March 2023
Vol. 27 | No. 3

The Hospitalist

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THE Hospitalist

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IN THE NEXT ISSUE...
Volunteering outside hospital walls

The first and only FDA-approved microbiota-based live biotherapeutic to prevent recurrence of *C. difficile* infection starting at first recurrence.[1,2,a]

[a]In the pivotal phase 3 trial, 32.8% of patients were treated at first recurrence of CDI following antibiotic treatment of CDI.[1]

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INDICATION

REBYOTA (fecal microbiota, live - jslm) is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI.

Limitation of Use

REBYOTA is not indicated for treatment of CDI.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer REBYOTA to individuals with a history of a severe allergic reaction (eg, anaphylaxis) to any of the known product components.

Warnings and Precautions

Transmissible infectious agents

Because REBYOTA is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Any infection suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Ferring Pharmaceuticals Inc.

Management of acute allergic reactions

Appropriate medical treatment must be immediately available in the event an acute anaphylactic reaction occurs following administration of REBYOTA.

Potential presence of food allergens

REBYOTA is manufactured from human fecal material and may contain food allergens. The potential for REBYOTA to cause adverse reactions due to food allergens is unknown.

Adverse Reactions

The most commonly reported (≥3%) adverse reactions occurring in adults following a single dose of REBYOTA were abdominal pain (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

Use in Specific Populations

Pediatric Use

Safety and efficacy of REBYOTA in patients below 18 years of age have not been established.

Geriatric Use

Of the 978 adults who received REBYOTA, 48.8% were 65 years of age and over (n=477), and 25.7% were 75 years of age and over (n=251). Data from clinical studies of REBYOTA are not sufficient to determine if adults 65 years of age and older respond differently than younger adults.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 1-800-332-1088.

Please see Brief Summary on next page and full Prescribing Information at www.REBYOTAHCP.com.

References

1. REBYOTA. Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals; 2022.
2. US Food and Drug Administration. FDA Approves First Fecal Microbiota Product. https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product. Accessed December 1, 2022.

FERRING PHARMACEUTICALS
Microbiome Therapeutics Development

REBYOTA™
(fecal microbiota, live-jslm) suspension, for rectal use

RESTORE HOPE

REBYOTA™
(fecal microbiota, live-jslm) suspension, for rectal use

REBYOTA™ (fecal microbiota, live - jslm) suspension, for rectal use

Brief Summary Please consult package insert for full Prescribing Information

INDICATIONS
REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI.
Limitation of Use: REBYOTA is not indicated for treatment of CDI.

CONTRAINDICATIONS
Do not administer REBYOTA to individuals with a history of a severe allergic reaction (e.g. anaphylaxis) to any of the known product components.

Each 150mL dose of REBYOTA contains between $1x10^8$ and $5x10^{10}$ colony forming units (CFU) per mL of fecal microbes including $>1x10^5$ CFU/mL of *Bacteroides*, and contains not greater than 5.97 grams of PEG3350 in saline.

WARNINGS AND PRECAUTIONS
Transmissible infectious agents: Because REBYOTA is manufactured from human fecal matter it may carry a risk of transmitting infectious agents. Any infection suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Ferring Pharmaceuticals Inc.

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ADVERSE REACTIONS
The most commonly reported (≥ 3%) adverse reactions occurring in adults following a single dose of REBYOTA were abdominal pain, (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

Clinical Trials Experience: The safety of REBYOTA was evaluated in 2 randomized, double-blind clinical studies (Study 1 and Study 2) and 3 open-label clinical studies conducted in the United States and Canada. A total of 978 adults 18 years of age and older with a history of 1 or more recurrences of *Clostridioides difficile* (CDI) infection and whose symptoms were controlled 24 – 72 hours post-antibiotic treatment were enrolled and received 1 or more doses of REBYOTA; 595 of whom received a single dose of REBYOTA.

Adverse Reactions: Across the 5 clinical studies, participants recorded solicited adverse events in a diary for the first 7 days after each dose of REBYOTA or placebo. Participants were monitored for all other adverse events by queries during scheduled visits, with duration of follow-up ranging from 6 to 24 months after the last dose. In an analysis of solicited and unsolicited adverse events reported in Study 1, the most common adverse reactions (defined as adverse events assessed as definitely, possibly, or probably related to Investigational Product by the investigator) reported by ≥3% of REBYOTA recipients, and at a rate greater than that reported by placebo recipients, were abdominal pain, (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).Most adverse reactions occurred during the first 2 weeks after treatment. After this, the proportion of patients with adverse reactions declined in subsequent 2-week intervals. Beyond 2 weeks after treatment only a few single adverse reactions were reported. Most adverse drug reactions were mild to moderate in severity. No life-threatening adverse reaction was reported.

Serious Adverse Reactions - In a pooled analysis of the 5 clinical studies, 10.1% (60/595) of REBYOTA recipients (1 dose only) and 7.2% (6/83) of placebo recipients reported a serious adverse event within 6 months post last dose of investigational product. None of these events were considered related to the investigational product.

USE IN SPECIFIC POPULATIONS
Pregnancy: REBYOTA is not absorbed systemically following rectal administration, and maternal use is not expected to result in fetal exposure to the drug.

Lactation: REBYOTA is not absorbed systemically by the mother following rectal administration, and breastfeeding is not expected to result in exposure of the child to REBYOTA.

Pediatric Use: Safety and effectiveness of REBYOTA in individuals younger than 18 years of age have not been established.

Geriatric Use: Of the 978 adults who received REBYOTA, 48.8% were 65 years of age and over (n=477), and 25.7% were 75 years of age and over (n=251). Data from clinical studies of REBYOTA are not sufficient to determine if adults 65 years of age and older respond differently than younger adults

For more information, visit www.REBYOTAHCP.com

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 1-800-332-1088.

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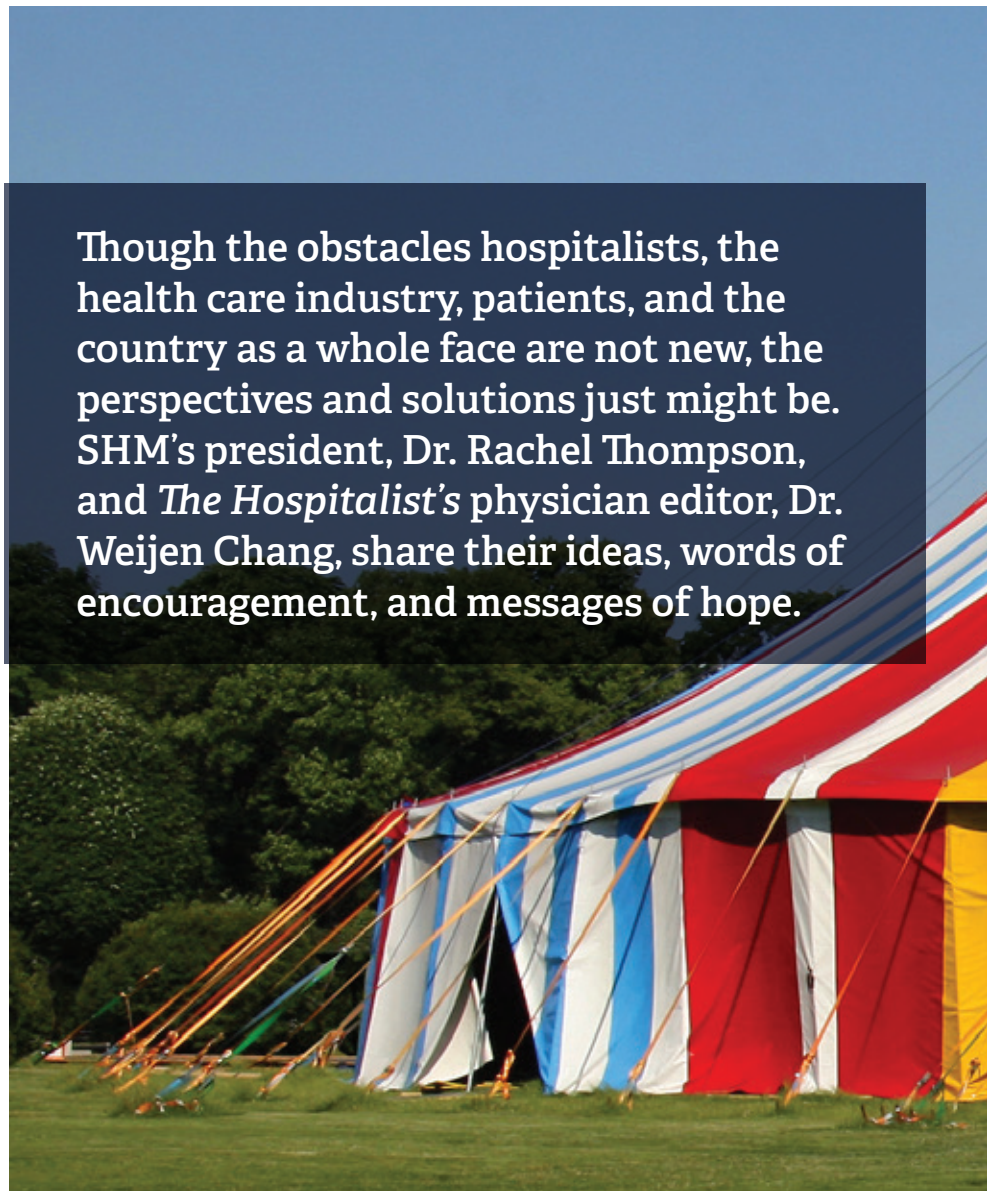
This brief summary is based on full Rebyota Prescribing Information which can be found at www.RebyotaHCP.com

US-REB-2200277

THE Hospitalist®

March 2023
Volume 27 | No. 3

The Hospitalist (ISSN 1553-085X) is published monthly on behalf of the Society of Hospital Medicine by Wiley Periodicals LLC, 111 River Street, Hoboken, NJ 07030-5774. Postmaster: Send all address changes to The Hospitalist Wiley Periodicals LLC, c/o The Sheridan Press, PO Box 465, Hanover, PA, 17331. Printed in the United States by Sheridan of Ohio, Brimfield, OH.



Though the obstacles hospitalists, the health care industry, patients, and the country as a whole face are not new, the perspectives and solutions just might be. SHM's president, Dr. Rachel Thompson, and *The Hospitalist's* physician editor, Dr. Weijen Chang, share their ideas, words of encouragement, and messages of hope.

Reflections Forward

By Rachel Thompson, MD, MPH, SFHM

Rising costs of care. Decreasing access to care. Inequities in access to quality care. Inequities in care. Systemic bias and racism. Polarizing politics. Decreasing resources. Aging systems. Aging itself. Increasing medical coding complexities. Rising mental health needs. Urban consolidation, rural abandonment. Burnout. The American medical system is facing a crisis horrific enough to give up—and some are. The great resignation, the big quit, the great reshuffle, quiet quitting. Health care workers have not escaped this consequence, and many are leaving the field—retiring early, seeking other paths, and not choosing medicine in the first place.

"In the midst of every crisis, lies great opportunity," at least according to Albert Einstein. I ask you to look back over the last three years and see the power of what we can do when we're rightfully motivated, even if by fear of something as big as a pandemic. We came together in ways no one could predict we would. We generated new knowledge in a matter of weeks that historically would have taken years. We found ways to expand our networks, and our ability to care.

Hospitalists played multiple vital roles in the pandemic response. We cared for more than 75% of patients hospitalized with COVID-19, and we took it to the next level. We led the development of infrastructure and innovation. We are the key leaders and change agents in acute care medicine. We are innovators and poised to make a difference. Our health systems experienced our power first-hand and are now demanding we step up to solve the puzzle of the future of acute care.

While we settle into this new normal with COVID-19 alongside influenza, RSV, etc., we're also confronted with the multiple stressors facing health care and a societal disequilibrium that defines our 2023 reality. It can be overwhelming but let's think back to our collective accomplishments.

We are BOLD. We developed new efficiencies of care. We implemented geo-rounding for everything from COVID-19 units to COVID-19 field hospitals. We challenged outdated bylaws and prevailed to allow our nurse practitioner and physician assistant colleagues to practice at the top of their licenses, celebrating our inclusive community. We tested myriad staffing solutions to spread the resources of clinicians and caregivers as broadly as we could. We are agile and flexible. We are not afraid to fail forward.

GETTY IMAGE

Dr. Thompson

Dr. Thompson is the chief medical officer at Snoqualmie Valley Hospital and Public Health District in Snoqualmie, Wash., and SHM's president.

We are INNOVATIVE. We quickly adopted remote monitoring for admission avoidance and early discharge. We flexed into tele rounding, sometimes with nothing more than an iPad. We experimented with hospital at home, and some truly leveraged this. We think outside the box, designing new ways to provide care.

We are COMPASSIONATE. Not only did we care for the medical disease in front of us, but we also considered the whole person. We led efforts to ensure Goals of Care evaluations. We led state discus-

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The Big Tent of Health Care Must be Bigger

By Weijen W. Chang, MD, FAAP, SFHM

As I feared in last year's Editor's Column, this past year has seen one crisis merge into successive crises, making our waking lives a nightmarish fever dream. Just when we thought we were emerging from COVID-19, we ran headlong into the "tripledemic" that struck not only children but also adults directly and indirectly.[1] Among these events has been the curtailing of women's rights in the Dobbs v. Jackson SCOTUS decision, myriad natural disasters, the behavioral health crisis, and the relentless toll of gun violence. This has all occurred against the backdrop of an aging population, a shrinking health care workforce,[2] unexpected shortages in formula and common medications,[3] and a global economic downturn triggered by a deranged despot's campaign to eradicate a neighboring country. Yet these catastrophes have distracted us from a much greater disaster for which we are dead-set aimed—the collapse of health care in this country.

As a recent Jan. 10, 2023, *Time* magazine article by Drs. Glatter and Papadakos state chillingly, a drumbeat of urban and rural health care facilities are closing due to massive financial losses.[4] Lumbering hospitals and health systems have fallen prey to a pack of debilitating forces that have pulled them into insolvency and oblivion.[5] These include, to name a few, the COVID-19 pandemic and the resulting temporary loss of lucrative elective procedures, the rise of locum tenens nurses and other health care workers commanding compensation multiples higher than their salaried colleagues, and inadequate reimbursements from commercial and government payors.[6]

The solutions that will save our health care system from ruin will need to be manifold, but one thing is certain—the big tent of health care must get bigger if we are to emerge from this crisis. Spreading the stakes and raising the poles will require a more inclusive workforce strategy at every level in both inpatient and outpatient settings. Let's first consider our openings to improve employment opportunities for international medical graduate (IMG) physicians in the U.S.

Our health system desperately needs more qualified physicians, and we need to support efforts to integrate IMGs into our health system quickly and effectively. Reducing the backlog of green cards for physicians and nurses is a first step. Still, we also need to reduce the regulations limiting H-1B visa holders to one place of employment, hampering their ability to respond to disasters or pandemics.

Dr. Chang

Dr. Chang is a pediatric and adult hospitalist at Baystate Medical Center and Baystate Children's Hospital, Springfield, Mass., associate professor of pediatrics at the University of Massachusetts Medical School Baystate, chief of pediatric hospital medicine and vice-chair for clinical affairs at Baystate Children's Hospital, and physician editor of The Hospitalist.

There have been efforts to improve the chances of IMGs staying and being employed in the U.S., such as the augmenting of the Conrad 30 Waiver Program, which allows physicians completing residency on a J-1 waiver to stay in the U.S. if they

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Reflections

Continued from page 5

sions of how to ration care if and when it came to it. We recognized inequities in care and outcomes, and we are determined to address these. We supported our colleagues. We care for our patients, and our communities; and we care for each other.

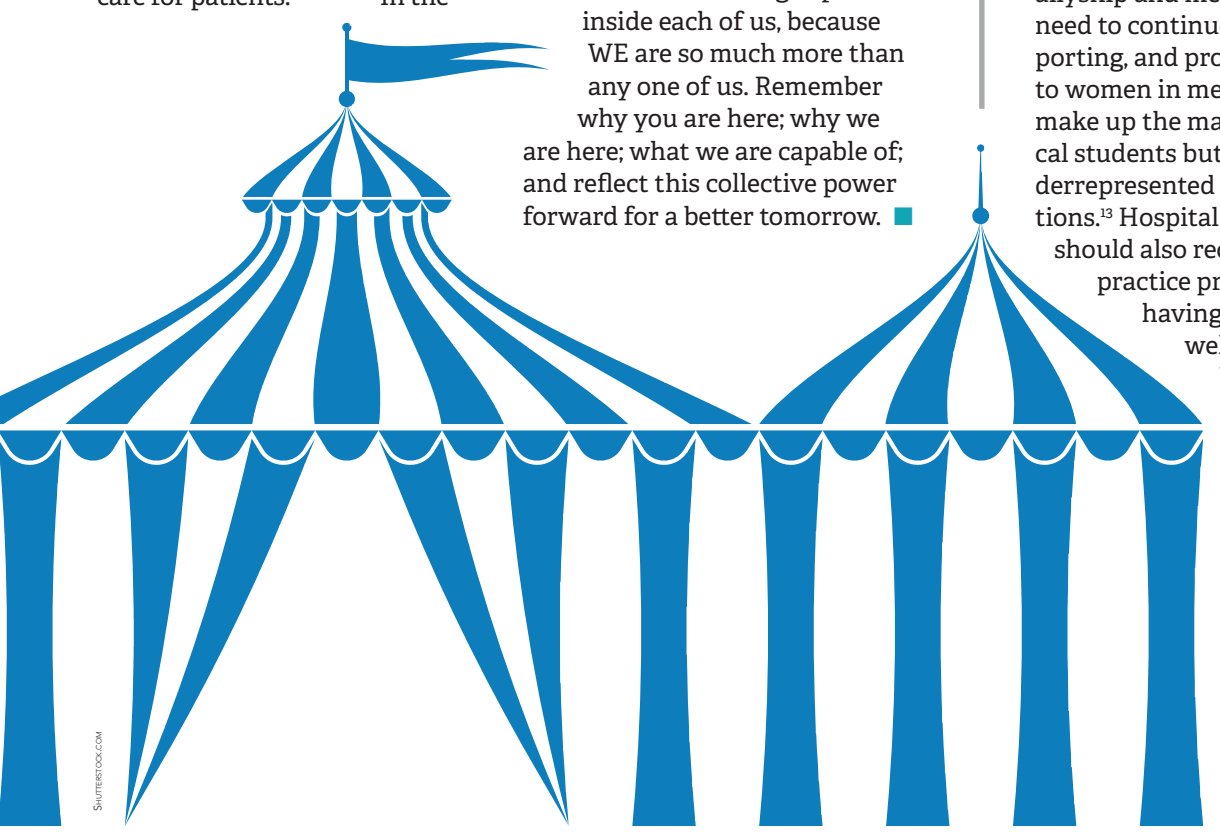
We are CONNECTED. We participated in unprecedented inter-system communication and collaboration. We leveraged our hospital medicine networks across historically rival health systems. We leveraged our broader networks across specialties to provide coordinated care. Our teams brought the rapidly developed scientific knowledge from the bench to the bedside to the patient. We are stronger together.

Reflecting on all that we've accomplished as the collective of hospital medicine, I have no doubt it will be our people, our community, that will bring us out of this storm and into a brighter future.

In 2022 we emboldened our voice. We no longer fear staking a claim; we know it's our duty. We will let you know that we believe gun violence in America is a health care crisis born of a lack of attention to our people and that abortion is health care, not political policy. We meticulously review and critique the Centers for Medicare and Medicaid rules finding every tiny detail that impacts our community. We take a stand and shout about per-country caps on green cards and how our colleagues and their families live under the threat of being sent away despite their great personal sacrifice to care for the American people. We did not back down when the X-waiver returned, and we prevailed in eliminating this blockade to provide appropriate care for patients. In the omnibus package at the close of 2022, we achieved a two-year expansion for telehealth flexibilities; we achieved an extension of the Conrad State 30 program to protect hospitalist immigrants, who are vital to the health care system; we mitigated an 8% cut in Medicare reimbursement, reducing this to 2%; we extended the Alternative Payment Model incentive in the hopes they will continue their evolution; and we extended the Hospital at Home waiver through the end of 2023. We supported getting the Dr. Lorna Breen Health Care Provider Protection Act into law, opening new avenues to fund mental and behavioral health for clinicians and caregivers. And all of this was just in 2022. Our SHM team and colleagues are poised to continue this work into 2023 and beyond.

In 2022 our community came together at SHM Converge and in many other venues made possible by SHM. Our chapters are growing strong and providing local and regional support and networking. Our special interest groups offer platforms for us to converse, collaborate, and construct. Our publications are reaching further and further. Our committees embrace essential tasks on behalf of all of our members to help create a better world. We launched "The Prez Room," a setting where members can speak directly with our Board about real issues we face daily. We've hosted several "Prez Room" sessions exploring pediatrics, leadership, and joy in medicine, and discussing SHM strategic planning. SHM provides a community where all people can participate and contribute.

With SHM at our backs, let's all dig down and not just find, but resurface that bright piece inside each of us, because WE are so much more than any one of us. Remember why you are here; why we are here; what we are capable of; and reflect this collective power forward for a better tomorrow. ■



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Big Tent

Continued from page 5

practice in underserved areas. This program has been hampered by an arbitrary limit on the waivers for each state (30), which have not been changed in decades. A bill designed to recapture 15,000 unused employment-based physician immigrant visas and 25,000 unused employment-based nurse immigrant visas, the Healthcare Worker Resilience Act, has bipartisan support but has not moved forward.[7]

Within the U.S. medical-school system, the increase in graduates has not kept pace with the ballooning needs of an aging population. The Association of American Medical Colleges recommended in 2006 that medical schools increase new enrollments by 30% in 2015, but that target was not reached until 2018.[8] Medical school graduates face a pool of residency positions that also hasn't kept pace with population needs. Not only do we need to support efforts to increase medical school enrollments and residency positions, but these efforts also need to focus on medical schools associated with historically black colleges or universities. Recently, Meharry Medical College in Nashville, Tenn., was placed on probationary status by the Liaison Committee on Medical Education after an onsite survey revealed a "need for some infrastructure updates and additional educational and financial resources for students." But these shortcomings are symptomatic of the lack of governmental support given to historically black colleges or universities in general[9] and specifically for their associated medical schools.[10]

Further efforts to expand the "big tent" of medicine will also require efforts to support LGBTQIA+ providers, who routinely face microaggressions from patients and colleagues.[11] We need to attempt to mitigate this through active allyship and mentorship.[12] We also need to continue celebrating, supporting, and providing mentorship to women in medicine, who now make up the majority of U.S. medical students but continue to be underrepresented in leadership positions.[13] Hospital medicine groups should also recognize advanced practice providers as vital to having a well-staffed and well-trained group but also adhere to best practices in their integration into hospitalist groups.[14]

While the challenges health care currently faces are daunting, hospital medicine remains a vanguard in addressing and overcoming these issues. *The Hospitalist* will continue to highlight the efforts of hospitalists at all levels and in all settings to provide high-quality, patient-centric, and inclusive care while ensuring that the providers are likewise given the support, mentorship, and education they need to succeed. ■

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In the Literature

University of New Mexico Research Reviews

By Krystle Apodaca, DNP, FHM, Abu Baker Sheikh, MD, Charles Pizanis, MD, FHM, Jacqueline O'Neill, MD, and Swathi Subramany, MD

University of New Mexico, Albuquerque, N.M.

IN THIS ISSUE

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5. MELD 3.0 is a more equitable and accurate predictor of mortality in patients with cirrhosis than MELD-Na
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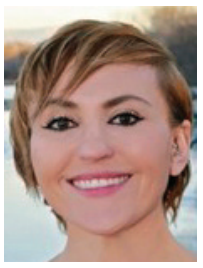
By Krystle Apodaca, DNP, FHM

1 Antibiotic overuse after discharge: a multi-hospital cohort study

CLINICAL QUESTION: Do patients need continued antibiotics after leaving the hospital?



Dr. Apodaca

BACKGROUND: Despite inpatient antimicrobial stewardship programs, studies suggest that up to half of antibiotics prescribed at discharge could be improved. How antibiotic overuse varies across hospitals and patient conditions has yet to be assessed. Understanding and addressing variations in antibiotic overuse may improve prescribing patterns.

STUDY DESIGN: Retrospective cohort study

SETTING: Michigan Hospital Medicine Safety Consortium that includes rural, community, and academic teaching hospitals

SYNOPSIS: This study evaluated 12,445 patients treated for pneumonia and 9,380 treated for a urinary tract infection (UTI) (N=21,825) from 46 unique hospitals over a two-year period. The authors found that despite 41.5% of these patients failing to meet diagnostic criteria (12.9% for pneumonia and 28.6% for UTI), 72.4% were prescribed an antibiotic at discharge and 49.1% experienced antibiotic overuse based on the metrics of unnecessary use, excess duration of use, and suboptimal use of fluoroquinolones. There was a five-fold variation among hospitals of percentage of patients discharged with antibiotic overuse ranging from 15.9% (95% CI, 8.7-24.6) to 80.6% (95% CI: 69.4-88.1).

BOTTOM LINE: Antibiotic stewardship during care transitions can decrease antibiotic overuse at discharge.

CITATION: Vaughn VM, et al. Antibiotic overuse after hospital discharge: a multi-hospital cohort study. *Clin Infect Dis*. 2021;73(11):e4499-e4506. doi: 10.1093/cid/ciaa1372.

2 Defining potential overuse of PT consults on hospital medicine services

CLINICAL QUESTION: Are physical therapy (PT) consults overused in patients who are at low risk for loss of mobility during hospitalization?

BACKGROUND: Hospital-associated disability can be dangerous and costly, but can be prevented by early mobilization. PT, a constrained inpatient resource, is primarily responsible for mobilization of hospitalized patients. No studies have used a validated physical function tool to measure the impact of PT consults on discharge mobility or destination.

STUDY DESIGN: Retrospective cohort study

SETTING: University of Chicago Medical Center, Ill.

SYNOPSIS: Calculating the Activity Measure-Post Acute Care Inpatient Mobility (AM-PAC) score for 3,592 patients admitted to direct-care hospital medicine teams over a one-year period, this study found that of the patients with a high AM-PAC score (>43.63) on admission, 89% (P <0.001) were discharged home with physical therapy being consulted on 38% of these patients. Additionally, the authors found patients admitted with a low AM-PAC score (≤43.63) gained mobility during their hospitalization (+5.69 on discharge AM-PAC score). Patients at high risk for loss of mobility during hospitalization will be most impacted by a physical therapy consult.

BOTTOM LINE: Using a standardized mobility scoring system on admission, such as AM-PAC, may help to appropriately allocate PT resources for patients whose outcomes will be impacted.

CITATION: Martinez M, et al. Defining potential overutilization of physical therapy consults on hospital medicine services. *J Hosp Med*. 2021;18. doi: 10.12788/jhm.3673.

Dr. Apodaca, @krystleapodaca, is a nurse practitioner hospitalist and assistant professor of medicine at the University of New Mexico Hospital, Albuquerque, N.M.

By Abu Baker Sheikh, MD

3 Endoscopic intervention within 6-24 hours for non-variceal upper GI bleeding leads to more favorable outcomes compared to early and late intervention

CLINICAL QUESTION: How does the timing of endoscopic intervention affect clinical outcomes in patients with acute non-variceal upper gastrointestinal (GI) bleeding?

Dr. Sheikh

BACKGROUND: Previous studies have shown that acute non-variceal upper GI bleeds should undergo endoscopic intervention within 24 hours, however the optimal window during the first 24 hours to optimize outcomes has not been well studied.

STUDY DESIGN: A retrospective, territory-wide, cohort study

SETTING: Hong Kong

SYNOPSIS: A territory-wide database covering patients in all public hospitals was used to identify 6,474 patients with a diagnosis of non-variceal GI bleeding who underwent esophagogastroduodenoscopy between the years 2013 and 2019. Patients were divided into three groups based on the timing of endoscopy: <6 hours (urgent), 6-24 hours (early) and 24-48 hours (late). Patients in the early group were found to have overall lower 30-day mortality (HR, 1.4 (urgent), 1.3 (late)), 30-day repeat endoscopy (HR, 1.2 (urgent), 1.0 (late)) and 30-day ICU admission after index endoscopy (HR, 1.4 (urgent), 0.72 (late)). Urgent endoscopy within 6 hours produces overall worse outcomes compared to endoscopy within 6-24 hours. Medical optimization with fluid resuscitation, blood transfusion, and medical therapies (initiation of proton pump inhibitors) prior to endoscopic therapy is crucial to producing positive patient outcomes. Limitations of the study: the sick patient population was excluded, and the timing of endoscopy varied between the two groups.

BOTTOM LINE: Endoscopy during the 6- to 24-hour window after admission results in lower 30-day mortality, repeat endoscopy, and ICU admission compared to <6 hours and 24 to 48 hours for non-variceal upper GI bleeds.

Continued on page 11

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INDICATION

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- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Drug interactions

- Drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans.

Dosage and administration

- **Dosage:**
  - For adults and pediatric patients weighing ≥40 kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2, administered only via intravenous infusion.
  - For pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.

ECMO=extracorporeal membrane oxygenation.

In the ACTT-1 overall study population, patients experienced

Median 10 days with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), p<0.001[1,2]

- Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing COVID-19 medical care

Significantly greater likelihood of improvement in clinical status, a key secondary endpoint[1]

- Patients were 54% more likely to have improved clinical status on Day 15 vs placebo; odds ratio for improvement: 1.54 (95% CI, 1.25 to 1.91)

Helped reduce progression to more severe disease, an additional secondary endpoint[1-3]

- 7% absolute reduction in incidence of new noninvasive ventilation or high-flow oxygen with VEKLURY (17%, n=307) vs placebo (24%, n=266) in patients who did not receive either at baseline (95% CI, -14 to -1)
- 10% absolute reduction in incidence of new mechanical ventilation or ECMO with VEKLURY (13%, n=402) vs placebo (23%, n=364) in patients who did not receive either at baseline (95% CI, -15 to -4)

Adverse reaction frequency was comparable between VEKLURY and placebo[1]

- All adverse reactions (ARs), Grades ≥3: 41 (8%) with VEKLURY vs 46 (9%) with placebo; serious ARs: 2 (0.4%)* vs 3 (0.6%); ARs leading to treatment discontinuation: 11 (2%)† vs 15 (3%)

ACTT-1 was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized patients with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19. Patients received VEKLURY (n=541) or placebo (n=521) for up to 10 days. The primary endpoint was time to recovery within 29 days after randomization. Secondary endpoints included clinical status of patients on Day 15 as assessed on an 8-point ordinal scale and incidence of new high-flow oxygen requirement or new mechanical ventilation or ECMO.[1]

*Seizure (n=1), infusion-related reaction (n=1).

†Seizure (n=1), infusion-related reaction (n=1), transaminases increased (n=3), ALT increased and AST increased (n=1), GFR decreased (n=2), acute kidney injury (n=3).

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration:**
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - For patients who are not hospitalized, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset.
- **Testing prior to and during treatment:** Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** VEKLURY is not recommended in individuals with eGFR <30 mL/min.
- **Dose preparation and administration:**
  - There are two different formulations of VEKLURY: VEKLURY for injection (supplied as 100 mg lyophilized powder in vial), the only approved dosage form of VEKLURY for pediatric patients weighing 3 kg to <40 kg; and VEKLURY injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). See full Prescribing Information.
  - Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established. There are insufficient human data on the use of VEKLURY during pregnancy. COVID-19 is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.
- **Lactation:** It is not known whether VEKLURY can pass into breast milk. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. Veklury. Prescribing Information. Gilead Sciences, Inc.; 2022. **2.** Beigel JH, Tomashek KM, Dodd LE, et al; ACTT-1 Study Group. Remdesivir for the treatment of COVID-19—final report. *N Engl J Med*. 2020;383(19):1813-1826. doi:10.1056/NEJMoa2007764 **3.** Beigel JH, Tomashek KM, Dodd LE, et al; ACTT-1 Study Group. Remdesivir for the treatment of COVID-19—final report. Supplementary appendix. *N Engl J Med*. 2020;383(19):1813-1826. Accessed May 24, 2022. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2007764/suppl_file/nejmoa2007764_appendix.pdf

GILEAD

VEKLURY® (remdesivir)
Brief summary of full Prescribing Information. Please see full Prescribing Information. Rx Only.

INDICATIONS AND USAGE

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), with positive results of SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized, with mild-to-moderate COVID-19, and at high risk for progression to severe COVID-19, including hospitalization or death.

DOSAGE AND ADMINISTRATION *[Also see **Warnings and Precautions, Adverse Reactions, and Use in Specific Populations**]*:

Testing Before Initiation and During Treatment: Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.

Recommended Dosage in Adults and Pediatric Patients ≥28 Days Old and Weighing ≥3 kg:

- For adults and pediatric patients weighing ≥40 kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2, administered only via intravenous infusion.
- For pediatric patients ≥28 days old and weighing ≥3 kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.

Treatment Duration:

- For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
- For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
- For patients who are not hospitalized, diagnosed with mild-to-moderate COVID-19, and at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset.

Renal Impairment: VEKLURY is not recommended in individuals with eGFR <30 mL/min.

Dose Preparation and Administration *[See full **Prescribing Information** for complete instructions on dose preparation, administration, and storage]*:

VEKLURY must be prepared and administered under supervision of a healthcare provider and must be administered via intravenous infusion only, over 30 to 120 minutes. Do not administer the prepared diluted solution simultaneously with any other medication.

- VEKLURY for injection (supplied as 100 mg lyophilized powder in vial) must be reconstituted with Sterile Water for Injection prior to diluting in a 100 mL or 250 mL 0.9% sodium chloride infusion bag.
- Care should be taken during admixture to prevent inadvertent microbial contamination; there is no preservative or bacteriostatic agent present in these products.

Dosage Preparation and Administration in Pediatric Patients ≥28 Days of Age and Weighing 3 kg to <40 kg:

The only approved dosage form of VEKLURY for pediatric patients ≥28 days of age and weighing 3 kg to <40 kg is VEKLURY for injection (supplied as 100 mg lyophilized powder in vial). Carefully follow the product-specific preparation instructions.

CONTRAINDICATIONS *[Also see **Warnings and Precautions**]*:

VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

WARNINGS AND PRECAUTIONS *[Also see **Contraindications, Dosage and Administration, Adverse Reactions,** and **Drug Interactions**]*:

Hypersensitivity, Including Infusion-related and Anaphylactic Reactions: Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time ≤120 minutes) can potentially prevent these signs and symptoms. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment.

Increased Risk of Transaminase Elevations: Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; the transaminase elevations were mild to moderate (Grades 1-2) in severity and resolved upon discontinuation. Because transaminase elevations have been reported as a clinical feature of COVID-19, and the incidence was similar in patients receiving placebo versus VEKLURY in clinical trials, discerning the contribution of VEKLURY to transaminase elevations in patients with COVID-19 can be challenging. Perform hepatic laboratory testing in all patients.

- Consider discontinuing VEKLURY if ALT levels increase to >10x ULN.
- Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.

Risk of Reduced Antiviral Activity When Coadministered With Chloroquine or Hydroxychloroquine: Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism which may lead to a decrease in the antiviral activity of VEKLURY.

ADVERSE REACTIONS *[Also see **Warnings and Precautions**]*:

Clinical Trials Experience: The safety of VEKLURY is based on data from three Phase 3 studies in 1,313 hospitalized adult subjects with COVID-19, four Phase 1 studies in 131 healthy adults, and from patients with COVID-19 who received VEKLURY under the Emergency Use Authorization or in a compassionate use program. The NIAID ACTT-1 study was conducted in hospitalized subjects with mild, moderate, and severe COVID-19 treated with VEKLURY (n=532) for up to 10 days. Study GS-US-540-5773 (Study 5773) included subjects hospitalized with severe COVID-19 and treated with VEKLURY for 5 (n=200) or 10 days (n=197). Study GS-US-540-5774 (Study 5774) was conducted in hospitalized subjects with moderate COVID-19 and treated with VEKLURY for 5 (n=191) or 10 days (n=193).

Adverse Reactions: The most common adverse reaction (≥5% all grades) was nausea.

Less Common Adverse Reactions: Clinically significant adverse reactions reported in <2% of subjects exposed to VEKLURY in clinical trials include hypersensitivity reactions, generalized seizures, and rash.

Laboratory Abnormalities: In a Phase 1 study in healthy adults, elevations in ALT were observed in 9 of 20 subjects receiving 10 days of VEKLURY (Grade 1, n=8; Grade 2, n=1); the elevations in ALT resolved upon discontinuation. No subjects (0 of 9) who received 5 days of VEKLURY had graded increases in ALT.

Laboratory abnormalities (Grades 3 or 4) occurring in ≥3% of subjects receiving VEKLURY in Trials NIAID ACTT-1, Study 5773, and/or Study 5774, respectively, were ALT increased (3%, ≤8%, ≤3%), AST increased (6%, ≤7%, n/a), creatinine clearance decreased, Cockcroft-Gault formula (18%, ≤19%, ≤5%), creatinine increased (15%, ≤15%, n/a), eGFR decreased (18%, n/a, n/a), glucose increased (12%, ≤11%, ≤4%), hemoglobin decreased (15%, ≤8%, ≤3%), lymphocytes decreased (11%, n/a, n/a), and prothrombin time increased (9%, n/a, n/a).

DRUG INTERACTIONS *[Also see **Warnings and Precautions**]*:

Due to potential antagonism based on data from cell culture experiments, concomitant use of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended.

Drug-drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans. Remdesivir and its metabolites are in vitro substrates and/or inhibitors of certain drug metabolizing enzymes and transporters. The clinical relevance of these in vitro assessments has not been established.

USE IN SPECIFIC POPULATIONS *[Also see **Dosage and Administration** and **Warnings and Precautions**]*:

Pregnancy

Risk Summary: There are insufficient human data on the use of VEKLURY during pregnancy to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. COVID-19 is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.

Lactation

Risk Summary: There are no available data on the presence of remdesivir in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, remdesivir and metabolites have been detected in the nursing pups of mothers given remdesivir, likely due to the presence of remdesivir in milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from the underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Pediatric Use

The safety and effectiveness of VEKLURY for the treatment of COVID-19 have been established in pediatric patients ≥28 days old and weighing ≥3 kg. Use in this age group is supported by the following:

- Trials in adults
- An open-label trial (Study GS-US-540-5823) in 53 hospitalized pediatric subjects

Geriatric Use

Dosage adjustment is not required in patients over the age of 65 years. Appropriate caution should be exercised in the administration of VEKLURY and monitoring of elderly patients, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of potential concomitant disease or other drug therapy.

Renal Impairment

All patients must have an eGFR determined before starting VEKLURY and while receiving VEKLURY as clinically appropriate. VEKLURY is not recommended in patients with eGFR less than 30 mL/min.

Hepatic Impairment

Perform hepatic laboratory testing in all patients before starting VEKLURY and while receiving VEKLURY as clinically appropriate.

OVERDOSAGE

There is no human experience of acute overdosage with VEKLURY. Treatment of overdose with VEKLURY should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. There is no specific antidote for overdose with VEKLURY.

214787-GS-006

GILEAD

CITATION: Guo CLT, et al. Timing of endoscopy for acute upper gastrointestinal bleeding: a territory-wide cohort study. *Gut*. 2022;71(8):1544-1550.

4 Duration of abstinence from alcohol prior to liver transplantation does not lead to increased survival in patients with alcohol-related liver disease

CLINICAL QUESTION: How does the duration of abstinence from alcohol affect patient survival, allograft survival, and relapse-free survival in patients undergoing liver transplantation?

BACKGROUND: Historically, abstinence from alcohol for at least six months has been a criterion used to determine which patients qualify for liver transplantation (LT). While this abstinence requirement has been shown to improve mortality in patients with alcohol-related liver disease (ALD), it has not been well studied in patients with severe alcoholic hepatitis (SAH) who are unlikely to survive more than six months without LT.

STUDY DESIGN: Retrospective cohort study

SETTING: U.S.

SYNOPSIS: This study included data from 163 patients who underwent LT at Johns Hopkins Hospital, Baltimore, and were divided into two groups: early LT (<6 months of abstinence) versus standard LT (>6 months of abstinence). Results showed that adherence to the six-month abstinence rule did not lead to superior outcomes in terms of one-year patient survival (94.1% versus 95.9%), allograft survival (92.7% versus 90.5%) or relapse-free survival (80.4% versus 83.5%).

This study questions LT candidacy requirements given that the duration of abstinence does not affect one-year patient mortality, allograft survival, or relapse-free survival in a statistically significant manner.

LIMITATIONS OF THIS STUDY INCLUDE: being a single-center study, and that patients in the study were primarily white males. Also, the treatments for alcohol use disorder were not reported.

BOTTOM LINE: Patients with >6 months of abstinence from alcohol do not have superior post-transplant one-year survival when compared to patients with <6 months of abstinence.

CITATION: Herrick-Reynolds KM, et al. Evaluation of early vs standard liver transplant for alcohol-associated liver disease. *JAMA Surg*. 2021;156(11):1026-1034.

5 MELD 3.0 is a more equitable and accurate predictor of mortality in patients with cirrhosis than MELD-Na

CLINICAL QUESTION: How does Model for End-Stage Liver Disease (MELD) 3.0 compare to MELD-Na in regard to liver transplant waitlist mortality?

BACKGROUND: The MELD-Na scoring system has been proven to be a reliable predictor of short-term survival in patients with cirrhosis and has been used to determine the order of priority for liver transplant (LT) candidates since 2016. However, there have been concerns that the utility and equitability of the MELD-Na is waning as liver disease epidemiology changes, necessitating a change to the current model to minimize waitlist mortality while addressing the sex disparity in LT recipients.

STUDY DESIGN: Retrospective cohort study

SETTING: U.S.

SYNOPSIS: This study used patient data from all LT candidates from 2016 to 2018 and performed univariate and multivariate analyses to extract potential predictors of waitlist survival. The main predictors incorporated into the MELD 3.0 were the addition of female sex, serum albumin, and a lowered ceiling for serum creatinine from 4.0 mg/dL to 3.0 mg/dL. MELD 3.0 was able to successfully reclassify 9% of patients who had died on the waitlist into different priority tiers while preventing 20 waitlist deaths per year.

The MELD 3.0 addresses the waitlist mortality and the ever-important issue of sex disparity in which women are significantly less likely to receive an LT than men with the same MELD scores.

Validation of MELD 3.0 in patient populations outside the U.S. would be required since MELD 3.0, like MELD and MELD-Na, was developed on the U.S. population.

BOTTOM LINE: MELD 3.0 is superior to the MELD and MELD-Na in minimizing waitlist mortality by incorporating female sex, serum albumin, and a creatinine cut-off, and addressing the existing sex disparity.

CITATION: Kim WR, et al. MELD 3.0: The model for end-stage liver disease updated for the modern era. *Gastroenterology*. 2021;161(6):1887-1895.e4.

6 Acetaminophen raises systolic blood pressure in those with hypertension

CLINICAL QUESTION: Does regular intake of acetaminophen cause an increase in blood pressure?

BACKGROUND: Acetaminophen is one of the most commonly used analgesics in the world. Because of its widespread use and limited demonstrated efficacy, there have been growing reservations regarding its long-term safety, particularly its influence on blood pressure (BP).

STUDY DESIGN: Single-center, randomized, double-blinded, placebo-controlled crossover trial

SETTING: United Kingdom

SYNOPSIS: 110 patients were randomized to receive 1 g of acetaminophen four times daily or corresponding placebo for two weeks; a two-week washout period completed the trial. The patients were subsequently transferred to the other treatment arm for an additional two weeks. The participants attended two long visits on days 0 and 14 and two short visits on days 4 and 7. Based on acetaminophen assays, 90 participants were included in the final analysis.

Regular acetaminophen caused a significant rise in mean daytime systolic blood pressure (132.8 ±10.5 to 136.5 ±10.1 mmHg [acetaminophen] versus 133.9 ±10.3 to 132.5 ±9.9 mmHg [placebo]; $P<0.0001$) and mean daytime diastolic blood pressure (81.2 ±8.0 to 82.1 ±7.8 mmHg [acetaminophen] versus 81.7 ±7.9 to 80.9 ±7.8 mmHg [placebo]; $P=0.005$).

THIS STUDY'S LIMITATIONS INCLUDE: being a single-center study, exclusively done on the white population, and including only patients with underlying hypertension so its impact on the normotensive population is unknown. Moreover, because the trial only lasted two weeks, it is challenging to predict whether the results would persist over time.

BOTTOM LINE: Acetaminophen elevates blood pressure by roughly 5/2 mmHg in patients with underlying hypertension (treated or untreated) within a two-week period when compared to placebo.

CITATION: MacIntyre IM, et al. PATH-BP (paracetamol in hypertension–blood pressure) investigators. Regular acetaminophen use and blood pressure in people with hypertension: the PATH-BP trial. *Circulation*. 2022;145(6):416-423.

7 Early initiation of dialysis improves survival: To start or not to start

CLINICAL QUESTION: What is the ideal estimated glomerular filtration rate (eGFR) at which to start dialysis in patients with advanced chronic kidney disease?

BACKGROUND: Uncertainty exists over the optimum time to start dialysis in order to lower mortality and cardiovascular events. The Initiating Dialysis Early and Late (IDEAL) trial, published in 2010, demonstrated that initiating dialysis at an eGFR of 10 to 14 mL/min/1.73 m2 was not associated with an improvement in survival or clinical outcomes as compared to patients with the eGFR 5 to 7 mL/min/1.73 m2.

STUDY DESIGN: A nationwide observational cohort study

SETTING: National Swedish Renal Registry of patients referred to nephrologists

SYNOPSIS: From 2007 to 2017, 10,290 patients were included in this study; an eGFR between 6 and 7 mL/min/1.73 m2 was used as the reference group, and 15 dialysis initiation techniques with eGFR values ranging from 4 to 19 mL/min/1.73 m2 in increments of 1 mL/min/1.73 m2 were evaluated.

Early initiation of dialysis (eGFR 15–16 mL/min/1.73 m2) was associated with a 5.1% (95% CI 2.5%–6.9%) lower absolute risk of mortality after five years as compared to eGFR 6-7 mL/min/1.73 m2. Additionally, an early start was linked to a 3.3% lower absolute risk of major adverse cardiovascular events. For 1.6 months' longer survival advantage, dialysis must be started on average four years earlier.

Rather than supporting a strategy of early initiation, the authors conclude the modest survival benefit may not outweigh the substantially longer period spent on dialysis.

BOTTOM LINE: Early initiation of dialysis increases survival by 1.6 months and modestly decreases cardiovascular events. However, to achieve maximum survival benefit, one would need to initiate dialysis four years earlier.

CITATION: Fu EL, et al. Timing of dialysis initiation to reduce mortality and cardiovascular events in advanced chronic kidney disease: nationwide cohort study. *BMJ*. 2021;375:e066306. doi: 10.1136/bmj-2021-066306.

Dr. Sheikh is associate program director for the department of internal medicine and assistant professor of medicine at the University of New Mexico Hospital, Albuquerque, N.M.

By Charles Pizanis, MD, FHM

8 Effectiveness of oxycodone hydrochloride (strong opioid) versus combination acetaminophen and codeine (mild opioid) for subacute pain after fractures managed surgically: A randomized controlled trial

CLINICAL QUESTION: Do less potent opioids suffice for adequate pain control for patients

with surgically managed fractures?

BACKGROUND: For post-surgical pain management at time of discharge, hospitalists try to balance the analgesic effects of opioid therapy with the risks of dependency and overdose. Data on optimal discharge opioid dosing for adult patients who have undergone surgical management of fracture are currently limited.

Dr.Pizanis

STUDY DESIGN: Double-blind, randomized controlled trial

SETTING: Trauma hospital in Sydney, Australia

SYNOPSIS: Adult patients who had sustained non-pathological fractures of a long bone (e.g., femur) or the pelvis, patella, calcaneus, or talus, and who underwent surgical fixation were eligible for the study. Participants were randomized at discharge to receive oxycodone 5 mg or 10 mg four times per day (strong-opioid arm) or acetaminophen-codeine 500 mg/8 mg or 1000 mg/16 mg four times per day (mild-opioid arm). Telephone pain assessments were conducted after discharge using the 0-10 Numerical Pain Rating Scale (NRS).

59 patients were randomized to the strong-opioid arm and 61 to the mild-opioid arm. The daily mean NRS score at day seven post-discharge was 4.04 (95% CI, 3.67-4.41) for the strong-opioid arm and 4.54 (95% CI, 4.17-4.9) for the mild-opioid arm. The difference between the mean daily pain scores during days 1 to 7 was not statistically significant (−0.50 [95% Cl, −1.11 to 0.12]; *P*=0.11).

BOTTOM LINE: Hospitalists should consider lower-potency opioids for patients with non-pathologic post-surgical pain at discharge to minimize the adverse effects of higher-potency opioids.

CITATION: Jenkin DE, et al. Effectiveness of oxycodone hydrochloride (strong opioid) vs combination acetaminophen and codeine (mild opioid) for subacute pain after fractures managed surgically: a randomized clinical trial. *JAMA Netw Open*. 2021;4(11):e2134988. doi: 10.1001/jamanetworkopen.2021.34988.

9 Bolus IV 0.9% saline leads to interstitial permeability pulmonary edema in healthy volunteers

CLINICAL QUESTION: Can intravenous fluid (IVF) administration cause direct lung injury independent of cardiogenic overload?

BACKGROUND: Bolus IVF therapy is a central component to managing critically ill patients with hypotension. In the clinical setting, pulmonary edema after IVF is thought to primarily occur by cardiogenic mechanisms, though studies in healthy subjects have suggested that IVF administration itself can lead to indirect lung injury and permeability pulmonary edema.

STUDY DESIGN: Randomized, crossover trial

SETTING: Intensive care unit at a tertiary hospital in Australia

SYNOPSIS: Fourteen healthy adult patients underwent two interventions: administration of a 30 ml/kg bolus of 0.9% saline over 20 minutes, or a sham intervention with no IVF administration. Participants had a two-week period between interventions. Before and soon after administration of each intervention, participants underwent pulmonary function tests, lung ultrasound, echocardiogram, and blood and urine sampling. Additionally at 45 minutes after intervention, patients underwent bronchoscopy with bronchoalveolar lavage to assess for biomarkers consistent with lung injury.

Mean bronchoalveolar lavage total protein concentration was significantly higher after IVF administration compared to sham (196.1 mcg/mL versus 129.8 mcg/mL, *P*=0.0020). Additionally, plasma concentrations of another lung injury marker, angiopoietin 2, were significantly higher after IVF administration (1.531 ng/mL versus 2.263 ng/mL, *P*=0.001) and not with sham. Both findings occurred in the absence of any echocardiographic evidence of cardiogenic edema.

BOTTOM LINE: Intravenous fluids can cause pulmonary edema both by means of cardiogenic and direct lung injury and should be considered potentially implicated in patients who develop worsening respiratory status even in the absence of heart failure or circulatory overload.

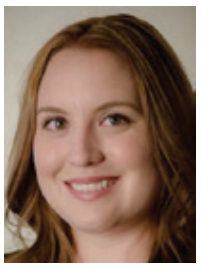
CITATION: Li H, Bersten A, et al. Bolus intravenous 0.9% saline leads to interstitial permeability pulmonary edema in healthy volunteers. *Eur J Appl Physiol*. 2021;121(12):3409-3419.

Dr. Pizanis is a hospitalist and associate professor of medicine at the University of New Mexico Hospital, Albuquerque, N.M.

By Jacqueline O'Neill, MD

10 Nutritional support improves mortality in frail, elderly patients

CLINICAL QUESTION: Is there a mortality benefit to optimizing nutritional status for malnourished patients with age-related frailty?



Dr. O'Neill

BACKGROUND: Age-related frailty syndrome has been associated with increased morbidity and mortality in critically ill patients. It has not been well studied whether optimizing nutrition in elderly hospitalized patients with frailty syndrome improves outcomes.

STUDY DESIGN: Randomized controlled trial

SETTING: Secondary and tertiary hospitals in Switzerland

SYNOPSIS: A subgroup analysis of data from the EFFORT Trial included 881 patients identified as having age-related vulnerability with overlapping characteristics of frailty syndrome, age ≥80, and cognitive impairment. Patients randomized to additional nutritional support had >50% reduction in risk of 30-day mortality (95% CI, 0.31-0.76; *P*=0.002). Secondary outcomes included a reduction in 30-day functional decline and improvement of reported quality of life at both 30 and 180 days.

BOTTOM LINE: Individualized nutritional support improves 30-day mortality in elderly hospitalized patients with age-related frailty syndrome. Hospitalists should consider dietary supplementation for elderly patients who screen positive for frailty and malnutrition on admission.

CITATION: Baumgartner A, et al. The impact of nutritional support on malnourished inpatients with aging-related vulnerability. *Nutrition*. 2021;89:111279. doi: 10.1016/j.nut.2021.111279.

11 Mirtazapine administration associated with moderate risk of hyponatremia

CLINICAL QUESTION: What is the incidence of hyponatremia in patients treated with mirtazapine?

BACKGROUND: The development of hyponatremia has been associated with selective serotonin inhibitors and other antidepressant medications. Several studies and reports have linked mirtazapine with the development of hyponatremia, but the overall incidence has yet to be defined.

STUDY DESIGN: Systematic review

SETTING: PubMed, Scopus, grey literature

SYNOPSIS: A retrospective review of the literature identified 10 eligible experimental and objectional studies evaluating mirtazapine-induced hyponatremia in adult and elderly patients prior to November 2021. A total of 1,007 out of 30,844 patients identified in the studies developed hyponatremia after initiating mirtazapine with an instance of 3.26% (95% CI, 3.06%-3.45%). Osmolality data provided on seven patients met criteria for diagnosis of syndrome of inappropriate antidiuretic hormone secretion.

BOTTOM LINE: Mirtazapine administration presents a moderate risk for the development of hyponatremia and should be discontinued in patients who have clinically significant hyponatremia.

CITATION: Moscona-Nissan A Sr, et al. Mirtazapine risk of hyponatremia and syndrome of inappropriate antidiuretic hormone secretion in adult and elderly patients: a systematic review. *Cureus*. 2021;13(12):e20823. doi: 10.7759/cureus.20823.

Dr. O'Neill is a hospitalist and assistant professor of medicine at the University of New Mexico Hospital, Albuquerque, N.M. ■

SHORT TAKES

Oral urea to treat hospitalized adults with hyponatremia

By Swathi Subramany, MD

A systematic review of eight articles (N=296 patients) shows that oral urea supplementation may be associated with increases in serum sodium levels among inpatients with hyponatremia and appears to be safe and well tolerated; however, the strength of evidence is considered low due to heterogeneity in patient and treatment characteristics, as well as study characteristics (retrospective observational studies, lack of control groups).

Citation: Schwartz E, et al. Oral urea supplementation in the treatment of acute hyponatremia among hospitalized adults: a systematic review. *J Am Nutr Assoc*. 2022:1-13.

Dr. Subramany, @SubramanySwathi, is a hospitalist and assistant professor of medicine at the University of New Mexico Hospital, Albuquerque, N.M.

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Removing the Barrier to OUD Treatment with Buprenorphine

What it means for hospitalists and patients

By Lisa Casinger

"Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has."

—Margaret Mead

They say there are two things you don't want to see made, laws and sausages. But, sometimes recounting the journey that turned an important issue into law can be inspiring. Such is the case of the passage of the Mainstreaming Addiction Treatment (MAT) Act to eliminate the X-waiver, part of the 2022 omnibus bill.

While the U.S. Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) announced the immediate elimination of the X-waiver for prescribing buprenorphine in January, Kendall Rogers MD, CPE, SFHM, chief of the division of hospital medicine and professor at the University of New Mexico Health Sciences Center, Albuquerque, said SHM's Public Policy Committee (PPC) started talking about this issue many years ago.


Dr. Rogers

The journey

"Since becoming X-waivered in 2006, I've advocated for the deregulation of buprenorphine," Dr. Rogers said. "SHM's PPC has been discussing this for years and was one of the early medical societies to publicly take a stance on the issue. The initiative gained momentum as we raised awareness with law makers, organized talks at our annual meetings, wrote op-eds, and supported #XtheXWaiver on social media."

The removal of the X-waiver requirement has been one of SHM's top policy priorities, and over the past five years, SHM's PPC members educated legislators during yearly Hill Days about the safety and efficacy of using buprenorphine to treat opioid use disorder (OUD), addressed their misconceptions and concerns about abuse and diversion, and encouraged them to support the passage of the MAT Act.

One of the biggest roles in any advocacy initiative is education, and it's no different in this case. Dr. Rogers said when the PPC started meeting with legislators he was surprised by the lack of awareness of the overdose issues and that there was a safe, effective treatment available.

Suparna Dutta, MD, MPH, FACP, SFHM, chief of the department of medicine at Hartford Hospital and associate professor of medicine at the University of Connecticut, and PPC member said, "I'm proud of the group because we came out early and said this is something we really want to advocate for—getting rid of the X-waiver, which was just an artificial construct, based on stigma and fear of how to treat this patient population. I think that made other groups comfortable with advocating for it as well."


Dr. Dutta

Though education has taken years, it's often as easy as repeatedly sharing your knowledge. "I addressed fears of diversion—are we substituting one addiction for another? I talked about what the evidence shows, what the literature shows, what my experience had been in prescribing this medicine and learning it about it," said Jennifer Cowart, MD, FACP, SFHM, vice chair for quality in the division of hospital internal medicine, patient safety officer at the Mayo Clinic Florida, and SHM PPC member.


Dr. Cowart

Hospitalists were among the earliest advocates for the use of buprenorphine to treat OUD patients because, along with

emergency medicine physicians, they're the specialties who see the impact of this illness on people who don't normally seek health care. They're also the physicians who see the patients who've been admitted for completely different reasons and ended up going through withdrawal during the inpatient setting.

Another part of advocacy is figuring out which "levers we need to pull," said Dr. Rogers. "Who controls this? It's not the DEA, they're just following whatever legislation exists. It's not the states, because it's a federal legislative initiative rooted in almost 100 years of laws." The goal was to find out what was preventing the deregulation of this medication.

"We've been working on this for several years, pulling all of the levers we felt we had at our disposal, and recognized that SHM was one of many organizations pulling all those levers at the same time. There's strength in numbers and I think that really showed," Dr. Cowart said.

Also, SHM's grassroots advocacy network played a big role. Lillian Freundlich, SHM's government relations specialist, makes sure that action items are shared with hospitalists who've signed up for that advocacy network, encouraging members to email or call their legislators.

The barriers

After a hospitalist identified and diagnosed patients with OUD and initiated therapy, often the challenge was finding a community partner to continue the therapy. One barrier to having enough physicians able to prescribe buprenorphine was the eight hours of continuing medical education (CME) required to receive an X-waiver.

"That's an entire day of CME," said Dr. Cowart. "CME budgets are being stretched tight across the country if you're even fortunate enough to work at an institution that has a CME budget. Eight hours on a single topic is a lot when you have a tight CME budget. And that was eight hours for MDs, it was 24 hours for advanced practice providers—which puts it out of reach for a lot of people. I would expect to see some quick development of high-quality CME that everyone could use—an hour would be sufficient."

For those hospitalists who earned their X-waiver and were able to prescribe buprenorphine, the next challenge was if there was someone to hand the patient off to once they were discharged from the hospital. Finding an X-waivered primary care physician or other practitioner was a challenge.

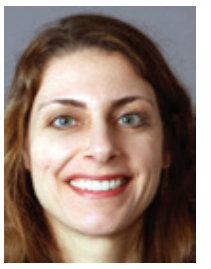
Dr. Cowart said, "The implications for hospitalists are huge, but now we really have to work to tell everyone that the artificial barrier is gone. We're trying to educate people on how and why you would prescribe it. I try to liken it as much as possible to insulin. When I diagnose diabetes, I discharge a patient with insulin. I would consider that standard of care. And I would consider it malpractice if I don't prescribe them the medicine they need for their diabetes and OUD. We have an effective treatment, and it should be the standard of care."

Dr. Dutta said treating OUD like a chronic disease may also help reduce the stigma associated with it.

While there will be new DEA training guidelines (as set forth by the Medication Access and Training Expansion Act, MATE Act, also part of the 2022 omnibus bill), which are being developed and will go into effect this summer, that education will be around *all* opioid prescribing, and not specific to buprenorphine. Dr. Cowart hopes the new national training benchmarks will enable changes at state medical boards and legislatures as well.

More access to treatment

Susan Calcaterra, MD, MPH, MS, the director of addiction medicine consultation service, associate professor of hospital medicine, associate program director of the addiction medicine fellowship at the University of Colorado Anschutz Medical Campus, Aurora, Colo., and a faculty expert for the SHM Center for Quality Improvement's opioid project, said "I'm hoping more patients will get access to life-saving medications to treat opioid use. And then the downstream effects are reduced morbidity and mortality related to opioids."



Dr. Calcaterra

Marlene Martin, MD, an associate professor of medicine at the University of California, San Francisco, and director of the Addiction Care Team and hospitalist at San Francisco General Hospital, is also a faculty expert for the SHM Center for Quality Improvement's opioid project. She said removal of the X-waiver should "make it easier for us to prescribe buprenorphine when it comes time to dishcharge our patients and link them to care." She also hopes it reduces some of the barriers previously experienced.

Dr. Martin

Dr. Rogers said, "The act was called the Mainstreaming Addiction Treatment Act—and I think the true goal of the MAT Act is for this to become *mainstream*. There's still a lot of work ahead for us to actually achieve its namesake. The big goal is to destigmatize OUD treatment, both in and out of the hospital."

Removing the barriers to care may mean more OUD patients can receive their post-acute care treatment through their primary care physicians "and the people with complex mental health comorbidities or who may be abusing multiple substances will have better access to the very scarce mental health resources they need," said Dr. Cowart.

According to DEA administrator Anne Milgram, removing this barrier will increase immediately the number of practitioners who can prescribe buprenorphine from 130,000 to 1.8 million in the U.S.

Next steps

Though the X-waiver is gone, there are still barriers to OUD treatment with buprenorphine—both immediate and ongoing.

The immediate concern is getting the word out. Though the DEA, SAMHSA, and SHM have communicated the news, informing and educating health care professionals is still crucial.

"We can help by continuing to encourage hospitals to prescribe buprenorphine and providing education that helps hospitals feel comfortable to actually do the work of prescribing," said Dr. Calcaterra.

Dr. Martin agrees that communication and education are important next steps. "We have to do substantial education on how to initiate and continue the medication to increase hospitalists' confidence and its actual use."

"I think it's going to take time," Dr. Dutta said. "Just because we're getting rid of the X-waiver doesn't mean that magically our patients are going to have access immediately everywhere. But I think we can use this to push for culture change in a way that we couldn't before."

Drs. Rogers, Dutta, Calcaterra, Martin, and Cowart agree—this journey was a success thanks to the efforts of many people across many institutions and organizations. It took determination, perseverance, and hope.

"And so, if nothing else, I hope this inspires people who are interested in advocacy but aren't sure if that actually is a way to make an impact. It is," Dr. Dutta said. "And if there are things they see in their day-to-day practice that could be improved—this journey has shown that advocacy can work." ■

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Bright Spots in the Future of Hospital Medicine

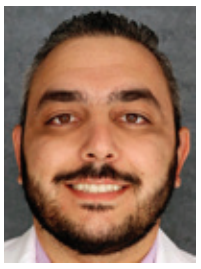
By Larry Beresford

As Americans start to rediscover their place in a (largely) post-pandemic world, hospitalists across the country are resuming and recommitting to a variety of extracurricular roles and responsibilities beyond their scheduled shifts on the hospital floors.

As we celebrate 2023 National Hospitalist Day on March 2, taking a peek into the future of hospital medicine, we offer you brief accounts of some of the roles 10 hospitalists are playing to advance the field, helping better to define its range and extent, improve quality on multiple levels, and commit to advancing diversity, equity, and inclusion in the care of hospitalized patients.

A clear path to a hospitalist career

Hospitalist Aram Alexander Namavar, MD, has approached his career in hospital medicine with a vision of what he wanted to do, how to get there, and the skills he needed to reach his goals. Along that journey, he has looked to SHM for opportunities to learn, network, contribute, and lead, starting as a recipient of a 2016 Student Hospitalist Scholar Grant while still a medical student at Loyola University in Chicago. Every step of the way, he's found opportunities to contribute to the larger field of hospital medicine while advancing his own career.


Dr. Namavar

Dr. Namavar joined SHM's Physicians in Training (PIT) Committee, helped to found and lead its Resident and Student Special Interest Group (SIG), created a mentorship program connecting trainees with working hospitalists, and played active roles in SHM local chapters in San Diego—where he completed his residency at the University of California, San Diego—and now in Los Angeles, where he's a first-year attending at Cedars-Sinai Medical Center.

"I was exposed to hospital medicine as an undergraduate at UCLA," Dr. Namavar said. While pursuing a graduate degree before applying to medical school, he became a mentee of Nasim Afsar, MD, MBA, MHM, an SHM past president, and now chief health officer at Oracle Cerner. With Dr. Afsar's encouragement, he took on a quality improvement project within UCLA's department of medicine.

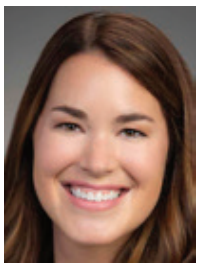
"I have a lot of ideas I want to pursue. I have tried to be very purposeful about all the activities I choose to do," he said. "To be honest, it was the encouragement of my mentors, staff at SHM, and others along the way that helped me clarify what I needed to do to become a hospitalist."

He is now focused on honing clinical skills and experience during his first year at Cedars-Sinai, to become the best doctor he can be. But he looks forward to adding layers of non-clinical, practice-focused skills to his repertoire.

"It's important for future doctors to recognize that hospital medicine can be a very supportive field, with lots of resources," Dr. Namavar said. "I always tell them, if they are interested in something, just ask a hospitalist."

The art of mentoring

For Lauren Spaeth, a fourth-year medical student at Ohio University Heritage College of Osteopathic Medicine's Dublin, Ohio campus, the early days of the COVID-19 pandemic turned her medical training upside down. As described in her December 4, 2021, posting in SHM's *The Future Hospitalist Round-Up*, Spaeth lost in-person interactions with classmates and teachers and almost all face-to-face encounters with hospitalized patients.


Ms. Spaeth

Instead, she pursued the remainder of her first year and all of her second-year studies in relative isolation, with virtual classes, training videos, and online review materials. "The dimension of human contact was suddenly taken away from me," Ms. Spaeth said. In the third year, she resumed in-person clinical rotations and started applying the knowledge she had been learning virtually to real patients.

"As an educator who oversees medical students and residents, I have a lot of mixed feelings about the impact of the pandemic on hospital medicine," said Sanjay A. Patel, MD, FACP, SFHM, @buckeye_sanjay, associate program director for internal medicine for OhioHealth's Riverside Methodist Hospital in Columbus, a member of SHM's PIT Committee, and Ms. Spaeth's mentor.


Dr. Patel

Ms. Spaeth met Dr. Patel during a summer research externship program between her first and second years of medical school. "Lauren would come once a week and observe rounds with my team," Dr. Patel said. "She was inquisitive about the clinical issues."

Ms. Spaeth described how a mentoring relationship formed from that experience, out of recognition of their shared interests in clinical medicine and approaches to patient care. Dr. Patel has continued to mentor her, which contributed to her success in applying for residency and securing interviews.

"My relationship with Dr. Patel also fueled my involvement in SHM, which has been a springboard for new opportunities," Ms. Spaeth said. Mentoring is not something that's taught in medical training—how to be a good mentor or mentee. "There's also a shared understanding in medicine that you're supposed to give back. Dr. Patel has modeled that for me, and I look forward to doing the same in the future."

Maintaining momentum for networking in a pandemic

Meera Udayakumar, MD, SFHM, executive medical director for quality and innovation for the University of North Carolina (UNC) Health Triangle East in Chapel Hill, N.C., has been a hospitalist since 2008, eventually becoming the medical director for hospital medicine at UNC Rex Hospital in Raleigh, N.C.


Dr. Udayakumar

"I saw how hospitalists can and should play a key role in hospital performance improvement. There are multiple projects for which hospitalists are the subject matter experts." She is also the medical director for UNC Health's Hospital at Home Program, which went live in 2021 and has cared for more than 750 acute inpatients in their own homes.

In April 2020, Dr. Udayakumar became president-elect of the North Carolina Triangle chapter of SHM, a role that includes responsibility for coordinating the chapter's annual local RIV (Research, Innovations, and Clinical Vignette) competition. "When I took on that position, chapter activities had been sidetracked by the pandemic crisis. But it became clear that for many hospitalists, it would be helpful to work on something non-COVID-19 related, such as our very engaging RIV competition."

The chapter's leadership agreed to convert the competition to a virtual format. Dr. Udayakumar put out a call for abstract submissions and recruited judges. Participants were invited to prepare an electronic poster submission for display in a virtual poster hall, and the top five submissions were judged during an online chapter meeting.

"There are many benefits to RIV for those who participate. It's a great way to learn how to produce abstracts and posters, plus great fun to share your work," she said. "There are universal problems in hospital care and it's good to see how others are addressing those problems and then to take those learnings back to your own group."

The N.C. Triangle Chapter is about 250 members strong. The 2020 competition that Dr. Udayakumar oversaw generated the group's greatest

number of submissions and posters to date. But she doesn't take credit for that outcome because the pandemic was driving the need to reconnect with hospitalist colleagues locally. "I changed the format of the competition to virtual but tried to keep the momentum from past years."

A local flavor to networking

John Vazquez, MD, @JohnVaz06707022, associate director of operations in the division of hospital medicine at Emory University School of Medicine in Atlanta, is a past president of SHM's Atlanta Chapter and chair of its District 5. In 2024, he becomes the chair of the Society's National Chapter Support Committee, which helps hospitalists come together with their peers in local chapters and offer something both social and educational.


Dr. Vazquez

"It's good to go to a local meeting with your peers on a Wednesday night, have a nice glass of wine and talk about afib—or about the problems we all share," he said. That's also an important way to grow the national society from the grassroots level and hear what frontline hospitalists are thinking.

At the national level, hospitalists can go to SHM meetings and visit its website. "But the local chapter comes to you and listens to your needs. It's not just about hearing an academic lecture," he said. It's also about offering support, especially when burnout has robbed many hospitalists of the joy of practice and made them forget why they ever became a doctor. "At the local level, we can push this kind of support. Doctors can see an educational talk and go home reinvigorated."

This is a year of hope, Dr. Vazquez said. "Back in 2020, everyone was in a tizzy from the pandemic. Now people want to reestablish who we are and how we practice and try to be on top of what's coming next. People are thinking about their careers again."

Some of the best chapter talks are about practice—not just clinical medicine, Dr. Vazquez said. Others take creative approaches like a Jeopardy-style quiz show—with a commitment to make sure it's fun. For Dr. Vazquez, an important priority is not just to support the existing chapters but to think strategically about the creation of new SHM chapters in communities that never had one, using the society's regional structure of 12 districts and supportive volunteers. "If you partner with a local group, once they've presented their first meeting, they're on their way."

Understanding the demographics of hospital medicine

Damian Crawford, MD was an academic hospitalist at Johns Hopkins Bayview Medical Center in Baltimore, when he opted to leave the academic world for a group-practice leadership position in a community-hospital setting. So, in 2019 he took a job with the national hospitalist company Sound Physicians as chief hospitalist at Frederick Health Hospital in Frederick, Md. There he leads a group of 20 full-time physicians and two advanced practice providers. He also directs the hospital's observation unit and works closely with emergency medicine and critical care.


Dr. Crawford

Dr. Crawford was invited to join SHM's efforts to advance diversity, equity, and inclusion (DEI) in hospital medicine as co-chair of its DEI Task Force, which in November of 2021 was elevated to a formal committee of the SHM Board of Directors. "The purpose of the DEI Task Force was to point SHM in the direction we believe it should go in promoting greater diversity for the field," he explained. This body itself has a diverse membership from across the country and meets monthly virtually to work on a variety of projects.

"DEI is such a broad subject. What can one health care organization do?" Dr. Crawford posed. "For me personally, I don't believe America has enough Black men in medicine, making up less than 3% of physicians. Someone else might say we don't have enough women in leadership positions in medicine." And this lack of diversity has negative real-life consequences in terms of outcomes such as higher mortality rates for Black patients.

"We spent a year brainstorming, and we saw that we didn't have good demographic data on the hospitalist workforce." So SHM initiated a process to start collecting demographic data as part of an updated member profile.

Dr. Crawford credits SHM's commitment to diversity at a time when the health care system has finally acknowledged the need to do better in this area. The DEI Committee includes SHM CEO Eric Howell, MD, MHM, and board member Flora Kisuule, MD, SFHM, director of the division of hospital medicine at Johns Hopkins Bayview Medical Center in Baltimore. "That signals its seriousness as an organization and shows its commitment to these issues," he said.

But how quickly can that buy-in change the face of hospital medicine? "I am very much aware that real change is not going to be quick," he said. With efforts like SHM's DEI Scholarship Fund, sponsored by Vituity, which awards a $25,000 scholarship to an underrepresented third-year medical student, and other mentoring programs and connections, it can help to develop a more diverse pipeline of future hospitalists, Dr. Crawford said.

A transitional role in hospital medicine

"Med-peds" occupies a unique role in hospital medicine, said David Fish, MD, SFHM, assistant professor of medicine and pediatrics at UMass Chan Medical School, Worcester, Mass., and Rachel J. Peterson, MD, @MPAcadHosp, assistant professor of clinical medicine and pediatrics and a hospitalist at Indiana University School of Medicine in Indianapolis. They are the chair and vice-chair, respectively, of SHM's Med-Peds SIG, which represents hospitalists who have completed a four-year residency combining both pediatric and adult medicine and are thus qualified to care for patients across the age spectrum.


Dr. Fish


Dr. Peterson

Dr. Fish said the Med-Peds SIG's top priority is to represent this niche specialty at the national level. "We advocate for career support and education for early career hospitalists and trainees."

"I find that often the interests of med-peds doctors around the country align around the needs of their patients who are adolescents or teens, who have complex conditions, and who are in the midst of a difficult transition from pediatric to adult medicine," Dr. Peterson said. "My hospitalist practice covers the entire age spectrum, but it is evolving. I have become an advocate in adult medicine for our patients who are adults but still getting care at the pediatric hospital."

Dr. Fish, who also helps to lead the Cystic Fibrosis Center at UMass, divides his time between inpatient adult medicine and inpatient pediatrics, with a small outpatient cohort. "A lot of people with our specialty carve out their own clinical niches in various ways."

Med-peds doesn't have a single professional home. "Doctors may look to different medical societies as their primary representative body, although SHM is where many of us feel most at home," he said. The recent development of fellowships for pediatric hospitalists adds to the complexity of the field. SHM has worked with the National Med-Peds Residents Association on a program exploring whether fellowship is the right path for trainees and young hospitalists.

But there seems to be growing interest in med-peds' dual role—judging by job postings. That may reflect how during COVID-19 viral surges some pediatric doctors were assigned to adult hospital responsibilities—despite a lack of training in adult medicine. "I've seen hospitals become more aware of the benefits of a more agile workforce," Dr. Peterson said.

"We are a group of clinicians that can have a unique skill set," Dr. Fish said. "That's been highlighted in recent years by how adaptable we can be. That's where we stand out. In the last few years, we have highlighted the value the med-peds hospitalist can bring to an institution, as well as to hospital medicine as a whole."

The excitement of public policy

Sarah Johnson Conway, MD, is a hospitalist at Johns Hopkins Hospital in Baltimore, chief medical officer of the Johns Hopkins Clinical Alliance, and assistant professor of medicine at Johns Hopkins University. The time she has spent working on issues such as acute care utilization, safe transitions of care out of the hospital, partnerships with federally qualified health centers, and value-based care strategies for Johns Hopkins Medicine sparked an interest in how health policy decisions get made and how hospitalist advocates can contribute to those decisions. That interest led her to join SHM's Public Policy Committee.


Dr. Conway

In addition to monthly Zoom meetings, SHM's committee convenes an annual "Hill Day," when members go to Congress to meet with their legislators. "It is an opportunity to share the critical role and purpose of hospitalists," Dr.

Conway said. "People sometimes get confused about what a hospitalist is, but now, in part due to the pandemic, there is a broader appreciation that we really are an essential part of the health care delivery system."

Serving on the Public Policy Committee has been an exciting opportunity to meet and learn from other hospitalists. "I have gained a lot of insights from my colleagues," she said. Some of the challenges they face are the same, and some are unique to their particular hospital and regional setting, she said.

Other policy issues that hospitalists should care about include the (temporarily waived) requirement for Medicare patients to spend three midnights in the hospital to qualify for discharge to a skilled nursing facility; prior authorization policies employed by Medicare Advantage plans; and the X-waiver that required physicians to complete a lengthy training to be able to prescribe buprenorphine for opioid use disorder. SHM, working alongside other medical groups, just successfully advocated getting the X-waiver requirement rescinded.

After a challenging couple of years during the pandemic, Dr. Conway said, now is a great time to be a hospitalist. "I feel ever more appreciated based on the key role we played through the pandemic. It brought our efforts to the forefront and strengthens our position for effective advocacy."

Burnout's buckets

Read G. Pierce, MD, division chief of hospital medicine and associate chair for faculty development and well-being at Dell Medical School at the University of Texas in Austin, has been a career hospitalist for two decades. He chose that path while finishing residency because of how the specialty combined clinical work with a focus on improving health systems.


Dr. Pierce

But after the first two or three years, Dr. Pierce was experiencing profound burnout in his work. "I didn't have a name for it. But it caused me to question whether I even wanted to continue to be a clinician. It was a real existential dilemma."

What enabled him to turn the corner on that existential crisis? Lots of little things, he said. "But the big thing that made a difference for me was when a mentor who could see what was happening to me asked me to give a talk to his hospitalist leadership development course on how physicians can avoid burnout and find a better sense of thriving in their work. Thankfully, I wasn't so burned out that I turned down his offer," he said. "I went to the medical literature to study what it said about burnout."

That assignment sparked a deep interest in the topic for Dr. Pierce. "I didn't want other clinicians to go through what I experienced." He has since given that talk to physician audiences dozens of times. In the early stages of the COVID-19 crisis, when a lot of clinicians—hospitalists in particular—were suffering from extraordinary levels of stress and long hours, he joined SHM's Hospitalist Well Being Task Force, which has developed a comprehensive toolkit on the subject.

The burnout literature has identified three main "buckets" that help clinicians understand burnout and its remedies, Dr. Pierce said. All of these are covered by SHM's Hospitalist Well-Being Advocates Toolkit, with practical tools and other guidance for clinicians. They include personal resilience—"things I do for myself"; the role of the culture of medicine and the local environment in lifting people up or dragging them down; and efficiency of practice and other system factors that impact how much energy must be put into delivering high-quality patient care.

Although things are changing in medicine, there still is a need for further culture change, he said. The culture is still heavily invested in calling out mistakes but not telling doctors when they're doing a good job—assuming that they get sufficient intrinsic satisfaction in their work. "We also select people for medical school who have strong drives to self-critique and relatively low levels of self-compassion. But now people coming into the field are asking questions and pushing back on the need to promote more sustainable practices," he said.

Where is the field today when it comes to preventing burnout? "Honestly, the answer is not clear," Dr. Pierce said. "I feel we are on the cusp of using the pandemic as a trigger for post-traumatic growth. But that being said, the pandemic was extraordinarily hard on our field, which was at the front lines for surge after surge. Hospitalists have a long history of being innovators, and we'll need to harness that spirit to achieve levels of well-being that we all desire." ■

Larry Beresford is an Oakland, Calif.-based freelance medical journalist, a specialist in hospice and palliative care, and a long-time contributor to The Hospitalist.

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How Hospitals Are Tackling Violence

Hospitalists discuss how they're dealing with an increase in unruly patients

By Karen Appold

Even before the onset of the COVID-19 pandemic, health care workers suffered more workplace injuries as a result of violence than any other profession, with approximately 654,000 harmed annually, according to American Hospital Association studies.[1] Since the pandemic began, violence against hospital employees alone has markedly increased. For example, 44% of nurses reported an increase in physical violence and 68% reported an increase in verbal abuse.[1]

The Joint Commission defines workplace violence as an act or threat occurring at a workplace that can include: verbal, non-verbal, written, or physical aggression; threatening, intimidating, harassing, or humiliating words or actions; bullying; sabotage; sexual harassment; physical assaults; or other behaviors of concern involving staff, licensed practitioners, patients, or visitors.[2]

Dr. Persoff

When asked if violence has increased at his hospital, Jason Persoff, MD, SFHM, an associate professor of medicine in the division of hospital medicine at the University of Colorado Hospital in Aurora, Colo., an urban, adult, academic hospital with 850 beds, said patients are becoming increasingly outspoken and dissatisfied with care due to limited visitor access to patients, increased delays in care due to overrun hospitals, and care at the hands of some burned out clinical staff.

In addition to that, after losing nearly one-third of all health care workers to the pandemic,[3,4] there is an exceptionally new, green workforce in place which results in more challenges as they grow as clinicians. "Frustration and misinformation have further demoralized clinicians and simultaneously created an antagonistic relationship from time to time as patients argue about what is and isn't scientific fact," Dr. Persoff said.

Nicole E. Webb, MD, FAAP, program director of the pediatric hospital medicine fellowship at Valley Children's Hospital, a free-standing tertiary children's hospital with 358 beds in Madera, Calif., blames a dramatic shortage of outpatient mental health resources for contributing to the increased violence at hospitals. "Part of it is a supply and demand issue, which stems from the fact that mental health care isn't reimbursed at a rate even remotely commensurate with medical services in this country," she said. "Because of this, many mental health practitioners are private pay or cash pay and there are far more patients who need their services than providers to see them. For publicly insured patients, the shortage is even more severe."

Dr. Webb

Che Matthew Harris, MD, a hospitalist in the department of medicine at Johns Hopkins Bayview Medical Center in Baltimore, an academic hospital with 420 beds, believes that as a society, Americans are under a stressed system which has led to a lot of anxiety, anger, fear, and distrust. "This may lead people to act out more aggressively and violently," he said. "Multiple factors are contributing to this worsening crisis, such as under-addressed mental health care needs, the opioid epidemic, unemployment, and an increased division in politics." In addition, the impact of COVID-19 resulted in death, isolation, and uncertainty about the future, which has also increased stress levels.

Dr. Harris

Training and education

In today's society, hospital staff must be well-prepared to deal with violence. Training and education are necessary. Employees at the University of Colorado Hospital, for example, are trained on how to use communication tools to minimize conflict and build therapeutic relationships with patients and families. They're also trained to identify issues when situations are escalating and how to use de-escalation tools.

Most situations are focused on prevention and are ultimately successful. "We take a zero-tolerance approach to belligerent or violent behavior and will work with police to protect staff from provocateurs and violent individuals," Dr. Persoff said.

Staff also learn how to respond to violence when it explodes, including where they can hide in safe rooms from active shooters or other violent acts.

Occasionally Dr. Persoff's hospital has had trespass visitors or repeat offenders. "All patients are entitled to an Emergency Medical Treatment and Labor Act screening exam, whether or not they have a history of violence," he said.

This act requires hospitals with emergency departments (EDs) to provide a medical screening examination to any individual who comes to the ED and requests such an examination and prohibits hospitals with EDs from refusing to examine or treat individuals with an emergent medical condition. "We don't allow our employees to be bullied, screamed at, attacked, or threatened," Dr. Persoff said.

As part of employee education, Valley Children's has mandated modules on dealing with violence. "Most incidents involve behavioral health patients; additional training is primarily targeted toward nursing and ancillary bedside staff," Dr. Webb said. The hospital's security department has a de-escalation program that's offered to higher-risk areas such as the ED. The training is also available upon request.

Hospitalists at Johns Hopkins Bayview Medical Center underwent four hours of crisis-prevention training, which included training on violence triggers, early identification of signs of aggression, how to de-escalate an

agitated patient, and basic self-defense skills to prevent injury, said Ishaan Gupta, MBBS, an assistant professor of medicine in the division of hospital medicine at the Center.


Dr. Gupta

Prevention plans

The Mayo Clinic has implemented multiple forms of prevention plans including everything from violent-patient flags in electronic medical records to passive weapons detection at key access points, said Ruth DeFoster, MD, a hospitalist in the department of medicine at the Mayo Clinic in Rochester, Minn., an academic hospital with 1,265 beds. Staff is encouraged to use its multi-disciplinary behavioral emergency response team before an act of violence occurs. The team includes security personnel and has a close working relationship with local law enforcement.


Dr. DeFoster

Johns Hopkins Bayview Medical Center installed magnetometers with increased security at the walk-in entrance of its ED. "This should help prevent and deter individuals from bringing weapons to the hospital," Dr. Harris said. "We're also working on bolstering de-escalation training for all staff; I'm hopeful that adequate training will help reduce aggression and violence."

Response plans

Johns Hopkins Bayview Medical Center has a code-green team that responds to aggressive or violent patients in the ED after de-escalation strategies have failed. This team is comprised of security guards, nurses, physicians, and behavioral specialists. "The code-green team has been successful because of its multi-disciplinary approach used for intervention," Dr. Harris said. Each member brings a unique quality and perspective on what may drive a patient to be violent and the best steps needed to control a situation.

Elizabeth Schulwolf, MD, MBA, FACP, FHM, chief medical officer at Dell Seton Medical Center at the University of Texas (Ascension) in Austin, a level-one trauma center with 210 adult beds,


Dr. Schulwolf


Getty Image

has onsite security to respond to escalating situations in the ED or inpatient areas. It recently increased security staffing both inside the hospital and in the parking garage adjacent to the hospital.

Behavior agreements are put in place for hospitalized patients who are verbally or physically abusive toward staff or those who present a danger to others. Patients are informed of the hospital's expectations for creating a safe environment. "If they're unable to meet the expectations, they are discharged from the hospital with care coordinated as best as possible," Dr. Schulwolf said.

When patients at the University of Colorado Hospital have profound complex psychosocial care issues and are unable to make their own health care decisions, specialized teams are designated to lead in those patients' care to optimize outcomes for the patients and staff alike, Dr. Persoff said. Teams focus on supporting the patient while also setting expectations for appropriate behaviors.

Reporting policies

Johns Hopkins Bayview Medical Center encourages reporting all workplace-violence incidents; a dedicated online form can be used and completed anonymously. "Now that the Joint Commission issued revised standards in 2022, I expect that there will be more robust reporting methods," Dr. Gupta said.

A survey study within the hospitalist division noted that more than 85% of all workplace-violence incidents weren't reported. "Workplace violence is so ingrained in the day-to-day work of health care workers that they have come to accept it as a part of their job," Dr. Gupta said.

"Effective reporting is one of the first areas which needs renewed focus," Dr. Gupta said. "There should be multiple methods of reporting which are user-friendly and, very importantly, without retaliation. Reporting should lead to discernible action for frontline staff."

At the Mayo Clinic, the staff is also encouraged to report acts of violence. "A supportive environment has highlighted the fact that no one needs to tolerate violence as part of their job," Dr. DeFoster said.

Hospitalist's roles

Dr. Gupta recommends de-escalation training for all hospital-based clinicians. The training would empower them to use the right tool for the right patient at the right time. He suggests three specific interventions which would be useful in all situations.

- Ensure safety for yourself and your patients. Ensure clear access to an exit, remove personal items which can be used as weapons (such as stethoscopes and jewelry), and be aware of your surroundings.
- Manage your own emotions. Be mindful of your verbal and non-verbal responses to patients. To de-escalate an angry patient, your tone and body language are sometimes more important than the words themselves.
- Explore the reasons for aggression. Aggression may be a symptom of an underlying medical problem such as delirium or psychosis. It could also be related to interpersonal conflict or related to hospital policies. Each type of problem requires a different approach to resolve it.

When patients are aggressive or abusive, Dr. Persoff said the first step is to understand why they're behaving that way. For example, is there a physiologic reason or an underlying disease process that may cause a patient not to recognize that their behavior is out of bounds? "Don't internalize their comments or epithets; this isn't about you, the clinician," he said. "It's about a complex issue that a patient or visitor is grappling with."

Most importantly, Dr. Persoff said it's imperative that clinicians are trained in how to work through complex interactions with techniques that can be learned and practiced every day. For example, the Institute of Healthcare Excellence offers courses designed to be used throughout an institution or health care system to learn how to listen actively and use language that fosters connection and respect.

Dr. Persoff maintains that no one should accept abuse as part of their job. "Any staff member who has been threatened or attacked should be offered the emotional space and psychological care needed to deal with a traumatic experience," he said.

Dr. Schulwolf recommends that hospitalists support nursing staff in enforcing acceptable behavior. "Physicians have a strong voice in setting expectations in the hospital when patients are able to manage their behavior," she concluded. ■

Karen Appold is an award-winning journalist based in Lehigh Valley, Pa. She has more than 25 years of editorial experience, including newspaper reporter, and newspaper and magazine editor.

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SHM

Connecting at Converge Via SIGs and Chapters

One of the many benefits of SHM membership is connecting and learning from fellow members. One of the best ways to do that is to join a Special Interest Group (SIG) or Chapter. SHM's SIGs are communities of hospitalists built around common topics of interest, practice areas, and care models while Chapters are communities of hospitalists built around geography.

There are more than two dozen SIGs covering a wide range of topics from academic leaders and pediatrics to quality improvement and value-based care.

As an SHM member, you can participate in as many SIGs as you want, and, if there's not a SIG for the topic that you're interested in you can apply to start one. Each SIG has its own online community and discussion boards, and you can network and connect with your fellow SIG members in person at SHM Converge 2023.

If you're already in a SIG you can catch up with your group at the Special Interest Forums (SIFs), throughout Converge. If you haven't joined a SIG yet or are interested in other topics, this is the perfect opportunity to learn more about the different groups, their goals, plans for the coming year, leadership, and more.

These 50-minute SIFs are group discussions, great networking opportunities, and low-commitment ways to learn more about each group. There are 31 SIFs scheduled, 29 of which are tied to a SIG. Looking for a job in pediatrics? Recently matched? Interested in quality improvement? Are you a rural hospitalist trying to navigate transfers? Curious about oncology? Interested in well-being? Want to learn more about women in hospital medicine? You may find the information you're looking by participating in a Special Interest Forum.

Two of the Special Interest Forums are focused on topics that are not currently SIGs—Oncology and Women in Hospital Medicine.

The Oncology SIF is "an informal gathering of generally a relatively small group of hospitalists who are involved in the niche field of onco-hospital medicine i.e., hospitalists who principally care for hospitalized cancer patients" said its leader, Barbara C. Egan, MD, FACP, SFHM, chief, hospital medicine service at Memorial Sloan Kettering Cancer Center in New York. Attend this SIF if you work within this space or if you're interested in this field even if you aren't actively working in it. Attendees will discuss challenges and successes and make personal connections so you can keep in touch when issues or challenges arise.

The Women in Medicine SIF leaders, Marisha Burden, MD, FACP, SFHM, professor of medicine, division head of hospital medicine at the University of Colorado School of Medicine in Aurora, Gaby Frank, MD, FACP, SFHM, medical director of the biocontainment unit at Denver Health Hospital Authority, and Emily Gottenborg, MD, a hospitalist and program director of hospitalist training at the University of Colorado at Denver, say the goal of this SIF is to have a dynamic and interactive discussion, while also ensuring attendees have the opportunity to contribute to the overall goal of eliminating the gender gap in hospital medicine.

Attendees will be encouraged to share their perspectives on the most pressing issues for women in hospital medicine and work together to generate project ideas to address the challenges of gender equity.

The Well-being SIF was an SHM Board-appointed task force until last month when it became a full-fledged SIG. It's leaders, Swati Mehta, MD, CPXP, FACP, SFHM, the national director of quality and patient experience for Vituity, a physician-led health care innovation company based in Emeryville, Calif., and a practicing hospitalist at Dignity Sequoia Hospital in Redwood City, Calif., and Read G. Pierce, MD, division chief of hospital medicine and associate chair for faculty development and well-being at Dell Medical School at the University of Texas in Austin will lead the SIF with a discussion on the SHM Wellbeing Champion Toolkit, what attendees do for their personal well-being and what their teams have done to address burnout, and what they hope to accomplish in the SIG's first year.

Scan this QR code to access the SIF Converge schedule.

Another way to connect and network is through your local chapter. There are more than 60 SHM chapters nationwide to provide networking, education, and collaboration within the hospital medicine community. The chapters are grouped into 12 geographic districts and four regions (East, South, Midwest, and West). All SHM members are assigned to a chapter based on the address in their membership profile. If there isn't a chapter in your area, you can apply to start one.

Whether in-person or virtual, chapters have a minimul of two local events per year and throughout Converge, there will be designated times for attendees to meet with people from their own chapters or explore volunteer opportunities to get involved.

If you happen to strike up a conversation with a local leader, be sure to ask about the amazing initiatives they undertake throughtout the year to engage membership. Attendees will see Chapter Excellence Award winners featured throughout Converge.

Scan this QR code to access the Chapter Meet Up Converge schedule.

There are two chapter leader events during Converge—the Chapter Leader Training and Chapter Leader Summit.

The Chapter Leader Training Program, conducted annually at Converge, was established by SHM staff and the Chapter Support Committee (CSC) in 2018 to provide in-person training to all SHM chapter leaders, including those whose terms begin at the annual conference. During training, leaders receive updates on SHM policy, procedures, and resources, review best practices (especially as it relates to chapter meetings and chapter leadership), and conduct both small table and large group discussions. It's also a great opportunity for chapter leaders to network and share ideas with other leaders from across the country.

R. Lucas Shelly, DO, SFHM, a hospitalist at WellSpan Hospitalists in Chambersburg, Penn., and the chair of the CSC and District 3 said, "New and seasoned chapter leaders will benefit from attending the Converge 2023 Chapter Leader Training session. They'll learn tips to handle the more difficult aspects of being a chapter leader and they'll benefit from the wide depth of knowledge from having so many leaders in one place."

The Chapter Leader Summit is a networking event for chapter leaders and district chairs. While chapter leaders meet virtually on a quarterly basis, the summit is an opportunity to meet in person. Leaders also celebrate chapter successes and awards and conduct the official transition of incoming and outgoing leaders, during the summit.

"The summit is where you can mingle among the finest leaders in hospital medicine," Dr. Shelly said. "You can make new friends, build your leader support group, and be inspired."

At Converge, you'll find an agenda packed with learning opportunities and education, but you'll also find occasions to network and collaborate with your colleagues and peers. Make the most of both. ■

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