts for adoption at hospitals of

different sizes, including community and academic centers.”

SHM can help you and your hospital improve treatment of VTE as well – learn how at www.hospitalmedicine.org/vtetreatment.

Share patient experience success stories

► Our Patient Experience Committee wants to showcase stories of when care teams or their counterparts in the hospital made a notable shift in a patient’s experience: a special moment

or interaction; a successful improvement project; an award for excellence in practice; a memo of commendation; a letter from a patient.

Email examples of success to Claudia Stahl at cstahl@hospitalmedicine.org by May 11. Submissions can include photos, letters, or videos. SHM will share these moments that “made all the difference” with members on its website via other channels soon to be announced.

— *Brett Radler*

New CF guidelines include lower sweat chloride threshold

By Whitney McKnight

Frontline Medical News

U pdated guidelines for the diagnosis and treatment of cystic fibrosis (CF) include two major changes.

The first important update is that clinicians use the latest classifications of the specific CF transmembrane conductance regulator (CFTR) gene mutations, from the Clinical and Functional Translation of CFTR (CFTR2) database, to aid with making a CF diagnosis in any patient, newborn to adult. The other of these changes relates to the chloride concentration level used to confirm CF diagnosis through a sweat test. Under the new guidelines, the sweat chloride threshold for “possible” CF or a CF-related disease was reduced to 30 mmol/L of chloride concentration from 40 mmol/L across all ages. The guidelines, written by an international team of collaborators, are available online (*J Pediatr.* 2017 Feb;181[suppl]:S4-15.e1. doi: 10.1016/j.jpeds.2016.09.064).

Since its inception in 2008, the CFTR2 project has described 300 of the 2,000 known CF-related mutations and their various functional and clinical impacts. The project involves amassing phenotypic and genotypic information from patient registries to collect, quantify, and describe mutations reported in individuals with CF. Such mutations are categorized as CF-causing, carrying a variety of potential clinical consequences, non-cystic fibrosis causing, or unknown. The previous guidelines relied on a 23-mutation panel from the ACMG and ACOG.

“We’ve more precisely defined what cystic fibrosis is,” Patrick R. Sosnay, MD, assistant professor of medicine at Johns Hopkins University, Baltimore, and coauthor of the guidelines, said in a statement. “The stakes in categorizing a mutation are particularly high.”

In the CFTR2 project, the “disease-liability” of each mutation is evaluated through a combination of sweat chloride and functional activity identified in cell-based systems, according to a supplement published simultaneously with the updated guidelines (*J Pediatr.* 2017 Feb;181[suppl]:S52-7.e2. doi: 10.1016/j.jpeds.2016.09.068). Data from this project led to the discovery of a cohort of 746 persons diagnosed with CF despite sweat chloride levels less than 60 mmol/L, which is the basis for the decision to lower the threshold of chloride concentration in sweat in order for an individual to be considered having a possible CF diagnosis.

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Lower *C. difficile* mortality with vancomycin than metronidazole

By Bianca Nogrady

Frontline Medical News

Treating *Clostridium difficile* infection with vancomycin achieves the same recurrence rates as does treatment with metronidazole but with a significantly lower 30-day mortality, new research suggests.

A retrospective, propensity-matched cohort study examined U.S. Department of Veterans Affairs health care system data from 47,471 patients with *C. difficile* infection who were treated with either vancomycin or metronidazole, according to a report published online Feb. 6 in *JAMA Internal Medicine*.

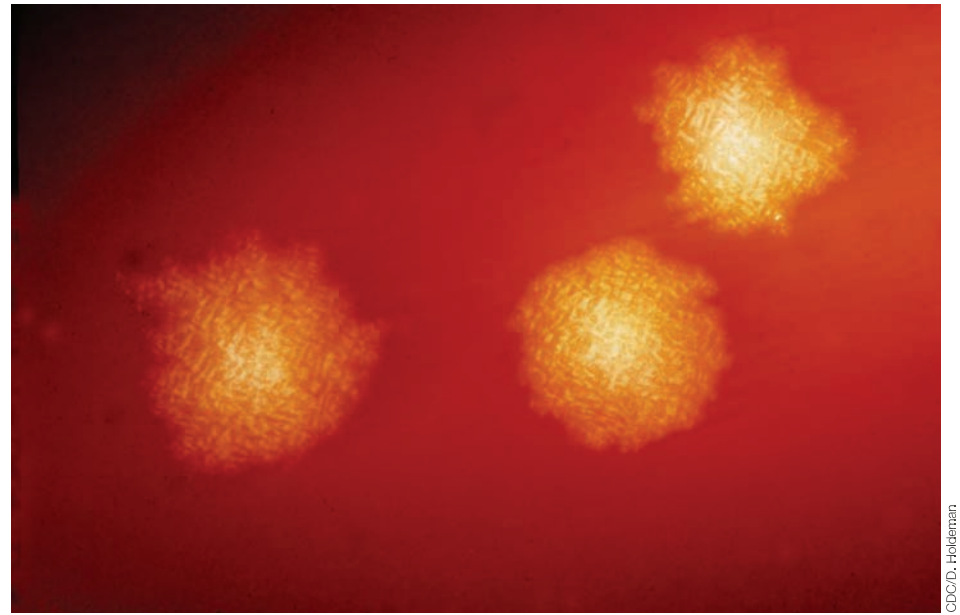
“Current guidelines recommend metronidazole hydrochloride as initial therapy for most cases of mild to moderate CDI [*Clostridium difficile* infection],” wrote Vanessa W. Stevens, PhD, of Veterans Affairs Salt Lake City (Utah) Health Care System, and her coauthors. “Although an early clinical trial found no difference in cure rates between vancomycin hydrochloride

and metronidazole, subsequent observational data and clinical trials suggest that metronidazole is inferior to vancomycin for primary clinical cure, especially in severe cases.”

Their study found patients treated with vancomycin had a similar risk of recurrence, compared with those treated with metronidazole (relative risk, 0.98; 95% confidence interval, 0.87-1.10), with an overall recurrence rate of 16%.

However, patients treated with vancomycin had a 14% reduction in 30-day mortality compared to the metronidazole-treated group. This was after adjustment for factors such as comorbidity scores, hospitalization history, receipt of chemotherapy, receipt of immunosuppressive medication or proton pump inhibitor therapy in the prior 30 days, or antibiotic use on the day of diagnosis.

The 30-day mortality was not significantly different among patients with mild to moderate CDI, but there was a significant 21% reduction among patients with



CCO/IO, Holdenman

severe infection. The number needed to treat to prevent one death among patients with severe infection was 25 (*JAMA Intern Med.* 2017 Feb 6. doi: 10.1001/jamainternmed.2016.9045).

“This is the largest study to date to compare vancomycin and metronidazole in a real-world setting and one of the few studies focused on downstream outcomes of CDI,” researchers reported.

The authors noted that despite strong evidence and guidelines supporting the use

of vancomycin for severe CDI – and the fact that 42% of episodes in the study were classified as severe – only 4%-6% of patients were prescribed vancomycin.

“One approach to minimizing the effects of increasing vancomycin use is to target vancomycin treatment to patients with severe disease,” they wrote.

The study was supported by researcher grants from the U.S. Department of Veterans Affairs. No conflicts of interest were declared.

Perioperative infliximab does not increase serious infection risk

By Deepak Chitnis

Frontline Medical News

Administration of infliximab within 4 weeks of elective knee or hip arthroplasty did not have any significant effect on patients’ risk of serious infection after surgery, whereas the use of glucocorticoids increased that risk, in an analysis of a Medicare claims database.

“This increased risk with glucocorticoids has been suggested by previous studies [and] although this risk may be related in part to increased disease severity among glucocorticoid treated patients, a direct medication effect is likely. [These data suggest] that prolonged interruptions in infliximab therapy prior to surgery may be counterproductive if higher dose glucocorticoid therapy is used in substitution,” wrote the authors of the new study, led by Michael D. George, MD, of the University of Pennsylvania in Philadelphia.

Dr. George and his colleagues examined data from the U.S. Medicare claims system on 4,288 elective knee or hip arthroplasties in individuals with rheumatoid arthritis, inflammatory bowel disease, psoriasis, psoriatic arthritis, or ankylosing spondylitis

who received infliximab within 6 months prior to the operation during 2007-2013 (*Arthritis Care Res.* 2017 Jan 27. doi: 10.1002/acr.23209).

The patients had to have received infliximab at least three times within a year of their procedure to establish that they were receiving stable therapy over a long-term period. The investigators also looked at oral prednisone, prednisolone, and methylprednisolone prescriptions and used data on average dosing to determine how much was administered to each subject.

The proposed guidelines conditionally recommend that all biologics should be withheld prior to surgery in patients with inflammatory arthritis, that surgery should be planned for the end of the dosing cycle and that current daily doses of glucocorticoids, rather than supraphysiologic doses, should be continued in adults with rheumatoid arthritis, lupus, or inflammatory arthritis.

The National Institutes of Health, the Rheumatology Research Foundation, and the Department of Veterans Affairs funded the study.

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IN THE LITERATURE



ITL: Physician reviews of HM-centric research

By Elizabeth Cerceo, MD, FACP, FHM, Jean-Sebastien Rachoin, MD, Ashley Coleman, DO, Jinyu Byron Lu, MD, Samer Badr, MD, Ritesh Patel, MD

Cooper Medical School of Rowan University, Camden, N.J.

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By Elizabeth Cerceo, MD, FACP, FHM

1 The cost of misdiagnosing cellulitis

CLINICAL QUESTION: What are the national health care costs of misdiagnosing cellulitis?

BACKGROUND: Lower extremity cellulitis is primarily a clinical diagnosis but many mimickers – such as venous stasis, lymphedema, gout, deep venous thrombosis, and contact dermatitis – can lead to a misdiagnosis rate of 30%-90%. Between 14% and 17% of emergency department patients with cellulitis are admitted, accounting for 10% of all infectious disease-related hospitalizations. Overdiagnosis leads to antibiotic misuse and increased hospital utilization.

STUDY DESIGN: Retrospective cross-sectional study.

SETTING: Emergency department of Massachusetts General Hospital, Boston.

SYNOPSIS: Among 259 ED patients identified from all screened (840 patients total) from June 2010 to December 2012, 79 (30.5%) were incorrectly diagnosed with lower extremity cellulitis and 52 of these misdiagnosed patients were admitted primarily for their cellulitis, resulting in 92.3% of this group receiving unnecessary antibiotics and 84.6% unnecessarily hospitalized.

The authors used cost estimates and previously published data from the Medical Expenditure Panel Survey (MEPS) provided by the Agency for Healthcare Research and Quality (AHRQ) 2010 to project that cellulitis misdiagnosis leads to 50,000-130,000 unnecessary hospitalizations and \$195-\$515 million in avoid-

able health care expense annually. The estimates include over 44,000 pseudocellulitis patients being exposed to antibiotics annually with an associated 13% readmission rate and medication complications such as rash and gastrointestinal side effects and implications for resistance selection and antimicrobial stewardship efforts. Nationally, the unnecessary antibiotics and hospitalization associated with misdiagnosis were estimated to cause more than 9,000 nosocomial infections, 1,000 to 5,000 *C. difficile* infections, and two to six cases of anaphylaxis annually.

BOTTOM LINE: Misdiagnosis of lower extremity cellulitis is common and leads to unnecessary patient exposures (antibiotics, hospitalization) and excessive health care spending.

CITATIONS: Weng QY, Raff AB, Cohen JM, et al. Costs and consequences associated with misdiagnosed lower extremity cellulitis. *JAMA Dermatol.* 2016; doi: 10.1001/jamadermatol.2016.3816.

2 NSAIDs and cardiovascular risk

CLINICAL QUESTION: Which NSAID confers the least cardiovascular risk?

BACKGROUND: Nonsteroidal anti-inflammatory drugs (NSAIDs) reduce pain and inflammation by decreasing prostaglandin production through cyclo-oxygenase (COX) inhibition. However, the COX enzyme stimulates protective prostaglandins for the GI mucosa. The development of cyclo-oxygenase-2 (COX-2) inhibitors did reduce the gastrointestinal side effects of NSAIDs, but subsequent trials pointed to increased cardiovascular events and resulted in rofecoxib being removed

from the market. Celecoxib remained on the market as the only COX-2 inhibitor, but the Food and Drug Administration required a cardiovascular safety trial.

STUDY DESIGN: Prospective randomized, double-blind noninferiority study.

SETTING: International (926 centers in 13 countries).

SYNOPSIS: The PRECISION trial enrolled 24,081 patients who required NSAIDs for arthritis pain and who either had established cardiovascular disease or an increased risk of CV disease. Patients were randomized to celecoxib 100 mg twice a day, ibuprofen 600 mg three times a day, or naproxen 375 mg twice a day. Patients were allowed to continue taking low-dose aspirin (325 mg or less daily). The primary composite outcome was cardiovascular death (including hemorrhagic death), nonfatal myocardial infarction, or nonfatal stroke. A secondary composite outcome was major adverse CV events (the primary outcome plus coronary revascularization or hospitalization for unstable angina or transient ischemic attack) and significant gastrointestinal events.

The primary outcome occurred in 188 patients in the celecoxib group (2.3%), 201 in the naproxen group (2.5%), and 218 in the ibuprofen group (2.7%). Celecoxib, as compared with either naproxen or ibuprofen, met all four prespecified noninferiority requirements (*P* less than .01 for noninferiority in both comparisons. Ibuprofen, as compared with naproxen, just met the noninferiority criteria (*P* = .025).

BOTTOM LINE: The PRECISION trial provides statistically strong evidence that the cardiovascular risk associated with moderate doses of celecoxib is not greater than that associated with nonselective NSAIDs (ibuprofen and naproxen).

CITATIONS: Nissen SE, Yeomans ND, Solomon DH, et al. Cardiovascular safety of celecoxib, naproxen, or ibuprofen for arthritis. *N Engl J Med.* 2016;375(26):2519-2529.

3 Palliative care: A systematic review for patients and their caregivers

CLINICAL QUESTION: What is the association of palliative care programs on quality of life, symptoms, and survival for patients and their caregivers?

BACKGROUND: Palliative care programs have expanded across the country: More than 65% of U.S. hospitals have such a program. Efforts have been made to assess

their effectiveness for terminally ill patients and their caregivers.

STUDY DESIGN: Systematic review and meta-analysis of 43 randomized controlled trials.

SETTING: Not applicable.

SYNOPSIS: Two reviewers independently assessed 43 trials (12,731 patients and 2,479 caregivers) with the main outcomes being quality of life, symptom burden, survival, mood, advance care planning, site of death, health care satisfaction, resource utilization, and health care expenditures. Estimates of QOL were translated to units of the Functional Assessment of Chronic Illness Therapy–palliative care scale (FACIT-Pal) instrument and symptom burden was translated into the Edmonton Symptom Assessment Scale (ESAS). Palliative care was associated with statistically and clinically significant improvements in patient QOL at the 1- to 3-month follow-up (standardized mean difference, 0.46; 95% CI, 0.08-0.83; FACIT-Pal mean difference, 11.36) and symptom burden at the 1- to 3-month follow-up (standardized mean difference, -0.66; 95% confidence interval, -1.25 to -0.07; ESAS mean difference, -10.30).

When analyses were limited to trials at low risk of bias (*n* = 5), the association between palliative care and QOL was attenuated but remained statistically significant (standardized mean difference, 0.20; 95% CI, 0.06-0.34; FACIT-Pal mean difference, 4.94), whereas the association with symptom burden was no longer statistically significant (standardized mean difference, -0.21; 95% CI, -0.42-0.00; ESAS mean difference, -3.28). Caregiver outcomes were mixed but with limited quality of evidence.

BOTTOM LINE: Although there was no significant association between palliative care and survival, palliative interventions were associated with improved patient QOL, patient and caregiver satisfaction, lower health care utilization, and symptom burden.

CITATIONS: Kavalieratos D, Corbelli J, Zhang D, et al. Association between palliative care and patient and caregiver outcomes: A systematic review and meta-analysis. *JAMA.* 2016;316(20):2104-2114. doi: 10.1001/jama.2016.16840 [HTTP://JAMANETWORK.COM/JOURNALS/JAMA/ARTICLE-ABSTRACT/2585979](http://jamanetwork.com/journals/jama/article-abstract/2585979)

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For the treatment of pediatric and adult patients with acquired methemoglobinemia¹

INDICATIONS AND USAGE

ProvayBlue™ (methylene blue) injection, 0.5% is indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia.

This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

IMPORTANT SAFETY INFORMATION

WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS

ProvayBlue™ may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs. Avoid concomitant use of ProvayBlue™ with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors.

CONTRAINDICATIONS

ProvayBlue™ is contraindicated in patients with severe hypersensitivity reactions to methylene blue or any other thiazine dye; and in patients with glucose-6-phosphate dehydrogenase deficiency (G6PD) due to the risk of hemolytic anemia.

WARNINGS AND PRECAUTIONS

Serotonin Syndrome with Concomitant Use of Serotonergic Drugs

The development of serotonin syndrome has been reported with use of methylene blue class products. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors). Some of the reported cases were fatal. Patients treated with ProvayBlue™ should be monitored for the emergence of serotonin syndrome. If symptoms of serotonin syndrome occur, discontinue use of ProvayBlue™, and initiate supportive treatment. Inform patients of the increased risk of serotonin syndrome and advise them to not to take serotonergic drugs within 72 hours after the last dose of ProvayBlue™.

Hypersensitivity

Anaphylactic reactions to methylene blue class products have been reported. If anaphylaxis or other severe hypersensitivity reactions (e.g., angioedema, urticaria, bronchospasm) should occur, discontinue use of ProvayBlue™ and initiate supportive treatment. ProvayBlue™ is contraindicated in patients who have experienced anaphylaxis or other severe hypersensitivity reactions to a methylene blue class product in the past.

Lack of Effectiveness

Methemoglobinemia due to aryl amines or sulfa drugs may not resolve or may rebound after response to treatment with ProvayBlue™.

If methemoglobinemia does not respond to 2 doses of ProvayBlue™ or if methemoglobinemia rebounds after a response consider additional treatment options.

Patients with G6PD deficiency may not reduce ProvayBlue™ to its active form. ProvayBlue™ may not be effective in patients with G6PD deficiency.

Hemolytic Anemia

Hemolysis can occur during treatment of methemoglobinemia with ProvayBlue™. The onset of anemia may be delayed one or more days after treatment with ProvayBlue™. The anemia may require red blood cell transfusions. Use the lowest effective number of doses of ProvayBlue™ to treat methemoglobinemia.

Discontinue ProvayBlue™ and consider alternative treatments of methemoglobinemia if severe hemolysis occurs.

Treatment of patients with G6PD deficiency with ProvayBlue™ may result in severe hemolysis and severe anemia. ProvayBlue™ is contraindicated for use in patients with G6PD deficiency.

Interference with In Vivo Monitoring Devices

The presence of methylene blue in the blood may result in an underestimation of the oxygen saturation reading by pulse oximetry. If a measure of oxygen saturation is required during or shortly after infusion with ProvayBlue™, it is advisable to obtain an arterial blood sample for testing by an alternative method.

A fall in the Bispectral Index (BIS) has been reported following administration of methylene blue class products. If ProvayBlue™ is administered during surgery, alternative methods for assessing the depth of anesthesia should be employed.

Effects on Ability to Drive and Operate Machinery

Treatment with ProvayBlue™ may cause confusion, dizziness and disturbances in vision. Advise patients to refrain from driving or engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery until such adverse reactions to ProvayBlue™ have resolved.

Interference with Laboratory Tests

ProvayBlue™ is a blue dye which passes freely into the urine and may interfere with the interpretation of any urine test which relies on a blue indicator, such as the dipstick test for leucocyte esterase.

ADVERSE REACTIONS

The safety of ProvayBlue™ was determined in 82 healthy adults 19-55 years of age, with a median age of 36 years. Each individual in the safety population received a single dose of ProvayBlue™ 2 mg/kg intravenously.

The most commonly reported adverse reactions ($\geq 10\%$) are pain in extremity, chromaturia, dysgeusia, feeling hot, dizziness, hyperhidrosis, nausea, skin discoloration and headache. There was one serious adverse reaction reported (syncope due to sinus pauses of 3-14 seconds).

Other adverse reactions reported to occur following administration of methylene blue class products include the following: hemolytic anemia, hemolysis, hyperbilirubinemia, methemoglobinemia; palpitations, tachycardia; eye pruritus, ocular hyperemia, vision blurred; abdominal pain lower, dry mouth, flatulence, glossodynia, tongue eruption; death, infusion site extravasation, infusion site induration, infusion site pruritus, infusion site swelling, infusion site urticaria, peripheral swelling, thirst; elevated liver enzymes; myalgia; dysuria; nasal congestion, oropharyngeal pain, rhinorrhea, sneezing; necrotic ulcer, papule, phototoxicity; and hypertension.

Table 1. Adverse Reactions Following Infusion of ProvayBlue™ 2 mg/kg

| Adverse Reaction | Any Grade TEAE (n=82) | Moderate - Severe TEAE (n=82) |
|-------------------|-----------------------|-------------------------------|
| Pain in extremity | 69 84% | 46 56% |
| Chromaturia | 61 74% | 0 |
| Dysgeusia | 16 20% | 1 1% |
| Feeling hot | 14 17% | 5 6% |
| Dizziness | 13 16% | 4 5% |

Table continued on the next page

The first and only FDA Approved methylene blue injection²

New Concentration

- IV Injection 5 mg/mL vs. existing methylene blue solutions (10 mg/mL)

Dosage

- 5 mg/mL: administer 1 mg/kg intravenously over 5-30 minutes
 - If methemoglobin level remains > 30% or if clinical signs and symptoms persist, a repeat dose of 1 mg/kg may be given 1 hour after the first dose
 - If methemoglobinemia does not resolve after 2 doses of ProvoyBlue™ (methylene blue) injection, 0.5% consider alternate treatments
- ProvoyBlue™ is approved for intravenous (IV) administration only

WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS

ProvoyBlue™ may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs. Avoid concomitant use of ProvoyBlue™ with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors.

| Adverse Reaction | Any Grade TEAE (n=82) | | Moderate - Severe TEAE (n=82) | |
|--------------------------|-----------------------|-----|-------------------------------|----|
| Hyperhidrosis | 11 | 13% | 2 | 2% |
| Nausea | 11 | 13% | 2 | 2% |
| Skin discoloration | 11 | 13% | 0 | |
| Headache | 8 | 10% | 6 | 7% |
| Musculoskeletal pain | 7 | 9% | 0 | |
| Paresthesia oral | 7 | 9% | 0 | |
| Paresthesia | 7 | 9% | 0 | |
| Infusion site pain | 5 | 6% | 1 | 1% |
| Feeling cold | 5 | 6% | 0 | |
| Pallor | 4 | 5% | 0 | |
| Dermatitis contact | 4 | 5% | 0 | |
| Syncope | 3 | 4% | 3 | 4% |
| Influenza like illness | 3 | 4% | 1 | 1% |
| Pruritus | 3 | 4% | 1 | 1% |
| Anxiety | 3 | 4% | 0 | |
| Decreased appetite | 3 | 4% | 0 | |
| Chest discomfort | 3 | 4% | 0 | |
| Back pain | 2 | 2% | 2 | 2% |
| Cold sweat | 2 | 2% | 1 | 1% |
| Dizziness postural | 2 | 2% | 1 | 1% |
| Muscle spasms | 2 | 2% | 1 | 1% |
| Presyncope | 2 | 2% | 1 | 1% |
| Vomiting | 2 | 2% | 1 | 1% |
| Arthralgia | 2 | 2% | 1 | 1% |
| Chills | 2 | 2% | 0 | |
| Diarrhea | 2 | 2% | 0 | |
| Discomfort | 2 | 2% | 0 | |
| Dyspnea | 2 | 2% | 0 | |
| Erythema | 2 | 2% | 0 | |
| Hypoesthesia oral | 2 | 2% | 0 | |
| Infusion site discomfort | 2 | 2% | 0 | |
| Limb discomfort | 2 | 2% | 0 | |
| Oral discomfort | 2 | 2% | 0 | |
| Catheter site pain | 2 | 2% | 0 | |
| Ecchymosis | 2 | 2% | 0 | |

ProvoyBlue™ (methylene blue) injection, 0.5%

New Concentration

To learn more, please call 1-800-645-1706
or visit www.provoyblue.com.

DRUG INTERACTIONS

Avoid concomitant use of ProvoyBlue™ with medicinal products that enhance serotonergic transmission including SSRIs, MAO inhibitors, bupropion, buspirone, clomipramine, mirtazapine and venlafaxine; because of the potential for serious CNS reactions, including potentially fatal serotonin syndrome. If the intravenous use of ProvoyBlue™ cannot be avoided in patients treated with serotonergic medicinal products, choose the lowest possible dose and observe closely the patient for CNS effects for up to 4 hours after administration.

Methylene blue inhibits a range of CYP isozymes in vitro, including 1A2, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4/5.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

ProvoyBlue™ may cause fetal harm when administered to a pregnant woman. Intra-amniotic injection of pregnant women with a methylene blue class product during the second trimester was associated with neonatal intestinal atresia and fetal death. Advise pregnant women of the potential risk to the fetus.

There is no information regarding the presence of methylene blue in human milk. Because of the potential for serious adverse reactions, including genotoxicity discontinue breast-feeding during and for up to 8 days after treatment with ProvoyBlue™.

Renal Impairment

Patients with any renal impairment should be monitored for toxicities and potential drug interactions for an extended period of time following treatment with ProvoyBlue™.

Hepatic Impairment

Methylene blue is extensively metabolized in the liver. Monitor patients with any hepatic impairment for toxicities and potential drug interactions for an extended period of time following treatment with ProvoyBlue™.

OVERDOSAGE

In case of overdose of ProvoyBlue™, maintain the patient under observation until signs and symptoms have resolved, monitor for cardiopulmonary, hematologic and neurologic toxicities, and institute supportive measures.

Please see Brief Summary of Full Prescribing Information on following pages and Full Prescribing Information, including BOXED WARNING at www.provoyblue.com.

REFERENCES: 1. ProvoyBlue™ [Package Insert]. PROVEPHARM SAS Marseille, France.
2. US Food and Drug Administration, Center for Drug Evaluation and Research. ProvoyBlue™ NDA 204630 Approval Letter

To report an Adverse Drug Event (ADE): Email: pv@luitpold.com;
Fax: 1-610-650-0170; **Phone:** 1-800-734-9236; **ADEs may be reported to the FDA:**
Phone: 1-800-FDA-1088; **Web:** www.fda.gov/safety/medwatch

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BRIEF SUMMARY PROVAYBLUE™ (METHYLENE BLUE)

DESCRIPTION

ProvayBlue™ (methylene blue), injection, 0.5% is an oxidation-reduction agent. ProvayBlue™ is a sterile solution intended for intravenous administration. Each ProvayBlue™, 10 mL ampule contains 50 mg ProvayBlue™ methylene blue and water for injection q.s. Each mL of solution contains 5 mg methylene blue and water for injection q.s. Methylene blue is 3,7-bis (dimethylamino) phenothiazin-5-ium, chloride.

INDICATIONS AND USAGE

ProvayBlue™ is indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia.

This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS

ProvayBlue™ may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs. Avoid concomitant use of ProvayBlue™ with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors.

CONTRAINDICATIONS

ProvayBlue™ is contraindicated in the following conditions:

- Severe hypersensitivity reactions to methylene blue or any other thiazine dye
- Patients with glucose-6-phosphate dehydrogenase deficiency (G6PD) due to the risk of hemolytic anemia

WARNINGS AND PRECAUTIONS

Serotonin Syndrome with Concomitant Use of Serotonergic Drugs

The development of serotonin syndrome has been reported with use of methylene blue class products. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors). Some of the reported cases were fatal. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, and hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, and incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, and diarrhea). Avoid concomitant use of ProvayBlue™ with serotonergic drugs.

Patients treated with ProvayBlue™ should be monitored for the emergence of serotonin syndrome. If symptoms of serotonin syndrome occur, discontinue use of ProvayBlue™, and initiate supportive treatment. Inform patients of the increased risk of serotonin syndrome and advise them to not to take serotonergic drugs within 72 hours after the last dose of ProvayBlue™.

Hypersensitivity

Anaphylactic reactions to methylene blue class products have been reported. Patients treated with ProvayBlue™ should be monitored for anaphylaxis. If anaphylaxis or other severe hypersensitivity reactions (e.g., angioedema, urticaria, and bronchospasm) should occur, discontinue use of ProvayBlue™ and initiate supportive treatment. ProvayBlue™ is contraindicated in patients who have experienced anaphylaxis or other severe hypersensitivity reactions to a methylene blue class product in the past.

Lack of Effectiveness

Methemoglobinemia may not resolve or may rebound after response to treatment with ProvayBlue™ in patients with methemoglobinemia due to aryl amines such as aniline or sulfa drugs such as dapsone. Monitor response to therapy with ProvayBlue™ through resolution of methemoglobinemia. If methemoglobinemia does not respond to 2 doses of ProvayBlue™ or if methemoglobinemia rebounds after a response, consider additional treatment options.

Patients with glucose-6-phosphate dehydrogenase deficiency may not reduce ProvayBlue™ to its active form in vivo. ProvayBlue™ may not be effective in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Hemolytic Anemia

Hemolysis can occur during treatment of methemoglobinemia with ProvayBlue™. Laboratory testing may show Heinz bodies, elevated indirect bilirubin and low haptoglobin, but the Coombs test is negative. The onset of anemia may be delayed 1 or more days after treatment with ProvayBlue™. The anemia may require red blood cell transfusions. Use the lowest effective number of doses of ProvayBlue™ to treat methemoglobinemia. Discontinue ProvayBlue™ and consider alternative treatments of methemoglobinemia if severe hemolysis occurs.

Treatment of patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency with ProvayBlue™ may result in severe hemolysis and severe anemia. ProvayBlue™ is contraindicated for use in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Interference with In Vivo Monitoring Devices

Inaccurate Pulse Oximeter Readings

The presence of methylene blue in the blood may result in an underestimation of the oxygen saturation reading by pulse oximetry. If a measure of oxygen saturation is required during or shortly after infusion of ProvayBlue™, it is advisable to obtain an arterial blood sample for testing by an alternative method.

Bispectral index monitor

A fall in the Bispectral Index (BIS) has been reported following administration of methylene blue class products. If ProvayBlue™ is administered during surgery, alternative methods for assessing the depth of anesthesia should be employed.

Effects on Ability to Drive and Operate Machinery

Treatment with ProvayBlue™ may cause confusion, dizziness and disturbances in vision. Advise patients to refrain from driving or engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery until such adverse reactions to ProvayBlue™ have resolved.

Interference with Laboratory Tests

ProvayBlue™ is a blue dye which passes freely into the urine and may interfere with the interpretation of any urine test which relies on a blue indicator, such as the dipstick test for leucocyte esterase.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Serotonin Syndrome with Concomitant Use of Serotonergic Drugs
- Anaphylaxis
- Lack of Effectiveness
- Hemolytic Anemia
- Interference with In-Vivo Monitoring Devices
- Effects on Ability to Drive and Operate Machinery

The most commonly reported adverse reactions (≥10%) are pain in extremity, chromaturia, dysgeusia, feeling hot, dizziness, hyperhidrosis, nausea, skin discoloration and headache.

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 practice.

The safety of ProvayBlue™ was determined in 82 healthy adults of median age of 36 years (range, 19-55 years); 54% were male, and 68% were white. Each individual in the safety population received a single dose of ProvayBlue™ 2 mg/kg intravenously. There was one serious adverse reaction reported (syncope due to sinus pauses of 3-14 seconds).

Table 1. Adverse Reactions Following Infusion of ProvayBlue™ 2 mg/kg

| Adverse Reaction | Any Grade TEAE (n=82) | Moderate-Severe TEAE (n=82) | | |
|--------------------------|-----------------------|-----------------------------|----|-----|
| Pain in extremity | 69 | 84% | 46 | 56% |
| Chromaturia | 61 | 74% | 0 | |
| Dysgeusia | 16 | 20% | 1 | 1% |
| Feeling hot | 14 | 17% | 5 | 6% |
| Dizziness | 13 | 16% | 4 | 5% |
| Hyperhidrosis | 11 | 13% | 2 | 2% |
| Nausea | 11 | 13% | 2 | 2% |
| Skin discoloration | 11 | 13% | 0 | |
| Headache | 8 | 10% | 6 | 7% |
| Musculoskeletal pain | 7 | 9% | 0 | |
| Paresthesia oral | 7 | 9% | 0 | |
| Paresthesia | 7 | 9% | 0 | |
| Infusion site pain | 5 | 6% | 1 | 1% |
| Feeling cold | 5 | 6% | 0 | |
| Pallor | 4 | 5% | 0 | |
| Dermatitis contact | 4 | 5% | 0 | |
| Syncope | 3 | 4% | 3 | 4% |
| Influenza like illness | 3 | 4% | 1 | 1% |
| Pruritus | 3 | 4% | 1 | 1% |
| Anxiety | 3 | 4% | 0 | |
| Decreased appetite | 3 | 4% | 0 | |
| Chest discomfort | 3 | 4% | 0 | |
| Back pain | 2 | 2% | 2 | 2% |
| Cold sweat | 2 | 2% | 1 | 1% |
| Dizziness postural | 2 | 2% | 1 | 1% |
| Muscle spasms | 2 | 2% | 1 | 1% |
| Presyncope | 2 | 2% | 1 | 1% |
| Vomiting | 2 | 2% | 1 | 1% |
| Arthralgia | 2 | 2% | 1 | 1% |
| Chills | 2 | 2% | 0 | |
| Diarrhea | 2 | 2% | 0 | |
| Discomfort | 2 | 2% | 0 | |
| Dyspnea | 2 | 2% | 0 | |
| Erythema | 2 | 2% | 0 | |
| Hypoesthesia oral | 2 | 2% | 0 | |
| Infusion site discomfort | 2 | 2% | 0 | |
| Limb discomfort | 2 | 2% | 0 | |
| Oral discomfort | 2 | 2% | 0 | |
| Catheter site pain | 2 | 2% | 0 | |
| Ecchymosis | 2 | 2% | 0 | |

Other adverse reactions reported to occur following administration of methylene blue class products include the following:

- Blood and lymphatic system disorders:** hemolytic anemia, hemolysis, hyperbilirubinemia, methemoglobinemia
- Cardiac disorders:** palpitations, tachycardia
- Eye disorders:** eye pruritus, ocular hyperemia, vision blurred
- Gastrointestinal disorders:** abdominal pain lower, dry mouth, flatulence, glossodynia, tongue eruption
- General disorders and administration site conditions:** death, infusion site extravasation, infusion site induration, infusion site pruritus, infusion site swelling, infusion site urticaria, peripheral swelling, thirst
- Investigations:** elevated liver enzymes
- Musculoskeletal and connective tissue disorders:** myalgia
- Renal and urinary disorders:** dysuria
- Respiratory, thoracic and mediastinal disorders:** nasal congestion, oropharyngeal pain, rhinorrhea, sneezing
- Skin and subcutaneous tissue disorders:** necrotic ulcer, papule, phototoxicity
- Vascular disorders:** hypertension

DRUG INTERACTIONS

Serotonergic Drugs

Avoid concomitant use of ProvayBlue™ with medicinal products that enhance serotonergic transmission including SSRIs (selective serotonin reuptake inhibitors), MAO inhibitors, bupropion, buspirone, clomipramine, mirtazapine and venlafaxine; because of the potential for serious CNS reactions, including potentially fatal serotonin syndrome. Although the mechanism is not clearly understood, literature reports suggest inhibition of MAO by methylene blue may be involved. In addition, in vitro studies cannot rule out the potential involvement of CYP 2D6 inhibition by methylene blue. If the intravenous use of ProvayBlue™ cannot be avoided in patients treated with serotonergic medicinal products, choose the lowest possible dose and observe closely the patient for CNS effects for up to 4 hours after administration.

Agents Metabolized by Cytochrome P450 Enzymes

Methylene blue inhibits a range of CYP isozymes in vitro, including 1A2, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4/5. This interaction could be more pronounced with narrow therapeutic index drugs that are metabolized by one of these enzymes (e.g. digoxin, warfarin, phenytoin, alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozone, quinidine, sirolimus and tacrolimus). However, the clinical relevance of these in vitro interactions is unknown.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

ProvayBlue™ may cause fetal harm when administered to a pregnant woman. Intra-amniotic injection of pregnant women with a methylene blue class product during the second trimester was associated with neonatal intestinal atresia and fetal death. Methylene blue produced adverse developmental outcomes in rats and rabbits when administered orally during organogenesis at doses at least 32 and 16 times, respectively, the clinical dose of 1 mg/kg. Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2-4% and 15-20%, respectively.

Clinical Considerations

Fetal/neonatal adverse reactions

Intra-amniotic injection of a methylene blue class product hours to days prior to birth can result hyperbilirubinemia, hemolytic anemia, skin staining, methemoglobinemia, respiratory distress and photosensitivity in the newborn. Following administration of ProvayBlue™ to a pregnant woman at term, observe the newborn for these adverse reactions and institute supportive care.

Data

Animal Data

Methylene blue was administered orally to pregnant rats at doses of 50 to 350 mg/kg/day, during the period of organogenesis. Maternal and embryofetal toxicities were observed at all doses of methylene blue, and were most evident at the 200 and 350 mg/kg/day doses. Maternal toxicity consisted of increased spleen weight. Embryo-fetal toxicities included reduced fetal weight, post-implantation loss, edema, and malformations including enlarged lateral ventricles. The dose of 200 mg/kg (1200 mg/m²) in rats is approximately 32 times a clinical dose of 1 mg/kg based on body surface area.

Methylene blue was administered orally to pregnant rabbits at doses of 50, 100, or 150 mg/kg/day, during the period of organogenesis. Maternal death was observed at the methylene blue dose of 100 mg/kg. Embryofetal toxicities included spontaneous abortion at all dose levels and a malformation (umbilical hernia) at the 100 and 150 mg/kg/day doses. The dose of 50 mg/kg (600 mg/m²) in rabbits is approximately 16 times a clinical dose of 1 mg/kg based on body surface area.

Lactation

Risk Summary

There is no information regarding the presence of methylene blue in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions, including genotoxicity discontinue breastfeeding during and for up to 8 days after treatment with ProvayBlue™.

Pediatric Use

The safety and effectiveness of ProvayBlue™ have been established in pediatric patients. Use of ProvayBlue™ is supported by two retrospective case series that included 2 pediatric patients treated with ProvayBlue™ and 12 treated with another methylene blue class product. The case series included pediatric patients in the following age groups: 3 neonates (less than 1 month), 4 infants (1 month up to less than 2 years), 4 children (2 years up to less than 12 years), and 3 adolescents (12 years to less than 17 years). The efficacy outcomes were consistent across pediatric and adult patients in both case series.

Geriatric Use

The retrospective case series included 3 patients age 65 years and over treated with ProvayBlue™ (or a bioequivalent formulation) and 5 treated with another methylene blue class product. The efficacy outcomes were consistent across adult and elderly patients in both case series. This drug is known to be substantially excreted by the kidney, so the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, treatment of methemoglobinemia in these patients should use the lowest number of doses needed to achieve a response.

Renal Impairment

Approximately 40% of methylene blue is excreted by the kidneys. Patients with any renal impairment should be monitored for toxicities and potential drug interactions for an extended period of time following treatment with ProvayBlue™.

Hepatic Impairment

Methylene blue is extensively metabolized in the liver. Monitor patients with any hepatic impairment for toxicities and potential drug interactions for an extended period of time following treatment with ProvayBlue™.

OVERDOSAGE

Hypotension, wheezing and reduced oxygenation have been reported in patients who received methylene blue class products in single doses of 3 mg/kg or more.

Administration of large intravenous doses (cumulative dose ≥ 7 mg/kg) of a methylene blue class product caused nausea, vomiting, precordial pain, dyspnea, tachypnea, chest tightness, tachycardia, apprehension, tremor, mydriasis, blue staining of the urine, the skin and mucous membranes, abdominal pain, dizziness, paresthesia, headache, confusion, mild methemoglobinemia (up to 7%) and electrocardiogram changes (T-wave flattening or inversion) These effects lasted 2-12 hours following administration.

Continued on the next page

A severe overdosage (single dose of 20 mg/kg or more) of a methylene blue class product caused severe intravascular hemolysis, hyperbilirubinemia and death.

In case of overdose of ProveyBlue™ (methylene blue), injection, 0.5%, maintain the patient under observation until signs and symptoms have resolved, monitor for cardiopulmonary, hematologic and neurologic toxicities, and institute supportive measures as necessary.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a two-year carcinogenicity study, rats were administered oral doses of methylene blue at 5, 25, or 50 mg/kg. Methylene blue caused pancreatic islet adenomas or carcinomas (combined) in male rats. In a two-year year carcinogenicity study, mice were administered oral doses of methylene blue at 2.5, 12.5, or 25 mg/kg. There were no drug-related neoplastic findings in mice.

Methylene blue was genotoxic in gene mutation assays in bacteria (Ames test), and in an in vitro sister chromatid exchange test and an in vitro chromosomal aberration test in Chinese hamster ovary (CHO) cells. Methylene blue was negative for micronucleus induction in bone marrow or peripheral blood collected from mice treated with methylene blue.

Fertility studies with methylene blue have not been conducted. In vitro, methylene blue reduced motility of human sperm in a concentration dependent manner.

CLINICAL STUDIES

Treatment of Acquired Methemoglobinemia

The efficacy of ProveyBlue™ was assessed on the basis of a methemoglobin decrease of at least 50% within 1 hour after intravenous administration of 1 – 2 mg/kg ProveyBlue™ (or a bioequivalent formulation) in 6 patients identified by retrospective chart review or literature search. The 6 patients included 3 males and 3 females of median age 54 years (range, 6 days to 69 years).

The median methemoglobin level at baseline was 37% (range, 11% to 47%). All 6 (100%) patients had a decrease in methemoglobin by at least 50% within 1 hour after treatment.

An additional 41 cases of treatment of methemoglobinemia with a methylene blue class product were identified in the published literature. These cases included 24 males and 17 females of median age 33 years (range, 9 days to 80 years). The median methemoglobin level at baseline was 40% (range, 10% to 98%). Of these 41 patients, 37 (90%) had a methemoglobin decrease of at least 50% within 1 hour after intravenous administration of the methylene blue class product.

In a combined analysis of all 47 patients treated intravenously with ProveyBlue™ (or a bioequivalent formulation) or with another methylene blue class product, there was no difference in response rate by dose. The methemoglobin decreased by at least 50% within 1 hour of infusion for 15/17 (88%) of patients treated with 1 mg/kg, 12/13 (92%) treated with 2 mg/kg and 16/17 (94%) treated with a different dose or for those whose dose was not reported.

PATIENT COUNSELING INFORMATION

Serotonin Syndrome

Advise patients of the possibility of serotonin syndrome, especially with concomitant use of serotonergic agents such as medications to treat depression and migraines. Advise patients to seek immediate medical attention if the following symptoms occur after treatment with ProveyBlue™: changes in mental status, autonomic instability, or neuromuscular symptoms with or without gastrointestinal symptoms.

Pregnancy

Advise pregnant women of the potential risk to the fetus with the use of ProveyBlue™ during pregnancy.

Breastfeeding

Advise patients to discontinue breast-feeding for up to 8 days after treatment with ProveyBlue™.

Driving and Using Machines

Advise patients to avoid driving and use of machines during treatment with ProveyBlue™. Driving can be affected as a result of a confusional state, dizziness and possible eye disturbances.

Phototoxicity

Advise patients to take protective measures against exposure to light, because phototoxicity may occur after administration of methylene blue.

Skin and Body Fluid Blue Discoloration

Advise patients that ProveyBlue™ may cause a blue discoloration of the skin and body fluids.

By Jean-Sebastien Rachoin, MD

4 AKI is common in young, critically ill adults

CLINICAL QUESTION: What are the epidemiology, risk factors, and associated morbidity and mortality of acute kidney injury (AKI) in critically ill children and young adults?

BACKGROUND: Adult studies on acute kidney injury have shown increasing mortality and morbidity when both plasma creatinine and urine output were used to diagnose AKI than when used alone. Studies of AKI in children have also been limited.

STUDY DESIGN: Prospective, observational study.

SETTING: International (32 pediatric intensive care units across Asia, Australia, Europe, and North America).

SYNOPSIS: 4,984 patients aged 3 months to 25 years with a predicted ICU stay of at least 48 hours were considered for enrollment, of which 4,683 were included in the final



Dr. Rachoin

analysis. The primary outcome was 28-day mortality. Secondary outcomes were length of stay in the ICU, receipt and duration of mechanical ventilation, receipt of extracorporeal membrane oxygenation, and renal-replacement therapy.

A total of 26.9% of patients developed AKI in the first 7 days of an ICU admission. Severe AKI increased mortality by day 28 (adjusted odds ratio, 1.77; 95% confidence interval, 1.17-2.68) and was associated with increased use of renal-replacement therapy and mechanical ventilation and longer stays in the ICU. Urine output predicted mortality more accurately than did plasma creatinine, and using plasma creatinine alone failed to identify two-thirds of patients with low urine output.

BOTTOM LINE: In critically ill young patients, AKI is a common occurrence and is associated with both an increased morbidity and mortality. In a majority of patients with low urine output, plasma creatinine was a poor discriminant of renal function.

CITATIONS: Kaddourah A, Basu RK, Bagshaw SM, et al. Epidemiology of acute kidney injury in critically ill children and young adults. *N Eng J Med.* 2017; 376 (1):11-20.

5 More readmissions with delays in discharge summaries

CLINICAL QUESTION: Is there an association between time to completion of discharge summary and hospital readmission?

BACKGROUND: Thirty-day hospital readmission is one of the quality indicators for inpatient care and a higher rate can result in monetary penalties. Several interventions aimed at reducing this occurrence have been studied in different settings with variable success. Timely completion of discharge summary can possibly affect readmissions by providing crucial information to outpatient providers caring for patients across the care continuum.

STUDY DESIGN: Retrospective cohort study.

SETTING: Johns Hopkins University, Baltimore.

SYNOPSIS: 87,994 consecutive discharges

led to 14,248 readmissions (16.2%). After controlling for patient characteristics, delays in completion of discharge summaries of greater than 3 days were associated with readmission (odds ratio, 1.09; 95% confidence interval, 1.04-1.13; $P = .001$). Every additional 3 days of delayed completion increased the adjusted odds of readmission by 1%.

BOTTOM LINE: Delays in completion of discharge summaries was significantly associated with higher rates of hospital readmission. It's unclear however whether timely completion is a surrogate indicator of other important causative factors.

CITATIONS: Hoyer EH, Odonkor CA, Bhatia SN, et al. Association between days to complete inpatient discharge summaries with all-payer hospital readmissions in Maryland. *J Hosp Med.* 2016; 11(6):393-400.

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By Ashley Coleman, DO

6 Evidence suggests fondaparinux is more effective than LMWH in prevention of VTE and total DVT in the postoperative setting

CLINICAL QUESTION: How do pentasaccharides compare to other anticoagulants in postoperative venous thromboembolism prevention?

BACKGROUND: Venous thromboembolism (VTE) remains a leading cause of preventable hospital related death. Pentasaccharides selectively inhibit factor Xa to inhibit clotting and exhibit a lower risk of heparin-induced thrombocytopenia (HIT) compared to low molecular weight heparin (LMWH) and unfractionated heparin. We lack a formal recommendation regarding the pentasaccharides superiority or inferiority, relative to other anticoagulants, in the perioperative setting.

STUDY DESIGN: Cochrane review.

SETTING: Hospital and outpatient.

SYNOPSIS: Authors searched randomized controlled trials involving pentasaccharides versus other VTE prophylaxis to obtain 25 studies totaling 21,004 subjects undergoing orthopedic, abdominal, cardiac bypass, thoracic, and bariatric surgery; hospitalized patients, immobilized patients, and those with superficial venous thrombosis. Selected studies pertained to fondaparinux and VTE prevention. Fondaparinux was superior to placebo in prevention of DVT and VTE. Compared with LMWH, fondaparinux reduced total VTE (relative risk, 0.55, 95% confidence interval, 0.42-0.73) and DVT (RR, 0.54, 95% CI, 0.40-0.71), but carried a higher rate of major bleeding compared with placebo (RR, 2.56, 95% CI, 1.48-4.44) and LMWH (RR, 1.38, 95% CI, 1.09-1.75). The all-cause death and major adverse events for fondaparinux versus placebo and LMWH were not statistically significant. Limitations of this review include the predominance of orthopedic patients, variable duration of treatment, and low-moderate quality data.

CONTINUED ON FOLLOWING PAGE

BOTTOM LINE: Fondaparinux demonstrates better perioperative total VTE and DVT reduction compared to LMWH, but it increases the incidence of major bleeding.
REFERENCE: Dong K, Song Y, Li X, Ding J, Gao Z, Lu D, Zhu Y. Pentasaccharides for the prevention of venous thromboembolism. *Cochrane Database Syst Rev.* 2016 Oct 31;10:CD005134.

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By Jinyu Byron Lu, MD

7 2016 Updates to AASLD Guidance Document on gastroesophageal bleeding in decompensated cirrhosis

CLINICAL QUESTION: What is appropriate inpatient management of a cirrhotic patient with acute esophageal or gastric variceal bleeding?

STUDY DESIGN: Guidance document developed by expert panel based on literature review, consensus conferences and authors' clinical experience.

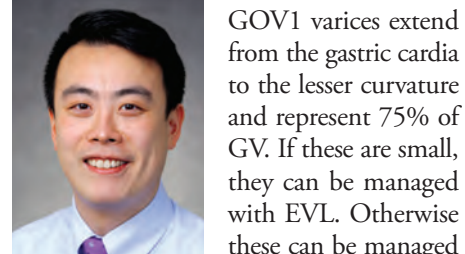
BACKGROUND: Practice guidelines for the diagnosis and treatment of gastroesophageal hemorrhage were last published in 2007 and endorsed by several major professional societies. Since then, there have been a number of randomized controlled trials (RCTs) and consensus conferences. The American Association for the Study of Liver Diseases (AASLD) published updated practice guidelines in 2016 that encompass pathophysiology, monitoring, diagnosis, and treatment of gastroesophageal hemorrhage in cirrhotic patients. This summary will focus on inpatient management for active gastroesophageal hemorrhage.

SYNOPSIS OF INPATIENT MANAGEMENT FOR ESOPHAGEAL VARICEAL HEMORRHAGE: The authors suggest that all VH requires ICU admission with the goal of acute control of bleeding, prevention of early recurrence, and reduction in 6-week mortality. Imaging to rule out portal vein thrombosis and HCC should be considered. Hepatic-Venous Pressure Gradient (HVPG) greater than 20 mm Hg is the strongest predictor of early rebleeding and death. However, catheter measurements of portal pressure are not available at most centers. As with any critically ill patient, stabilization of respiratory status and ensuring hemodynamic stability with volume resuscitation is paramount. RCTs evaluating transfusion goals suggest that a restrictive transfusion goal of Hgb 7 g/dL is superior to a liberal goal of 9 g/dL. The authors hypothesize this may be related to lower HVPG observed with lower transfusion thresholds. In terms of treating coagulopathy, RCTs evaluating recombinant VIIa have not shown clear benefit. Correction of INR with FFPs similarly not recommended. No recommendations are made regarding utility of platelet transfusions. Vasoactive drugs should be administered when VH is suspected with the goal of decreasing splanchnic blood flow. Octreotide is the only vasoactive drug available in the United States. RCTs show that antibiotics administered prophylactically decrease infections, recurrent hemorrhage, and death. Ceftriaxone 1 g

daily is the drug of choice in the United States and should be given up to a maximum of 7 days. A reasonable strategy is discontinuation of prophylaxis concurrently with discontinuation of vasoactive agents. After stabilization of hemodynamics, patients should proceed to endoscopy no more than 12 hours after presentation. Endoscopic Variceal Ligation (EVL) should be done if signs of active or recent variceal bleeding are found. After EVL, select patients at high risk of rebleeding (Child-Pugh B with active bleeding seen on endoscopy or Child-Pugh C patients) may benefit from TIPS within 72 hours. If TIPS is done, vasoactive agents can be discontinued. Otherwise, vasoactive agents should continue for 2-5 days with subsequent transition to nonselective beta blockers (NSBB) such as nadolol or propranolol. For secondary prophylaxis of esophageal bleeding, combination EVL and NSBB is first-line therapy. If recurrent hemorrhage occurs while on secondary prophylaxis, rescue TIPS is recommended.

SYNOPSIS OF INPATIENT MANAGEMENT FOR GASTRIC VARICEAL HEMORRHAGE:

Management of Gastric Variceal Hemorrhage is similar to Esophageal Variceal (EV) Hemorrhage and encompasses volume resuscitation, vasoactive drugs, and antibiotics with endoscopy shortly thereafter. Balloon tamponade can be used as a bridge to endoscopy in massive bleeds. In addition to the above, anatomic location of Gastric Varices (GV) affects choice of intervention. GOV1 varices extend from the gastric cardia to the lesser curvature and represent 75% of GV. If these are small, they can be managed with EVL. Otherwise these can be managed with injection of cyanoacrylate glue.



Dr. Lu

GOV2 varices extend from the gastric cardia into the fundus. Isolated GV type 1 varices (IGV1) are located entirely in the fundus and have the highest propensity for bleeding. For these latter two types of "cardio-fundal varices" TIPS is the preferred intervention to control acute bleeding. Data on the efficacy of secondary prophylaxis for GV bleeding is limited. A combination of NSBB, cyanoacrylate injection, or TIPS can be considered. Balloon Occluded Retrograde Transvenous Obliteration (BRTO) can be considered if fundal varices are associated with a large gastrosplenic or splenorenal collateral. However, no RCTs have compared BRTO with other strategies. Isolated GV type 2 (IGV2) varices are not localized to the esophageal or gastric cardio-fundal region and are rare in cirrhotic patients but tend to occur in pre-hepatic portal hypertension. Management requires multidisciplinary input from endoscopists, hepatologists, interventional radiologists, and surgeons.

BOTTOM LINE: For esophageal variceal bleeding related to cirrhosis: volume resuscitation, antibiotic prophylaxis, and vasoactive agents are mainstays of therapy to stabilize patient for endoscopic intervention within 12 hours. This should be followed by early TIPS within 72 hours in high risk patients.

A similar approach applies to gastric variceal bleeding, but interventional management is dependent on the anatomic

location of the varices in question.

CITATIONS: Garcia-Tsao G et al. Portal hypertensive bleeding in cirrhosis: Risk stratification, diagnosis and management – 2016 practice guidance by the American Association for the Study of Liver Diseases. *Hepatology* 2017 Jan;65(1):310-35.

8 Taking the hammer to sickle pain crises

CLINICAL QUESTION: Are any novel medicines designed to interrupt the pathophysiology of vaso-occlusion available to reduce the frequency and severity of pain crises in sickle cell anemia?

BACKGROUND: Hypoxemia-dependent HbS polymerization is just the initiating step in a complex cascade of events leading to sickle pain crises. Animal studies have suggested that blockade of P-selectin, an adhesion molecule expressed by endothelium, blunts the aggregation of sickled erythrocytes, leukocytes and activated platelets and may reduce progression to vaso-occlusive crises.

STUDY DESIGN: Multicenter, double-blinded, randomized placebo-controlled trial.

SETTING: International (60 study sites in 3 countries) from August 2013 to January 2015.

SYNOPSIS: Crizanlizumab is a humanized monoclonal antibody directed against P-selectin. A total of 198 patients aged 16-65 with HbSS, HbSC, HbSbeta+ and select other genotypes experiencing 2-10 pain crises in the 12 months prior to trial were block randomized to receive high-dose crizanlizumab, low-dose crizanlizumab, or placebo. Roughly 62% of enrolled patients in all three arms were already taking hydroxyurea – for which dose changes during trial period were forbidden. Patients not already on hydroxyurea could not initiate treatment during the trial period. The primary outcome was annualized rate of sickle pain crises (defined as pain without other demonstrable cause requiring medical facility visit and treatment with oral or parenteral narcotics or NSAIDs), including acute chest, hepatic or splenic sequestration crises and priapism. Secondary outcomes were annualized rates of hospital days, rates of uncomplicated crises, time to first and second crises, rates of acute chest syndrome and Brief Pain Inventory questionnaire. Primary outcome data were processed via intention-to-treat analysis.

For high-dose crizanlizumab, there were a median 1.63 crises per year compared to 2.98 in the placebo group, representing a 45.3% lower rate ($P = .01$). The protective effect of crizanlizumab was more pronounced in the per-protocol analysis (1.04 crises per year for the high dose group). In the subgroup of patients on concomitant hydroxyurea, the median annualized crisis rate among high dose versus placebo was 2.43, compared with 3.58, representing a 32.1% lower rate. In the non-hydroxyurea subgroup, the median annualized crisis rate for high dose versus placebo was 1.0 vs. 2.0, representing a 50% lower rate. Secondary endpoints similarly trended in favor of crizanlizumab in a dose-dependent fashion, although statistical significance was mixed.

BOTTOM LINE: Crizanlizumab, a humanized monoclonal antibody that blocks the action of the endothelial adhesion molecule

P-selectin, is promising as a novel medication to reduce frequency of vaso-occlusive crises in patients with HbS-related disease.

CITATION: Ataga KI, Kutler A, Kanter J, et al. Crizanlizumab for prevention of pain crises in sickle cell disease. *N Engl J Med.* 2016 Dec. 3. doi: 10.1056/NEJMoa1611770.

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By Samer Badr, MD

9 Anticoagulants: more harm than good in isolated calf DVT

CLINICAL QUESTION: Is therapeutic anticoagulation superior to placebo in patients with symptomatic acute calf deep venous thrombosis (DVT)?

BACKGROUND: Medical evidence supporting the usage of therapeutic anticoagulation in symptomatic acute isolated calf DVT is lacking. This type of DVT has a low embolic potential. The bleeding risk of anticoagulation might therefore be higher than its benefit.

STUDY DESIGN: Double-blind, placebo-controlled trial.

SETTING: Twenty-three centers in Canada, France and Switzerland.

SYNOPSIS: A total of 259 outpatients with a first acute symptomatic objectively confirmed isolated calf DVT were enrolled to receive either a therapeutic dose of the low-molecular weight heparin nadroparin (122 patients), or a placebo (130 patients).

The primary efficacy outcome (a composite endpoint of extension of calf DVT to proximal veins, contralateral proximal DVT and symptomatic pulmonary embolism) was not statistically significant between the two groups (3% in the nadroparin group and 5% in the placebo group, $P = .54$). The primary safety outcome (the number of patients with major or clinically relevant non-major bleeding) was significantly higher in the nadroparin group (4% in nadroparin group, 0 patients in the placebo group, $P = .0255$).

The study was limited by the relative low number of patients (goal was 286 patients). The results of the study do not apply to inpatients and to cancer patients as patients with high risk for extension or recurrence of their DVT were excluded.

BOTTOM LINE: Therapeutic anticoagulation in low-risk outpatients with isolated calf DVT will likely cause more harm from bleeding than benefit.

CITATION: Righini M, Galanaud J, Guenaguez H, et al. Anticoagulant therapy for symptomatic calf deep vein thrombosis (CACTUS): A randomised, double-blind, placebo-controlled trial. *The Lancet Haematology.* 2016;3(12):e556-e562. doi: 10.1016/S2352-3026(16)30131-4.

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Postdischarge antibiotics for complicated pneumonia

CLINICAL QUESTION: Are oral antibiotics as effective as intravenous (IV) antibiotics in the treatment of complicated pneumonia after discharge to home?

BACKGROUND: Pneumonia is the most common illness among hospitalized children and adolescents (excluding neonates). Among children admitted with community acquired pneumonia, 15% may develop a complicated pneumonia (one with a pleural effusion or empyema). Treatment for these complicated pneumonias may include a variety of invasive procedures, such as video-assisted thorascopic surgery or chest tube placement.

Typically, a long course of antibiotics is prescribed on discharge, which may be oral or parenterally administered via a peripherally inserted central catheter (PICC). Previous studies have shown that oral antibiotics are equivalent to parenteral antibiotics for outpatient treatment of osteomyelitis. However, little evidence exists comparing the effectiveness of the two routes in treating complicated pneumonia.

The rate of PICC complications in complicated pneumonia also has not been well studied.

STUDY DESIGN: Retrospective cohort study.

SETTING: Thirty-eight children's hospitals

affiliated with the Children's Hospital Association.

SYNOPSIS: Over 4 years, 7,820 encounters were identified with 2,123 patients ultimately being included in the cohort. Inclusion criteria were age 2 months to 18 years, and discharge diagnoses of pneumonia and pleural effusion. The authors excluded patients with chronic medical conditions, length of stay (LOS) less than 4 and more than 14 days, patients transferred to or from other institutions, and patients receiving no antibiotics on hospital day 1. The final criteria attempted to avoid inclusion of patients with nosocomial pneumonia. After application of these criteria, individual patient records were reviewed.

Patients were categorized as PICC or oral antibiotics based upon antibiotic route at their initial discharge. Treatment failure was defined as an ED revisit or rehospitalization that led to a change in antibiotic, lengthening of antibiotic course, or pleural drainage. Records were searched for evidence of PICC complications, adverse drug reactions, and other illness-related revisits. Patients in the PICC arm and oral arm were matched by age, race, insurance, LOS, positive vs. negative blood culture, ICU admission, and timing and

type of pleural drainage.

Fifty-seven patients had treatment failure (2.7%). In matched analysis, there was no difference in treatment failure between PICC and oral routes (PICC treatment failure odds ratio, 1.26 95%, confidence interval, 0.54-2.94). PICC complications were found in 7.1% of patients. Patients with PICC had significantly higher rates of adverse drug reactions (OR, 19.1 95%, CI, 4.2-87.3) and illness-related revisits (OR 3.27 95%, CI, 1.65-6.48), and all revisits (OR, 4.71 95%, CI, 2.97-7.46).

PICC use varied markedly across geographic regions and institutions, with rates varying from less than 10% of cases to approximately 70%. Of geographic regions, the Mid-Atlantic used PICCs least often while the East North Central used them the most.

BOTTOM LINE: Treatment failure with both oral and PICC treatment of complicated pneumonia occur at the same rate, and are uncommon. Patients with PICCs had an increased rate of complications, including adverse drug reactions and revisits.

CITATION: Shah SS, Srivastava R, Wu S, et al. Intravenous versus oral antibiotics for postdischarge treatment of complicated pneumonia. *Pediatrics*. 2016;138(6):e20161692. doi: 10.1542/peds.2016-1692.

By Ritesh Patel, MD

10 Emergency department visits from adverse drug events

CLINICAL QUESTION: The purpose of this study was to describe emergency department (ED) visits for adverse drug events in year 2013-2014 compared to year 2005-2006 to learn changing patterns of ADEs and to help advance medication safety initiatives in outpatient settings.

BACKGROUND: Adverse drug events (ADEs) are the most common cause of iatrogenic harm to patients and there have been significant national-level initiatives to prevent them as a part of patient safety. In the outpatient setting, where 90% of prescription drug expenditures occur, preventing ADEs remains a patient safety challenge because patients can have complex medication regimens, at times prescribed by multiple clinicians, with far less monitoring compared with hospitalized patients.

SETTING AND STUDY DESIGN: Active, public health surveillance in 58 EDs in the United States that participate in the National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance Project. Trained data abstractors at each hospital reviewed each ED visit to identify

any clinician-diagnosed ADEs that were the reason for the ED visit. Reports were coded by CDC and analyzed.

SYNOPSIS: Based on 42,585 cases, 4.0 (95% confidence interval, 3.1-5) ED visits for ADEs per 1,000 individuals occurred annually in the United States in 2013-2014 and 27.3% (22.2%-32.4%) of ED visits for ADEs resulted in hospitalization.

An estimated 34.5% (95% CI, 30.3-38.8) of ED visits for ADEs occurred among adults aged 65 or older in 2013 compared with an estimated 25.6% (95% CI, 21-30) in 2005-2006. The population rate for adults older than 65 years was 9.7 visits per 1,000 individuals, compared with 3.1 visits per 1,000 individuals for those younger than 65 years. Older adults experienced higher hospitalization rates 43.6% (95% CI, 36.6-50.5). When adjusted for the U.S. population, the hospitalization rate for ADEs among older individuals was seven times higher compared with younger patients.

A single medication was implicated in most ED visits for ADEs (83.8%; 95% CI, 81.5-86.1). Supratherapeutic effects of ingestion of excess dose was the most common type of ADE (37.2%; 95% CI, 34.7-39.6). Medication errors were documented in 1 of 10 ED visits for ADEs

(10.5%; 95% CI, 8.9-12.2).

The most commonly implicated drug classes were anticoagulants (17.6%), systemic antibiotics (16.1%), diabetes agents (13.3%), opioid analgesics (6.8%), antiplatelets (6.6%), renin-angiotensin



Dr. Patel

system inhibitors (3.5%), antineoplastic agents (3%) and sedative/hypnotics (3%). Since 2005-2006, the proportions of ED visits for ADEs involving anticoagulants, antiplatelets, and diabetic agents have increased, whereas proportions involving antibiotics have decreased.

In children aged 5 years or younger, antibiotics were the most common drug class (56.4; 95% CI, 51.8-61). Among children and adolescents aged 6-19 years, antibiotics also were the most common class (31.8%; 95% CI, 28.7-34.9), followed by antipsychotics (4.5%; 95% CI, 3.3-5.6).

Among older adults, three drug classes recently targeted by federal patient safety initiatives (anticoagulants, diabetes agents, and opioid analgesics) were implicated in an

estimated 59.9% (95% CI, 56.8-62.9) of ED visits. Four anticoagulants (warfarin, rivaroxaban, dabigatran, and enoxaparin) and five diabetes agents (insulin and four oral agents) were among the 15 most common drugs implicated. Medications to always avoid in older adults according to Beers criteria were implicated in 1.8% (95% CI, 1.5-2.1) of ED visits for adverse drug events.

SUMMARY: The most common drug classes implicated in ED visits for ADEs in the United States are the same ones identified a decade ago – anticoagulants, antibiotics, diabetes agents, and opioid analgesics. The proportion of ED visits for ADEs involving anticoagulants has increased during the last decade with increased anticoagulant use. The prevalence of potentially inappropriate medication use in older patients also remains high.

CITATION: *JAMA*. 2016;316(20):2115-25. doi: 10.1001/jama.2016.16201.

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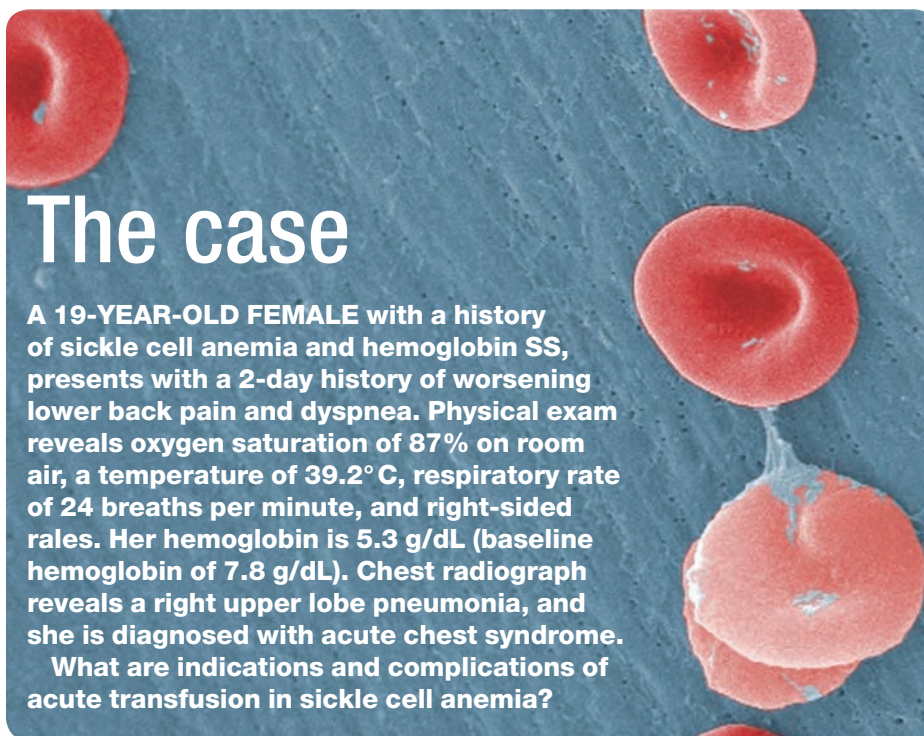
KEY
CLINICAL
QUESTION

What are indications, complications of acute blood transfusions in sickle cell anemia?

By Keri T. Holmes-Maybank, MD, FHM, Temeia D. Martin, MD, Ashley A. Duckett, MD, FHM

KEY POINTS

- SCA patients are at risk for serious transfusion complications including iron overload, delayed hemolytic transfusion reaction, and hyperviscosity in addition to the usual transfusion risks.
- Do not transfuse an uncomplicated vaso-occlusive crisis without symptomatic anemia.¹⁻³
- Repeated transfusions create alloimmunization in SCA patients increasing risk for life-threatening transfusion reactions and difficulty locating phenotypically matched RBCs.
- Transfusion should be considered in SCA patients experiencing acute chest syndrome, aplastic anemia, splenic sequestration with acute anemia, acute hepatic sequestration, and severe intrahepatic cholestasis.^{1,2}
- If available, exchange transfusion should be considered for SCA patients experiencing multisystem organ failure, acute stroke, and severe acute chest syndrome.^{1,2}



The case

A 19-YEAR-OLD FEMALE with a history of sickle cell anemia and hemoglobin SS, presents with a 2-day history of worsening lower back pain and dyspnea. Physical exam reveals oxygen saturation of 87% on room air, a temperature of 39.2°C, respiratory rate of 24 breaths per minute, and right-sided rales. Her hemoglobin is 5.3 g/dL (baseline hemoglobin of 7.8 g/dL). Chest radiograph reveals a right upper lobe pneumonia, and she is diagnosed with acute chest syndrome. What are indications and complications of acute transfusion in sickle cell anemia?

CDC/Janice Haney Carr

Background

Chronic hemolytic anemia is a trademark of sickle cell anemia (SCA) or hemoglobin (Hb) SS, as is acute anemia during illness or vaso-occlusive crises. Blood transfusions were the first therapy used in sickle cell disease, long before the pathophysiology was understood. Transfusion of red blood cells (RBCs) increases the percentage of circulating normal Hb A, thereby decreasing the percentage of abnormal, sickled cells. This increases the oxygen-carrying capacity of the patient's RBCs, improves organ perfusion, prevents organ damage, and can be life saving. SCA patients are the largest users of the United States rare donor blood bank registry.¹

Unfortunately, transfusion comes with many risks, including infection, transfusion reactions, alloimmunization, iron overload, hyperviscosity, and volume overload.

As SCA is a low-prevalence disease in a minority population, very few studies have been performed. Currently, the guidance available regarding blood transfusion is primarily based on expert opinion.

What to transfuse

No studies definitively recommend the type of RBC transfusion SCA patients should receive.² Academic medical centers and sickle cell centers use non-sickle cell, leukoreduced (white blood cells removed), and phenotypically matched RBC for transfusion. Intensive phenotypic matching, including ABO, Rh, and minor antigens,

and sometimes S, may reduce alloimmunization and hemolytic transfusion reactions.¹

Leukoreduced and intensive phenotypically matched RBCs are not possible in many medical centers. Previous studies have noted decreased incidence of febrile nonhemolytic anemia transfusion reactions, cytomegalovirus transmission, and human leukocyte antigen alloimmunization in leukoreduced blood transfusions, however, these studies did not include SCA patients.²

Complications from transfusion

Complications from blood transfusions include febrile nonhemolytic transfusion reaction, acute hemolytic transfusion reaction (ABO incompatibility), transfusion-associated lung injury (TRALI), transfusion-associated circulatory overload (TACO), infections, and anaphylaxis. The National Heart, Lung, and Blood Institute guidelines specifically highlight the complications of delayed hemolytic transfusion reaction, iron overload, and hyperviscosity in SCA. Approximately 30% of SCA patients have alloantibodies.² SCA patients may also develop autoimmunization, an immune response to their own RBC, particularly if the patient has multiple autoantibodies.

Infection is a risk for all individuals receiving transfusion. Screening for hepatitis B, hepatitis C, HIV, human T-cell lymphotropic virus, syphilis, West Nile virus, *Trypanosoma*, and bacteria are routinely performed but not 100% conclusive. Other

diseases not routinely screened for include Creutzfeldt-Jakob disease, *Babesia*, human herpesvirus-8, dengue fever, malaria, and newer concerns such as Zika virus.^{2,3}

Febrile nonhemolytic transfusion reactions present as an increase in body temperature of more than 1°C during or shortly after receiving a blood transfusion in the absence of other pyrexia stimulus. Febrile nonhemolytic transfusion reaction occurs more frequently in patients with a previous history of transfusions. The use of leukoreduced RBCs reduces the occurrence to less than 1%.²

TRALI presents with the acute onset of hypoxemia and noncardiogenic pulmonary edema within 6 hours of a blood transfusion in the absence of other etiologies. The mechanism of TRALI is caused by an inflammatory response causing injury to the alveolar capillary membrane and the development of pulmonary edema.¹

TACO presents with cardiogenic pulmonary edema not from another etiology. This is usually seen after transfusion of excessive volumes of blood or after excessively rapid rates of transfusion.¹

Delayed hemolytic transfusion reaction (DHTR) may be a life-threatening immune response to donor cell antigens. The reaction is identified by a drop in the patient's hemoglobin below the pretransfusion level, reticulocytopenia, a positive direct Coombs test, and occasionally jaundice on physical exam.² Patients may have an unexpectedly high hemoglobin S% after transfusion from the hemolysis of donor cells. The pathognomonic feature is development of a new alloantibody. DHTR occurs more often in individuals who have received recurrent transfusions and has been reported in 4%-11% of transfused SCA patients.³ Donor and native cells hemolyze intra- and extravascularly 5-20 days after receiving a transfusion.² DHTR is likely underestimated in SCA as it may be confused with a vaso-occlusive crisis.

Iron overload from recurrent transfusions is a slow, chronic process resulting in end organ damage of the heart, liver, and pancreas. It is associated with more frequent hospitalizations and higher mortality in SCA.³ The average person has 4-5 g of iron with no process to remove the excess. One unit of packed red blood cells adds 250-300 mg of iron.² Ferritin somewhat correlates to iron overload but is not a reliable method because it is an acute-phase reactant. Liver biopsy is the current diagnostic gold standard, however, noninvasive MRI is gaining diagnostic credibility.

Hb SS blood has up to 10 times higher

TABLE 1 Indications for simple transfusion and exchange transfusion^{1,2}

| Indication | Simple Transfusion | Exchange Transfusion |
|--|--------------------|----------------------|
| Acute chest syndrome | X ^{1,2} | |
| Aplastic anemia | X ^{1,2} | |
| Preoperatively – general anesthesia | X ^{1,2} | |
| Acute splenic sequestration with severe anemia | X ² | |
| Acute hepatic sequestration | X ² | X ^{2**} |
| Severe intrahepatic cholestasis | X ² | X ^{2**} |
| Multisystem organ failure | X ^{2*} | X ^{1,2} |
| Severe acute chest syndrome | | X ² |
| Acute stroke | X ^{1,2*} | X ^{1,2} |

*If exchange transfusion is not available. **Consider exchange transfusion as well as simple transfusion.

TABLE 2 Inappropriate indications for transfusion¹

| Indication |
|--|
| Uncomplicated vaso-occlusive crisis ^{1,2} |
| Priapism ^{1,2} |
| Acute renal failure without multisystem organ failure ² |
| Asymptomatic acute anemia ² |
| Leg ulcer ¹ |
| Infection ¹ |
| Minor surgery without general anesthesia ¹ |
| Avascular necrosis ¹ |
| Uncomplicated pregnancy ¹ |
| Transient ischemic attack ¹ |

1. American Red Cross. A Compendium of Transfusion Practice Guidelines. Second Edition, April 2013. Available at <http://www.redcrossblood.org/hospitals/educational-resources>

2. US Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease, Expert Panel Report, 2014. Available at <https://www.nhlbi.nih.gov/sites/www.nhlbi.nih.gov/files/sickle-cell-disease-report.pdf>



Spencer Grant/Science Source

viscosity than does non-sickle cell blood at the same hemoglobin level. RBC transfusion increases the already hyperviscous state of SCA resulting in slow blood flow through vessels. The slow flow through small vessels from hyperviscosity may result in additional sickling and trigger or worsen a vaso-occlusive crisis. Avascular necrosis is theorized to be a result of hyperviscosity as it occurs more commonly in sickle cell patients with higher hemoglobin. It is important not to transfuse to baseline or above a hemoglobin of 10 g/dL to avoid worsening hyperviscosity.²

When to consider transfusion

Unfortunately, there are no strong randomized controlled trials to definitively dictate when simple transfusions or exchange transfusions are indicated. Acute simple transfusions should be considered in certain circumstances, including acute chest syndrome, acute stroke, aplastic anemia, preoperative transfusion, splenic sequestration plus severe anemia, acute hepatic sequestration, and severe acute intrahepatic cholestasis.²

Exchange transfusion (erythrocytapheresis) should be considered for seriously ill patients, including those with multisystem organ failure, severe acute chest syndrome, and acute stroke.² It may also be used for hepatic sequestration and acute intrahepatic cholestasis.^{1,2} The benefits of removing sickled cells include an increased percent-

age of Hb A and the ability to transfuse a greater volume with a lower net volume to decrease hyperviscosity and iron overload. Exchange transfusion increases the volume of donor blood exposure, increasing the risk of alloimmunization.

Few studies compare simple transfusion and exchange transfusion.² The decision to use exchange transfusion over simple

Infection is a risk for all individuals receiving transfusion. Screening for hepatitis B, hepatitis C, HIV, human T-cell lymphotropic virus, syphilis, West Nile virus, *Trypanosoma*, and bacteria are routinely performed but not 100% conclusive.

transfusion often is based on availability of exchange transfusion, ability of simple transfusion to decrease the percentage of hemoglobin S, and/or the patient's current hemoglobin to avoid hyperviscosity from simple transfusion.³ Exchange transfusion should be considered for hemoglobin greater than 8-9 g/dL.²

Acute hepatic sequestration (AHS) occurs with the sequestration of RBCs in the liver and is marked by greater than 2

g/dL decrease in hemoglobin and hepatic enlargement, compared with baseline. The stretching of the hepatic capsule results in right upper quadrant pain. AHS often develops over a few hours to a few days with only mild elevation of liver function tests. AHS may be underestimated as two-thirds of SCA patients have hepatomegaly. Unless the hepatomegaly is radiographically moni-

tored it may not be possible to determine an acute increase in liver size.²

Severe acute intrahepatic cholestasis (AIC) is characterized by the sudden onset of right upper quadrant pain, increasing hepatomegaly, light-colored stools, and jaundice due to total serum bilirubin greater than 50 mg/dL. Thrombocytopenia, hypoalbuminemia, elevated alkaline phosphatase, increased prothrombin time, and partial thromboplastin time are also present.

This presentation is suggestive of cholestatic jaundice or choledocholithiasis but without evidence of common duct obstruction or cholangitis. AIC may prove fatal if not recognized and treated promptly.²

Aplastic crisis presents as a gradual onset of fatigue, shortness of breath, and sometimes syncope or fever. Physical examination may reveal tachycardia and occasionally frank heart failure. The hemoglobin is usually far below the patient's baseline level with an inappropriate, severely low reticulocyte count. Aplastic crisis should be transfused immediately because of the markedly short life expectancy of hemoglobin S RBCs, but does not need to be transfused to baseline.²

Acute splenic sequestration presents as a decrease in hemoglobin by greater than 2 g/dL, elevated reticulocyte count and circulating nucleated red blood cells, thrombocytopenia, and sudden splenomegaly.² The goal of transfusion is for partial correction because of the risk of hyperviscosity when the spleen releases the sequestered RBCs.

Acute chest syndrome (ACS) presents as a pneumonia radiographically consistent with a respiratory tract infection caused by cough, shortness of breath, retractions, and/or rales. ACS is the most common cause of death in SCA. ACS is usually from infection but may be because of fat embolism,

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intrapulmonary aggregates of sickled cells, atelectasis, or pulmonary edema.² If ACS has a hemoglobin decrease of greater than 1g/dL, consider transfusion.^{1,2}

Severe acute chest syndrome is distinguished by radiographic evidence of multilobe pneumonia, increased work of breathing, pleural effusions, and oxygen saturation below 95% with supplemental oxygen. Severe ACS may have a decrease in hemoglobin despite receiving transfusion. Exchange transfusion is recommended because of the high mortality in severe ACS.²

Preoperative transfusion is used to decrease the incidence of postoperative vaso-occlusive crisis, acute stroke, or ACS for patients receiving general anesthesia.

The goal for transfusion hemoglobin is 10 g/dL. In SCA patients with a hemoglobin greater than 9 g/dL, exchange transfusion may be considered to avoid hyperviscosity.^{1,2}

Multisystem organ failure (MSOF) is severe and life-threatening lung, liver, and/or kidney failure. MSOF may occur after several days of hospitalization. It is often unanticipated and swift, frequently presenting with fever, a rapid increase in anemia, thrombocytopenia, and altered mental status. Lung failure often presents as ACS. Liver failure is marked by hyperbilirubinemia, elevated transaminases, and coagulopathy. Kidney failure is marked by elevated creatinine, with or without change in urine output and hyperkalemia. Rapid treatment

with transfusion or exchange transfusion reduces mortality.

The incidence of acute ischemic stroke in SCA decreases with prophylactic transfusion of patients with elevated transcranial Dopplers. Acute stroke is usually secondary to stenosis or an occlusion of the internal carotid or middle cerebral artery. Acute hemorrhagic stroke may present as severe headache and loss of consciousness. Acute stroke should be confirmed radiographically, then exchange transfusion instituted rapidly.²

When not to transfuse

- Do not transfuse for simple vaso-occlusive crisis in the absence of symptoms attributable to acute anemia.¹⁻³
- Do not transfuse for priapism.²
- Do not transfuse for acute renal failure unless there is MSOF.²

Back to the case

The patient was admitted for vaso-occlusive crisis and was started on patient-controlled analgesia with hydromorphone and IV fluids. Azithromycin and ceftriaxone were initiated empirically for community-acquired pneumonia. She was given one unit of phenotypically matched, leukoreduced RBCs for acute chest syndrome. Her hemoglobin increased to 6.1 g/dL. Her fever resolved on day 2, and her dyspnea improved on day 3 of hospitalization. She

was weaned off of her patient-controlled analgesia on day 4 and discharged home on day 5 with moxifloxacin to complete 7 days of antibiotics.

Bottom line

Acute simple transfusions and exchange transfusions are indicated for multiple serious and life-threatening complications in SCA. However, transfusion has many serious and life-threatening potential adverse effects. It is essential to conduct a thorough risk-benefit analysis for each individual SCA patient. Whenever possible, intensive phenotypically matched and leukoreduced RBCs should be used. **TH**

Dr. Holmes-Maybank, Dr. Martin, and Dr. Duckett are hospitalists in the division of hospital medicine at Medical University of South Carolina, Charleston. They also work in a sickle cell patient-centered medical home in Charleston.

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Set a goal, or two, or three



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their career growth,” says Amir K. Jaffer, MD, MBA, SFHM, chief medical officer at New York Presbyterian Queens Hospital in New York City.

For employed hospitalists, goal setting – and achievement – can counter career stagnation, says Sanjay Bhatia, MD, FHM, CDIP.

“They show up, do a job, and go home. Many are not encouraged to develop their careers,” says Dr. Bhatia, chief medical officer, Prime Healthcare–Lower Bucks Hospital, Bristol, Pa.; founding partner, First Docs/Mercer Bucks Medical, Levittown, Pa.; and CEO/president, Prime Clinical Solutions, Freehold, N.J.

Setting goals will help hospitalists establish skill sets and achieve accomplishments that will keep their career growth on track, adds Surinder Yadav, MD, vice president of hospital medicine at Emeryville, Calif.–based CEP America, a national organization specializing in acute-care staffing, including hospitalist, intensivist, and emergency medicine programs.

When someone consistently reaches their goals (that is, improving outcomes) and feels accomplished, it enhances engagement of their work, says Ms. Treharne, who advises hospitalist groups.

Determine, pursue goals

There are many reasons why goal setting is important. So what guidelines can a hospitalist use to set goals? In order to establish goals for your current role, Ms. Treharne advises reviewing your job description – which should be updated as your role evolves.

“Determine what you need to do in order to progress toward meeting these requirements,” she says. “Find out what resources are available to support your efforts.”

Regarding setting career goals, Dr. Jaffer says hospitalists should consider things that really move them.

“For hospitalists in the early stages of their careers, it may take some time to determine them,” he says. “But when a passion develops, hospitalists can identify opportunities which will allow them to create a niche for themselves or an area of expertise.”

Then, hospitalists can work with individuals within their organization and beyond to increase their expertise.

“Find one or more mentors, take educational courses or even pursue an advanced degree, and write about your area of expertise either by publishing articles or abstracts, giving poster presentations, or lecturing,” Dr. Jaffer advises. “That will establish you as an expert and lead to promotions.”

Dr. Bhatia believes it’s natural and important for hospitalists to pursue administrative roles and become experts on how hospitals and post-acute care facilities work, because they transition patients to these institutions and they employ hospitalists. He has also seen hospitalists pursue entrepreneurial goals, such as becoming involved in information technology by developing apps or becoming C-suite executives, and starting other medical-based businesses such as home-based physician visits and telemedicine ventures and even nonmedical-based businesses such as real estate investing. Another avenue is teaching residency programs and developing an academic career.

“The key is to have good teammates, partners, and ancillary staff in each endeavor,” Dr. Bhatia says. “You can learn a lot from them as well. My experiences beyond being a hospitalist make me very valuable as a hospitalist. I’ve found that varied experiences create a synergistic and value-added service to a hospital.”

Stay on target

In order to reach your goals, Dr. Bhatia recommends creating daily task lists as well as setting goals quarterly and annually and evaluating them at those intervals. Determine action steps to reach long-term goals. “I keep these lists on my smartphone, so they’re always in my mind’s eye,” he says. “I look at the big picture on a daily basis and work toward my goals.”

In an effort to help faculty members reach their goals, Dr. Jaffer, when he was a division director at Rush University Medical Center in Chicago, scheduled biannual professional reviews with each team

member. It was a formal process adapted from the annual professional review that he learned while at the Cleveland Clinic. Members were asked to complete a faculty self-reflection assessment and answer questions such as:

- Since our last meeting, what committees and educational opportunities have you participated in?
- What types of quality improvement projects and presentations have you done?
- What achievements are you most proud of?
- Regarding the goals you listed at your last review, where have you had the most growth? What would you define as opportunities for growth?

At Rush, Dr. Jaffer asked members of his division to set one or two professional goals each year. “I suggested they set goals that will make them feel fulfilled professionally, so their careers remain gratifying,” he says.

Group goals

Hospitalists should play an integral role in developing a hospital’s strategic and operational plan. “By having hospitalists provide feedback in the planning process, prior to annual finalization of the plan, the hospital’s and hospitalist program’s objectives can be aligned,” Ms. Treharne says. “It’s important that their goals align, in order for both to be successful.”

Dr. Jaffer suggests starting at the beginning of each fiscal year. HM groups should, as a team, create quality, operational, and efficiency goals, which align closely with the hospital’s goals. Some examples: clinical productivity work relative value units (wRVUs), doctor-patient communication scores, observed-to-expected length of stay, readmission rates, and percentage of patients discharged by 1 p.m.

“We set goals both as individuals and as a group,” Dr. Jaffer says. “Then, we create a scorecard for each hospitalist on a quarterly basis and share each hospitalist’s data with them, as well as create a group dashboard. As a group, hospitalists can view both individual data and the group’s data. This feed-

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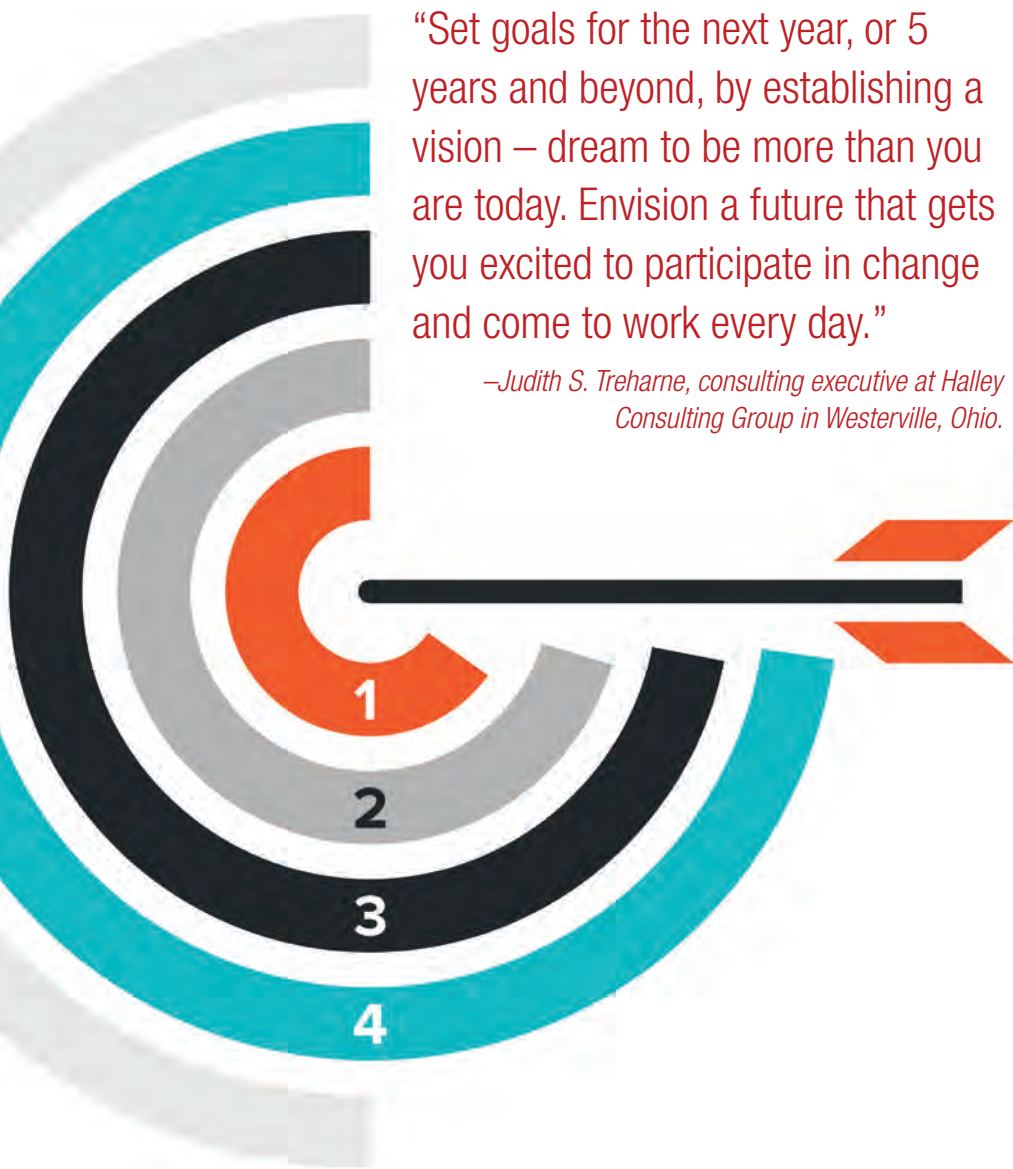
“For hospitalists in the early stages of their careers, it may take some time to determine [career goals]. But when a passion develops, hospitalists can identify opportunities which will allow them to create a niche for themselves or an area of expertise.”

–Amir K. Jaffer, MD, MBA, SFHM



“They show up, do a job, and go home. Many are not encouraged to develop their careers.”

–Sanjay Bhatia, MD, FHM, CDIP



“Set goals for the next year, or 5 years and beyond, by establishing a vision – dream to be more than you are today. Envision a future that gets you excited to participate in change and come to work every day.”

—Judith S. Treharne, consulting executive at Halley Consulting Group in Westerville, Ohio.



Check in and articulate your goals with those in your inner circle – seek their advice on a regular basis. Measure results and be willing to adapt if you’re not progressing as you’ve envisioned.

—Maureen E. Uy

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back helps them identify where they need to improve their performance.”

Dr. Bhatia has found that setting group goals on a quarterly basis works well. Goals involve recruitment needs, patient satisfaction, case mix index, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), utilization, and length of stay.

“Metrics should be recorded and shared monthly by either the hospital’s information technology department or the hospitalist group’s software,” he says.

Data: top of mind

Each provider needs to understand that success for the team also means individual success.

“Focus on helping each other to achieve high performance and high-quality care,” Dr. Yadav says. “Engage with each other and with the hospital at large. Aim to be involved in projects and to help find solutions to problems or barriers within the system.”

When you implement a change in a process and expect to see improvement regarding a particular measure, be sure to give the new process adequate time to shift the outcome.

“Many good ideas have been cast aside because they were deemed unsuccessful before there was sufficient time for the process to stabilize and the improvement to be seen,” Ms. Treharne says.

When setting targets and measures, set expectations regarding how long the new process will need to be in place prior to evaluating the change.

“Pilot programs are often a good way to try something out before completely changing a process with potential unwanted outcomes,” she says.

If a clinical operational or efficiency goal that involves the whole group and performance is below target, look to best practices to help you achieve success, Dr. Jaffer says. Create a work group and appoint a champion.

Hopefully, reaching your goals will translate into success.

“Success for me is about having a positive impact on people and processes, and being content with my personal life and having time and resources to pursue my passions,” Dr. Jaffer concludes.

Setting goals for now and then

When looking to set goals, Ms. Treharne recommends starting with long-term goal setting.

“Set goals for the next year, or 5 years and beyond, by establishing a vision – dream to be more than you are today,” she says. “Envision a future that gets you excited to participate in change and come to work every day.”

When looking to create long-term goals, Maureen E. Uy, managing partner, Uy Creative Communications, Milwaukee, and member of the National Society of Healthcare Business Consultants, advises thinking about how you would complete the following statements:

- I could become more valued in my job by doing _____.
- I could make more income by _____.
- I’d like to increase my knowledge of _____.

Then, develop short-term goals that will help you work toward achieving your long-term goals.

“Map out a path from today using the metrics available and applicable to the future state,” Ms. Treharne says. “Creating that path allows you to determine the short-term goals. How far can you get in what period of time? Be realistic, but stretch yourself so you’re not complacent.”

Document this path in a quarterly action plan with a complementary monthly tactical plan. Plans should identify accountable parties, resources needed, data requirements, and timelines, Ms. Treharne says. Review your progress monthly.

Check in and articulate your goals with those in your inner circle – seek their advice on a regular basis, Uy says. Measure results and be willing to adapt if you’re not progressing as you’ve envisioned. **TH**

Ms. Appold is a freelance writer in Pennsylvania.



“Focus on helping each other to achieve high performance and high-quality care. Engage with each other and with the hospital at large. Aim to be involved in projects and to help find solutions to problems or barriers within the system.”

—Surinder Yadav, MD

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Are you getting the most out of your EHR?

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“It took a good 6 months, probably longer for some, for people to feel comfortable, to start smiling again and really feel like, ‘This isn’t so bad and actually might be working for us,’” said Carol Nwelue, MD, medical director of Sparrow’s adult hospitalist service.

Then, the gears started moving. Gradually, Dr. Nwelue and Chris Nemets, Sparrow’s chief nursing informatics officer, began to field questions like, “I want to do this with the EHR; why can’t I do that?” The staff wanted more out of the new system, and Sparrow’s use of its EHR, Epic, began to evolve.

Although Sparrow is now probably ahead of the curve when it comes to maximizing its EHR use, its story carries themes that are familiar to hospitalists and to the medical field: The beginning is scary and bumpy; there typically is a long getting-used-to period; and then some hospitalists get anxy and try to get more out of the system, but only gradually – and not without pain.

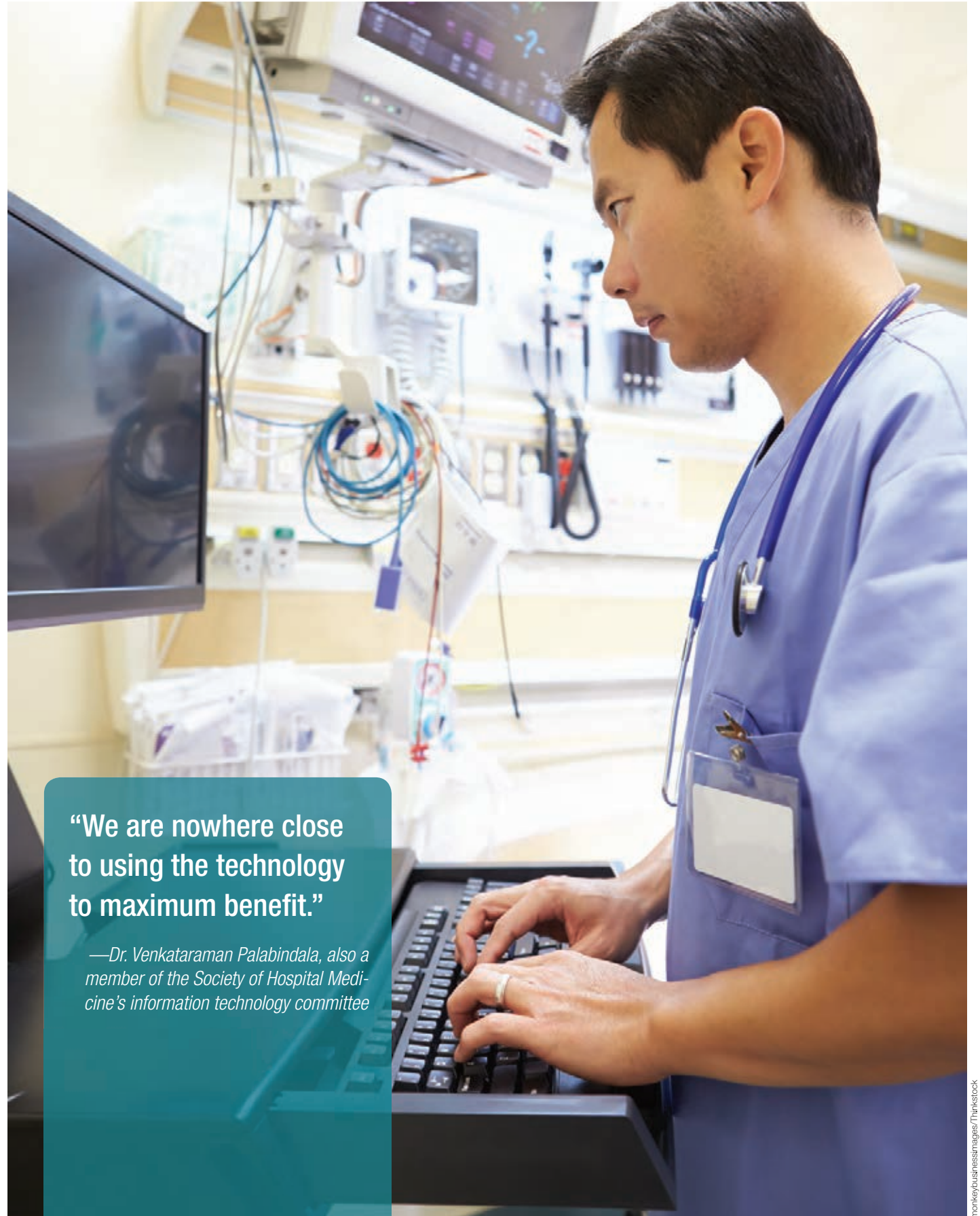
The bottom line is that most hospitals have a long way to go, said Venkataraman Palabindala, MD, a hospitalist and assistant professor of medicine at the University of Mississippi Medical Center in Jackson.

“We are nowhere close to using the technology to maximum benefit,” said Dr. Palabindala, also a member of the Society of Hospital Medicine’s information technology committee.

How well hospitalists are maximizing their use of EHRs varies from center to center and doctor to doctor. But, for those that are more advanced, Dr. Palabindala and other advocates of better EHR use mention these characteristics that drive the change:

- They have hospitalist leaders with a strong interest in IT who like to tinker and refine – and then share the tricks that work with others at their center.
- They belong to EHR-related committees or work at centers with hospitalists with a big presence in those committees.
- They keep their eyes on what other centers are doing with EHRs and use those projects as models for projects at their own centers.
- They are willing to make changes in their own processes, when feasible, so that they can better dovetail with the EHR.
- They keep their lines of communication open with their EHR vendors.
- They attend user meetings to get questions answered and share information and experiences.

At Sparrow, two committees – one nurse-led and one physician-led – guide EHR enhancement. The committees are a place where, yes, doctors can vent about the EHR (the phrase they use is “pain points”), but



“We are nowhere close to using the technology to maximum benefit.”

—Dr. Venkataraman Palabindala, also a member of the Society of Hospital Medicine’s information technology committee

also a place where they can get constructive feedback. The committees also keep an eye out for EHR projects elsewhere that they might be able to do themselves.

EHR: a CAUTI example

In 2014, Sparrow doctors and nurses

wanted to lower their number of catheter-associated urinary tract infections (CAUTI). With the EHR that had gone live 2 years before, they had the data that they needed. They just had to figure out how to turn the data into a workable plan. Ah, if only things were so simple with

EHRs. As any health center that has gone through the great transition from paper to digital can attest, having the data puts you only at the foot of the mountain.

But using a program that Texas Health System had developed as a model, Sparrow

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“It took a good 6 months, probably longer for some, for people to feel comfortable, to start smiling again and really feel like, ‘This isn’t so bad and actually might be working for us.’”

—Carol Nwelu, MD, medical director of Sparrow’s adult hospitalist service

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got its CAUTI program up and running. The new system included not just a placement order, but the discontinuation order, too. Advisories on best practice were built into the work flow, including alerts on when catheters had been in for 48 hours, and metrics were created to track how well the whole thing worked.

Implementation was simple, but the refinement took some time, said Ms. Nemets, the chief nursing informatics supervisor, who helped oversee the project.

“Once the data [were] obtained and validated, it was quickly shown that more needed to be done within this clinical program to impact our CAUTI numbers,” she said. “With collaboration from end users, the system was tweaked more and BPAs [best practice advisories] were added and removed in certain areas and shifted the focus from physician-facing to nursing-facing in most areas.”

It appears to be working: CAUTI incidence at 836-bed Sparrow Hospital has dropped from a total of 52 in 2014 to 11 over the first 3 quarters of 2016.

Sparrow has also built programs to better use its EHR for sepsis, medical reconciliation, and methicillin-resistant *Staphylococcus aureus* screening, and one is being developed for heart failure.

Vendor engagement = QI opportunity

Sparrow and many other health systems are motivated to use more of Epic’s features and to innovate through an Epic rewards program that gives rebates for advanced use that can total hundreds of thousands of dollars. That innovation helps Epic problem solve and it can then point to that innovation in its marketing.

Almost all hospitals, and their hospitalists, are using the EHR for such basics as reducing unnecessary testing, medical reconciliation, and documenting more accurately, said Eric Helsher, vice president of client success at Epic, whose job is to foster the spread of new and better ways to use the EHR. Most hospitals use the EHR, to at least some degree, for targeted quality improvement (QI) and patient safety programs, he said.

Dr. Palabindala pointed to record-sharing features as a way clinicians can share records within minutes without having to bother with faxing or emailing. Integrating smart-paging into the EHR is another way for doctors to communicate – it may not be as good as a phone call, but it’s less disruptive during a workday, he notes.

Epic is just now rolling out a secure text-messaging system hospitalists and others can use to communicate with one another – the header of the text thread clearly shows the patient it is referencing, Mr. Helsher said. Other EHR uses, such as telemedicine, are being used around the country but are far less widespread. But users are generally becoming more ambitious, he said.

“For the last 5-10 years, we’ve been in such an implementation rush,” Mr. Helsher explained. “Now, at much more of a macro scale, the mentality has changed to ‘OK, we have these systems, let’s go from the implementation era to the value era.’”

Corinne Boudreau, senior marketing manager of physician experience at Meditech, said their sepsis tool has been very popular, while messaging features and shortcut commands for simpler charting are gradually coming into wider use. Meditech also expects their Web-based EHR – designed to give patients access on their mobile devices – will give doctors the mobility they want.

Still, there’s a wide range in how much hospitalists and other doctors are using even the fundamental tools that are available to them.

“I think that between implementation and maximization there is a period of adoption, and I think that that’s where a lot of folks are these days,” she said.

As “physician engagement” has become a buzzword in the industry, Meditech has worked with physician leaders on how to get doctors to absorb the message that the EHR really can help them do their jobs better.

“If you get [doctors] at the right time, you show them how it can make things easier or take time off their workload,” Ms. Boudreau said. “For some physicians that time to get them might be first thing in the morning before they see patients. Another physician might want to do it in the evening. If you hit that evening physician in the morning, you’ve missed that window of opportunity.”

Given the demands on doctors’ time and either an inability or unwillingness to put the time in that’s needed to learn about all functions the EHR can offer, there’s a growing acknowledgment that doctors often can’t simply do this on their own.

“There’s more recognition that this is a project that needs to be resourced,” Ms. Boudreau said. “They’re already strapped for time; to put something additional on top of it needs to be accommodated for. It needs to be resourced in terms of time; it needs to be resourced in terms of compen-

Is hospitalists’ EHR efficiency taken advantage of?

By Thomas R. Collins

Even though their level of EHR use can be hit or miss, hospitalists tend to be ahead of the game, many agree. But that can come with some drawbacks. They’re often the go-to people everyone else in the hospital relies on to handle the system that some think is too unwieldy to bother with.

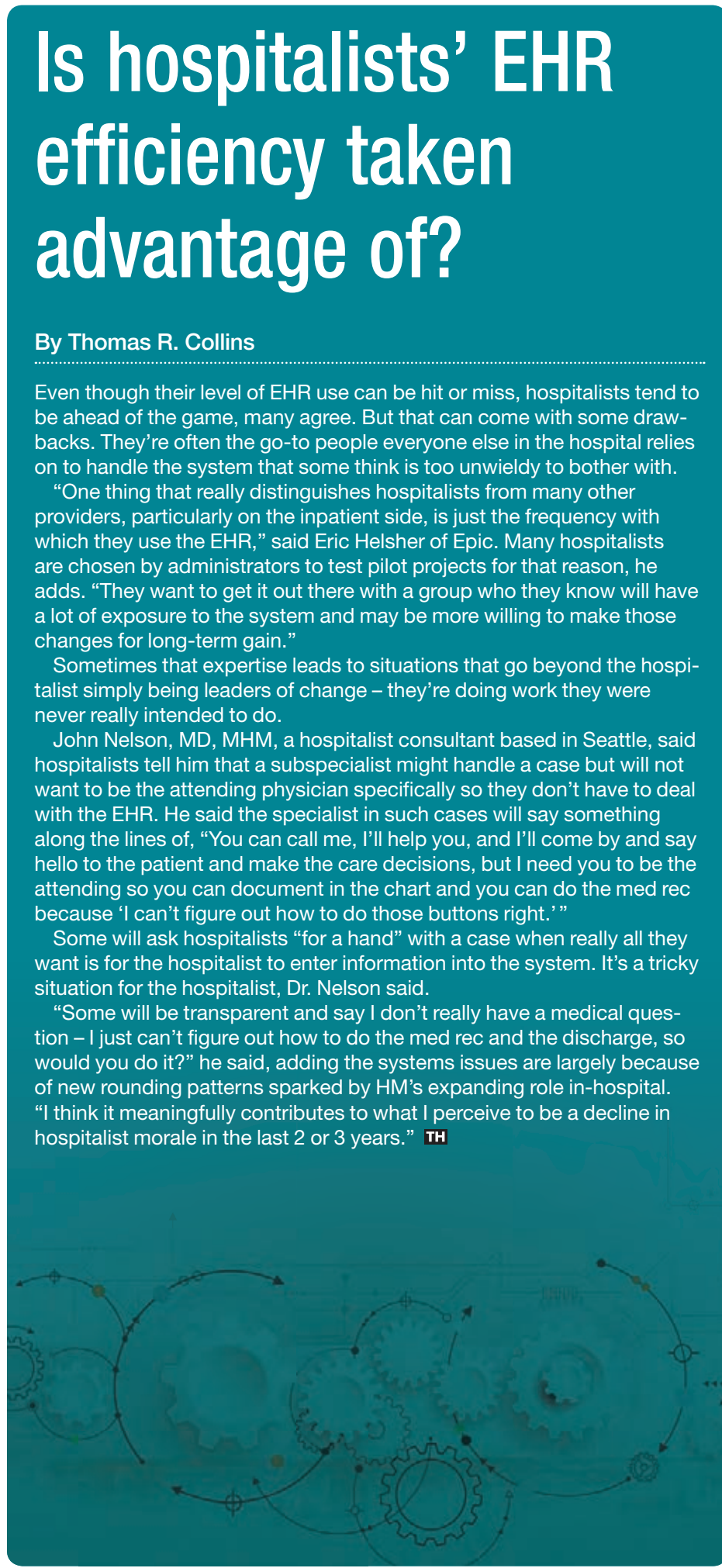
“One thing that really distinguishes hospitalists from many other providers, particularly on the inpatient side, is just the frequency with which they use the EHR,” said Eric Helsher of Epic. Many hospitalists are chosen by administrators to test pilot projects for that reason, he adds. “They want to get it out there with a group who they know will have a lot of exposure to the system and may be more willing to make those changes for long-term gain.”

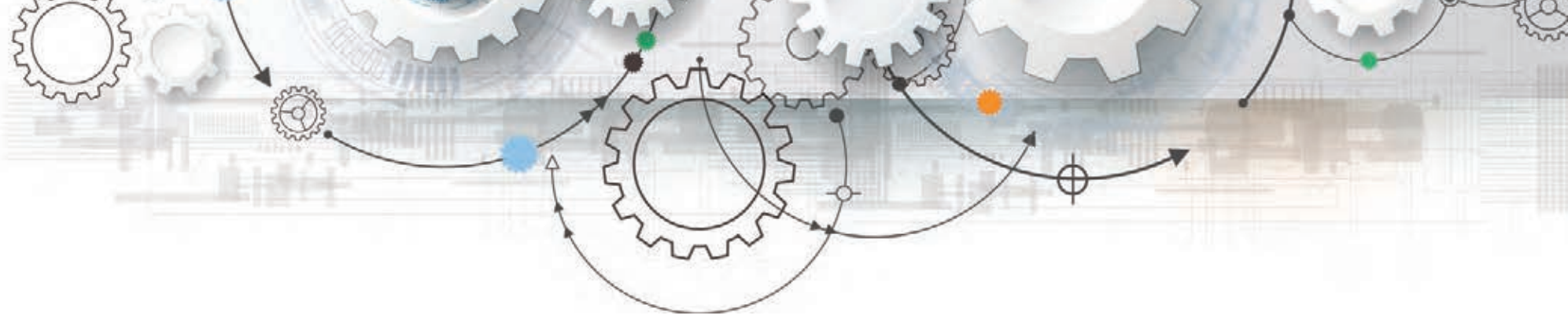
Sometimes that expertise leads to situations that go beyond the hospitalist simply being leaders of change – they’re doing work they were never really intended to do.

John Nelson, MD, MHM, a hospitalist consultant based in Seattle, said hospitalists tell him that a subspecialist might handle a case but will not want to be the attending physician specifically so they don’t have to deal with the EHR. He said the specialist in such cases will say something along the lines of, “You can call me, I’ll help you, and I’ll come by and say hello to the patient and make the care decisions, but I need you to be the attending so you can document in the chart and you can do the med rec because ‘I can’t figure out how to do those buttons right.’”

Some will ask hospitalists “for a hand” with a case when really all they want is for the hospitalist to enter information into the system. It’s a tricky situation for the hospitalist, Dr. Nelson said.

“Some will be transparent and say I don’t really have a medical question – I just can’t figure out how to do the med rec and the discharge, so would you do it?” he said, adding the systems issues are largely because of new rounding patterns sparked by HM’s expanding role in-hospital. “I think it meaningfully contributes to what I perceive to be a decline in hospitalist morale in the last 2 or 3 years.” **TH**





“Once the data [were] obtained and validated, it was quickly shown that more needed to be done within this clinical program to impact our CAUTI numbers. With collaboration from end users, the system was tweaked more and BPAs [best practice advisories] were added and removed in certain areas and shifted the focus from physician-facing to nursing-facing in most areas.”

—Chris Nemets, Sparrow's chief nursing informatics officer

sation. There need to be governance and support of that.”

Early adopters vs. late bloomers

Many hospitalists and HM groups have advanced, but some places have lagged behind, said John Nelson, MD, MHM, a veteran hospitalist, practice management consultant, and longtime columnist with *The Hospitalist*.

“We find it's reasonably common to go to a place where they're still keeping their census in an Excel spreadsheet,” he said. “Last year, we found people who do billing on paper and index cards.”

He said that often, a failure to adopt new EHR functionality isn't because hospitals and HM groups are avoiding it. He said he sees IT shortcomings as a major blocker.

“They want to use it,” he said. “Inertia might be part of the reason people are failing to fully capture the benefit the EHR could offer, [but] the bigger reason is local IT configurations and support.”

As an example, Dr. Nelson explained that at some of the centers he has worked with the name of the attending physician is not always reflected in the EHR. That's a big no-no, he said. The problem, he's sometimes found, isn't really the EHR, but quirks in the hospital system: The EHR is locked down for that information and can be changed only by a person in the admitting department.

“It would require the hospitalist to call

down [to admissions] and get someone else to make that change – and that's tedious a big headache. They give up and don't do it anymore,” he said. “Ideally, you'd want to make it so the hospitalists can make the change themselves.”

At his center, Overlake Hospital Medical Center in Bellevue, Wash., a go-to hospitalist is David Chu, MD, who has gone through Epic training and shares tips with colleagues. He is one of a relatively few physicians there who has taken the time to use the drop-down menu feature for putting information into a chart.

That might sound like a fairly basic use for a multimillion-dollar EHR system. But it still can take hours and hours to get it right.

“The way to do it is a little bit of a programmer's way of looking at things,” Dr. Chu said, noting it involves programming-style language with double colons, commas, and quotations marks.

“For me, I think it took a good 10, 12, 15 hours on my part to get things going,” he said. “It was a good time investment up front to help me on that end, but it's just hard getting people to want to commit that time, especially if they're not that savvy with computers.”

His hospitalist colleague, Ryan Chew, MD, is more advanced – he has a taxonomy-like shorthand he uses to give him the right set of basic fields for a given type of case. For someone admitted with pneumo-

nia, he'd want to know certain things all the time. Were they short of breath? Did they have chest pain? What were their vital signs? What about inflammatory markers?

Dr. Chew can get all of those fields to pop up by typing “.rchppneumonia.” The “.” means that a special code is to follow. The “rc” is for Ryan Chew, the “hp” is for history and physical, and “pneumonia,” is the type of case. For cases that require other information to be entered, he can add that as needed.

Hospitalists might try to write shortcut phrases, but unless they have a well-defined system, it won't be helpful over the long run, he said.

“If you don't have a good organization system ... you'll never remember it,” Dr. Chew said.

But even he hasn't created the drop-down menus. He said he just hasn't been willing to take the time, especially since he feels his own way of doing things seems to be working just fine.

Effort is essential

Expanding the functionalities of the EHR takes effort, no doubt. As a result, some physicians and hospitalist groups have not been open-minded to the idea – and opportunities – of the EHR as a database.

“I think for some people, even still, working with the EHR, it's become more something they've learned to get used to rather

than something that they sought to take advantage of, in terms of helping things,” Dr. Chew said. “They're still working against the EHR a little bit.”

Dr. Palabindala agreed, and said that regardless of resistance or complaint, EHRs work.

“No matter how much we argue, it is proven in multiple studies that EHRs showed increased patient safety and better documentation and better transfer of the data,” he said.

He suggests hospitalists make more of an effort.

“I strongly encourage hospitalists to be part of the every EHR-related committee, including CPOE [computerized physician order entry], analytics, and utilization-review committees,” he said. “Learning about the upgrades and learning about all the possible options, exploring clinical informatics on a regular basis is important. I also encourage [hospitalists] to participate in online, EHR-related surveys to learn more about the EHR utility and what is missing in their home institution.”

He acknowledges that it's “hard to develop a passion.” Then he put it in terms he thought might resonate: “Think of it like a new version of smart phone. Show the enthusiasm as if you are ready for next version of iPhone or Pixel.” **TH**

Mr. Collins is a freelance writer in South Florida.

How hospitalists used EHR to help solve medication reconciliation

By Thomas R. Collins

Medication reconciliation might be one of the most important factors involved in keeping patients safe when they're in the hospital. But it has proven to be one of the most challenging tools to use within EHR systems.

“When you ask other organizations about that, it's the same across the board,” said Carol Nemets, nursing informatics supervisor with Sparrow Health in Lansing, Mich. “Everybody seems to be struggling with med-

rec; the whole process.”

The med-rec system in the EHR is fine, if it used as designed, she says. When it's not used appropriately, “It's just a mess.”

“It's kind of an intertwined ball of yarn,” Ms. Nemets explained. “If you don't have good information in [the EHR] at the beginning, it's very difficult to get it all straightened out through the process.”

Sparrow knew during on-boarding of its new EHR system that it didn't mesh with their existing work flow. For example, Sparrow nurses had

always been involved with medication reconciliation, but were not involved with the new EHR, Ms. Nemets said. Also, the timing of when various med-rec steps were completed did not mesh.

In another quirk, Ms. Nemets said medications marked as “Reviewed” in the system had not, in fact, been reviewed. So the “Reviewed” function was essentially meaningless.

“Those meds had not actually been reviewed,” hospitalist Chris Nwelue confirms.

So they had to iron all of those

things out before the system could be truly useful, Dr. Nwelue says. They had to decide what would be helpful in holding people accountable for getting the right information into the chart in a timely way, so that physicians could order the right medications for patients.

“We had to use our innovation, and our end-users' input, to get to that point,” Ms. Nemets said. “We do that a lot here.”

Mr. Collins is a freelance writer in South Florida.

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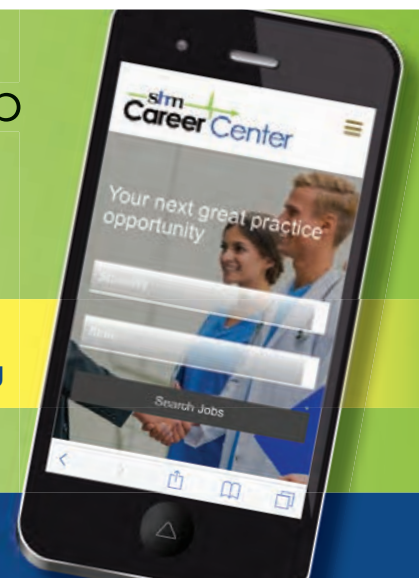
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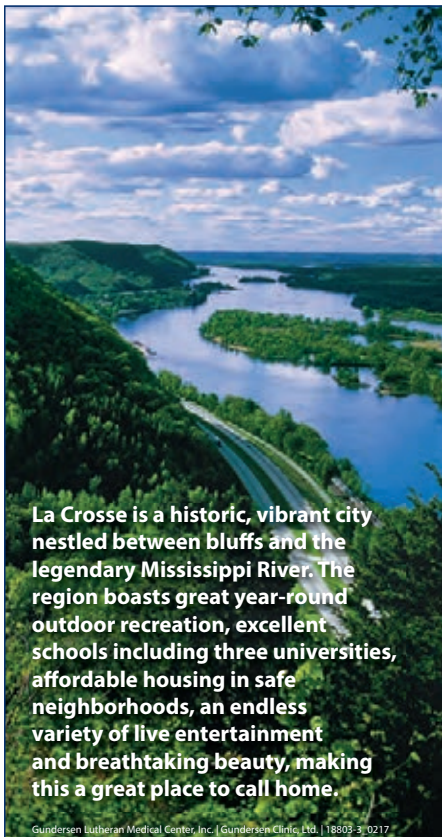
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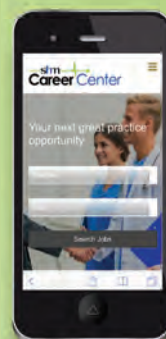
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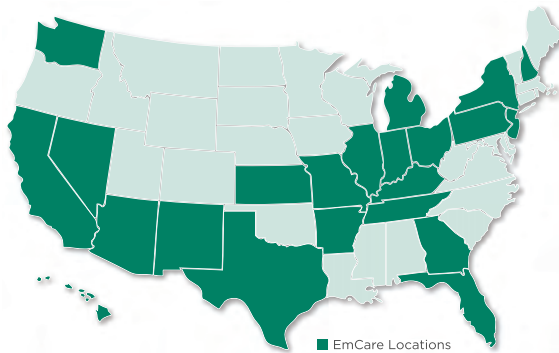


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A.O. Fox Memorial Hospital, an acute care community hospital and affiliate of the Bassett Healthcare Network, is seeking a BC/BE Hospitalist to provide quality patient care.

This Hospitalist position is located in Oneonta, NY. It will consist of a 7 on 7 off schedule with the option for other flexible scheduling. The unit consists of 53 bed med/surg beds. Subspecialty Services are available in Cardiology, Cancer Care and Orthopedics. A fully integrated EMR system is in place.

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For confidential consideration, please contact:

Debra Ferrari, Medical Staff Recruitment
Bassett Healthcare Network
One Atwell Road
Cooperstown, NY, 13326
phone: 607-547-6982; fax: 607-547-3651 or email:
debra.ferrari@bassett.org
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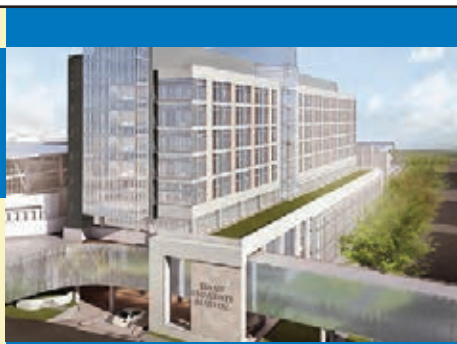
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 Penn State Milton S. Hershey Medical Center
 c/o Heather Peffley, PHR FASPR – Physician Recruiter
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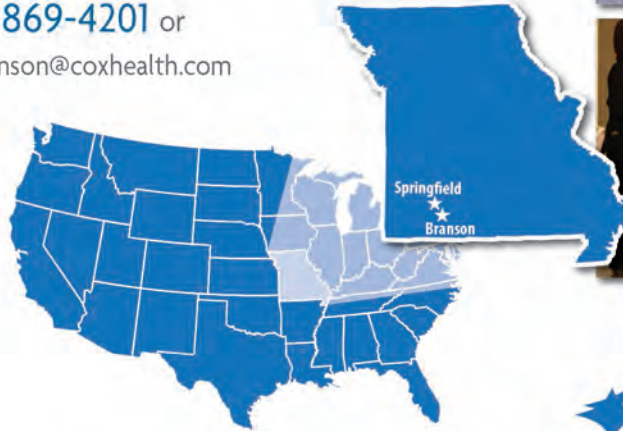
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The beginning of the end

Will President Trump's efforts to repeal the Affordable Care Act mean the end of efforts to lower costs, improve quality?



Dr. Chang is pediatric editor of *The Hospitalist*. He is associate clinical professor of pediatrics at the University of Massachusetts, Worcester, and chief of pediatric hospital medicine at Baystate Children's Hospital, Springfield, Mass. Send comments and questions to Weijen.ChangMD@bhs.org.

No matter on which side of the aisle you sit, and even if you'd prefer to just sit in your car and check Instagram, the results of the November election were likely a surprise. Speculation abounds by pundits and so-called experts as to what a Trump presidency means for health care in this country. The shape and scope of health care initiatives that a Trump administration will attempt to advance in place of the Affordable Care Act (ACA), which has likely met its demise, is unknown at the time of this writing. How Trump's new initiatives fare in Congress and then get translated into practical changes in health care delivery and financing is even more muddled.

The U.S. medical community has remained largely silent, which is wise given the lack of evidence that would support any rational prediction, but perhaps it's easier to pronounce judgment from across the pond. *The Lancet* recently reported the comment of Sophie Harman, PhD, a political scientist at Queen Mary University in London, who told an audience at the London School of Hygiene & Tropical Medicine to "ignore the dead cat in the room."¹ I spent 6 months of my residency in the United Kingdom, and this

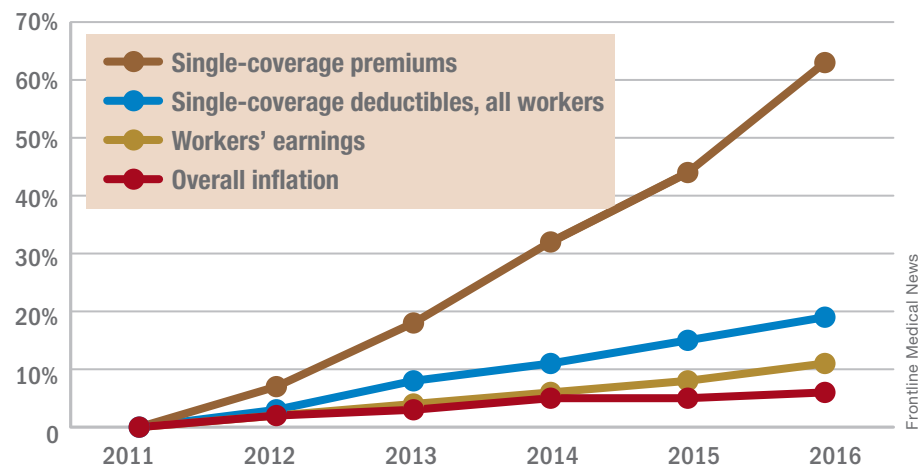
Whatever @realDonaldTrump has in mind, the truth not publicized by either party is that the drift of health care costs to patients and families, even amongst the insured, has already been killing household budgets.

phrase never came up in my travels across the wards, streets, and pubs of the mother country. Apparently, the "dead cat strategy" is a legislative maneuver to distract attention from a party's political shortcomings by raising a ruckus about a salacious or social hot-button topic. In this case, the dead cat may just be the carcass of Obamacare, exuding the fetor of millions of people losing their health insurance.

The BMJ, another respected U.K. journal, offered the pronouncement by Don Berwick, MD, former administrator of the Centers for Medicare & Medicaid Services, that Trump's election would be "disastrous" for U.S. health care, but not much else.²

Whatever @realDonaldTrump has in mind, the truth not publicized by either party is that the drift of health care costs to patients and families, even amongst the insured, has already been killing house-

Figure 1. Cumulative increases in expenses, earnings



Note: Based on data from the Kaiser/HRET 2016 Employer Health Benefits Survey and from the Bureau of Labor Statistics.

Source: Kaiser Family Foundation, Health Research and Education Trust

hold budgets. It has happened via a thousand cuts, in the form of increasing copays and deductibles, and is likely to get worse. Twenty million Americans gained insurance through either Medicaid expansion or subsidized health insurance as a result of ACA, which led to an overall reduction in out-of-pocket costs for Americans on

protections to limit out-of-pocket expenses, into doubt.

Before the ACA expanded Medicaid coverage, patients faced significant wait times and travel costs associated with the low numbers of providers accepting Medicaid's low reimbursement rate.⁸ These numbers had begun to improve after the ACA increased primary care physicians' Medicaid reimbursements to Medicare rates in 2013 and 2014, but only a limited number of states will continue the increases after the end of federal subsidies.

For people who purchased plans on the ACA's marketplace, out-of-pocket exposure is capped in 2017 at no more than \$7,150 for an individual plan and \$14,300 for a family plan before marketplace subsidies. Even those who qualified for cost-sharing deductions, with incomes between 100% and 250% of the federal poverty level, had out-of-pocket caps that varied widely depending on plan and state. For example, in 2016 at the \$17,000 annual income level, out-of-pocket caps could range from \$500 to \$2,250.⁹

Clinician concern

On a provider level, incentives to reduce readmissions and limit health care-associated harm events mandated by the ACA may soon evaporate, throwing into question many quality metrics pursued by health systems. In response, will health system administrators abandon efforts to reduce readmissions and hospital-acquired conditions (HACs)? Or will health systems, despite the lack of a Medicare penalty "stick," move forward with efforts to reduce readmissions and HACs? There's no question of what would benefit the pocketbooks of our patients the most – every hospital-

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zation results in significant direct out-of-pocket costs, not to mention lost productivity and income.¹⁰

It seems unlikely that a Republican-led government will pursue efforts to decrease out-of-pocket expenses. More likely, new proposals will aim to provide tax benefits to encourage use of health savings accounts (HSAs), continuing the shift of health care to employees.¹¹ HSAs benefit employers, who pay less for the health care costs of employees, but are associated with worsened adherence to recommended treatments for patients.^{8,12}

A 2016 study analyzed health care policies considered by Trump, including the following:

- Full repeal of the ACA.
- Repeal of the ACA plus tax deductions of health insurance premiums.
- Repeal of the ACA plus block grants to

states for Medicaid and Children's Health Insurance Program (CHIP).

- Repeal plus promotion of selling health insurance across state lines.

Not surprisingly, all four scenarios resulted in significant increases in out-of-pocket expenses for those in individual insurance plans.¹³

Although at the time of writing, the "replace" segment of "repeal-and-replace" is not known, Mr. Trump's nominee for Secretary of Health & Human Services (HHS), Rep. Tom Price (R-Ga.), has given a hint of what he would champion based on his prior legislative proposals. Along with his support of increasing accessibility of armor-piercing bullets, reduced regulations on cigars, and opposition to expanding the State Children's Health Insurance Program, he proposed H.R. 2300, "Empower Patients First Act." This would eliminate the ACA's Medicaid expansion and replace it with flat tax credits based on age, not income, which turns out

to offer greater subsidies relative to income for those with higher incomes. A 30-year-old would, on average, face a premium bill of \$2,532, along with a potential out-of-pocket liability of \$7,000, with only a \$1,200 credit to cover this from Mr. Price's plan.¹⁴

In sum

So what's a conscientious advocate for the physical and financial health of patients to do? Beyond political action, hospitalists need to keep abreast of the effect of changes in health care policy on their patients, as unpleasant as it may be. Do you know what the copays and out-of-pocket costs are for your patient's (or your own) health care? Knowing how your recommendations for treatment and follow-up affect your patient's pocketbook will not only help protect their finances, but will also protect their health, as people are less likely to be compliant with treatment if it involves out-of-pocket costs.

And easy as it would be to simply tune out the partisan rancor, stay engaged as a citizen, if for nothing else, the benefit of your patients. **TH**

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Revisiting citizenship bonus and surge capacity



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I devoted an entire column to the idea of a citizenship bonus in November 2011. At that time I expressed some ambivalence about its effectiveness. Since then I've become disenchanted and think it may do more harm than good.

SHM's 2016 State of Hospital Medicine (SOHM) Report, based on 2015 data, shows that 46% of Hospital Medicine Groups (HMGs) connect some portion of bonus dollars to a provider's citizenship.¹ This is a relatively new phenomenon in the last 5 years or so. My anecdotal experience is that it isn't limited to hospitalists; it is pretty common for doctors in any specialty who are employed by a hospital or other large organization.

The intent is good. It is a financial incentive for the doctor to redirect some time and

Motivates Us. It's a short and very thought-provoking book summarizing research that suggests the effect of providing external rewards like compensation is to "...extinguish intrinsic motivation, diminish performance, crush creativity, and crowd out good behavior."

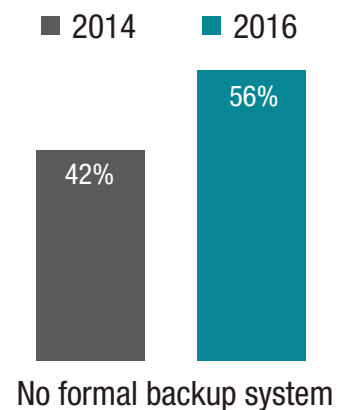
The second reason for my ambivalence is my experience working with a lot of HMGs around the country. Those that have a citizenship bonus don't seem to realize improved operations, more engaged doctors, or lower turnover, and so on. In fact, my experience is that the bonus tends to do exactly what Pink says – steer individuals and the group as a whole away from what is desired.

I'm not ready to say a citizenship bonus is always a bad idea. But it sure seems like it

both practical and affordable are hard to come up with. Like then, I still think the most important thing to keep in mind is that the fewer shifts a provider works annually (the more time off), the busier the average working day to achieve typical annual productivity. This in turn means the regularly scheduled staffing will have less "headroom" to handle busy days.

But if every hospitalist in the group went from, say, 156 to 190 shifts annually, the practice might be able to staff every day with an additional provider without adding staff or spending more money. And a doc's average day would be less busy, which for some people (okay, not very many) would be a worthwhile trade-off. I realize this is a tough sell and to many people it sounds crazy.

The 2014 SOHM showed 42% of HMGs had "no formal backup system," and this had climbed to 58% in the 2016 Report. I don't know if jeopardy or surge backup systems are really becoming less common, but it seems pretty clear they aren't becoming more common. So it's worth thinking about whether there is a practical way to remove inhibitors of surge capacity.



attention away from direct patient care and toward organizational concerns like systems and processes. As the pace of change in healthcare reimbursement and clinical practice seems to accelerate every year, it makes sense to provide compensation for the increasing amount of work outside of direct patient care required of us all.

HMGs vary in their definitions of what constitutes citizenship, but usually include things like committee participation, lectures, grand rounds presentations, community talks, research publications.

Our hospitalist group at my hospital has well-defined criteria that require attendance at more than 75% of meetings as a "light switch" (pays nothing itself, but "turns on" availability to citizenship bonus). Bonus dollars are paid for success in any one of several activities, such as making an in-person visit to two PCP offices or completing a meaningful project related to practice operations or clinical care.

I've been a supporter of a citizenship bonus for a long time, but two things have made me ambivalent or even opposed to it. The first is a book by Daniel Pink titled *Drive: The Surprising Truth About What*

works out badly for many or most groups.

But if you do have a citizenship bonus, then don't make the mistake of tying it to very basic expectations of the job, like attending group meetings or completing chart documentation on time. Doing those things should never be seen as a reason for a bonus.

Jeopardy ('surge') staffing: Not catching on?

As I write, influenza has swept through our region, and my hospital – like most along the west coast – is experiencing incredibly high volumes. I enter the building through a patient care unit that has been mothballed for several years, but today people from building maintenance were busy getting it ready for patients. The hospital is offering various incentives for patient care staff to work extra shifts to manage this volume surge, and our hospitalists have days with encounters near or at our highest-ever level. So surge capacity is once again on my mind.

In September and October of 2010 I wrote about some ways to address hospitalist surge capacity (here and here). Unfortunately, all are imperfect; solutions that are

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Endnotes

1. Note that this is down from 2014, when 64% of groups reported having a citizenship element in their bonus. But I'm skeptical this is a real trend of decreasing popularity and suspect the drop is mostly explained by a much larger portion of respondents in this particular survey coming from hospitalist management companies which I think much less often have a citizenship bonus.



HOSPITALIST EMPLOYMENT MODELS: WHICH FITS YOU BEST?

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As a job seeker, you might be tempted to snag the best paying opportunity. But there's another factor you should consider: culture. Each employment model has cultural benefits and limitations that will significantly impact your day-to-day practice. Below are the four major types to consider.

HOSPITAL EMPLOYEE

Many hospitals directly employ hospitalists in hopes of fostering physician alignment with their administrative goals. For most of us, this is the most familiar model and the one we experienced during residency.

COMPANY EMPLOYEE

Several companies are in the business of managing physician practices for hospitals. Some specialize in hospital medicine. Others offer multiple service lines. When it comes to designing hospital medicine programs, management companies often have a greater depth and breadth of experience than hospital leaders.

INDEPENDENT CONTRACTOR

Self-employment is another option. Physicians following this model work as independent contractors for hospitals and practice management companies.

PHYSICIAN PARTNER

Another model to consider is a physician partnership or independent group. These can be local, regional, or national. CEP America is one example of a national physician partnership. Partnerships are practices in which all physicians have the opportunity to become owners. Finances are transparent, and physician owners share profits as well as responsibility for success.



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