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The Hospitalist

VOLUME 21 No. 2 | FEBRUARY 2017

AN OFFICIAL PUBLICATION OF THE SOCIETY OF HOSPITAL MEDICINE

# Hot-button issue: Physician burnout

## As research validates and offers solutions, hospitalist groups can work harder – and smarter – to prevent and treat this broad-scoped issue.

By Richard Quinn

Some 15 years ago, when Daniel Roberts, MD, FHM, decided at the end of his medical residency that his career path was going to be that of a hospitalist, he heard the same thing. A lot.

"Geesh, don't you think you're going to burn out?"

The reasons for such a response are well known in HM circles: the 7-on, 7-off shift structure; the constant rounding; the push-pull between clinical, administrative, and – what many would term – clerical work.

Now, the practicing hospitalist at Mayo Clinic in Phoenix sees trainees coming out of residency thinking that the shift work aspect of HM will protect them from burnout. Forget worrying about it, some of them say. As with most things related to the scourge of physician burnout, the reality is more nuanced. Burnout is not inevitable nor preventable nor untreatable.

"The truth is somewhere between," Dr. Roberts said.

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Darrin Klimek/Thinkstock

# Eight things hospitalists need to know about post-acute care

## Staffing, reimbursement, and patient populations vary widely. Experts suggest training, and opportunities for improvement.

By Karen Appold

Whether you're a hospitalist who works only in a hospital, a hospitalist who works only in a post-acute care (PAC) setting, or a hospitalist who works in both types of facilities, knowing about current trends at PAC facilities and what the future may hold can help you excel in your current capacity and, ultimately, improve patient care.

SECOND IN A TWO-PART SERIES EXAMINING POST-ACUTE CARE

*The Hospitalist* tapped experts in the post-acute space to tell us what they thought HM should know about working in PAC – which, in many ways, is quite different from the hospital setting. Here's a compilation of their top eight must-knows.

### 1 PAC settings rely more on midlevel medical staff than hospitals do.

PAC facilities employ more midlevel providers, such as nurse practitioners and physician assistants, because they can support the level of medical complexity and decision making 95% of the time, says James D. Tollman, MD, FHM, president of Essex Inpatient Physicians in Boxford, Mass. Further, they are more heavily staffed

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Q&A SHM MEMBER SPOTLIGHT

SHM resources help Alessandra G. Cornelio, MPH, develop her career. Now, she is paying it forward.

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2016 APEX AWARDS FOR PUBLICATION EXCELLENCE

A faculty development course in point-of-care ultrasound was held November 2016 in Tokyo, in preparation for the first ultrasound course at next month's annual meeting of the Japanese Society of Hospital General Medicine.

## Japan could benefit from hospital medicine expansion, leadership

The need for hospitalists continues to increase in Japan. There are approximately 9,000 hospitals in Japan, and approximately 80% of these hospitals are small- to medium-sized hospitals (<300 beds) where the need for hospital medicine is greatest. Historically, internal medicine subspecialists from nearly all subspecialties served as the primary attending physicians of hospitalized patients because inpatient internal medicine physicians, or hospitalists, did not exist.

Most subspecialists caring for hospitalized patients learned to practice internal medicine "on the fly" because they were not required to complete training in internal medicine before pursuing a subspecialty. After medical school, all graduates are required to complete a 2-year internship known as the National Obligatory Initial Postgraduate Clinical Training Program (NOIPCTP). The level of training during the NOIPCTP is similar to the third and fourth years of medical school in the United States.

After internship, medical school graduates can request a subspecialty training position in any hospital, as long as they have completed the NOIPCTP. There is no centralized application process or "match" for graduate medical education in Japan. Internal medicine, as a specialty with its own structured residency program, has not yet been formally established in Japan, and there has been no pathway to become an internal medicine–trained hospitalist.

The aging population and increasing complexity of hospitalized patients are the two main drivers of hospital medicine in Japan. Recently, the number of patients who have had adverse events because of inpatient medical errors has risen, and the transparency of these adverse events is making the need for hospitalists more apparent. In addition to improving the day-to-day medical management of hospitalized patients, hospitalists are needed to serve as champions of quality improvement, patient safety, and hospital throughput.

Leaders of the Japanese health care system recognize the need to improve the quality of inpatient care. The first step is to establish internal medicine as a specialty with dedicated internal medicine residency training programs. The Japanese Board of Medical Specialties approved establishing standardized, 3-year internal medicine residency training programs starting this spring, but that decision has been met with resistance for various reasons, namely, concern for creating a disparity due to the shortage of internists in rural areas. Therefore, launch of this initiative has been postponed until April 2018.

In the meantime, the concept of hospital-based internists has been gradually gaining the support of subspecialists in Japan. Hospitalists are anticipated to work as the primary medical team leaders, directing and coordinating care among subspecialists in the future.

Despite its gradual spread, there are several challenges to growth. First, there are many terms for hospitalists, such as "hospital general practitioners" and "general internal medicine physicians." A unified term for hospitalists would foster acceptance among Japanese physicians.

Additionally, some physicians, namely ,subspecialists, still question whether hospitalists are needed in Japan (even though potential loss of clinical revenue is not a significant concern among subspecialists).

Another challenge is lack of standardized training programs that define the skill set of hospitalists. Standardization of internal medicine training will also improve efficiency of communication between hospitalists and subspecialists.

An important milestone in the Japanese hospital medicine movement was the establishment of a society of hospitalists, known as the Japanese Hospitalist Network (JHN). The JHN has a quarterly publication (*Hospitalist*) targeted at junior faculty and residents that reviews topics in hospital medicine.

The JHN is affiliated with a larger society, the Japanese Society of Hospital General Medicine (JSHGM), which holds meetings twice a year. A unique offering at the next JSHGM meeting in March is a point-of-care ultrasound training workshop. Although this is the first such workshop for hospitalists in Japan, there are many training courses designed for the country's hospitalists.

The emergence of such courses in Japan has paralleled the increasing need for hospitalists in Japan. We hope these courses for hospitalists will pave the road for the continued growth of hospital medicine in Japan.

***–Toru Yamada, MD, Taro Minami, MD, and Nilam J. Soni, MD, MS, FHM***

*Dr. Yamada is an internist in the department of general medicine/family and community medicine at Nagoya (Japan) University and practices at Tokyo Bay Urayasu Ichikawa Medical Center in Chiba. Dr. Minami is assistant professor of medicine in the division of pulmonary, critical care, and sleep medicine at Brown University in Providence, R.I., and director of ultrasound and simulation training at Memorial Hospital of Rhode Island. Dr. Soni is associate professor of medicine in the division of hospital medicine at the University of Texas, San Antonio, and a hospitalist with the South Texas Veterans Health Care System in San Antonio.*

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by licensed practical nurses than are acute-care settings.

A hospitalist might work at a PAC facility only several days a week. In fact, Medicare and state regulations dictate what duties physicians can perform there and how often they can see patients. The hospitalist also serves in the role of primary care physician and specialist in this setting because none of these types of physicians is present, Dr. Tollman says.


Dr. Tollman

Usually, there is no physician or nurse practitioner presence at night. Clinicians rely on nursing staff's assessment to make decisions regarding changes in patient status during off hours, says Virginia Cummings, MD, director of long-term care, gerontology division, at Boston-based Beth Israel Deaconess Medical Center.

Although the pace of care traditionally has been slower at a PAC facility than at a hospital, within the last few years, the pace at the former has increased. This is because newer reimbursement models are resulting in earlier hospital discharge for patients who are more acutely ill at the time of discharge. "Years ago, patients at PAC facilities needed to be seen only biweekly by a physician," says Arif Nazir, MD, CMD, FACP, AGSF, who is chief medical officer, Signature HealthCARE, in Louisville, Ky. "Now, many need to be seen several times a week."


Dr. Nazir

## 2 Testing takes longer, and options are limited.

Access to some acute urgent resources such as laboratory testing, imaging tests, and pharmacy products is more challenging at PAC facilities because most of these resources are not on-site. Consequently, there is a time lag between ordering tests and new medications and implementing these orders.


Dr. Liistro

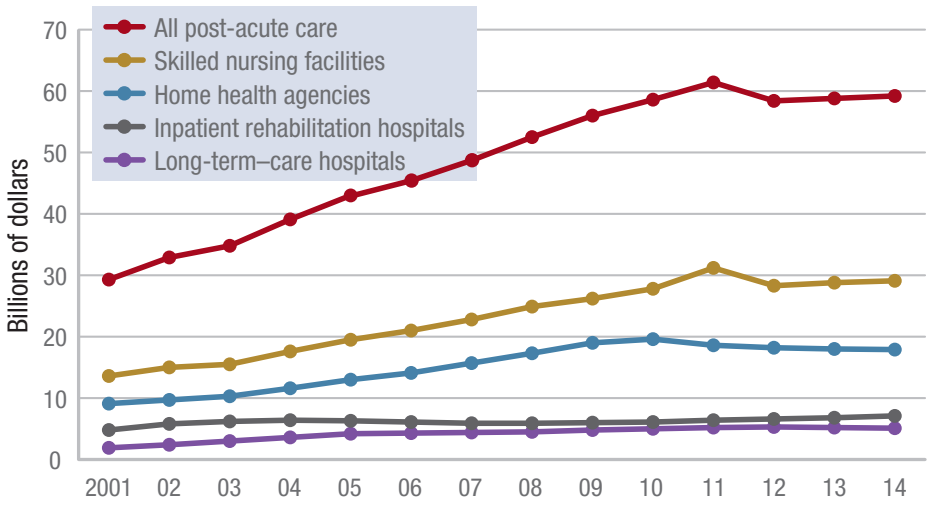
"If a patient needs something performed diagnostically immediately, they usually have to be transported to the emergency room or a facility with the necessary testing equipment," Dr. Tollman says.

"Most of the time patients in PAC settings have had their most urgent needs resolved, but they could develop those needs again," Dr. Nazir says. "Therefore, it is important for a hospitalist taking care of a patient to be aware of what resources a facility has available promptly."

However, Paul T. Liistro, managing partner, Arbors of Hop Brook Limited Partnership in Manchester, Conn., and Vernon Manor Health Care Center in Vernon, Conn., and administrator, Manchester Manor Health Care Center, notes that it's possible for a laboratory service or mobile diagnostic unit to provide laboratory testing or certain imaging at a PAC facility. More involved diagnostics, such as an MRI or a PET scan, typically require testing at a remote location.

"But, as technology improves and big machines become smaller machines and staff members become more proficient in their positions, PAC facilities will have the ability to care for more patients efficiently," Mr. Liistro said.

**Figure 1: Medicare post-acute care expenditures, 2001-2014**




Note: Based on data from the CMS Office of the Actuary.
Source: Medicare Payment Advisory Commission

## 3 Patient populations mainly include rehab and terminally ill patients.

Patients are typically sent to a PAC facility either to recover from an illness or injury or because they are chronically ill and have exhausted treatment options. Regarding the latter, "They are mostly there for palliation; we don't perform daily tests or prescribe aggressive medications on these patients," Dr. Nazir says.

Dr. Cummings explains that PAC clinicians go through "the dying process with the patient."

"They may or may not have assistance from hospice organizations," she says, "and when they don't, [hospitalists] take on the role of palliative care providers."


Dr. Cummings

Dr. Cummings has seen an increase in psychiatric patients entering PAC facilities.

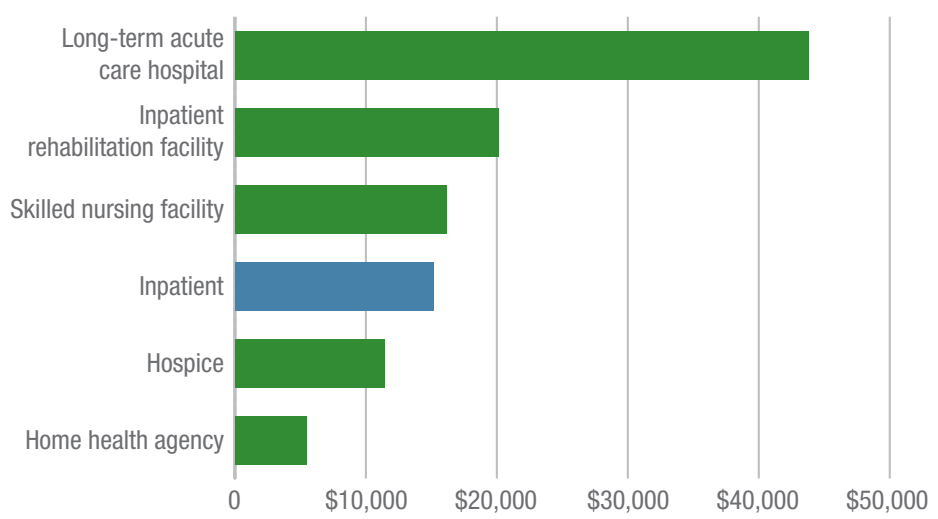
"Many patients with chronic psychological problems are aging, and there are fewer inpatient psychiatric beds available to those with concurrent medical and psychiatric problems," she says. Much of this work is now being done in PAC settings.

## 4 You can build a relationship with your patient.

Because the pace of a PAC facility is slower and a patient typically stays in a PAC facility longer than at a hospital, there's time for a hospitalist to have more in-depth conversations with patients and their families.

"Building a deeper relationship with a patient may give the hospitalist an opportunity to discover the cause of an acute problem," Dr. Nazir says. "They can go in-depth into the psychosocial aspect of medicine and may be able to find out what led to the initial problem and the real root cause, which can help prevent future recurrences, such as repeat falls or forgetting to take a medication."

**Figure 2: Medicare standardized costs per user by setting, 2014**




Note: Based on data from the CMS Geographic Variation Public Use File, 2014.
Source: DHG Healthcare

## 5 Using EHRs can improve transitions.

Care transitions between a hospital and PAC facility can be compromised by a lack of information sharing, and they can affect the quality and safety of patient care, says Dori A. Cross, a doctoral candidate in health services organization and policy at the University of Michigan School of Public Health in Ann Arbor. Handoffs between providers require information continuity – information that is complete, timely, and in a usable format – to ensure appropriate medical decisions and to provide high-quality care during and after transition.

Electronic health records (EHRs) as well as health information exchanges (HIEs) allow providers to communicate and share patient information. For example, hospitals can send information electronically to PAC facilities ("push" exchange) or make information available online securely for PAC providers to log in and access ("pull" exchange). According to a 2014 survey by the American Hospital Association, more than 50% of hospitals report sending structured summary-of-care records electronically to long-term care settings; a little less than half of those hospitals (23% of the total sample of hospitals) were also receiving information electronically from long-term care sites.[1]

"This bidirectional exchange, in particular, can make it easier to share information across provider organizations electronically and, in turn, improve care delivery," says Ms. Cross, who authored an accepted paper on the subject in the *Journal of Post-Acute and Long-Term Medicine*.

## 6 Hospitalists can work with providers in PAC settings to improve transitions.

Despite improvements in the electronic transfer of medical information, gaps still exist and can cause problems. One chasm when discharging patients to a PAC facility, is when a hospital IT system is incapable of communicating with the PAC facility system. In this instance, Dr. Nazir says, the hospitalist "can help bridge the gap."

"[We] can verbally relay relevant information to physicians at PAC facilities so they understand the patient's status, needs, and expectations," he says. "Furthermore, hospitalists and a PAC facility's administration can brainstorm methods to improve the systems of care so the patient receives more effective and timely care."

## 7 Hospitalists switching to the PAC setting should have formal training.

The two main obstacles for hospitalists who change from working in a hospital to a PAC facility are the lack of exposure to PAC

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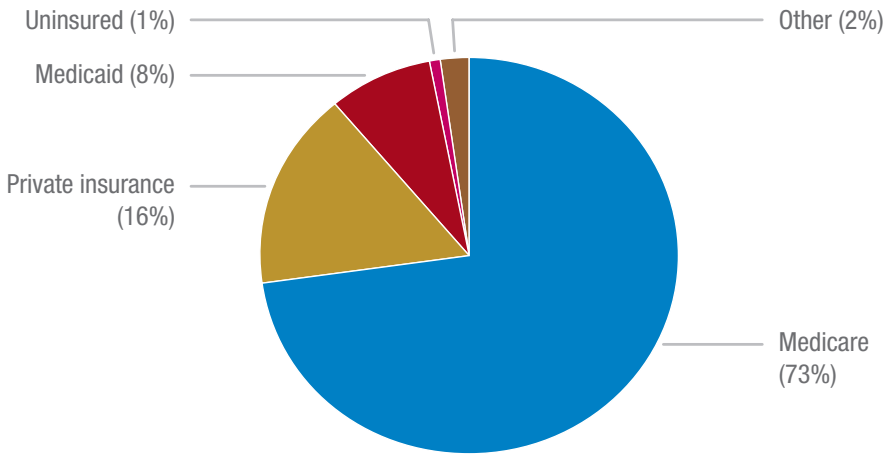
**Figure 3: Distribution of post-acute stays by primary payer, 2013**




Note: Based on data from the National Inpatient Sample, 2013.
Source: Agency for Healthcare Research and Quality

Dr. Mathew

work in training and the assumption that it requires the same skills sets of a typical hospitalist, according to Manoj K. Mathew, MD, SFHM, national medical director of Los Angeles–based Agilon Health. The PAC setting has quite a number of differences, compared with a hospital setting. For example, some regulations apply specifically to PAC facilities. In addition to formal training, hospitalists can benefit from using SHM's Post-Acute Care Transitions Toolkit, having a mentor, or using resources from other organizations that function in this space such as The Society for Post-Acute and Long-Term Care Medicine, Dr. Nazir says.

Dr. Mathew points out that hospitalists working in a PAC setting should have specific skills sets that focus more on being a social worker, a care manager, and a dispenser of palliative care than simply on being comfortable with acuity of illness. "Don't assume that a good hospitalist is easily a good candidate to work in a skilled nursing facility [SNF]," he says.

## 8 A variety of payers and payment models are in play.

Commercial insurers continue to be major payers for PAC, especially for individuals younger than 65 years. Medicare and Medicaid, administered by the Centers for Medicare & Medicaid Services, are the primary payers for patients aged 65 years and older.

"Fewer patients are paying privately for PAC today than in the past," says Gina Zimmermann, executive director of nursing care center accreditation at the Joint Commission in Oakbrook Terrace, Ill. "Bundled payments and value-based purchasing are becoming more of a reality for PAC, and it's inevitable that originators of various bundled payment and purchasing arrangements currently in place or being developed are including some type of 'scorecard' process to help rank or judge the various providers that want to be involved in these arrangements.

"These scorecards are using a variety of criteria to rank providers, such as length of stay, cost, readmissions to hospitals, and quality."

Because Medicare Part A covers many patients discharged to a PAC setting, any changes in payment incentives or benefit structures by the Medicare program will drive changes in PAC.

"For example, as Medicare implements payment adjustments for hospitals that have high rates of readmissions, hospitals have a new incentive to work closely with SNFs and other providers of PAC to ensure patients can avoid unnecessary readmissions," says Tiffany A. Radcliff, PhD, a health economist and associate professor in the department of health policy and management at Texas A&M University School of Public Health in College Station.

Dr. Zimmermann

Providers must follow the billing rules for each payer. The rules for Medicare payments are outlined on the CMS's website. Bundled payments for PAC under the Medicare Part A program are scheduled to be implemented by 2018. TH

*Ms. Appold is a freelance medical writer in Pennsylvania.*

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1. Cross DA, Adler-Milstein J. Investing in post-acute care transitions: electronic information exchange between hospitals and long-term care facilities [published online ahead of print Sept. 14, 2016]. *JAMA*. doi: 10.1016/j.jamda.2016.07.024.

Q&A

# SHM Practice Administrators' Mentor Program benefits both parties

SHM resources help Alessandra G. Cornelio, MPH, develop her career. Now, she is paying it forward.

By Felicia Steele

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

**This month, The Hospitalist spotlights Alessandra G. Cornelio, MPH, the acquisition manager at Hartford Healthcare Medical Group in Connecticut. Ms. Cornelio is an active member of SHM's Practice Administrators Committee. She developed and now directs the Practice Administrators' Mentor Program.**

**Question: Why did you choose to become a practice administrator in hospital medicine? How has SHM helped in your professional growth?**

**Answer:** I was finishing my internship at the Middlesex Hospital Cancer Center. I was interested in hospital administration and learning more about the inpatient side of health care. I chose to work within hospital medicine because I wanted to help build a team of compassionate doctors who could provide an excellent patient experience while maintaining an environment with safe, high-quality care.

To complement my career goals, SHM helped my professional growth by exposing me to the variety of topics and issues that practice administrators deal with regularly in their practices. I was also able to review and learn from the many resources available on the SHM website, such as white papers and articles, which were extremely useful for a new administrator.

**Q: What prompted you to join the Practice Administrators Committee? What are some of the most impactful projects the committee is currently working on?**

**A:** Within my first year of being a practice administrator, I attended a practice administrators' forum at the SHM annual meeting in Washington. I found that the information was relevant to my daily functions as an administrator, and I was also able to meet and share ideas with other practice administrators from throughout the country. Down the line, I learned that SHM needed new members for the Practice Administrators Committee. I wanted to become more involved in a meaningful way, so I decided to apply.

The Practice Administrators Committee is a hardworking committee that takes on many meaningful projects. Most recently, the team has been working on developing a more user-friendly website for practice administrators, and a subgroup of the committee has cross-referenced "The Key Principles and Characteristics of an Effective Hospital Medicine Group" with existing resources, which will prove valuable to all administrators in the final product.

> Many mentors, including myself, found value in acting as a mentor. I learned from my mentees as well as made connections and friendships with other professionals in the field.
>
> —*Alessandra G. Cornelio, MPH*

**Q: Can you discuss how you began leading the work group for the Practice Administrators' Mentor Program and how it has evolved since its inception?**

**A:** As part of the committee's initiative to help fellow practice administrators, we formed a subcommittee to begin developing a mentor program. (Former SHM staffer) Joseph Miller and I worked together to create an appropriate program model through research and brainstorming. We also utilized the HMX Practice Administrators Community to ask fellow practice administrators what they would expect from a mentor program and if they would participate. There was a strong favorable response rate, and we were able to implement a pilot program.

We implemented two different tracks for the program – the buddy system track and the career development track. The buddy system track is for those of any level of expertise or experience who are more interested in short-term assistance or in need of a sounding board. The career development track is a more traditional approach, matching a seasoned practice administrator with a less experienced practice administrator.

The program was designed to have annual cohorts, with the Practice Administrators Committee members as mentors. There is a detailed application process to ensure that each mentee is matched with an appropriate mentor, based on their interests and needs. We provide an orientation webinar to both parties before kicking off the relationship to present program expectations. The pilot program used this model, and comments from 6-month and annual evaluations showed tremendous satisfaction with the structure and value of this program.

There were approximately 16 pairs during the pilot year, and the following year, we grew to almost 20 pairs. Our goal as a committee is to maintain this program year after year, and in order to expand, we'll need more than just the committee members to volunteer as mentors. There are so many talented practice administrators, and it would be wonderful to fold them into this gratifying program to pay it forward.

Many mentors, including myself, found value in acting as a mentor. I learned from my mentees as well as made connections and friendships with other professionals in the field.

**Q: Given your intimate involvement, how have you seen the Practice Administrators' Mentor Program benefit both the mentors and the mentees? Can you provide any specific examples?**

**A:** Mentees are able to connect with seasoned mentors and can ask specific questions about career development and any issues they may be experiencing. Mentors are able to share their experiences and pass along important and valuable lessons learned to mentees. I served as a mentor, even though I did not yet consider myself a qualified candidate. However, I found that I was more equipped than I had realized, and I was able to assist my mentee with many aspects of career development (i.e., resume building, discussions with the C-suite, etc.).

My mentee was a practice coordinator who had only been in hospital medicine for 1 year. She had little experience hiring hospitalists, so this was a major area that we worked on together during our yearlong connection. I introduced her to collaborating with her HR department when posting positions, as well as working with permanent placement agencies. Her service was also undergoing a change in leadership, which can be difficult for any service line to experience. We discussed ways in which she could present important information to the new medical director that would produce a meaningful conversation.

In turn, my mentee introduced me to new online resources and was able to connect me with the manager of her practice, who assisted me with streamlining the payroll structure in my practice. I truly enjoyed my experience developing and participating in the program. 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.

## NEWS & NOTES

# Trending at SHM

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

By Brett Radler

### Make a difference with SHM

➤ Grow professionally, expand your curriculum vitae, and get involved in work you are passionate about with colleagues across the country with SHM's volunteer experiences. New opportunities are constantly being added that will bolster your strengths, sharpen your professional acumen, and enhance your profile in the hospital medicine community at www.hospitalmedicine.org/getinvolved.

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*Brett Radler is SHM's communications specialist.*

# ‘I can handle it’

## The state of hospitalist group backup systems

By Tierza Stephan, MD, SFHM

It took my hospital medicine group (HMG) 20 years to implement a formal backup system. Of all the reasons we resisted creating a backup system, foremost was that we did not want to mandate additional work. Because our compensation model did not have a mechanism to financially reward hospitalists for unexpectedly having to come in on unscheduled workdays (other than the work relative value units [RVUs] generated by seeing patients), there was not enough motivational energy to get a system started.

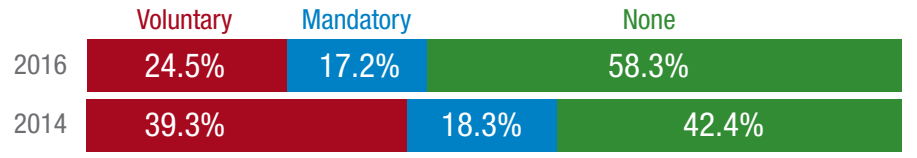
It turns out our group is not unlike many other HMGs across the nation. According to the 2016 *State of Hospital Medicine* report (SoHM), 58.3% of adult-only HMGs, 72.2% of pediatric-only HMGs, and 52.6% of HMGs serving both adults and children did not have staffing backup systems. Interestingly, the report also showed that for groups serving adults only, academic HMGs were more likely to have formal backup systems in place (62.6%, compared with 37.3% in nonacademic HMGs).

The reason most HMGs create backup systems is to have a consistent and fair approach for dealing with unanticipated absences and/or high-volume census. In addition to creating a safety net, implementing a backup system addresses the common problem of the same hospitalists disproportionately filling in during times of crisis.

Although our group created a formal backup system starting January 2015, it is not comprehensive and deals only with high patient volumes occurring during the late evening and night hours. Hospitalists rotate through a schedule, taking a week of backup call for which no additional compensation is offered. Then, if they are actually called to come in, an hourly stipend is paid in addition to work RVUs generated. Implementing a backup system was not necessarily a popular idea. Nevertheless, the system has successfully remained in place. Triggering the system infrequently, having a clear set of criteria for when to activate backup, and providing additional compensation for the additional work are key factors in our system’s success.

Surprisingly, according to the latest State of Hospital Medicine (SoHM) report, roughly 30% of HMGs serving adults had backup systems that offered no additional compensation for either being on backup call or for being called in to work. On the other end of the spectrum, 22% of groups serving adults offered compensation for being on call *and* additional pay if called in to work.

**Figure 1: Backup staffing systems for adult-only HMGs**




Note: Based on data from the 2016 and 2014 State of Hospital Medicine reports.
Source: Society of Hospital Medicine

When data from the 2016 SoHM report are compared with the 2014 SoHM report, the proportion of groups with formal backup systems actually decreases for both adults-only HMGs and HMGs serving both adults and children. For adult-only HMGs, there was a decline to 41.8% from 57.6%. For adult/pediatric HMGs, there was a decline to 47.4% from 58.8%. It also is notable that pediatric HMGs in particular are much less likely to have formal backup systems, only 27.8%, which has changed little since the last survey (28.8 % in 2014).

All in all, the reasons for the decline in backup systems are unclear. Possibly, the decrease is because of issues surrounding compensation, as approximately one-third of survey respondents with backup systems received no additional compensation. But in my view, it’s more likely that the reason for the decreased percentage of groups with backup systems has to do with differences in the particular set of HMGs that responded to the survey this year. TH

*Dr. Stephan is a hospitalist at Abbott Northwestern Hospital in Minneapolis and a member of SHM’s Practice Analysis Committee.*

## NEWS & NOTES

# Trending at SHM

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

By Brett Radler

### Top 10 reasons to attend 2017 Quality and Safety Educators Academy

➤ It’s your last chance to register for the 2017 Quality and Safety Educators Academy (QSEA), which will be held Feb. 26-28 in Tempe, Ariz.

Looking for some reasons to attend? Here are the top 10:

- **Education.** Develop and refine your knowledge in quality and patient safety.
- **Desert beauty.** Enjoy sunny Tempe, or travel to nearby Phoenix or Scottsdale.
- **Curriculum development.** Return to your institution with a collection of new educational strategies and curriculum development tactics.
- **Professional development.** Hone your skills and be the best that you can be to meet the increasing demand for medical educators who are well versed in patient safety and quality.
- **Relationships.** Build your network with faculty mentors and colleagues who have similar career interests.
- **Institutional backing.** Engage your institutional leaders to support and implement a quality and patient safety curriculum to meet the Accreditation Council for Graduate Medical Education core competencies and improve patient care.
- **Hands-on learning.** Engage in an interactive learning environment, with a 10:1 student to faculty ratio, including facilitated large-group sessions, small-group exercises, and panel discussions.
- **Variety.** Each day has its own topic that breaks down into subtopics, covering the breadth of information you need to know to succeed.
- **Faculty.** All sessions are led by experienced physicians known for their ability to practice and teach quality improvement and patient safety, mentor junior faculty, and guide educators in curriculum development.
- **Resources.** Leave with a toolkit of educational resources and curricular tools for quality and safety education.

Reserve your spot today before the meeting sells out at www.shmqsea.org.

### SHM committees address practice management topics

➤ SHM’s Practice Management Committee has been researching, deliberating case studies, and authoring timely content to further define HM’s role in key health care innovations. As the specialty has grown and evolved, so have hospitalists’ involvement in comanagement relationships.

The committee recently released a white paper addressing the evolution of comanagement in hospital medicine. Be on the lookout for that in early 2017.

Similarly, telemedicine is rapidly expanding, and the committee found it imperative to clarify the who, what, when, where, why, and how of telemedicine programs in hospital medicine. You can also expect this white paper in early 2017.

The committee also has created guidelines on how to raise awareness of cultural humility in your HM group, deemed the “5 R’s of Cultural Humility.” Look for a campaign around the guidelines to launch at HM17 in May in Las Vegas.

SHM’s Health Information Technology Committee has been diligently analyzing and reporting on survey results that captured hospitalists’ attitudes toward electronic health records. The purpose of this white paper is to effect change on EHR systems by informing conversations with decision makers, and to provide HM a definitive voice in the landscape of the tumultuous world of EHRs. More information is coming soon.

### Leadership Academy 2017 has a new look

➤ Don’t miss out on the only leadership program designed specifically for hospitalists. SHM Leadership Academy 2017 will be at the JW Marriott Camelback Inn in Scottsdale on Oct. 23-26.

For the first time, the Leadership Academy prerequisite of attendance in the first-level, foundations course has been removed. Essential Strategies (formerly Leadership Foundations), Influential Management, and Mastering Teamwork courses are available to all attendees, regardless of previous attendance. Prior participants have made recommendations to help interested registrants determine which course fits them best in their leadership journey.

All three courses run concurrently over the span of 4 days. This expanded meeting will provide attendees with world-class networking opportunities, creating opportunities for a more engaging, impactful educational experience.

Learn more about SHM’s Leadership Academy at www.shmleadershipacademy.org.

*Brett Radler is SHM’s communications specialist.*

# SHM launches fund to enhance reach, impact of chapters

## Funds to foster innovative approaches to chapter engagement

**By Claudia Stahl**

As hospital medicine continues to experience unparalleled growth, the Society of Hospital Medicine seeks to supplement its chapter program via a new $100,000 Chapter Development Fund. The monies will be used to further enhance the reach and impact of SHM's 50 regional chapters.

Chapters can request up to $5,000 from the fund annually to support projects that promote networking, education, leadership opportunities, and improvements in health care delivery. In addition to growing the chapters, SHM expects that the additional resources will help facilitate relationships with local hospitals and medical schools, and demonstrate the value of membership.

The fund establishes a centralized, consistent source of financial support for chapter activities, which previously relied on external sponsorship that varied from year to year. Chapters can submit a plan to the SHM Chapter Support Committee, which will evaluate requests for "innovation, the potential to grow and engage membership, and improve sustainability," says Rachel Thompson, MD, SFHM, chair of SHM's Chapter Support Committee.

"Chapters that were struggling now feel that they have the support they need to improve, and the ones that have figured out the basics can push their creative limits. That innovation can be passed along and benefit [all chapters]," Dr. Thompson said.

Fund usage already has led to a number of success stories (see graph, above). During the program's pilot phase, six chapters – Gulf States, Iowa, Los Angeles, Michigan, New Mexico, and San Francisco – acquired 77 new SHM members through a variety of innovative methods.

With a $5,000 boost, the Gulf States Chapter increased its membership by 10% with a new meeting and member engagement plan.

Dr. Palabindala

"We were struggling in recruitment and saw this as an opportunity to attract members," said chapter leader Venkataraman Palabindala, MD. "We used the funds to create 15 'coupons' for membership. The rest of the money [was used] to start a regional meeting … where chapter leaders were invited to lead talks. [The meeting] really helped us."

Another example of success comes from the Iowa Chapter, which attracted 14 new members through a multidisciplinary membership drive.

"We … requested funding for a few specific areas. One was marketing, where we had fliers written up to target specific groups, including … students, APPs (advanced-practice practitioners), residents, students, and pharmacists, as well as other physicians," said chapter leader Melinda Johnson, MD, SFHM.

The Iowa Chapter also used funding for SHM-branded "giveaways" (coffee mugs, portable chargers, etc.) to leave behind during meetings with prospective members. Vouchers, offering a 50% discount on a 1-year membership for new members during the pilot program, were especially effective. The combined activities "really increased visibility for SHM within our state and with disciplines besides physicians," Dr. Johnson said.

Chapters can apply for support on a rolling basis by submitting a proposal to the Chapter Support Committee. For the full details, visit **www.hospitalmedicine.org/chapterdevelopment**.

When thinking about ideas, Dr. Thompson advises chapters to begin with "a brainstorm of all of the … exciting things that you have wanted to do for your membership. Then think about the ones that are attainable and map out how to get there. The pilot showed that in a short time, you can reach many people when you plan your project out with timing and specific goals … and let the committee support you."

In addition to a financial boost, fund recipients enjoy personalized mentorship from the committee, a benefit that both Dr. Johnson and Dr. Palabindala found invaluable. For new and developing chapters, "the support you get, the money, as well as the goal setting and feedback, is amazing," Dr. Palabindala said.

Chapters, Dr. Johnson said, provide members with networking and leadership opportunities – and ensure that the unique, localized needs of their communities are represented at SHM.

"They become your professional home, providing opportunities," she said, "that improve personal and professional satisfaction. Anyone is welcome to participate in the conversation."

For more information on how you can become involved in an SHM chapter, visit **www.hospitalmedicine.org/chapters**. TH

*Ms. Stahl is a content manager for the Society of Hospital Medicine.*

**Chapters participating in the SHM Chapter Development Fund pilot program**

| Chapter | Project | Funding | Membership growth |
|---|---|---|---|
| Gulf States | Collaboration with Gulf States regional meeting; membership vouchers | $5,000 | 20 new members |
| Iowa | Personalized multidisciplinary membership drive | $5,000 | 14 new members |
| Los Angeles | Grow resident and student presence in chapter and hospital medicine | $5,000 | 11 new members |
| Michigan | Event broadcasting and member outreach by video conferencing | $5,000 | 20 new members |
| New Mexico | Reduce burnout by increasing engagement and practice satisfaction in hospital medicine | $4,000 | 3 new members |
| San Francisco | 1. Point of care ultrasound workshop and collaborative<br>2. Essay contest: Finding your voice | $2,000<br>$1,000 | 9 new members |



# Use familiar terminology to allay patients' fears

*Dr. Sharp is a chief hospitalist with Sound Physicians at UF Health in Jacksonville, Fla.*

**By Larry Sharp, MD, SFHM**

***Editor's note:*** *"Everything We Say and Do" is an informational series developed by SHM's Patient Experience Committee to provide readers with thoughtful and actionable communication tactics that have great potential to positively impact patients' experience of care. Each article will focus on how the contributor applies one or more of the "key communication" tactics in practice to maintain provider accountability for "everything we say and do that affects our patients' thoughts, feelings, and well-being."*

### What I say and do

I clearly explain diagnoses and treatment plans in plain terms.

### Why I do it

We hear repeatedly from patients and families that a major source of their fear comes from "not knowing." Fear of the unknown. If our patients and their families do not understand the message we are trying to communicate, these fears will be realized. It is our responsibility to explain their medical situation(s) to them in plain terms that they can comprehend, so as to allay those fears and enable them to become active, informed participants in their care.

### How I do it

I start by reminding myself that I want to treat each patient as I would want a member of my own family to be treated. No one else in my family is in the medical field, so this means I must avoid medical terminology and use more familiar, everyday phrases. For example, I say "heart doctor" or "lung doctor" instead of "cardiologist" or "pulmonologist." I also prefer "sonogram" to "ultrasound" because most people have heard that term in relation to a pregnancy. Even "EEG" and "EKG" need more plain descriptions.

I also try to use common, relatable analogies when explaining diseases. My favorite is to describe COPD (or any restrictive lung disease) like an old, hard sponge as compared with normal lungs, which are like a new, soft sponge.

I use the Teach-Back Method (which has already been well-discussed in this column by Dr. Trina Dorrah) to check for comprehension. If there are still issues with my message not being received as I had hoped, then I try again to find the terminology or an analogy that will connect with that patient.

Hopefully, using familiar, relatable language in this manner gives my patients and their families a better understanding of their diagnoses and care plans, quells their fears, and enhances their experience. TH

SNEAK PEEK

# The Hospital Leader blog

## Is QI really a dirty word for residents and physicians?

**By Chris Moriates, MD**

***Editor's note:*** *First published on* The Hospital Leader blog *under the title, "How I Realized QI Could Be a Dirty Word"*

With the recent election, there has been a new recognition of the various "bubbles" we all seem to be living in. It reminds me of the parable I like to often mention, popularized by the late great writer David Foster Wallace: Two fish were swimming along when an older fish swam by, nodded his head at them and said, "Mornin' boys, how's the water?" The two young fish nod back and swim for a bit, then one turns to the other and says, "What the hell is water?"


Dr. Chris Moriates

Recently, I read a paper that helped me realize I had been swimming in a different lake from most of the "real world" in medicine. I trained and then spent the first 4 years of my postresidency career at the University of California, San Francisco, where quality improvement (QI) was well established and celebrated. Sure, I suppose there were some eye rolls from a few surgeons; I would hear on occasion the off-hand snide remark from a cardiology attending, but by and large, QI was not controversial at UCSF. It is what we do. As residents, we led QI projects and contributed to QI projects from our colleagues. As a hospitalist faculty member, I led my own QI-related projects and mentored residents and other faculty who led their own QI projects.

Imagine the hard reality that hit me when I read this quote from a resident: "Truly, the first thing I think of when I hear [QI] is going to make more work for residents."

Wait – is QI actually a dirty word for other residents and physicians?

The quote comes from an *Academic Medicine* study titled "'It Feels Like a Lot of Extra Work': Resident Attitudes About Quality Improvement and Implications for an Effective Learning Health Care System." I read on, and it got worse.

"This hasn't really made any difference to the patients. Like this checklist we do on rounds, like I don't know. Maybe it has."

And, by far, most concerning: "There's like the central line protocols … If you suspect that anybody has any type of bacteremia, you don't do a blood culture; you just do a urine culture and pull the lines … we just don't even test for it because the quality improvement then like marks you off."

Wow.

That is some harsh truth about unintended consequences right there. (Also, apparently us kids of the 1990s still say "like" a lot, which is, like, not very professional and also like kinda grating.)

The residents in this study were from the University of Utah, Salt Lake City – an institution I frequently – and publicly – admire for their incredible progress on systematically introducing value improvement into their practice.

What can we do? TH

*Read the full post at hospitalleader.org.*

## ALSO ON "THE HOSPITAL LEADER" BLOG

**POST:** THIS Is What Teamwork Looks Like
*By Danielle B. Scheurer, MD, MSCR, SFHM*

**POST:** The Medicaid Overhaul and How Hospitals and Their Providers Could Be Hardest Hit
*By Brad Flansbaum, DO, MPH, MHM*

**POST:** Count Me – and My Intuition – In
*By Tracy Cardin, ACNP-BC, SFHM*

# Journal of Hospital Medicine

## Association of geriatric syndromes with hospital outcomes

By Roman Romero-Ortuno, PhD, Duncan R. Forsyth, MA, Jane Wilson, MBBS, Ewen Cameron, MD, Stephen Wallis, MB, BChir, Richard Biram, MBBS, Victoria Keevil, PhD

**BACKGROUND:** Frailty, history of dementia (HoD), and acute confusional states (ACS) are common in older patients admitted to hospital.
**OBJECTIVE:** To study the association of frailty six or more points in the Clinical Frailty Scale [CFS]), HoD, and ACS with hospital outcomes, controlling for age, gender, acute illness severity (measured by a Modified Early Warning Score in the emergency department), comorbidity (Charlson Comorbidity Index), and discharging specialty (general medicine, geriatric medicine, surgery).
**DESIGN:** Retrospective, observational study.
**SETTING:** Large university hospital in England.
**PATIENTS:** We analyzed 8,202 first nonelective inpatient episodes of people ages 75 years and older between October 2014 and October 2015.
**MEASUREMENTS:** The outcomes studied were prolonged length of stay (LOS 10 days), inpatient mortality, delayed discharge, institutionalization, and 30-day readmission. Statistical analyses were based on multivariate regression models.
**RESULTS:** Independently of controlling variables, prolonged LOS was predicted by CFS greater than or equal to 6: odds ratio = 1.55; 95% confidence interval, 1.36-1.77; *P* less than .001; HoD: OR = 2.16; 95% CI, 1.79-2.61; *P* less than .001; and ACS: OR = 3.31; 95% CI, 2.64-4.15; *P* less than .001. Inpatient mortality was predicted by CFS greater than or equal to 6: OR = 2.29; 95% CI, 1.79-2.94, *P* less than .001. Delayed discharge was predicted by CFS greater than or equal to 6: OR = 1.46; 95% CI, 1.27-1.67; *P* less than .001; HoD: OR = 2.17; 95% CI, 1.80-2.62; *P* less than .001, and ACS: OR = 2.29; 95% CI, 1.83-2.85; *P* less than .001. Institutionalization was predicted by CFS greater than or equal to 6: OR=2.56; 95% CI, 2.09-3.14; *P* less than .001; HoD: OR = 2.51; 95% CI, 2.00-3.14; *P* less than .001; and ACS: OR = 1.93; 95% CI, 1.46-2.56; *P* less than .001. Readmission was predicted by ACS: OR = 1.36; 95% CI, 1.09-1.71; *P* = .006.
**CONCLUSION:** Routine screening for frailty, HoD, and ACS in hospitals may aid the development of acute care pathways for older adults. TH

*Read the full article at journalofhospitalmedicine.com.*

## ALSO IN JHM THIS MONTH

### Screening for Depression in Hospitalized Medical Patients

**AUTHORS:** Waguih William IsHak, MD, FAPA, Katherine Collison, Itai Danovitch, MD, MBA, Lili Shek, MD, Payam Kharazi, Tae Kim, DO Candidate, Karim Y. Jaffer, MD Candidate, Lancer Naghdechi, DO Candidate, Enrique Lopez, PsyD, Teryl Nuckols, MD, MSHS, FHM

### Patient-Level Exclusions from mHealth in a Safety-Net Health System

**AUTHORS:** Keiki Hinami, MD, MS, Bhrandon A. Harris, MD, Ricardo Uriostegui, MD, Wilnise Jasmin, MD, MBA, Mario Lopez, MD, William E. Trick, MD

### Medical and Economic Burden of Heparin-Induced Thrombocytopenia: A Retrospective Nationwide Inpatient Sample (NIS) Study

**AUTHORS:** Ranjan Pathak, MD, Vijaya Raj Bhatt, MD, Paras Karmacharya, MD, Madan Raj Aryal, MD, Anthony A. Donato, MD, MHPE

### Assessment of the Readability, Understandability and Completeness of Pediatric Hospital Medicine Discharge Instructions

**AUTHORS:** Ndidi I. Unaka, MD, MEd, Angela Statile, MD, MEd, Julianne Haney, Andrew F. Beck, MD, MPH, Patrick W. Brady, MD, MSc, Karen E. Jerardi, MD, MEd

### Impact of Patient-Centered Discharge Tools: A Systematic Review

**AUTHORS:** Karen Okrainec, MD, MSc, Davina Lau, BSc, Howard B. Abrams, MD, Shoshanna Hahn-Goldberg, PhD, Ronak Brahmbhatt, MBBS, MPH, Tai Huynh, MBA, Kenneth Lam, MD, Chaim M Bell, MD, PhD

NEWS | Clinical developments and health care policy, regulations

# Selected elderly trauma patients do well in non-ICU wards

By Doug Brunk
*Frontline Medical News*

CORONADO, CALIF. – When elderly patients are appropriately triaged, they can be selectively admitted to non–intensive care wards with acceptable outcomes, results from a single-center study showed.

"Trauma centers across the U.S. are caring for elderly trauma patients with greater frequency," researchers led by Marc D. Trust, MD, wrote in an abstract presented during a poster session at the Western Surgical Association annual meeting.

"Literature showed improved outcomes in this population from aggressive care and invasive monitoring. This may have led to an increased utilization of intensive care resources for these patients," they noted.

In an effort to assess the safety of admitting this population of patients to non–intensive care units, Dr. Trust, a resident at the University of Texas at Austin, and his associates retrospectively reviewed the medical records of 3,682 trauma patients aged 65 and older who were admitted from 2006 to 2015. They compared demographic data and outcomes between patients admitted to the ICU and those admitted to the surgical ward. The primary endpoint was mortality; secondary endpoints were transfer to higher level of care and hospital length of stay.

The mean age of the 3,682 patients was 76 years and 1,838 (50%) were admitted to the ICU, while the remaining 1,844 (50%) were admitted to the surgical ward. When the researchers compared patients admitted to the ICU with those admitted to the surgical ward, they observed significant differences in mortality (7% vs. 0.82%, respectively; *P* less than .001), as well as systolic blood pressure on admission (146 vs. 149 mm Hg, respectively; *P* = .0002), pulse (85 vs. 81 beats per minute; P less than .0001), Glasgow Coma Scale (14 vs. 15; *P* less than .001), Injury Severity Score (16 vs. 8; *P* less than .001), and hospital stay (a mean of 8 vs. 4 days; *P* less than .0001). In addition, fewer than 1% of patients admitted to the surgical ward required transfer to a higher level of care (*P* less than .0001).

Compared with those admitted to the surgical ward, those admitted to the ICU were older (77 vs. 76 years old; *P* = .003), more likely to be male (54% vs. 45%; *P* = .007), more tachycardic (HR 84 vs. 81; *P* = .004), more severely injured (ISS score of 5 vs. 4; *P* less than .0001), and more likely to have a longer hospital stay (a mean of 6 vs. 4 days; *P* less than .0001). Two patients admitted to the surgical ward died (0.26%; *P* = .0009) and none required transfer to a higher level of care.

The researchers reported having no financial disclosures.

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IN THE LITERATURE

# Physician reviews of HM-centric research

By Claire Ciarkowski, MD, Joshua M. Marr, MD, MPH, Kencee K. Graves, MD, Ryan D. Murphy, MD, Heather Balch, MD, Joshua Labrin, MD, FACP, SFHM

University of Utah School of Medicine

## IN THIS ISSUE



### By Ryan D. Murphy, MD

## 1 New guidelines for patients requiring red blood cell transfusion

**CLINICAL QUESTION:** What is a safe target hemoglobin level for patients requiring red blood cell transfusion, and how long can red blood cells be stored prior to transfusion?

**BACKGROUND:** The AABB, formerly the American Association of Blood Banks, notes several new, large, rigorous studies on transfusion thresholds were published since their last guideline in 2012. Additionally, there are concerns from initial studies of increased morbidity and mortality with transfusions of red blood cells stored for longer periods of time.

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

**SETTING:** Summary findings from the AABB clinical transfusion medicine committee.

**SYNOPSIS:** Thirty-one randomized clinical trials (RCTs) evaluating blood transfusion thresholds were reviewed and analyzed, including 12,587 patients across various clinical scenarios. The authors recommend a restrictive threshold of 7 g/dL for most hospitalized adult patients in the appropriate clinical context. For patients undergoing orthopedic or cardiac surgery, or with cardiovascular disease, a threshold of 8 g/dL is recommended, as it was the threshold used in studies of these patients (though such patients may actually tolerate a lower value).

No recommendations were made for patients with acute coronary syndrome, hematological or oncological disorders, severe thrombocytopenia, or chronic transfusion-dependent anemia given limited data.

To determine a safe period of time for blood storage prior to transfusion, 13 RCTs were reviewed and analyzed. The authors recommend that patients requiring transfusion receive red blood cell units at any period within the standard issue period (less than 42 days), rather than limit transfusion to fresh units (less than 10 days).

**BOTTOM LINE:** A restrictive red blood cell transfusion threshold of 7-8 g/dL is safe in most clinical settings, and there is no advantage to using fresh units as opposed to those stored for the standard period.

**CITATION:** Carson JL, Guyatt G, Heddle NM, et al. Clinical practice guidelines from the AABB. JAMA. 2016;316(19):2025-35.

## 2 High-flow oxygen noninferior to noninvasive ventilation postextubation

**CLINICAL QUESTION:** Is high-flow oxygen noninferior to noninvasive ventilation (NIV) in preventing postextubation respiratory failure and reintubation?

**BACKGROUND:** Studies that suggest NIV usage following extubation reduces the risk of postextubation respiratory failure have led to an increase in use of this practice. Compared with NIV, high-flow, conditioned oxygen therapy has many advantages and fewer adverse effects, suggesting it might be a useful alternative.

**STUDY DESIGN:** Randomized clinical trial.

**SETTING:** Three ICUs in Spain.

**SYNOPSIS:** Investigators randomized 604 patients who were identified for planned extubation and at high risk of extubation failure to either NIV or high-flow oxygen therapy via nasal cannula for 24 hours following extubation. Per the noninferiority threshold, high-flow oxygen therapy was noninferior to NIV with respect to rates of reintubation (22.8% vs. 19.1%, respectively; one-sided 95% CI, –9.1% to ∞) and postextubation respiratory failure (26.9% vs. 39.8%, respectively; one-sided 95% CI, 6.6% to ∞).

Rates of most secondary outcomes, including infection, mortality, and hospital length of stay (LOS) were similar between the two groups. ICU LOS was significantly less in the high-flow oxygen group (3d vs. 4d; 95% CI, –6.8 to –0.8).

Additionally, every patient tolerated high-flow oxygen therapy, while 40% of patients in the NIV arm required withdrawal of therapy for at least 6 hours due to adverse effects (*P* less than .001).

**BOTTOM LINE:** High-flow oxygen immediately following extubation may be a useful alternative to NIV in preventing postextubation respiratory failure.

**CITATION:** Hernández G, Vaquero C, González P, et al. Effect of postextubation high-flow nasal cannula vs conventional oxygen therapy on reintubation in low-risk patients: a randomized clinical trial. JAMA. 2016;315(13):1354-61.

*Dr. Murphy is a clinical instructor at the University of Utah School of Medicine and an academic hospitalist at the University of Utah Hospital.*

### By Kencee K. Graves, MD

## 3 Dabigatran has less bleeding than rivaroxaban in atrial fibrillation

**CLINICAL QUESTION:** Does dabigatran or rivaroxaban have more bleeding episodes?

**BACKGROUND:** Alternatives to warfarin exist for stroke prevention in nonvalvular atrial fibrillation (AF). The RE-LY and ROCKET-AF trials demonstrated noninferiority to warfarin for both dabigatran (a direct thrombin inhibitor) and rivaroxaban (a factor Xa inhibitor), respectively. Although indirect comparisons have been done using data from these trials, direct, head-to-head comparisons are not available.

**STUDY DESIGN:** New-user cohort study.

**SETTING:** Medicare beneficiaries 65 years or older with AF and a prescription for either dabigatran or rivaroxaban.

**SYNOPSIS:** Researchers enrolled 52,240 patients on dabigatran and 66,651 patients on rivaroxaban. Exclusions comprised those taking warfarin, residing in a skilled nursing facility, or already hospitalized on the study's index date, as well as those with a separate indication for anticoagulation. $CHADS_2$ and HAS-BLED scores were calculated. Primary outcomes were thromboembolic stroke, intracranial hemorrhage, major extracranial bleeding events, and acute myocardial infarction. Mean duration of treatment was 108 days, with mean 111 days of follow-up.

Intracranial hemorrhage and extracranial major bleeding events were significantly greater in the rivaroxaban group than the dabigatran group. There was no significant difference in thromboembolic stroke events.

Dr. Graves

Limitations include short treatment and follow-up times. Additionally, the study is not generalizable to younger populations.

**BOTTOM LINE:** In elderly patients with nonvalvular AF, rivaroxaban was associated with more adverse bleeding events than dabigatran, with no difference in stroke prevention.

**CITATION:** Graham DJ, Reichman ME, Wernecke M, et al. Stroke, bleeding, and mortality risks in elderly Medicare beneficiaries treated with dabigatran or rivaroxaban for nonvalvular atrial fibrillation. JAMA Intern Med. 2016;176:1662-71.

## 4 Do not use steroids in patients with severe sepsis without shock

**CLINICAL QUESTION:** Does hydrocortisone therapy prevent progression to septic shock in patients with severe sepsis without shock?

**BACKGROUND:** Current sepsis management guidelines recommend use of hydrocortisone in patients with septic shock who are unable to restore hemodynamic stability with IV fluids and pressors; current guidelines also recommend against use of corticosteroids without shock. However, these recommendations are based on two RCTs and remain controversial.

**STUDY DESIGN:** Multicenter, placebo-controlled, double-blind RCT.

**SETTING:** Thirty-four intermediate or intensive care units in German university and community hospitals.

**SYNOPSIS:** Investigators randomly assigned 380 patients to hydrocortisone or placebo. Patients were included if they had clinical evidence of infection, evidence of SIRS (systemic inflammatory response syndrome), and evidence of organ dysfunction. Patients were excluded if they had any of the following: sepsis-induced hypotension, separate indication for systemic steroid use, or hypersensitivity to steroids. Primary

outcome was the occurrence of septic shock within 14 days. Secondary outcomes included time to septic shock or death, death in the ICU or hospital, organ dysfunction, ventilator therapy, renal replacement therapy, and secondary infection.

Study results showed no significant difference in the primary outcome between groups, or in any of the secondary outcomes. In a post-hoc analysis, there was more hyperglycemia and less delirium in the study group.

Study limitations are inclusion of patients only after consent, potentially missing early septic shock, and the fact that many analyses were done post-hoc.

**BOTTOM LINE:** Steroids should be avoided in severe sepsis without shock.

**CITATION:** Keh D, Trips E, Marx G, et al. Effect of hydrocortisone on development of shock among patients with severe sepsis. JAMA. 2016;316(17):1775-85.

*Dr. Graves is an assistant professor at the University of Utah School of Medicine and associate program director of quality and patient safety for the University of Utah Internal Medicine residency training program.*

## By Claire Ciarkowski, MD

### 5 Hospital-acquired VTE with high risk of recurrence

**CLINICAL QUESTION:** Is the risk of recurrence for a venous thromboembolism (VTE) acquired as an inpatient higher than other reversible risk factors?

**BACKGROUND:** In patients with acute VTE, transient provoking factors place patients at lower risks for recurrent VTE, while persistent factors (that is, cancer) increase risk for recurrence. Unprovoked VTE places patients at intermediate to high risk, but few data are present for VTE experienced while in the hospital.


Dr. Ciarkowski

**STUDY DESIGN:** Single-center, population-based, prospective cohort study.

**SETTING:** Tromso, Norway.

**SYNOPSIS:** Using repeat health surveys from 1994 to 2012, researchers followed 822 patients with a validated, first-lifetime VTE. Hospital-related VTE was defined as a VTE within 8 weeks of hospitalization related to medical illness, surgery, or in patients with active cancer.

This global definition of hospital-related VTE was not associated with an increased risk of recurrent VTE (hazard ratio, 0.99; 0.69-1.41). However, in separate groups, the cumulative risk of recurrence after 5 years in hospital-related VTE due to medical illness was similar to nonhospital-related VTE (20.1% vs. 18.4%), higher than VTE related to surgery (11%), and lower than VTE related to cancer (27.4%).

Risk-adjusted analyses maintained these differences in recurrence risk dependent on reason for hospitalization (cancer, medical illness, surgery). When compared with nonhospital VTE, however, hospital-related VTE was associated with a threefold higher risk of death.

Study limitations included being from a single center, possibly underpowered due to low number of events.

**BOTTOM LINE:** Hospital-related VTE has a high risk of recurrence, but risk level is variable and dependent on the reason for hospitalization.

**CITATION:** Bjøri E, Arshad N, Johnsen HS, Hansen J-B, Brækkan SK. Hospital-related first venous thromboembolism and risk of recurrence [published online ahead of print, Sept. 2, 2016]. *J Thromb Haemost.* doi: 10.1111/jth.13492.

### 6 Long-term oxygen for COPD with moderate desaturation

**CLINICAL QUESTION:** Does using supplemental oxygen in patients with stable chronic obstructive pulmonary disease (COPD) result in a longer time to death or first hospitalization?

**BACKGROUND:** Previous trials have shown that use of long-term, supplemental oxygen in COPD and severe resting hypoxia reduced mortality, however, data are inconclusive if its use in mild-moderate COPD has the same effect.

**STUDY DESIGN:** Parallel-group, randomized, unblinded clinical trial.

**SETTING:** Outpatient clinical centers.

**SYNOPSIS:** Researchers randomized 738 patients from 42 outpatient centers with stable COPD and moderate resting desaturation ($SpO_2$, 89%-93%) or moderate exercise-induced desaturation (6-minute walk test, $SpO_2$ greater than 80% for five minutes, and greater than 90% for 10 seconds) to long-term supplemental oxygen or no supplemental oxygen. Time-to-event analysis found no differences in the composite primary outcome of death or first hospitalization (HR, 0.94; 95% confidence interval, 0.79-1.12), or in any other secondary outcomes of COPD exacerbations, or COPD-related or all-cause hospitalizations.

Limitations included lack of blinding, possible exclusion of patients with higher COPD severity, and lack of assessment of immediate effects of oxygen on symptoms or exercise performance.

**BOTTOM LINE:** Long-term, supplemental oxygen provided no benefit in mortality or time to first hospitalization among other outcomes in patients with stable COPD and resting or exercise-induced moderate desaturations.

**CITATION:** The Long-Term Oxygen Treatment Trial Research Group. A randomized trial of long-term oxygen for COPD with moderate desaturation. N Engl J Med. 2016;375:1617-27.

*Dr. Ciarkowski is a clinical instructor at the University of Utah School of Medicine and an academic hospitalist at the University of Utah Hospital.*

In elderly patients with non-valvular AF, rivaroxaban was associated with more adverse bleeding events than dabigatran, with no difference in stroke prevention.

## By Heather Balch, MD

### 7 Consensus guidelines for calcium channel blocker poisoning

**CLINICAL QUESTION:** What is the best management approach for adults who are admitted to the hospital with a calcium channel blocker (CCB) overdose?

**BACKGROUND:** There is significant morbidity and mortality from cardiac drug poisoning. Overall, the level of evidence in the literature on the treatment of CCB toxicity is very low. Prior to the current publication there were no guidelines for treating patients admitted to the hospital with a CCB overdose.

**STUDY DESIGN:** Expert workgroup panel convened to develop evidence-based guidelines for the in-hospital management of CCB poisoning.

**SETTING:** Panel members participated in online votes, telephone meetings, and two face-to-face meetings to develop the guidelines.


Dr. Balch

**SYNOPSIS:** In symptomatic CCB poisoning, the following first-line measures are strongly recommended: IV calcium, with norepinephrine or epinephrine in the presence of shock, and high-dose IV insulin (with other first-line treatments) if there is myocardial dysfunction.

Further lower-strength suggestions were made: insulin therapy as monotherapy if cardiac dysfunction present, or in combination with other therapies if there is no cardiac dysfunction; atropine in the setting of symptomatic bradycardia; and dobutamine or epinephrine in the presence of cardiogenic shock.

For refractory CCB, toxicity suggestions included incremental doses of high-dose insulin (if myocardial dysfunction is present, or even if it is not present in peri-arrest situations), IV lipid emulsion therapy, and pacemaker for unstable bradycardia (if there is no evidence of cardiac dysfunction). If the patient is in refractory shock or peri-arrest, the panel suggests the use of venoarterial extracorporeal membrane oxygenation (VA-ECMO).

Limitations included the limited availability of evidence.

**BOTTOM LINE:** Management of CCB toxicity should include IV calcium and high-dose IV insulin, with vasopressors for shock, and other additional therapies for refractory cases.

**CITATION:** St-Onge M, Anseeuw K, Cantrell FL, et al. Experts' consensus recommendations for the management of calcium channel blocker poisoning in adults [published online ahead of print, Oct. 3, 2016]. *Crit Care Med*. doi: 10.1097/CCM.0000000000002087.

### 8 Ventilator use in patients with advanced dementia

**CLINICAL QUESTION:** Does the increasing number of ICU beds in the U.S. affect the use of mechanical ventilation in nursing home patients with advanced dementia?

**BACKGROUND:** Some physicians are concerned that increases in ICU beds in the U.S. will translate to increased treatment of advanced dementia in the ICU, which might not line up with their preferences or improve mortality.

**STUDY DESIGN:** Retrospective cohort study.

**SETTING:** Hospitals that completed the

CONTINUED ON PAGE 18

## SHORT TAKES

### CELLULITIS OFTEN MISDIAGNOSED

This retrospective, cross-sectional study showed that 30.5% of patients admitted with lower-extremity cellulitis were misdiagnosed, leading to unnecessary antibiotic exposure, hospitalizations, and health care spending.

**CITATION:** Weng QY, Raff AB, Cohen JM, et al. Costs and consequences associated with misdiagnosed lower extremity cellulitis (published online ahead of print, November 2016]. *JAMA Dermatol.* doi: 10.1001/jamadermatol.2016.3816.

### ATRIAL FIBRILLATION AND NON-STROKE ADVERSE OUTCOMES

This systematic review and meta-analysis showed that AF is associated with not only mortality and stroke, but also multiple cardiovascular and renal outcomes of significant importance.

**CITATION:** Odutayo A, Wong CX, Hsiao AJ, et al. Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis. BMJ. 2016;354:i4482.

### PATTERNS OF DIETARY SUPPLEMENT USE HAVE CHANGED OVER TIME

Serial cross-sectional survey of 38,000 adults during 1999-2012 demonstrated stable supplement usage, with changes in the type of supplements used (decreased use of multivitamin/multiminerals, increased use of individual supplements).

**CITATION:** Kantor ED, Rehm CD, Du M, White E, Giovannucci EL. Trends in dietary supplement use among US adults from 1999-2012. JAMA. 2016;316(14):1464-74.

American Hospital Association (AHA) annual survey.

**SYNOPSIS:** From 2000 to 2013, there were 635,008 hospitalizations of 380,060 Medicare patients with advanced dementia who had been in a nursing home in the 120 days prior to hospital admission. ICU admissions increased to 38.5% from 16.9% during the same period. The rate of mechanical ventilation per 1,000 hospital admissions increased to 78 from 39, and 1-year mortality for ventilation was unchanged.

For each increase in 10 ICU beds within a hospital, the adjusted odds ratio for receiving mechanical ventilation was 1.06 (95% CI, 1.05-1.07).

Limitations of the study include that only hospitals completing the AHA annual survey were studied, and also, information was lacking on individual patients.

**BOTTOM LINE:** The use of mechanical ventilation increased in hospitalized nursing home patients with advanced dementia, correlating with increased ICU bed capacity, yet with no changes in survival.

**CITATION:** Teno JM, Gozalo P, Khandelwal N, et al. Association of increasing use of mechanical ventilation among nursing home residents with advanced dementia and intensive care unit beds [published online ahead of print, Oct. 10, 2016]. JAMA Int Med. 2016;176(12):1809-16.

*Dr. Balch is a clinical instructor at the University of Utah School of Medicine and an academic hospitalist at the University of Utah Hospital.*

**By Joshua M. Marr, MD, MPH**

## 9 Prevalence of pulmonary embolism among syncope patients

**CLINICAL QUESTION:** What is the prevalence of acute pulmonary emboli (PE) in patients admitted for syncope?

**BACKGROUND:** An acute pulmonary embolism is a differential consideration among patients admitted with syncope. However, current guidelines do not guide evaluation.

**STUDY DESIGN:** Cross-sectional study.

**SETTING:** Two academic and nine non-academic hospitals in Italy.

**SYNOPSIS:** Five hundred-sixty patients admitted with a first episode of syncope were evaluated for a PE. Patients with atrial fibrillation, treatment with anticoagulation, recurrent syncope, or who were pregnant were excluded. The simplified Wells score was used to stratify patients into low and high-risk groups, while low-risk groups received D-dimer testing; 230 patients had a positive D-dimer or a high-risk Wells score and received either CT pulmonary angiography or VQ scans.

Ninety-seven of the 230 patients were found to have a PE (42.2%), leading to a prevalence of 17.3% among the entire cohort. The study did not include the 1,867 patients who were discharged from the ED without admission, potentially leading to bias and overestimating the prevalence of pulmonary emboli (PE).

**BOTTOM LINE:** The prevalence of PE in patients with syncope is higher than previously thought, highlighting the importance of considering acute PE in patients hospitalized with syncope.

**CITATION:** Prandoni P, Lensing AWA, Prins MH, et al. Prevalence of pulmonary embolism among patients hospitalized for syncope. N Engl J Med. 2016;375(16):1524-31.

## 10 Conservative oxygen therapy in critically ill patients

**CLINICAL QUESTION:** Does a conservative oxygenation strategy improve clinical outcomes, compared with standard clinical practice among critically ill patients?

**BACKGROUND:** Supraphysiologic levels of oxygen have been linked to direct cellular injury through generation of reactive oxygen species. Hyperoxia is known to cause airway injury, including diffuse alveolar damage and tracheobronchitis; it also is linked to worse clinical outcomes in various cardiac and surgical patients. ICU patients have not been studied.

**STUDY DESIGN:** Open-label, RCT.

**SETTING:** Single-center, academic hospital in Italy.

**SYNOPSIS:** Investigators randomized 480 adults admitted to the ICU for at least 72 hours to either standard practice (allowing $PaO_2$ up to 150 mmHg, $SpO_2$ 97%-100%) or the conservative protocol ($PaO_2$ 70-100 mmHg or $SpO_2$ 94%-98%). Patients who were pregnant, readmitted, immunosuppressed, neutropenic, with decompensated COPD or acute respiratory distress syndrome were excluded. Outcomes included ICU mortality, hospital mortality, new-onset organ failure, or new infection.

Dr. Marr

Enrollment was slow, the authors noted, partially due to an earthquake that damaged the facility, and the trial was stopped short of the planned 660 patient sample size.

In an intent-to-treat analysis, there was a statistically significant decrease in ICU and hospital mortality, shock, liver failure, and bacteremia among the conservative group.

Limitations included possible confounding from higher illness severity in the standard practice group, as well as the single-center focus that terminated early due to enrollment challenges.

**BOTTOM LINE:** A conservative oxygen strategy had a statistically significant decrease in ICU and hospital mortality, shock, liver failure, and bacteremia.

**CITATION:** Girardis M, Busani S, Damiani E, et al. Effect of conservative vs conventional oxygen therapy on mortality among patients in an intensive care unit. JAMA. 2016;316(15):1583-9.

*Dr. Marr is a clinical instructor at the University of Utah School of Medicine and an academic hospitalist at the University of Utah Hospital.*

Dr. LaBrin

*Joshua LaBrin, MD, FACP, SFHM, an assistant professor at the University of Utah School of Medicine and academic hospitalist at the University of Utah Hospital, co-wrote and edited this month's ITL. He is a member of The Hospitalist's editorial advisory board.*

## SHORT TAKES

### EARLY MOBILIZATION IN SURGICAL PATIENTS IMPROVES OUTCOMES

An international RCT of 200 surgical intensive care unit (SICU) patients demonstrated that early, interprofessional mobilization significantly improved patient mobility in the SICU and at hospital discharge, with decreased SICU length of stay.

**CITATION:** Schaller SJ, Anstey M, Blobner M, et al. Early, goal-directed mobilization in the surgical intensive care unit: a randomized controlled trial. Lancet. 2016;388:1377-88.

### PREVENTING PHYSICIAN BURNOUT

Meta-analysis of 52 randomized and cohort studies of physician burnout found that both individual-focused and structural/organizational interventions were able to improve physician burnout, depersonalization, and high emotional exhaustion.

**CITATION:** West CP, Dyrbye LN, Erwin PJ, Shanafelt TD. Interventions to prevent and reduce physician burnout: a systematic review and meta-analysis. Lancet. 2016;388(10057):2272-81.



## ADDITIONAL REVIEWS AT THE-HOSPITALIST.ORG

For more physician review of HM-relevant research, visit the-hospitalist.org.

KEY CLINICAL QUESTION

# How should urine electrolytes be ordered and interpreted in acute kidney injury and electrolyte abnormalities?

By Sri Lekha Tummalapalli, MD, MBA, Mona Krouss, MD, Celine Goetz, MD

## KEY POINTS

- In acute kidney injury, the FENa and FEUrea may be calculated to distinguish prerenal azotemia from ATN; however, FENa and FEUrea may be low in a wide variety of conditions other than prerenal azotemia.
- Urine sodium and osmolality values are helpful in diagnosing the cause of hyponatremia, but have a number of limitations in nonoliguric patients and those with CKD.
- An elevated transtubular potassium gradient (TTKG) may indicate renal loss of potassium in patients with hypokalemia.
- A positive urine anion gap (UAG) in the setting of a normal anion gap metabolic acidosis points to renal causes of the metabolic acidosis, whereas a negative UAG points to extrarenal causes such as bicarbonate losses in the GI tract.

## The case

**A 50-YEAR-OLD WOMAN** naive to the health care system presents to the ED with nausea, malaise, and decreased exercise tolerance for several weeks. Physical exam reveals mild bilateral lower extremity edema. Her labs are notable for an elevated creatinine of 7.0. She is admitted for work-up of her renal disease.

Nephrology was consulted and recommended obtaining urine electrolytes. The admitting hospitalist is unsure which urine electrolytes are appropriate to order, and in turn orders all of the urine electrolytes in the order set.

Which urine electrolytes should be ordered in various clinical contexts?

### Introduction

Hospitalists have been on the forefront of efforts to tailor testing and resource utilization to eliminate wasteful practices in health care. To order and interpret diagnostic tests appropriately, a hospitalist needs to have a thorough understanding of the diagnostic utility of laboratory tests. There is a lack of clear diagnostic guidelines, so ordering all the urine electrolytes in a "blanket" strategy is a common practice. We will discuss the diagnostic utility of each of the urine electrolytes in a variety of clinical scenarios.

### Acute kidney injury

Both the fractional excretion of sodium (FENa) and the fractional excretion of urea (FEUrea) have long been used as part of the standard work-up for determining if acute kidney injury (AKI) is due to prerenal causes. Although these markers prove to be beneficial in the work-up of AKI, both the FENa and FEUrea have several limitations.

***FENa*** measures the ratio of sodium excreted in the urine, compared with how much is filtered through the kidney. A FENa of less than 1% in oliguric patients may indicate prerenal azotemia, as an increased reabsorption of sodium is the appropriate response of functioning nephrons to decreased renal perfusion. Values greater than 3% may be consistent with acute tubular necrosis (ATN) due to inappropriate sodium excretion in the setting of tubular damage.

Importantly, a FENa value of less than 1% occurs in a number of conditions other than prerenal azotemia due to dehydration, including hypervolemic prerenal states such as cirrhosis or heart failure, AKI due to radiocontrast or heme pigments, acute glomerulonephritis, transition from prerenal to postischemic ATN or sepsis, and in acute interstitial nephritis (AIN).[1,2] Approximately 10% of patients with nonoliguric ATN have a FENa less than 1.0%. Moreover, use of diuretics can falsely elevate the FENa due to inhibition of sodium reabsorption. FENa values above 3% can occur in volume contraction in patients with chronic kidney disease (CKD) or in elderly patients as their sodium reabsorption is impaired.[3] Acute volume loss (e.g. blood loss) or, more commonly, administration of diuretics or intravenous fluids, can also alter the interpretation of the FENa.[2]

When is the FENa reliable? FENa measurements were first validated and studied in patients with a marked reduction in glomerular filtration rate (GFR) and oliguria.[2] Subsequent studies have shown that, when patients are oliguric, the FENa is more accurate.[3] The FENa is best utilized when urine sodium and creatinine are collected at the same time as the serum values, because serum creatinine levels tend to fluctuate with time and are not often accurate markers of GFR.[3]

***FEUrea*** is used primarily for diagnostic evaluation in patients who have an AKI with recent use of diuretics. Because urea is absorbed and excreted in the proximal tubule, the value will theoretically not be altered by the use of diuretics. The FEUrea will be less than 35% in prerenal azotemia and greater than 50% in ATN. The current evidence suggests that the FEUrea is most reliable in diagnosing prerenal azotemia in patients who have used diuretics when the FENa is high but the FEUrea is low.[2]

Many of the limitations of the FENa also apply to the FEUrea, including interpretation in the elderly and use in acute volume changes. However, the FEUrea has unique limitations, particularly in patients with sepsis, as cytokines released in sepsis may interfere with urea transporters in the kidney and colon.[2] Its interpretation also relies on intact functioning of the proximal tubule, which can be altered in many conditions, including uncontrolled diabetes. Overall, the FENa and FEUrea can be helpful to determine the etiology of AKI, but only in certain clinical scenarios.

### Hyponatremia

Hyponatremia is the most common electrolyte abnormality in hospitalized patients, with a prevalence of up to 30% in critically ill patients.[4] It often is acquired during the hospitalization itself. A detailed history and physical exam, including careful assessment of volume status, is as important as laboratory values in establishing the cause of hyponatremia.

Urine sodium and urine osmolality are measured to understand whether the renin-aldosterone-angiotensin system (RAAS) and antidiuretic hormone (ADH) are activated. If renal blood flow or renal delivery of sodium is decreased, renin secretion from the juxtaglomerular apparatus will be activated, ultimately leading to increased reabsorption of sodium in the distal tubules and collecting ducts. Thus, low urine sodium signals that the RAAS is activated due to decreased serum sodium concentration or decreased renal blood flow from hypovolemia or low effective arterial circulation from cirrhosis or heart failure.

Most causes of hyponatremia will have low urine sodium values, including hypovolemia, cirrhosis, heart failure, "tea-and-toast" diet, beer potomania, and primary polydipsia. However, the urine sodium may be unreliable in patients who are not oliguric or who have CKD.

Diuretic-induced hyponatremia from thiazide or loop diuretics will likely have elevated urine sodium levels. Similarly, the syndrome of inappropriate antidiuretic hormone secretion (SIADH) will have an elevated urine sodium above 20-40 mEq/L.

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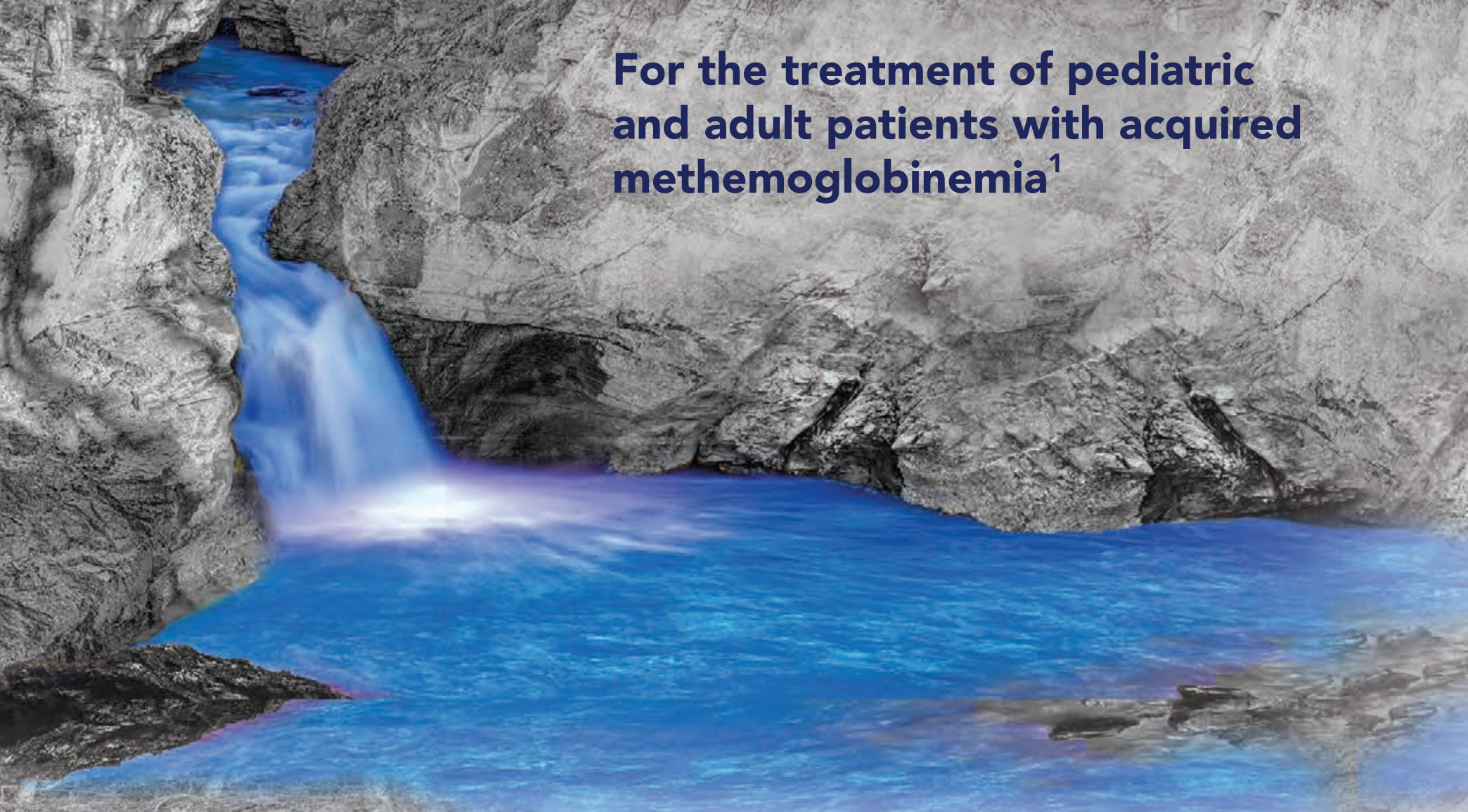

# For the treatment of pediatric and adult patients with acquired methemoglobinemia[1]

## 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 (≥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 injection[2]

**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 ProvayBlue™ (methylene blue) injection, 0.5% consider alternate treatments
- ProvayBlue™ is approved for intravenous (IV) administration only

**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.**

| 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 | |

ProvayBlue™
(methylene blue) injection, 0.5%

## New Concentration

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

### DRUG INTERACTIONS

Avoid concomitant use of ProvayBlue™ 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 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.

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**

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. 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 ProvayBlue™.

**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 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

In case of overdose of ProvayBlue™, 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.provayblue.com.**

REFERENCES: **1.** ProvayBlue™ [Package Insert]. PROVEPHARM SAS Marseille, France. **2.** US Food and Drug Administration, Center for Drug Evaluation and Research. ProvayBlue™ 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, pimozide, 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 1mg/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/m$^2$) in rats is approximately 32 times a clinical dose of 1mg/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/m$^2$) 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 breast-feeding 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*

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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 ProvayBlue™ (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 ProvayBlue™ was assessed on the basis of a methemoglobin decrease of at least 50% within 1 hour after intravenous administration of 1 – 2 mg/kg ProvayBlue™ (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 41cases 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 ProvayBlue™ (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 ProvayBlue™: 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 ProvayBlue™ during pregnancy.

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

**Driving and Using Machines**
Advise patients to avoid driving and use of machines during treatment with ProvayBlue™. 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 ProvayBlue™ may cause a blue discoloration of the skin and body fluids.



**TABLE 1: Urine studies to order and interpret in four common clinical scenarios**

| Clinical Scenario: | Order: | Calculate: | Interpretation: |
|---|---|---|---|
| Acute Kidney Injury | Urine Sodium OR Urine Urea<br>Urine Creatinine<br>Serum Sodium OR Serum Urea<br>Serum Creatinine | FENa: $\frac{Na_{urine} \times Cr_{serum}}{Na_{serum} \times Cr_{urine}}$ OR<br>FEUrea: $\frac{Urea_{urine} \times Cr_{serum}}{Urea_{serum} \times Cr_{urine}}$ | If FENa <1%, consider pre-renal and other causes<br>If FEUrea <35%, consider pre-renal and other causes |
| Hyponatremia | Urine Sodium<br>Urine Osmolality<br>Serum Osmolality | Assess RAAS and ADH action | If $Na_{urine}$ is low, RAAS is likely activated<br>If $Osm_{urine}$ is high, ADH is activated |
| Hypokalemia | Urine Potassium<br>Urine Osmolality<br>Serum Potassium<br>Serum Osmolality | TTKG: $\frac{K_{urine} \times Osm_{serum}}{K_{serum} \times Osm_{urine}}$ | If TTKG is high, consider renal potassium losses |
| Normal anion gap metabolic acidosis | Urine Sodium<br>Urine Potassium<br>Urine Chloride | UAG: $Na_{urine} + K_{urine} - Cl_{urine}$ | If UAG is positive, consider renal causes of acidosis<br>If UAG is negative, consider GI causes of acidosis |

Urine osmolality becomes elevated when ADH is secreted in response to reduced plasma volume or increased plasma osmolality. Urine osmolality is low in cases such as primary polydipsia, which creates a maximally dilute urine of 40-100 mEq/L, and in tea-and-toast diets or beer potomania due to low solute intake. Urine osmolality can be elevated in hypovolemic states as well as SIADH, and is variable in hypothyroidism and selective serotonin reuptake inhibitor administration. Thus, urine sodium, and not urine osmolality, is the most useful differentiator between SIADH and hypovolemic states.

In a study of 555 patients with hyponatremia secondary to SIADH, mean urine sodium was found to be 72 (range, 30-251) and the median urine osmolality was 379 (range, 123-1019).[5]

In cases of marked hyperglycemia, serum osmolality should be measured to evaluate hyperglycemia as a cause of hyperosmolar hyponatremia. Pseudohyponatremia in the setting of hyperlipidemia, hypertriglyceridemia, or hyperparaproteinemia represents a laboratory artifact due to lower plasma water concentration in the specimen sample and should be excluded.

## Hypokalemia

About 20% of patients are hypokalemic during an inpatient hospitalization. There is a broad differential for hypokalemia, including medical, nutritional, and medication-related causes. Exogenous insulin administration or endogenous production in cases of refeeding syndrome drives potassium intracellularly via the N+/K+ ATPase. Increased sympathetic activity from alcohol withdrawal, acute myocardial infarction, head injury, or thyroid imbalance, as well as iatrogenic causes such as albuterol administration, also drive potassium intracellularly. Diarrhea and nasogastric tube suction lead to gastrointestinal (GI) potassium losses, while antibiotics, chemotherapeutic agents, and diuretics can cause hypokalemia through renal potassium wasting. Hyperaldosteronism and renal tubular acidosis are less common causes.[6]

The history, review of medications, physical exam, and initial basic laboratory testing (electrolytes, BUN, creatinine, magnesium) should assess for pseudohypokalemia, poor oral intake, diuretic use, acid-base disturbances, or GI losses.

Measuring urine potassium is useful in the work-up of the hypokalemic patient when these conditions are not evident. Urine potassium – either 24-hour or spot urine potassium-to-creatinine ratio – can help determine if urinary potassium wasting is a factor. Potassium is excreted at a near constant rate throughout the day. A urine potassium-to-creatinine ratio corrects for variations in urine volume. When this ratio is greater than 13 mEq/g, renal potassium losses should be suspected. If the ratio is less than 13 mEq/g, hypokalemia is likely due to transcellular potassium shifts, GI losses, diuretics, or poor intake.

The transtubular potassium gradient (TTKG) can also be calculated using the serum and urine potassium and urine osmolality, and reflects the amount of potassium excreted in the tubule (see Table 1). The TTKG should decrease in hypokalemia when urinary potassium excretion is appropriately suppressed. A TTKG greater than 4 is inappropriately high and indicates renal potassium wasting, whereas a TTKG less than 3 suggests extrarenal causes such as cellular shifts.

## Hyperkalemia

Several concepts in hypokalemia are relevant to hyperkalemia. Redistribution of potassium into the extracellular fluid can cause hyperkalemia when the body tries to counterbalance low extracellular pH by potassium-hydrogen exchange. Medications may cause an extracellular shift of potassium (e.g. digoxin) or induce diminished potassium excretion (e.g. NSAIDs, spironolactone, ACE/ARBs).

CKD and end-stage kidney disease are common causes of hyperkalemia in the hospitalized patient – as functioning nephrons decrease, poor Na-K exchange ensues. Hypoaldosteronism and type 4 renal tubular acidosis are also on the differential diagnosis. Pseudohyperkalemia secondary to thrombocytosis, erythrocytosis, or activated platelets should be considered and evaluated.

Appropriate renal excretion of potassium is mediated by the connecting segment between the distal tubule and the collecting duct, and the cortical collecting duct itself. There are four major causes of hyperkalemia due to reduced urinary potassium secretion: reduced aldosterone secretion, reduced response to aldosterone, reduced distal sodium and water delivery (often related to low effective arterial blood volume), and kidney injury.[6]

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Measurement of 24-hour urinary potassium excretion is of limited utility in patients with persistent stable hyperkalemia because urinary potassium excretion is related to potassium intake. The TTKG was previously used to assess the degree of aldosterone activity by estimating the potassium concentration in the cortical collecting tubule. However, some assumptions upon which this calculation was based have been considered invalid by the original studies' authors, and the TTKG to evaluate potassium abnormalities is no longer uniformly recommended.[7,8] Ultimately, if patients have persistent hyperkalemia, work-up for hypoaldosteronism should be considered.

## Normal anion gap metabolic acidosis

The urine anion gap (UAG) is used to determine the cause of normal anion gap hyperchloremic metabolic acidosis by indirectly measuring urinary excretion of ammonium. To maintain a normal acid/base balance, hydrogen ions are excreted in the urine with simultaneous reabsorption of bicarbonate. Hydrogen ions are bound to ammonia (NH3) to form ammonium (NH4+), which is excreted as NH4Cl in the urine.

The UAG is calculated by adding urine sodium and urine potassium and subtracting urine chloride (see Table 1). In a patient without an acid/base disturbance, the UAG is positive because more Na and K is absorbed in the gastrointestinal system compared to Cl, and thus more Na and K is excreted in the urine. In a normal anion gap metabolic acidosis through an acid load or bicarbonate loss, the normal response of the kidney is to excrete more hydrogen ions, resulting in more chloride excretion as NH4Cl. This leads to a negative urine anion gap, as Cl excretion outweighs Na and K excretion. When NH4+ excretion is impaired, such as in distal renal tubular acidosis (RTA), the urine anion gap will remain positive despite the metabolic acidosis. Thus, a positive UAG points to renal causes of the normal anion gap metabolic acidosis, whereas a negative UAG points to extrarenal causes such as bicarbonate losses in the GI tract.[9]

## Additional considerations

Urine studies can also be useful for assessment of proteinuria and albuminuria in a patient with CKD or diabetes, diagnosis of plasma cell dyscrasias, the diagnosis and prevention of nephrolithiasis, and a wide variety of other conditions.

## Back to the case

Our patient was admitted with an elevated creatinine of unclear chronicity, and subacute symptoms of uremia. Because she was oliguric, urine and serum sodium and creatinine were measured before intravenous fluids were administered. Her FENa was 2%, which was not consistent with prerenal azotemia or ATN. She was found to have CKD secondary to previously undiagnosed diabetes. Upon further questioning, she had been taking high-dose NSAIDs for her chronic knee pain. Her renal function improved mildly by withholding NSAIDs, and she was discharged with appropriate nephrology follow-up.

## Bottom line

Urine electrolytes have specific indications and utilities for different clinical scenarios, and should be ordered in a targeted manner that can aide in diagnosing AKI, hyponatremia, hypokalemia, and normal anion gap metabolic acidosis. TH

*Dr. Tummalapalli, Dr. Krouss, and Dr. Goetz are hospitalists in the department of medicine at the Icahn School of Medicine at Mount Sinai in New York City.*

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QUALITY IMPROVEMENT

# Do 30-day readmissions mean anything?

Hospitalists have been paying close attention to 30-day readmission figures since public reporting and payment programs embraced that number as an indicator of the quality of hospital care. But there is limited evidence to demonstrate 30-day readmission is really a meaningful interval of time, according to a recent study, "Rethinking Thirty-Day Hospital Readmissions: Shorter Intervals Might Be Better Indicators of Quality of Care."

"I began to dig through the literature to find some sort of evidence to support this figure – I couldn't find anything. In talking with quality experts, they all, more or less, believe that things that happen outside of 7 or 10 days are really out of the control of the clinician," says lead author David L. Chin, PhD, of the Center for Healthcare Policy and Research at the University of California, Davis.

Dr. Chin and his team examined the 30-day risk of unplanned inpatient readmission at the hospital level for Medicare patients aged 65 and older in four states and for three conditions: acute myocardial infarction, heart failure, and pneumonia. Across states and diagnoses, the hospital-level quality signal captured in readmission risk was highest on the first day after discharge, and it declined quickly to its lowest level at day 7.

"The rapid decay in the quality signal suggests that most readmissions after the 7th-day postdischarge were explained by community- and household-level factors beyond hospitals' control," the authors concluded.

Dr. Chin said the study results show the 30-day measure is "a blunt instrument."

"It isn't really measuring anything that we're supposed to be measuring," he explains. "Essentially, 97% of the reasons a person comes back to the hospital is due to some other, non-hospital thing."

He does not advocate for 7 days as the new standard, however.

"This is more intended to be a message that this is really not the right way of approaching [readmissions] to begin with," he says. "I think we convincingly showed that it shouldn't be 30 days, but we don't really have a very good picture of what is driving readmission. Hospitals are getting dinged on these things that have happened that, really, they don't have direct influence on."

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PRACTICE MANAGEMENT

# *There's an app for … end-of-life communications*

Hospitalists wanting to help patients navigate end-of-life decisions or assist bereaved families in dealing with the death of a loved one have some new tools, according to the New York Times article, "Start-Ups for the End of Life."

End-of-life preferences are a challenge to decide and communicate, so a start-up called Cake helps users do both by taking them through questions about everything from life support options to the handling of social media accounts. Customers' answers populate their Cake profile, where they can add additional messages for family members or friends. The platform stores the profile in the cloud and shares it with those customers have designated.

A start-up called Grace is intended to help its users deal with the myriad issues family members face after a death; it connects users with estate lawyers, financial planners, funeral homes, and caterers. Grace customers receive a list of tasks to complete before and after a death, and it includes relevant paperwork. The app also has staff ready to assist customers.

Currently, there's little guidance available in this area, Alex Kruger, Grace's cofounder and chief executive, and a licensed funeral director, told the New York Times: "At Grace we say, 'Here are the 17 things you need to do this week' and you can check them off as you do them. Here's what you do the week before someone dies, when they die, and then 2 weeks later."

Another start-up mentioned in the article that could be relevant to hospitalists and their patients is called Parting. It provides an online directory of funeral homes searchable by ZIP code so users can quickly compare prices, services, and locations.


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QUICK BYTE

# CLEANING ROBOTIC SURGICAL INSTRUMENTS

Robotic surgical instruments can retain some contamination even after cleaning, a new study suggests. Over 21 months, the researchers assessed protein residue on robotic and standard surgical instruments that were cleaned according to manufacturers' instructions. The cleanings were 99.1% effective on the standard instruments but 97.6% effective on the robotic instruments, suggesting complete eradication of surface contaminants from robotic surgical instruments may not be possible with the current cleaning procedures.

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*Ms. Bopp is a freelance writer in New Jersey.*

QUALITY IMPROVEMENT

## Overuse as medical error

Hospitalists may recognize a culture of overuse at their hospitals, but how can they address it? That's the question behind an HM16 abstract, "Occam's Conference: Overuse as a Medical Error."

"We wanted to change the culture of overuse here among the hospitalists and the house staff," said lead author Hyung Cho, MD, director of quality and patient safety at the Icahn School of Medicine at Mount Sinai in New York. "We wanted to frame it in a way that people can recognize and feel free to talk about and also give it the weight that it deserves. It's a common thing that we all do: the chest x-ray or the EKG before a surgery, things like that."

Seeing overuse as a medical error is a place to start.

"A framework in which overuse is considered a medical error would facilitate understanding of the drivers of overuse and systems factors that lead to it," the authors wrote.

Dr. Cho and colleagues chose a monthly inpatient conference format, with all the relevant players gathered together.

"We also wanted to use the formula that Brandon Combs had with the 'Do No Harm' project, which is taking cases of overuse that actually lead to harm or a near miss. I think people respond to that as opposed to just talking about the cost, which people have a hard time actually figuring out," Dr. Cho said.

The resulting Occam's Conference provides a process to identify and discuss overuse as a medical error. It uses a fish-bone diagram to help analyze each case.

"That conversation needs to happen," Dr. Cho said. "You realize that people are all on the same page, and if they're not, they need to get on the same page and have an open dialogue."

### Reference

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# Hot-button issue: Physician burnout

CONTINUED FROM PAGE 1

Burnout is a hot topic among hospitalists and all of health care these days, as the increasing burdens of a system in seemingly constant change have fostered pressures inside and out of hospitals. Increasingly, researchers are studying and publishing about how to recognize burnout, ways to deal with, or even proactively address the issues. Some MDs – experts in physician burnout – make a living by touring the country and talking about the issue.

But what causes burnout, specifically and exactly?

"The simplistic answer is that burnout is what happens when resources do not meet demand," said Colin West, MD, PhD, FACP, of the departments of internal medicine and health sciences research at the Mayo Clinic in Rochester, Minn., and a leading researcher on the topic of burnout. "The more complicated answer, which, at this point, is fairly solidly evidence based actually, is that there are five broad categories of drivers of physician distress and burnout."

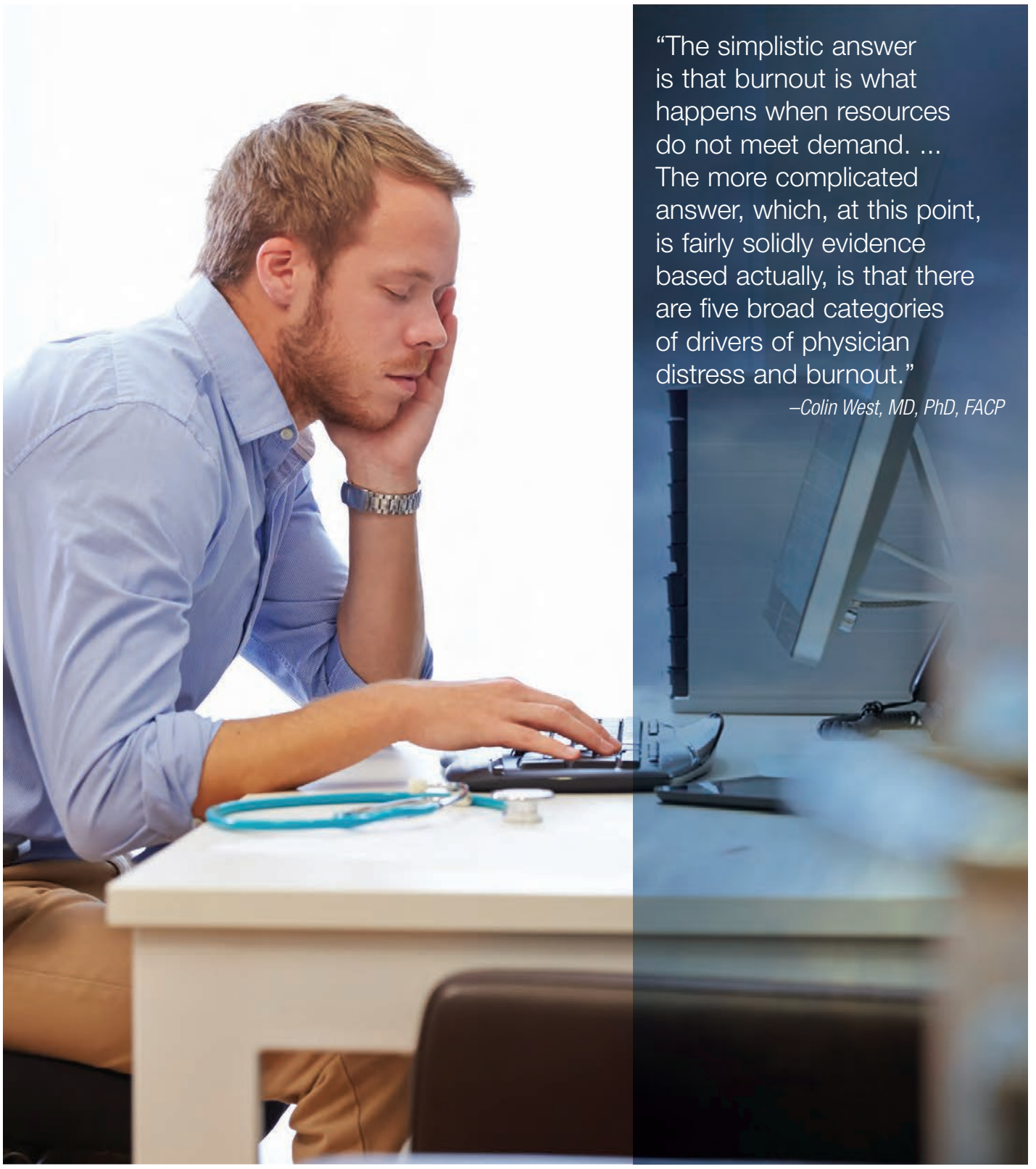
Dr. West's hierarchy of stressors encompasses:

- Work effort.
- Work efficiency.
- Work-home interference.
- A sense of meaning.
- "Flexibility, control, and autonomy."

Basically, the five drivers lead to this: Physicians who work too much and too inefficiently, with too little control and sense of purpose, end up flaming out more so than do doctors who work fewer hours, with fewer obstacles – all the while feeling satisfied with their autonomy and value.

Academic hospitalist John Yoon, MD, of the department of medicine at the University of Chicago, says that health care has to work harder to promote its benefits as being more important than a highly paid profession. Instead, health care should focus on giving meaning to its practitioners.

"I think it is time for leaders of HM groups to honestly discuss the intrinsic meaning and essential 'calling' of what it means to be a good hospitalist," Dr. Yoon wrote in an email interview with *The Hospitalist*. "What can we do to make the hospitalist vocation a meaningful, long-term career, so that they do not feel like simply revenue-generating 'pawns' in a medical-bureaucratic system?"




## A 'meaningful' career

The modern discussion of burnout as a phenomenon traces back to the Maslach Burnout Inventory, a three-pronged test that measures emotional exhaustion, depersonalization, and personal accomplishment.[1] But why does burnout hit physicians – hospitalists, in particular – so intensely? In part, it's because – like their predecessors in emergency medicine – hospitalists are responsible for managing the care of patients other specialties consult with, operate on, or for whom they run tests.

"Once the patients come up from the emergency [department] or get admitted to the hospital from the outside, the hospitalist is the one who is largely running that show," said Dr. West, whose research shows that HM doctors suffer burnout more than the average across medical specialties.[2] "So they're the front line of inpatient medicine."

Another factor contributing to burnout's impact on hospitalists is that the specialty's rank and file (by definition) work within the walls of institutions that have a lot of contentious and complicated issues that – while outside the purview of HM – can directly or indirectly affect the field. Dr. West calls it the hassle factor.

"You want to get a test in the hospital and, even though you're the attending on the service, you end up going through three layers of bureaucracy with an insurance company to be able to finally get what you know that patient needs," he said. "Anything like that contributes to the burnout problem because it pulls the physician away from what they want to be doing, what is purposeful, what is meaningful for them."

For Dr. Yoon, the exhaustion and cynicism borne out by the work of Maslach and Dr. West's team are measures indicative of a field in which physicians struggle more and more to "make sense of why their practice is worthwhile.

"In the contemporary medical literature, we have been encouraged to adopt the concepts and practices of industrial engineering and quality improvement," Dr. West added. "In other words, it seems that to the extent physicians' aspirations to practice good medicine are confined to the narrow and unimaginative constraints of mere scientific technique (more data, higher 'quality,' better outcomes) physicians will struggle to recognize and respond to their practice as meaningful. There is no intrinsic meaning to simply being a 'cog' in a medical-industrial process or an 'independent variable' in an economic equation."

Finding meaning in one's job, of course, is less empirical an endpoint than using a reversal agent for a GI bleed. Therein lies the challenge of battling burnout, whose causes and interventions can be as varied as the people who suffer the syndrome.

"You have to first make sure you understand the relevance of burnout in your group and in your practice," said Jerome Siy, MD, SFHM, CHIE, head of the department of hospital medicine at HealthPartners in

"You have to first make sure you understand the relevance of burnout in your group and in your practice. Because just like every group has a different culture and every group has a different work model, you need to identify what is it in your group that is going on … when you do that, you can then really distill out, what are the issues going on for your group?"

—*Jerome Siy, MD, SFHM, CHIE*

Minneapolis–St. Paul, Minn. "Because just like every group has a different culture and every group has a different work model, you need to identify what is it in your group that is going on … when you do that, you can then really distill out, what are the issues going on for your group?"

## Local, customized solutions

Once a group leader identifies the symptoms of burnout, the obvious question is how to address it.

Dr. West and his colleagues have identified two broad categories of interventions: individual-focused approaches and organizational solutions. Physician-centered efforts include such tacks as mindfulness, stress reduction, resilience training, and small-group communication. Institutional-level changes are, typically, much harder to implement and make successful.

"It doesn't make sense to ... simply send physicians to stress-management training so that they're better equipped to deal with a system that is not working to improve itself," Dr. West said. "The system and the leadership in that system needs to take responsibility from an organizational standpoint."

Health care as a whole has worked to address the systems-level issue. Duty-hour regulations have been reined in for trainees to be proactive in addressing both fatigue and its inevitable endpoint: burnout.

In a report, "Controlled Interventions to Reduce Burnout in Physicians: A Systematic Review and Meta-Analysis,"[3] published online Dec. 5 in *JAMA Internal Medicine*, researchers concluded that interventions associated with small benefits "may be boosted by adoption of organization-directed approaches.

"This finding provides support for the view that burnout is a problem of the whole health care organization, rather than individuals," they wrote.

But the issue typically remains a local one, as group leaders need to realize that what could cause or contribute to burnout in one employee might be enjoyable to another.

Several year ago, Dr. Roberts was tasked at his hospital, the Mayo Clinic in Phoenix, with getting more involved in a transition from one electronic health records (EHR) program to another. In fact, "roped" into the project is the terminology he uses in hindsight.

"The prospect of doing that was daunting," Dr. Roberts recalled. "I didn't know much about EHRs and it was going to be a lot of meetings ... and [it] was going to take me away from patient care. It really ended up being rewarding, despite all the time and frustration, because I got to help represent the interests of my hospitalist colleagues, the physician assistants, and nurses that I work with in trying to avoid some real problems that could have arisen in the EHR."

Doing that work appealed to Dr. Roberts, so he embraced it. That approach is one championed by Thom Mayer, MD, FACEP, FAAP, executive vice president of EmCare, founder and CEO of BestPractices, medical director for the NFL Players Association, and clinical professor of emergency medicine at George Washington University, Washington, and University of Virginia, Charlottesville. Dr. Mayer travels the country talking about burnout and suggests a three-pronged approach.

First, find what you like about your job and maximize those duties.

Second, label those tasks that are tolerable and don't allow them to become issues leading to burnout.

Third, and perhaps most difficult, "take the things [you] hate and eliminate them to

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Now, the practicing hospitalist at Mayo Clinic in Phoenix sees trainees coming out of residency thinking that the shift work aspect of HM will protect them from burnout. Forget worrying about it, some of them say. As with most things related to the scourge of physician burnout, the reality is more nuanced. Burnout is neither inevitable nor preventable nor untreatable.

—*Daniel Roberts, MD, FHM*

CONTINUED FROM PAGE 27

the best extent possible from [your] job."

"I'll give you an example," he said. "What I hear from emergency physicians and hospitalists is: 'What do I hate? Well, I hate chronic pain patients.' Well, does that mean you're going to be able to eliminate the fact that there are chronic pain patients? No. But, what you can do is ... really drill down on it, and say 'Why do you hate that?' The answer is, "Well, I don't have a strategy for it." No one likes doing things when they don't know what they're doing.

"Now you take the chronic pain patient and the problem is, most of us just haven't really thought that out. Most of us haven't sat down with our colleagues and said, 'What are you doing that's working? How are you handling these people? What are the scripts that I can use, the evidence-based language that I can use? What alternatives can I give them?' Instead of just assuming that the only answer to the problem of chronic pain is opioids."

### The silent epidemic

So if there are measurements for burnout, and even best practices on how to address it, why is the issue one that Dr. Mayer calls a silent epidemic? One word: stigma.

"We as physicians can't afford to propagate that stigma any further," Dr. Roberts said. "People who have even tougher jobs than we have, involving combat and hostage negotiation and things like that, have found a way to have honest conversations about the impact of their work on their lives. There is no reason physicians shouldn't be able to slowly change the culture of medicine to be able to do that, so that there isn't a stigma around saying, 'I need some time away before this begins to impact the safety of our patients.' "

Dr. West said that when data show that as many as half of all physicians show symptoms of burnout, there is no need to stigmatize a group that large.

Dike Drummond, MD, a family physician, coach, and consultant on burnout prevention, said that the No. 1 mistake physicians and leaders make about burnout is labeling it a "problem."

"Burnout does not have a single solution because it is not a problem to begin with," he added. "Burnout is a classic dilemma – a never-ending balancing act. Think of the balancing act of burnout as a teeter-totter, like the one you see in a children's playground. On one side is the energy you put into your practice and larger life … and on the other side your ability to recharge your energy levels.

"To prevent burnout you must keep your energy expenditure and your recharge activities in balance to keep this teeter-totter in a relatively horizontal position. And the way you address the dilemma is with a strategy: three to five individual tools you use to lower your stress levels or recharge your energy balance."

And a strategy is a long-term approach to a long-term problem, he said.

"Burnout is not necessarily a terminal condition," Dr. Roberts said. "If we can structure their work and the balance in their life in such a way that they don't experience it, or that when they do experience it, they can recognize it and make the changes they need to avoid it getting worse, I think we'd be better off as a profession."

*Mr. Quinn is a freelance writer in New Jersey.*

## Physician burnout causes


*Based on scale 1-7, with 1 responses equal to "does not contribute at all" and 7 equal to "significantly contributes."

Source: Medscape Lifestyle Report 2016: Bias and Burnout; published Jan 13, 2016

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# Don't assume work is sole burnout determinant

By Richard Quinn

Physician burnout is almost always linked to issues at work. Blame is placed on added duties piled onto a to-do list that barely makes enough time for prolonged patient interaction in the first place. Fault is laid upon the hours and hours per week – or even per day – wasted on cumbersome data entry into bulky electronic health record (EHR) systems.

But Dike Drummond, MD, a family physician and burnout coach/consultant, says burnout should not be viewed as job specific.

"To say that burnout is always about work is absolutely an error," said Dr. Drummond, whose website is www.thehappymd.com. "You can have people flame out spectacularly at work and nothing has changed about work at all. It's because something's going on at home that's made it impossible to recharge on their time off. And, that list of recharge-blocking issues is huge."

Money problems, marital problems, family problems: Dr. Drummond says any and all of those issues can eliminate the doctor's ability to recharge at home.

"The strain of your practice continues, but now without the ability to balance your energy with some recovery when you're away from the hospital, burnout can come on very rapidly," he said. "So when you see a colleague flaming out at work, one of the questions you must ask is, "How is it going at home?" You may be the first to learn their spouse left them 2 weeks ago."

Dr. Drummond's advice is: Don't always blame the stresses of work. Build your recharge strategy (rest, hobbies, date nights) and make sure you maintain your recharge capabilities.

"Ideally, with a hospitalist-type schedule, when you're on you're on and when you're off you're off," he said. "It should be easier to create that boundary for hospitalists than other specialists who chart from home or are on call.

"The off switch on your doctor programming is called a boundary ritual. Pick some activity you do on the way home from work, saying to yourself, 'With this action, I am coming all the way home.' It can be as simple as a deep releasing breath as you step out of your car at home. Make sure you take that breath and let it all go before you walk into the house after each shift."

Colin West, MD, PhD, FACP, of the departments of internal medicine and health sciences research at the Mayo Clinic in Rochester, Minn., and a leading researcher on the topic of burnout, refers to this phenomenon as "work-home interference." On the bright side for hospitalists, he says, is that aspects of HM work schedules may help mitigate burnout; some work can be left at the hospital when shifts end, rather than following physicians into their home lives.

But Dr. West acknowledged that the rigors of the traditional 7-on/7-off schedule come with their own unique burnout challenges for hospitalists as well.

"A hospitalist can say 'Well, jeez, I'm on nights for the next week, and that means during the day I'm sleeping and recovering,'" Dr. West explained. "Well, how do you maintain a family life for that period of time when you're basically off-cycle with your family? There are those kinds of stressors. It's a mixed bag for hospitalists there."

*Mr. Quinn is a freelance writer in New Jersey.*

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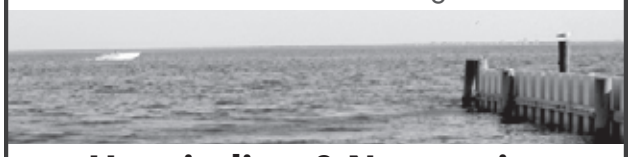

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# Burnout: No laughing matter

## Organizational, individual efforts are needed to combat this serious – and growing – condition.

*Dr. Scheurer is a hospitalist and chief quality officer at the Medical University of South Carolina in Charleston. She is physician editor of* The Hospitalist. *Email her at scheured@musc.edu.*

Much has been written about burnout in U.S. physicians over the course of many years. Burnout is a syndrome that is exemplified by emotional exhaustion, depersonalization, and a low sense of personal accomplishment. It appears that hospitalists are particularly prone to burnout, being at the very front line of patient care. In addition, the prevalence of burnout appears to be getting worse. According to a survey from the American Medical Association, the prevalence of burnout in 2011 was 45%. Three years later in 2014 the prevalence was up to 55%.[1,2]

Although triggers for the onset and intensity of burnout likely vary by specialty, a recent Medscape Lifestyle Report found the most common causes of burnout among physicians included:[3]

- Bureaucratic tasks.
- Work hours.
- Computerization.
- Compensation.

And there is convincing evidence that burnout is detrimental not only to the individual experiencing it but also to those who have to work with the individual, the patients and families being cared for by them, and the system as a whole. In physicians, burnout has been linked to:

- Lower work satisfaction.
- Disrupted personal relationships.
- Substance misuse.
- Depression.
- Suicide.

Burnout also leads to lower productivity, higher job turnover, and early retirement. In addition, from a systems perspective, burnout is associated with higher medical errors, reduced quality of patient care, and lower patient satisfaction. And, at its most extreme, burnout is deadly: Sadly, every year, 300-400 physicians in the United States commit suicide. Female physicians are 2.3 times more likely to commit suicide than are female nonphysicians; for males, the risk is 1.4 times higher among physicians, compared with the general population.[1]

### Proactive approaches

Despite all these sobering statistics on the prevalence and outcomes of burnout among physicians, the ongoing question is, what can we do about it? Although awareness and recognition of burnout has grown substantially over time, successful interventions to prevent or mitigate burnout have not. Many potential interventions and ideas have surfaced and have been published, but none have had impressive impacts or have been adopted widely within or across institutions. According to a *Modern Healthcare* survey of approximately 100 health care CEOs, only about one-third reported that their organization had programs to address physician burnout, although about another one-third reported attempts to develop such programs.[1]

The good news is that at least there is a lot of activity around *trying* new interventions to reduce burnout, including in medical schools and graduate training programs. The thought is that if you can employ healthy resilience tactics during training, these can be carried throughout a career to diminish the risk and/or severity of burnout, despite any challenges that arise along the way.

SEE PHYSICIAN BURNOUT, PAGE 1

Some of these interventions are aimed at individuals (to enhance personal resilience and coping skills) while others are aimed at the level of organizations (to reduce organizational stress and/or workload). A recent *Modern Healthcare* article found several good examples:[1]

- New York's Albert Einstein College of Medicine's WellMed program has been designed to help students develop healthy and balanced habits and attitudes, and to enhance their personal resilience, for the short and the long term.
- Baystate Health in Massachusetts hosts a physician leadership academy that offers training in communication, unconscious bias, strategy, and other management skills, to enhance individual resilience and organizational engagement.
- HealthPartners, a not-for-profit, Minnesota-based health care organization, has specific programs to engage physicians and allow them to have organizational impact, as well as programs to simplify technology use.

Despite all these sobering statistics on the prevalence and outcomes of burnout among physicians, the ongoing question is, what can we do about it? Although awareness and recognition of burnout has grown substantially over time, successful interventions to prevent or mitigate burnout have not.

### Organization efforts are key to prevent, treat

The key to reducing burnout does seem to be employing a combination of self-directed and organization-directed interventions, each of which enhances resilience and reduces workplace stressors (i.e., administrative tasks and workload). Specific to hospitalists, Leslie Flores, MBA, recently wrote about burnout at The Hospital Leader blog. Her list included several specific examples to reduce the top causes of burnout among busy hospitalists:[4]

- **Modifying the skill mix** in hospital medicine groups so that less costly support staff are doing much of the work not requiring a physician's expertise, freeing up hospitalists to provide better care to more patients.
- **Reducing unnecessary interruptions** and the stress they cause, via both technology and process improvement.
- **Paying deliberate attention** to hospitalists' personal and professional well-being.
- **Adjusting hospitalist schedules** and work flow so that hospitalists can be more efficient (that is, do less low-value work and re-work) and have better work-life balance.
- **Ensuring that hospitalists have the training**, clinical competencies, and support to comfortably perform in expanded clinical roles.

Many of these systemic solutions were recently validated as likely able to have an impact on burnout (and seem to be more effective than interventions focused on individual resilience).[5] A recent meta-analysis found that physician-directed interventions were associated with small but significant reductions in burnout; these were primarily mindfulness-based stress reduction techniques, educational interventions targeting physicians self-confidence and communication skills, exercise, or a combination of these features. More effective were organization-directed interventions, which were associated with more significant reductions in burnout; these were primarily aimed at reducing workload and enhancing teamwork and leadership.

### In sum

It is important for all of us hospitalists to understand and try to mitigate burnout within our teams. Although individual-focused interventions can have some effect, most efforts should focus primarily on system-based interventions to reduce administrative burdens and workload. Through such system design and redesign, we can likely reduce burnout among our teams, and therefore improve the sustainability of our specialty. TH

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# Female physicians, lower mortality, lower readmissions: A case study

## My own career-long experience with a wonderful female doctor.

*Dr. Whitcomb is Chief Medical Officer at Remedy Partners in Darien, Conn. He is a cofounder and past president of SHM. Email him at wfwhit@comcast.net.*



Week in, week out for the past 25 years, I have had a front-row seat to the medical practice of a certain female physician: my wife, Heather. We met when we worked together on the wards during residency in 1991; spent a year in rural Montana working together in clinics, ERs, and hospitals; shared the care of one another's patients as our practices grew in parallel – hers in skilled nursing facilities, mine in the hospital; and reunited in recent years to work together as part of the same practice.

Throughout this time, we have talked about cases over dinner, on morning runs, and at just about any other time as the need has arisen. From all of this, I have had the opportunity to learn a lot about her approach to medical practice.

When I saw the paper by Yusuke Tsugawa, MD, MPH, PhD, and his associates showing lower mortality and readmission rates for female physicians versus their male counterparts, I began to wonder if the case of Heather's practice style, and my observations of it, could help to interpret the findings of the study (*JAMA Intern Med.* 2016 Dec 19. doi: 10.1001/jamainternmed.2016.7875). The authors suggested that female physicians may produce better outcomes than male physicians.

The study in question, which analyzed more than 1.5 million hospitalizations, looked at Medicare beneficiaries hospitalized with a medical condition treated by general internists between 2011 and 2014. The authors found that patients treated by female physicians had lower 30-day mortality (adjusted rate, 11.07% vs. 11.49%, *P* less than .001) and readmissions (AR, 15.02% vs. 15.57%, *P* Less than .001) than those treated by male physicians within the same hospital. The differences were "modest but important," coauthor Ashish K. Jha, MD, MPH, wrote in his blog. Numbers needed to treat to prevent one death and one readmission were 233 and 182, respectively.

In the discussion section of the article, the authors cite studies showing that female physicians are more likely than males are to practice evidence-based medicine and more likely to provide patient-centered communication. They also cite evidence from the financial industry showing that women may be more calculated and risk-averse in making consequential decisions.

MORE QUALITY-FOCUSED ARTICLES, P. 25

My observations of Heather's practice approach, compared with my own, center around three main themes:

### She spends more time considering her approach to a challenging case.

She has less urgency in deciding on a definitive course of action and more patience in sorting things out before proceeding with a diagnostic and therapeutic plan. She is more likely to leave open the possibility of changing her mind; she has less of a tendency to anchor on a particular diagnosis and treatment. Put another way, she is more willing to continue with ambiguous findings without lateralizing to one particular approach.

### She brings more work-life balance to her professional responsibilities.

Despite being highly productive at work (and at home), she has worked less than full time throughout her career. This means that, during any given patient encounter, she is more likely to be unburdened by overwork and its negative consequences. (See this month's cover story on "physician burnout" or Dr. Danielle Scheurer's opinions on preventing and treating burnout on p. 38.) It is my sense that many full-time physicians would be happier (and more effective) if they simply worked less. Heather has had the self-knowledge to take on a more manageable workload; the result is that she has remained joyous in practice for more than 2 decades.

### She is less dogmatic and more willing to customize care based on the needs of the individual patient.

Although a good fund of knowledge is essential, if such knowledge obscures the physician's ability to read the patient, then it is best abandoned, at least temporarily. Heather refers to the body of scientific evidence frequently, but she reserves an equal or greater portion of her cognitive bandwidth for the patient she is caring for at a particular moment.

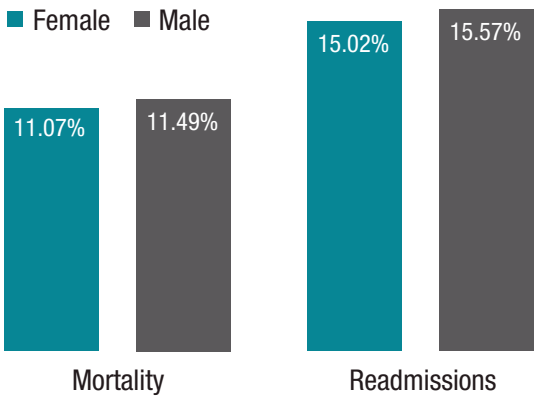
How might the observations of this case study help to derive meaning from the study by Dr. Tsugawa and his associates, so that all patients may benefit from whatever it is that female physicians do to achieve better outcomes?

First, if physicians – regardless of their sex – simply have an awareness of anchoring bias or rushing to land on a diagnosis or treatment, they will be less likely to do so in the future.

Next, we can learn that avoiding overwork can make for more joy in work, and if this is so, our patients may fare better. When I say "avoiding overwork," that might mean rethinking our assumptions underlying the amount of work we take on.

Finally, while amassing a large fund of knowledge is a good thing, balancing medical knowledge with knowledge of the individual patient is crucial to good medical practice. TH

The authors found that patients treated by female physicians had lower 30-day mortality (adjusted rate, 11.07% vs. 11.49%, $P < .001$) and readmissions (adjusted rate, 15.02% vs. 15.57%, $P < .001$) than those treated by male physicians within the same hospital. The differences were "modest but important."

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# HOSPITALIST EMPLOYMENT MODELS: WHICH FITS YOU BEST?

## HOSPITALISTS ARE ENJOYING A FAVORABLE EMPLOYMENT MARKET.

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.

**BY SURINDER YADAV, MD**
**Vice President of Hospital Medicine for CEP America**

### 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. Its attractions include defined benefits with predictable schedules and workloads. The hospital also assumes responsibility for billing, risk management, and staffing. As a result, its physicians have relatively little administrative burden.

This model has potential downsides. For one, clinical autonomy is limited. Directives affecting the practice often come from the top down. This can squelch engagement and limit opportunities for career development. In this model, highly motivated physicians may find themselves working alongside those who only do the minimum for productivity requirements.

### 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. They can bring expertise, fresh ideas, and best practices to the table.

Being employed by a management company has some of the same perks as working directly for a hospital, including predictable schedules and benefits. Most also offer practice management services, though the level of support varies.

Individual physicians employed in this model have very little voice in practice matters. In some large companies, the top clinical leaders oversee an enormous number of physicians and practice locations. Even if they are in touch with the needs of the front-line hospitalists, they may be spread too thin to offer meaningful support. In addition, some physicians find corporate culture at odds with clinical practice.

### INDEPENDENT CONTRACTOR

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

Independent contractors can choose long- or short-term jobs, take breaks between assignments, and increase their workload to boost earnings. On the downside, these physicians have fewer opportunities to innovate or create change.

### 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.

This model fosters cooperation among physicians, because everyone is motivated toward the same goal. This collaborative spirit can also cross service lines. For example, when a partnership staffs both the hospital and emergency medical services, colleagues work together to facilitate admissions. Patients see everyone working together as one team, which is a great satisfier.

Salary is definitely an important consideration, but in the end, cultural fit will be the best predictor of your long-term career satisfaction.

Partnership is ideal for physicians who hunger for autonomy as well as collaboration. In larger groups, the partnership provides administrative support so that physicians can focus locally on patient care, workflows, schedules, and so on.

Being an owner requires an entrepreneurial mindset. The partnership model is a good fit for physicians who want to be engaged in developing best practices and innovative protocols that fit the needs of their hospital and patient community.

### MAKING THE RIGHT DECISION

Salary is definitely an important consideration, but in the end, cultural fit will be the best predictor of your long-term career satisfaction. Being familiar with the basics of each category can help inform your decisions.

**For more information about CEP America's partnership model and employment opportunities, visit go.cep.com/YourBestFit**

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