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IN THE NEXT ISSUE ...

Hospitalist researchers, budgeting, and more



For patients hospitalized with COVID-19,1

HELP REDUCE DISEASE PROGRESSION AND SHORTEN RECOVERY TIME^{1,2}

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (\geq 28 days old and weighing \geq 3 kg), who are:

- 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 (\geq 5% all grades) were increases in ALT and AST.

Dosage and administration

 Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

ECMO=extracorporeal membrane oxygenation.

In the ACTT-1 overall study population, patients experienced DAYS SHORTER RECOVERY TIME WITH VEKLURY

Median 10 days with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% Cl, 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 endpoint¹

- Patients were 54% more likely to have improved clinical status on Day 15 vs placebo; odds ratio for improvement: 1.54 (95% Cl, 1.25 to 1.91)
- Helped reduce progression to more severe disease, an additional secondary endpoint¹⁻³
- 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% Cl, -15 to -4)

Adverse reaction frequency was comparable between VEKLURY and placebo¹

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**, 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 <u>total</u> treatment duration of up to 10 days.
- For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 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 for outpatient use.
- Testing prior to and during treatment: Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- Lactation: VEKLURY can pass into breast 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 breastfeed child from VEKLURY or from an underlying maternal condition. 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.; 2023. **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



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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), who are:

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.

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 \geq 28 days old and weighing \geq 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: No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

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
- 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 ka:

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, one Phase 3 study in 279 non-hospitalized adult and pediatric subjects (12 years of age and older weighing at least 40 kg) with mild to moderate 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). Study GS-US-540-9012 included non-hospitalized subjects, who were symptomatic for COVID-19 for \leq 7 days, had confirmed SARS-CoV-2 infection, and had at least one risk factor for progression to hospitalization treated with VEKLURY (n=279; 276 adults and 3 pediatric subjects 12 years of age and older weighing at least 40 kg) for 3 days.

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.

Remdesivir and its metabolites are in vitro substrates and/or inhibitors of certain drug metabolizing enzymes and transporters. Based on a drug interaction study conducted with VEKLURY, no clinically significant drug interactions are expected with inducers of cytochrome P450 (CYP) 3A4 or inhibitors of Organic Anion Transporting Polypeptides (OATP) 1B1/1B3, and P-glycoprotein (P-gp)

USE IN SPECIFIC POPULATIONS [Also see Dosage and Administration and Warnings and Precautions1:

Pregnancy

Risk Summary: A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in 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

Risk Summary: A published case report describes the presence of remdesivir and active metabolite GS-441524 in human milk. Available data (n=11) from pharmacovigilance reports do not indicate adverse effects on breastfed infants from exposure to remdesivir and its metabolite through breastmilk. There are no available data on the effects of remdesivir 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 \geq 28 days old and weighing \geq 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

No dosage adjustment of VEKLURY is recommended for patients with any degree of renal impairment, including those on dialysis.

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-014



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Is ChatGPT a Better Doctor Than You?

By Weijen Chang, MD, FAAP, SFHM

hat question may be on the minds of many physicians today. We've seen that ChatGPT can pass the U.S. medical licensing exams. Artificial intelligence (AI) is rapidly improving the interpretation of diagnostic tests (EKGs, X-rays, and CT scans). And, ChatGPT was able to generate responses to medical questions more empathetically than real physicians. There doesn't seem to be any end to the list of things AI-driven tools can do better than physicians and with endless efficiency.

To be perfectly honest, as long as AI doesn't figure out (and ruthlessly address) the fact that humans are inherently destroying life as we know it on Earth, I'm looking forward to some of the advances promised by AI-driven tools. Yes, there's a risk of some subspecialties going by the wayside. Yet the premise of evidence-based medicine was always to improve patients' health, with the risk of obsolescence of whole medical industries inherent to our work.

Who doesn't want their note written by an AI-powered scribe, as long as the appropriate patient privacy protections are in place? While they're at it, AI can correctly apply charges and submit them, saving me hours staring at a maddeningly slow billing program. Perhaps AI can respond to the clinical documentation improvement queries thrown my way, or at least provide me with some strong suggestions. I'd be happy to let an AI chatbot handle prior authorizations for me. And, while electronic health record (EHR) systems are beginning to incorporate decision support, meshing these seamlessly with physician workflow will likely improve with AI-driven innovation. I'd wager AI will keep up with the newest anticoagulation recommendations better than I.

In fact, AI may have arrived on the health care scene none too soon. We're facing a worsening labor shortage on all fronts. And, while AI can't replace any of these professionals, it can assist and expedite much of the electronic drudgery inherent to their work.

I'm also looking forward to the promise of AI predicting the currently unpredictable ebb and flow of patients, which leads to waste in staffing, pharmacy stock, and medical hardware. Hospital administrators will welcome AI's promise of improving systemic inefficiencies in emergency department throughput, discharge efficiency,



Dr. Chang

Dr. Chang is a pediatric and adult hospitalist at Baystate Medical Center and Baystate Children's Hospital, associate professor of pediatrics at the University of Massachusetts Medical School Baystate in Springfield, Mass, and physician editor of The Hospitalist.

and operating room scheduling.

Before you hang up your stethoscope (or handheld ultrasound), let's all consider the unfulfilled promise of EHRs. While falling asleep charting with pen and paper is a memory of only the oldest of physicians (like me), the variability in EHR vendors, builds, and implementation has meant that physicians can experience a wide range of frustrating and error-inducing EHRs depending on their workplace. I would expect the penetration of AI tools in the health care industry to be no different, with some truly helpful AI implementation and perhaps even more annoying and soul-sucking implementation.

But even if your build of AI does hand you all the available answers, sometimes there are no answers to be had in medicine. I recall the words of an oncologist I once worked with—when there's nothing left to order, the real doctoring begins. As advanced as AI may become, it will never understand the pain of losing a loved one, the fear of facing disability or death, or the anxiety of a worried parent. Sitting at the bedside, holding a patient's hand, looking into a family member's eyes—this is the real doctoring that only we, the flesh and blood, imperfect, forgetful humans can provide. So, listen to that vet's story a little longer, play video games with your patients, and don't be afraid to tell patients about your own challenges. We're only human—let's not forget that.

Read more hospitalists' thoughts on ChatGPT on page 13.

University of Colorado Anshutz Medical Research Reviews

the Literature

By Juan N. Lessing, MD, FACP, Erin Bredenberg, MD, Leela Chockalingam, MD, Courtney Enix, MD, Kristen Harakal, PA-C, Marina Mutter, MD, Kirsten Salline, MD, and Katarina Sanford, PA-C

UCHealth at the University of Colorado Anshutz Medical Campus, Aurora, Colo.

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By Juan N. Lessing, MD, FACP

Cellulitis is frequently misdiagnosed

CLINICAL QUESTION: How accurate is the initial diagnosis of cellulitis in adult patients compared to subsequent specialist consultation?

BACKGROUND: Diagnosis of cellulitis leads to

an estimated 650,000 hospital admissions annually. As a clinical diagnosis-with no definitive confirmatory laboratory, microbiologic, or imaging result—cellulitis is frequently misdiagnosed, leading to diagnostic delay, as well as unnecessary cost,



Dr. Lessing

antibiotics, and hospitalization. The authors sought to determine how often the initial diagnosis of cellulitis might be incorrect when compared to subsequent specialist reviews as a reference standard.

STUDY DESIGN: Systematic review and meta-analysis

SETTING: Consecutive adult patients seen by generalist physicians treated for cellulitis, with subsequent secondary evaluation by a specialist in either infectious disease or dermatology. Patients were seen in inpatient, outpatient, emergency department, and observation settings.

SYNOPSIS: Using PRISMA guidelines, 5,572 citations were screened for eight studies that met all inclusion criteria. On meta-analysis of 887 patients initially diagnosed with cellulitis, 359 (40%) were felt by the subspecialist to have a non-cellulitis diagnosis. Excluding the single outpatient study, the "pseudo cellulitis" rate was 39%. Stasis dermatitis/venous stasis was the most common noninfectious, and abscess was the most common infectious, alternative diagnosis. To assess for risk of bias, the authors used the QUADAS-2 tool and found a high risk for bias in the reference standard domain. as consultants were not blind to the initial diagnosis of cellulitis. The authors rated as unclear the risk for timing bias as the effect on diagnostic accuracy of waiting, often for a day, and of being on antibiotics, until the consultant saw the patient, is unknown.

BOTTOM LINE: Similar to prior studies, this study found cellulitis is frequently misdiagnosed. The best way to reduce cellulitis misdiagnosis is unclear, but what is clear is even common conditions are commonly misdiagnosed. Revisit the need for antibiotics or continued hospitalization if an alternative diagnosis seems likely.

CITATION: Cutler TS, Jannat-Khah DP, et al. Prevalence of misdiagnosis of cellulitis: A systematic review and meta-analysis. J Hosp Med. 2023;18(3):254-61.

Dr. Lessing is an associate professor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Erin Bredenberg, MD

Partial oral antibiotic therapy may be effective in treating complicated MRSA among people with IDU

CLINICAL QUESTION: Are oral antibiotics

effective in completing treatment for complicated methicillin-resistant Staphylococcus aureus (MRSA) among patients with injection drug use (IDU)?

BACKGROUND: Mounting evidence suggests that oral antibiotics may be effective

Dr. Bredenberg

in completing treatment for invasive infections after an initial period of intravenous (IV) antibiotic therapy. However, prior studies have not focused specifically on people with IDU and/or complicated MRSA bacteremia.

STUDY DESIGN: Retrospective cohort study

SETTING: Single-site study at a large teaching hospital in a major metropolitan U.S. area

SYNOPSIS: 238 patients with recent or active IDU during the five-year study period met the inclusion criteria of hospitalization for MRSA bacteremia with complications (endocardi-



Among patients who received at least 10 days of inpatient IV antibiotics, there was no difference in the primary outcome of treatment failure at 90 days between the group treated with standard-of-care therapy compared to the partial oral therapy group. Patients who received partial IV treatment only without oral therapy had a higher rate of treatment failure as compared to either of the other groups.

BOTTOM LINE: Patients with IDU and complicated MRSA infections who leave the hospital before completion of standard-of-care IV antimicrobial therapy should receive oral antibiotics at discharge.

CITATION: Wildenthal JA, Atkinson A, et al. Outcomes of partial oral antibiotic treatment for complicated Staphylococcus aureus bacteremia in people who inject drugs. Clin Infect Dis. 2023;76(3):487-96.

Dr. Bredenberg is an assistant professor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

SHORT TAKES

ILR PLACEMENT RESULTS IN HIGHER **RATES OF BRADYCARDIA DETECTION** WITHOUT EFFECTS ON CLINICAL OUT-COMES

By Erin Bredenberg, MD

In this post-hoc analysis, placement of an implantable loop recorder (ILR) in patients 70 years or older with diabetes, hypertension, heart failure, and/or prior stroke led to increased detection of bradycardia and increased pacemaker placement as compared to usual care. However, clinical outcomes including syncope and sudden death were no different between ILR and control groups.

CITATION: Diederichsen SZ, Xing LY, et al. Prevalence and prognostic significance of bradyarrhythmias in patients screened for atrial fibrillation vs usual care: Post hoc analysis of the LOOP randomized clinical trial. JAMA Cardiol. 2023;8(4):326-34.

Dr. Bredenberg is an assistant professor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.



By Leela Chockalingam, MD

3 PE presents in one-third of patients with recent onset of exertional dyspnea

CLINICAL QUESTION: What is the prevalence

of pulmonary embolism (PE) among emergency department (ED) patients with recent onset (less than one month) of exertional dyspnea?

BACKGROUND: PE is



often associated with theDiscretediagnostic triad of pleuriticDr. Chockalingam

chest pain, dyspnea, and occasional hemoptysis. Non-specific symptoms, such as subacute dyspnea on exertion, may delay the diagnosis of PE. Despite the plausibility of PE presenting with dyspnea on exertion with or without other symptoms, no prior studies have established the rate of PE among patients with recent-onset exertional dyspnea. Guidelines and pretest probability calculators do not address this population's risk.

STUDY DESIGN: Multi-center prospective cross-sectional study

SETTING: 14 Italian EDs from September 2018 to August 2020

SYNOPSIS: In 417 patients with severe (grade 3-4 on the modified Medical Research Council dyspnea scale) acute-onset dyspnea, PE was excluded in 32.1% (n = 134) using age-adjusted d-dimer and low-risk simplified Wells score. CT pulmonary angiograms identified PE in 47.3% of the remaining 283 patients. PE was found in 32.1% (95% CI, 27.8 to 36.8) of the 417 participants. PE was more frequent (44.1%) in those with other signs/symptoms of venous thromboembolism (n = 213), and less frequent (19.6%) in those with isolated exertional dyspnea (n = 204). Among those with isolated exertional dyspnea, prevalence was lower (14.6%) in those with alternative diagnosis for dyspnea (n = 96), and higher (24.1%) in those without alternative diagnosis (n = 108). All PEs except one were in segmental or larger arteries. The trial was stopped early according to predetermined rules after an interim analysis showed PE prevalence greater than 20%.

Exclusion criteria included age greater than 75, prior history of venous thromboembolism, current anticoagulation, chronic dyspnea (greater than one month), and less severe dyspnea.

BOTTOM LINE: In this sample, PEs were found in one-third of all patients with acute-onset exertional dyspnea, and almost half of those with positive d-dimers and/or elevated pretest probability.

CITATION: Prandoni P, Lensing AWA, et al. Prevalence of pulmonary embolism among patients with recent onset of dyspnea on exertion. A cross-sectional study. *J Thromb Haemost*. 2023;21(1):68-75.

Dr. Chockalingam is an instructor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Courtney Enix, MD

4 Anticoagulation for AFib increases bleeding risk and death in patients over 65 with cognitive impairment

CLINICAL QUESTION: In older patients with atrial fibrillation (AFib), does frailty or cognitive function affect the risk of anticoagulation use?

BACKGROUND: In older patients with AFib, both the risk of stroke and the use of preventat-

vive anticoagulation are common. However, the

impact of cognitive impairment and frailty on the risks of anticoagulation use in older patients with AFib is unknown.

STUDY DESIGN: Observational prospective cohort study

SETTING: Seven ambulato-

ry cardiology and internal medicine centers in Massachusetts and Georgia, between 2016 and 2018

SYNOPSIS: 1,244 patients 65 years and older (average 75.5) with AFib were enrolled, and outcomes were observed during two years. Participants had CHADS2-VASC scores >2 (average 4.4). Cognitive function and frailty were determined using the Montreal Cognitive Assessment Battery and Fried frailty scale, respectively; 528 cognitively impaired individuals (42.4%) and 172 frail participants (13.8%) were observed. There were higher rates of composite major bleeding and death in individuals with cognitive impairment (adjusted HR, 2.23; 95% CI, 1.08 to 4.61) compared to those without (adjusted HR, 0.94; 95% CI, 0.49 to 1.79; P for interaction = 0.08). The number needed to harm was 8.4 for major bleeding and death among cognitively impaired individuals compared to 103 in cognitively intact. There was no significant difference in major bleeding or death among participants with or without frailty. Limitations include the study's observational nature and inability to attribute causation. The low prevalence of frail patients limits the ability to evaluate clinical outcomes based on frailty status. Additionally, the incidence of stroke in this study was lower than in prior historic trials. underpowering stroke as an outcome.

BOTTOM LINE: Anticoagulation for AFib was associated with a higher incidence of major bleeding events and death in patients 65 years of age and older with cognitive impairment. There was no significant difference in harms associated with anticoagulation use based on frailty status.

CITATION: Wang W, Lessard D, et al. Differential effect of anticoagulation according to cognitive function and frailty in older patients with atrial fibrillation. *J Am Geriatr Soc.* 2023;71(2):394-403.

Dr. Enix is an assistant professor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Kristen Harakal, PA-C



CLINICAL QUESTION: Does early administration of glucocorticoids to intensive care unit (ICU) patients with severe community-acquired pneumonia (CAP) reduce mortality?

BACKGROUND: Previous, randomized, controlled trials have shown efficacy in using glucocorticoids in CAP treatment as far as



Dr. Enix

stay. However, there is no substantial evidence regarding a reduction in mortality due to the use of glucocorticoids.

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

SETTING: 31 French ICUs



IN THE LITERATURE

Ms. Harakal

SYNOPSIS: The study randomized 795 ICU patients with severe CAP to continuous infusion of 200 mg hydrocortisone daily versus saline infusion in a 1:1 ratio within 24 hours of meeting the severity criteria. All patients received standard-of-care CAP treatment, including antibiotics and supportive measures. At baseline, respiratory support included mechanical ventilation (44%, half of them non-invasive), highflow nasal cannula (42%), and non-rebreather mask (14%). The primary outcome was 28-day all-cause mortality, which occurred for 6.2% of patients treated with hydrocortisone and 11.9% receiving the placebo. Absolute risk reduction (ARR) was 5.6% (95% CI, 1.7 to 9.6%, P = 0.006), and the number needed to treat (NNT) was 18 to prevent one death. Notable secondary outcomes included 11.5% ARR in the need for endotracheal intubation (NNT = 9) and 10% ARR in the need for vasopressors (NNT = 10). The only statistically significant difference in safety outcomes was higher mean insulin requirements for those assigned to hydrocortisone. Some limitations include the exclusion of patients with septic shock, no standardized isolation of causative microbes, and the inclusion of only a small number of immunocompromised patients.

BOTTOM LINE: Early administration of hydrocortisone in severe CAP is associated with a lower risk of all-cause 28-day mortality.

CITATION: Dequin PF, Meziani F, et al. Hydrocortisone in severe community-acquired pneumonia. *N Engl J Med.* 2023;388(21):1931-41.

Ms. Harakal is an instructor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Marina Mutter, MD



CLINICAL QUESTION: What are medicine floor

patients told about their hospital discharge instructions and by whom?

BACKGROUND STUDIES:

Prior studies have demonstrated suboptimal communication with patients about discharge plans of care, leading to preventable harm. In addition, a lack of



Dr. Mutter

clarity exists among team members about the responsibility of discharge communication.

SHORT TAKES

NON-MRI-CONDITIONAL ICDS HAVE PRESERVED SHOCK FUNCTION AFTER MRI

By Marina Mutter, MD

Non-magnetic resonance imaging (MRI)-conditional implantable cardioverter defibrillators (ICDs) appropriately detected and treated tachyarrhythmias after an MRI, with 4,177 arrhythmia episodes detected in 237 patients during a median follow-up of 2.2 years.

CITATION: Ra J, Oberdier MT, et al. Implantable defibrillator system shock function, mortality, and cause of death after magnetic resonance imaging. *Ann Intern Med.* 2023;176(3):289-97.

clinical stabilization and reduction in length of

IN THE LITERATURE

STUDY DESIGN: Observational quality improvement study

SETTING: Internal medicine services at two urban, tertiary-care teaching hospitals

SYNOPSIS: A trained observer observed the communication of 33 medicine patients and their providers on the day of discharge. Only one patient received counseling on six key discharge communication domains; 59% of patients were not informed about the purpose of a medication change, 48% were not informed about the purpose of follow-up appointments, 82% were not counseled on red-flag symptoms, and only 3% were asked to teach back their discharge instructions. Nurses spent the most total time with patients on the day of discharge, though there were variable roles noted in who communicated what aspects of discharge education. Limitations of this study include the small sample size, inclusion of only English and Spanish-speaking patients, and lack of non-teaching hospital data.

BOTTOM LINE: Gaps remain in discharge education at teaching hospitals, with the health care teams in this study providing substandard explanations to patients regarding discharge plans.

CITATION: Trivedi SP, Corderman S, et al. Assessment of patient education delivered at time of hospital discharge. JAMA Intern Med. 2023;183(5):417-23.

Dr. Mutter is an assistant professor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Kirsten Salline, MD

Systemic corticosteroids for patients with severe CAP

CLINICAL QUESTION: Among patients hospital-

ized with community-acquired pneumonia (CAP), does the addition of corticosteroids reduce mortality?

BACKGROUND: Corticosteroids are used as an adjunctive treatment in infections like bacterial meningitis and COVID-19-related pneu-



Dr. Salline

monia. Previous trials and meta-analyses have been mixed in their findings of whether mortality and clinical outcomes are improved with the addition of steroids to standard antibiotic therapy for the treatment of CAP.

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

SETTING: The included studies were conducted

in hospital wards and intensive care units (ICUs) in the U.S., Europe, the Middle East, and Asia.

SYNOPSIS: 16 studies comprising almost 4,000 patients met inclusion criteria. Seven studies had populations that included ICU patients. Steroid interventions were diverse and included both intravenous and oral corticosteroids, ranging in duration from 1 to 20 days. The primary outcome of all-cause mortality was 9.5% versus 10.8% for those with and without steroid therapy, respectively. The 95% confidence interval was wide and included a possibility of a 33% relative reduction and a 7% relative increase in mortality. In six trials that reported on ICU admission post-randomization, corticosteroids showed benefit, with 3.1% requiring ICU admission versus 4.7% in the standard care group (RR, 0.66; 95% CI, 0.45 to 0.97).

In eight trials that reported on need for mechanical ventilation post-randomization, adjunctive corticosteroids again showed benefit, with 4.2% in the steroid group requiring intubation versus 7.1% in the standard care group (RR, 0.51; 95% CI, 0.33 to 0.77).

Major limitations of this meta-analysis include heterogeneity in disease severity between study populations and steroid treatment intensity. Nine studies included only hospital ward patients, three studies included only ICU patients, and four studies included a mix of ward and ICU patients. The study authors did not perform a subgroup analysis pooling ICU and non-ICU studies separately.

BOTTOM LINE: Corticosteroids may benefit patients more severely ill from CAP as evidenced by lower rates of ICU admission and need for mechanical ventilation. The effect estimate for mortality reduction had a wide confidence interval, indicating continued uncertainty and the need for more studies.

CITATION: Saleem N, Kulkarni A, et al. Effect of corticosteroids on mortality and clinical cure in community-acquired pneumonia: A systematic review, meta-analysis, and meta-regression of randomized control trials. Chest. 2023;163(3):484-97.

Dr. Salline is an instructor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

By Katarina Sanford, PA-C

Transcatheter arterialization provides R safe and effective treatment for nooption CLI

CLINICAL QUESTION: Is transcatheter arterialization of lower extremity deep veins safe and effective in preventing above-ankle amputation in patients with advanced chronic limb ischemia (CLI) who are otherwise not candidates for arterial revascularization?

BACKGROUND: About 20% of patients with CLI

are not candidates for arterial revascularization ("no-option") due to insufficient distal arterial target vessels, and have low amputation-free survival (42%). Transcatheter arterialization of deep veins involves percutaneous creation of an arteriovenous



fistula using a stent to connect the tibial artery to an adjacent vein to provide oxygenated blood to the distal lower extremity through reverse flow in pedal veins and may be an option for these patients with CLI.

STUDY DESIGN: Prospective, single-group, multicenter study

SETTING: 20 sites in the U.S.

SYNOPSIS: Investigators enrolled 105 participants with no-option CLI who had focal or extensive tissue loss or gangrene, 74% of whom had prior unsuccessful revascularization. They included patients on dialysis with stable AV fistula or peritoneal dialysis. All patients received dual antiplatelet therapy for at least three months.

Following 104 (99%) successful procedures of creating an artery-to-vein connection, 66% of the patients had amputation-free survival at six months, which exceeded the performance goal (54%). At six months, 25% of participants had complete wound healing, and another 51% had wound healing in process. The amputation-free survival differed by dialysis status, 37% and 73% for those requiring and not requiring dialysis, respectively. At six months, 19% experienced stent occlusion, and 37% needed reintervention.

Limitations include few patients dependent on dialysis (19), short-term follow-up (12 months), lack of a control group (randomization for major amputation was deemed unfeasible both ethically and practically), the procedure may require a specialist center, and the study was during the COVID-19 pandemic with 12 reported infections and five deaths that were related to COVID-19.

BOTTOM LINE: Transcatheter arterialization for CLI may provide a safe and effective option for patients who may otherwise be relegated to amputation, aside from dialysis-dependent patients, in which further study may be warranted.

CITATION: Shishehbor MH, Powell RJ, et al. Transcatheter arterialization of deep veins in chronic limb-threatening ischemia. N Engl J Med. 2023;388(13):1171-80.

Ms. Sanford is an instructor in the division of hospital medicine at the University of Colorado Anshutz Medical Campus in Aurora, Colo.

The Hospitalist Editorial Board Applications Open

8

The Hospitalist's editorial advisory board is a volunteer group of SHM members who share their professional expertise and insight through the pages of the magazine and through our expanding digital offerings. Members help develop and focus content relevant to hospitalists, recommend sources for articles, and may serve as sources or write articles. The editorial board meets virtually every month and in person annually at SHM Converge to

hospital medicine.

The editorial board serves as a representation of the SHM membership, as such we strive for diversity in our demographics, type of institution, location, and length of career*. We look for candidates who are passionate about hospital medicine, active and engaged in SHM, and eager to share their expertise and ideas.

Participation offers an unprece-

discuss relevant and timely topics in dented opportunity to communicate January 15, 2024, at midnight ET. with peers and further the hospital medicine movement.

> *This includes trainee members. Trainees with a background in adult or pediatric hospital medicine, including med-peds, are encouraged to apply.

Editorial board members serve a two-year term; trainee members serve a one-year term.

The deadline for submissions is

Scan the OR code for more information and to apply.



Gender Disparities Among Hospitalists

How do we close the gap?

By Maya Defoe, MD, Areeba Kara, MD, MBBS, SFHM, and Marisha Burden, MD, MBA, FACP, SFHM

ince gender-based discrimination in education was prohibited by the passage of Title IX, women have steadily gained parity in the numbers graduating from medical school classes. The illusion of gender equity, however, starts to erode rapidly as women lose ground at each subsequent rung of the professional ladder. Women leaders of hospital medicine and full professors in hospital medicine are a rarity. Gender-based disparities in income among hospitalists also continue to exist, culminating in perverse, pervasive, and persistent disparities for women in medicine.

Multiple factors contribute to the current state, including gender bias and harassment from colleagues, supervisors, and patients, the disproportional burden of household and parental responsibilities placed on women, and the expectations that women should take on more nurturing tasks that are often less highly weighted towards academic promotion (e.g., leading non-academic committees such as wellness or diversity, equity, and inclusion instead of focusing on obtaining grants for research). Additionally, women often receive biased feedback in evaluations which can also impact career trajectories.¹⁻³ While gender bias can be subtle, like assuming a woman colleague will be in charge of taking notes in a meeting instead of a man, some policies explicitly widen the gender divide. Paid parental leave is one example of such a policy.

Institution-level policies emphasizing maternal rather than parental leave perpetuate gender inequity. Restricting family leave to the primary caregiver forces women to assume the brunt of childbearing responsibilities from the outset, propagating the existing gender discrepancy in household duties. Women consequently experience a "motherhood tax" where mothers are perceived as less committed or too busy to take on leadership roles. Compared to men academic hospitalists who take leave, women report far more negative impacts related to financial well-being, work-life integration, and career advancement. Even if a woman is childless, the assumption of future motherhood may lead to discrimination.

The factors that prevent women from climbing the leadership ladder are the same circumstances that often lead women to leave the workforce. Since women account for 50% of employed hospitalists and have been shown to have better clinical outcomes, their retention in the workforce is vital to the future of this field.

Strategies that make a difference

There are organizational strategies that have been shown to mitigate disparities in salary, career advancement during life transitions (e.g., parental leave), speaking opportunities, and micro- or macro-aggressions. Much of the literature suggests there are basic principles organizations can adopt to address these disparities.

Applying Donabedian principles

Hospitalists well-versed in the quality sphere may be familiar with Donabedian principles, which highlight that outcomes are a direct result of intertwining processes and structures. Much of the literature on successful outcomes in eliminating gender disparities in the workplace comes from processes and structures that systematically address the issues that lead to gender disparities in the first place.

One example of a successful process is open calls for speaking roles at national meetings. SHM has implemented an open-call process for workshop and didactic speakers, and more recently plenary speakers. Northcutt, et al.,⁴ showed that when an opencall system is in place, gender disparities are eliminated without a negative impact on conference ratings (in fact increasing scores were seen).

Regarding minimizing the motherhood tax, offering equal paid parental leave to birthing and non-birthing parents is only a start. Pylkkänan, et al.,⁵ found equitable leave policies did not necessarily translate to men taking longer leaves, suggesting that specific encouragement of men to take parental leave is also necessary to promote gender equality within the workforce. Moreover, allowing for flexibility in terms of when the leave is taken can help allow for a ramping-up period while returning to work to prevent the perceived negative impacts of taking extended leave.

Promoting transparency

A key component of any organizational initiative to mitigate disparities is increasing transparency around decision-making





Dr. Kara



Dr. Burden

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processes and sharing the policies and procedures for determining salaries, promotions, and job opportunities. Research suggests that one way to mitigate bias in negotiations for women is to ensure there is decreased ambiguity in the economic structure of a negotiation.⁶ One strategy that helps to level the playing field is posting salary ranges for open positions and requiring that all positions available are publicly posted. In the state of Colorado, the Equal Pay for Equal Work Act requires that employers do not discriminate between employees based on sex by paying an employee of one sex a wage rate less than the rate paid to an employee of a different sex for substantially similar work. A specific requirement of this act is that all job openings and open promotional opportunities are posted with a hiring rate or range.7

Commitment to following outcomes

Once institutions have evaluated practices for inequities within salaries, leadership appointments, workload distributions, and gender-based harassment, to name a few, leaders must stay committed to evaluating whether proposed interventions lead to gender equity in the long term. Furthermore, institutions should be willing to re-evaluate strategies if inequity persists.

Gender gaps persist in medicine; however, processes, policies, organizational culture, and commitment make a difference and should be emphasized as we envision an equitable future.

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SHM SIG Leaders Reflect on 2023

Hospitalists educate, collaborate, grow, and inspire

By Lisa Casinger



Academic Leaders SIG chair, Romil Chadha, MD, MBA, MPH, FACP, SFHM

Chief medical information officer at the University of Kentucky Healthcare, associate professor of medicine at the University of Kentucky in Lexington, Ky.

SIG accomplishments:

We met monthly and discussed multiple vital topics like advanced practice practitioner (APP) integration, SHM's 2023 State of Hospital Medicine Report, administrative harm, virtual hospitalist, leadership full-time equivalents, scheduling software, and distribution of teaching services. Our membership grew, and we expanded our network. We are close to starting a round-robin process for academic promotion letter writing.

Best of 2023: I switched roles from hospital medicine division chief to chief medical information officer for the University of Kentucky Healthcare. We took a family trip to India. Our son qualified for the state archery competition a second time, and our daughter transitioned to an independent swimmer.

Share: Goodhart's Law: "When a measure becomes a target, it ceases to be a good measure."

Diversity, Equity and Inclusion (DEI) SIG co-chair, Areeba Kara (@ areeba_kara), MD, MBBS, MS, FACP, SFHM

Associate professor of clinical medicine and associate division chief, division of general internal medicine and geriatrics at Indiana University School of Medicine in Indianapolis



SIG accomplishments: We kicked off our year by hosting both diversity, equity, and inclusion, and women in hospital medicine special interest forum during SHM Converge 2023. Our group continues to grow, and we recruited a SIG secretary through an open-call process. The SIG hosted SHM's second annual Pride mixer in June and led SHM's participation in Spirit Day to express solidarity with LGBTQIA+ youth. SIG members delivered a webinar on unconscious bias and health care disparities (and what you can do as a hospitalist), planned a Tweetorial on gender disparities in pay, and held a DEI-focused Journal Club in November.

Best of 2023: Watching my mentees succeed has brought me immense personal and professional joy this year. Help someone else—it will make you happy at least twice!

Share: I rediscovered how much I enjoy reading fiction. Stopping the doom scrolling and the Netflix flitting has brought me calm. Go back and do something you used to love; you've probably forgotten how much fulfillment it brought you.

Palliative Care SIG chair, Elizabeth Gundersen, MD, FAAHPM, FHM

Associate professor, medicine-internal medicine, and assistant dean for student affairs at the University of Colorado School of Medicine in Aurora, Colo.

SIG accomplishments: It's

been a year of renewal for the Palliative Care SIG! Following the palliative-care mini-track and SIG meeting at SHM Converge 2023, we reconstituted our executive committee and planned a series of webinars for 2023 through 2024. Many of our members don't have access to a robust palliative-care service and recognize that regardless of that access, palliative-care skills are at the heart of patient-centered care. Our past and future programs include discussions around communication, prognostication, and resources for those wishing to strengthen their palliative-care skills. That will take us to SHM Converge 2024, where we have another awesome mini-track and SIG meeting planned.

Best of 2023: I took a huge personal and professional risk and moved from South Florida to the foothills of Colorado. I'm now experiencing a brand-new set of challenges and rewards. It's been difficult at times, but it's been worth it! The personal and professional growth have been amazing, and I look forward to more of the same.

Share: Vulnerability is worth it. Moving across the country and starting a new position has required me to ask for help and say "I don't know" more than feels comfortable. However, if I don't ask, I'll never learn! Having the courage to ask for help and giving myself grace when I don't know something has made me a better person and a better doctor. I firmly believe that when team members can lean on each other, it makes the entire team stronger and our patient care better.

Hospitalists Trained in Family Medicine (HTFM) SIG vice chair, Krishna Syamala, MD, FAAFP, FHM

A hospitalist at SSM Health St. Joseph Lake Saint Louis in Lake Saint Louis, Mo.

SIG accomplishments:

Members of our SIG are concerned about the recent decision by the American Board of Internal

Medicine (ABIM) to discontinue focused practice in hospital medicine boards by the end of this year. We've had extensive discussions among our SIG executive committee members and our counterparts in the American Board of Family Medicine (ABFM) and the American Academy of Family Physicians.

We planned three webinars this year that focused on hospital medicine fellowships, hospitalists trained in family medicine in academics, and leadership roles.

For the last several years there have been extensive discussions about creating a critical-care



pathway for family-medicine-trained hospitalists. The recent turn of events by the ABIM has provided the headwinds to achieve the goal. We are encouraging our SIG members to be

part of local SHM chapters in leadership roles to help mitigate the hiring bias for hospitalists trained in family medicine.

We are also in the process of requesting ABFM to come up with a Maintenance of Certification focused on hospital medicine, similar to what ABIM is implementing next year.

Med-Peds SIG chair, David Fish, MD, SFHM

Assistant professor in pediatrics and medicine at Baystate Medical Center, University of Massachusetts Chan Medical School in Springfield, Mass.



SIG accomplishments:

Over the last year, our SIG

has made moves to increase engagement opportunities for our members as well as provide additional opportunities for mentorship for med-peds hospitalists across the country. We have also actively been working on increasing our scholarly output as a group.

Best of 2023: This has been a busy year both professionally and personally. I've made a big career shift, changing institutions to Baystate Medical Center where I'm further advancing my career in medical education. We're currently developing a fellowship program to create training opportunities in pediatric and med-peds hospital medicine. I've also had the opportunity to watch my kids develop into the amazing individuals they are. Most recently they decided to dive head-first into music; I have a little drummer and a singer!

Share: Over the last year, I've continued to be amazed by the resourcefulness of those in our field as we navigated yet another crisis with the respiratory surge of last winter. It really demonstrates the strength that we have as clinicians and leaders, and I think all hospitalists should be aware of the impact they can make at both the local and national levels.

Quality Improvement (QI) SIG chair, Harvir Singh Gambhir MD, FACP, CPL, CPHQ, FHL,

FHM Black Belt (Lean SixSigma); vice chair for quality improvement and patient safety of department of medicine, associate chief of

quality of division of hospital



medicine, associate program director of internal medicine residency program, associate professor, and hospitalist at SUNY Upstate Medical University in Syracuse, N.Y.

SIG accomplishments: As a QI SIG, we planned our executive meetings in a structured manner to serve our QI members to share their QI work, so they have an opportunity to collaborate with the QI community.

Best of 2023: As part of the QI lead in my institute, we transformed sepsis care and management to impact clinical care and improve metrics. Personally, I got back to my fitness discipline and lost 20 pounds.

Share: We as hospitalists are uniquely posi-





tioned to lead in various domains, and we must learn skills to practice leadership every day to transform health care.

Patient Experience (PX) SIG chair, Hospitalist Well-being SIG vice chair, Swati Mehta, MD, FACP, CPXP, SFHM

Director of quality and performance and national director of quality and experience for Vituity, a hospitalist at Common Spirit Health System in Redwood City, Calif.



The Well-being SIG was born out of the trials and tribulations of the pandemic which made it very clear that hospitalists need a safe space to discuss their challenges, share their individual and their teams' burnout journey, and collectively look for solutions. The Well-being SIG hosted a webinar where an expert panel shared their experiences and journeys to well-being. We are also looking to partner with other SIGs (such as the PX and APP SIGs) as we realize that for any quality initiative to work at a hospital, clinician well-being is the core and foundational first step.

Best of 2023: I was able to present at CommonSpirit National Grand Rounds this year, not once but twice! I was able to represent SHM both times, first by presenting the work we did as a well-being taskforce, sharing the toolkit that was created, and second by discussing patient experience and how SHM is leading the charge in that domain as well. Personally, reading the book "Wonder Drug," written by two physicians who tie well-being, patient connection, and compassion together, has been powerful for me, as that connects two of my biggest passions. We need to fill our cups first before we pour into others, and when we connect with our patients, our cups get filled! PX and well-being are two sides of the same coin!

Substance Use Disorders SIG chair, Susan L. Calcaterra, (@ CalcaterraSusan), MD,

Director of addiction medicine consultation service, associate professor of medicine in divisions of general internal medicine and hospital medicine at the University of Colorado Hospital in Aurora, Colo.

MPH

SIG accomplishments: Among its accomplishments, the Substance Use Disorders SIG held three events:

A meet-and-greet at SHM Converge 2023 where we heard from many hospitalists about their efforts to provide evidence-based addiction treatment to hospitalized patients in private, academic, community, urban, and suburban hospital settings.

A presentation by Drs. Alex Logan and Mar-

⁴⁴Over the last year, I've continued to be amazed by the resourcefulness of those in our field as we navigated yet another crisis with the respiratory surge of last winter. It really demonstrates the strength that we have as clinicians and leaders, and I think all hospitalists should be aware of the impact they can make at both the local and national levels.⁹⁷

Dr. David Fish

lene Martin, "Inpatient Management of Opioid Withdrawal in the Fentanyl Era."

Presentation by Dr. Anna Maria South and Rebekah Joab, JD from the Legal Action Center, "The Americans with Disabilities Act and Its Applications for People with Substance Use Disorder—Advocacy Tools for Common Clinical Scenarios Encountered by Hospitalists".

Best of 2023: I was invited by Drs. Katie Welter and Kevin O'Leary to give Grand Rounds in the Division of Hospital Medicine at Northwestern Memorial Hospital in Chicago. It was a wonderful opportunity to connect with colleagues across the country and to learn of their efforts to expand access to medication treatment for substance use disorders in the hospital setting.

Share: The most satisfying part of my 2023 has been collaborating with colleagues across the country on various projects and publications. Developing these relationships has enriched my professional life. I've learned, not only in 2023 but over the years, that when I partner with others on projects or publications, the final products will be exponentially better and more impactful, and will likely lead to other opportunities for growth and collaboration.

NP/PA SIG chair, Kasey Bowden MSN, FNP, AGACNP, ACNP, FHM

Assistant professor of medicine, co-associate division head of hospital medicine at University of Colorado School of Medicine in Aurora, Colo.

SIG accomplishments: The

NP/PA [nurse practitioner/physician assistant] SIG has hosted several webinars on topics such as split or shared billing, onboarding best practices for NPs and PAs, and a joint webinar with the newly formed Hospitalist Well-being SIG on enhancing physician-NP and physician-PA wellness in hospital medicine. Several members of our NP/PA SIG also collaborated to write an article for an upcoming issue of The Hospitalist outlining the similarities and differences among nurse practitioners and physician assistants, and how to optimize NP and PA utilization on hospital medicine teams.

Share: This year has reminded me of the positive power of teams and togetherness, both personally and professionally. With the field of medicine, and the world, in a constant state of flux, there's never been a more important time to lean on others and lift one another up to create positive outcomes for ourselves, our colleagues, our patients, and our communities.



Physician Advisors SIG chair, Aziz Ansari, DO, FAAHPM, FACP, SFHM

Associate chief medical officer for clinical optimization and revenue integrity, and professor of medicine at Loyola University Medical Center in Maywood, III.



SHM

SIG accomplishments: My-

self and the other leaders, Dr. Christopher Boyle, vice-chair, and Dr. Diana Childers, secretary, are very proud of the Physician Advisors SIG's activities for 2023. We have a newly revitalized executive council that meets four times a year to plan, dialogue, and execute engagement activities for the year. Our goal is to have four activities between SHM Converge conferences. The SIG provides an excellent forum to learn from shared experiences and develop a more organized approach for physician advisors to optimize operational outcomes in their respective hospitals.

Best of 2023: Personally, 2023 has been an exciting year with a daughter starting college and a new chapter of life starting! Professionally, having a bigger role in running clinical operations at my medical center and having the privilege of chairing a recharged Physician Advisor SIG have been very rewarding.

Share: Take advantage of opportunities that come knocking on the door. And at the same time, protect yourself and continue the journey of finding the right balance of work and personal life that works for you!

Hospital Medicine Disaster Preparedness

and Management SIG chair, Maria (Gaby) Frank, MD, FACP, FAOS, SFHM

Hospitalist in the division of hospital medicine, medical director of bio-containment unit at Denver Health Hospital Authority in Denver, and professor of medicine,



director of faculty development and advancement in division of hospital medicine at University of Colorado School of Medicine in Aurora, Colo.

SIG accomplishments: Successful and well-attended Special Interest Forum at SHM Converge 2023, with recruitment of new executive members to our SIG.

Launched our webinar series on disaster medicine for hospitalists. Thus far we've had two webinars ("Everything Everywhere All At Once: Introduction to Disaster Response and Preparedness for Hospitalists" presented by Dr. Jason Persoff, and "Medical Management and Principles of Radiation Injuries" presented by Dr. Riley Jones), that are available in the SHM HMX SIG library for asynchronous viewing. Our goal is to offer quarterly webinars starting in 2024.

Partnering with the Education Committee for the Rapid Clinical Updates, we will be contributing two expert speakers to discuss "Burn Management for Hospitalists" and "CO Toxicity Management" in January 2024.

SIG members collaborated on submitting a workshop and a didactic session for SHM Converge 2024. Although not accepted for presentation, it helped strengthen our SIG members' collaboration and shared vision.

Best of 2023: Some of the most fulfilling professional experiences are those involved with developing partnerships, collaborations, and relationships. These opportunities included the many professional national meetings where we get to meet face-to-face with colleagues we normally only see virtually. I also had the honor of being

Share: I would like to share with hospitalists a thought. Even though it is not something I first learned in 2023, I feel it is worth highlighting. Unfortunately, several mass-casualty incidents have made the news during 2023, from man-made (such as the conflicts in Ukraine-Russia, Isra-el-Gaza (Hamas), mass shootings, etc.) to natural disasters (multiple earthquakes, wildfires, hurricanes, etc.). With hospitalists frequently being the largest group in most institutions, the need for disaster preparedness and management training for hospitalists becomes imperative. Our SIG will continue to aim to develop easy-to-use and easy-to-access resources available for all hospitalists.

Pediatric SIG chair, Klint Schwenk, MD, FAAP, MBA, SFHM

Pediatric hospitalist, University of Louisville School of Medicine at Norton Children's Hospital in Louisville, Ky.

SIG accomplishments: In 2023, our SIG set a goal to find ways to connect with

the other SIGs and combine efforts for education and advocacy. One of our open forums was co-sponsored by the Med-Peds SIG and focused on ways to incorporate health equity and patient-centered communication into clinical pathways. Our speaker was Dr. Rohini Harvey from Baystate Medical Center. In February, we plan to have a webinar about diagnostic errors, which will be relevant to many SHM members with hopes of finding additional SIG co-sponsors with which to network.

As both hospitalists and pediatricians, we hope to advocate for our patient population on a larger scale within SHM. We plan to continue to network with leadership within the SHM Public Policy Committee.

Best of 2023: Professionally, my biggest accomplishment this year was launching a new bronchiolitis and high-flow nasal cannula protocol at our children's hospital with big goals to reduce the overuse of high-flow nasal cannulas. Personally, this year was about getting back on track. That included fitness and wellness goals, and a desire to travel and take personal time. I don't know that I will ever achieve a work-life balance, but prioritizing yourself helps keep your professional goals in line as well.

Point of Care Ultrasound SIG co-chair, Benji K. Mathews, MD, MBA, SFHM

Senior medical director, hospital specialty services, HealthPartners, Minneapolis/ St.Paul, West-Central Minnesota, Western Wisconsin

SIG accomplishments: Our

SIG, formed in 2018, boasts well over 1,000 members and has aimed to support the many hospitalists throughout the nation to support, learn, and network as they navigate the use of the powerful diagnostic tool with bedside ultrasound.

Dr. Gordy Johnson and I co-chair the group and this year we started a year-long journey of providing very practical simulive [simulated live] webinars for our hospitalist with Q and A sessions that allow lots of interaction. Many individual hospitalists and leadership teams are trying to navigate approaches to building programs, approaching credentialing and billing, and thinking through best devices. The goal is to provide quality educational content. The webinars include:

- Starting a POCUS Education Program
- Ways to Learn POCUS and Approaches to
 POCUS Training
- Starting a Procedure Service and Building Procedural Competency
- Which Device is Right for You?
- Credentialing and Billing
- Unique Applications of POCUS Focus on VexUS
- Image Storage and Quality Assurance

Best of 2023: I had the opportunity to travel with family for a couple of weeks through the year and with friends on a ski trip.

Share: An important lesson that kept coming back this year was to embrace the challenge of uncertainty and change. We are in an era of constant change. When we feel uncomfortable, it means that we have the potential to grow and discover something new. It often means we have a chance to make a difference in ourselves and the spaces around us—often through innovations. Rather than ignoring or avoiding this feeling, amplify and lean into it. That is how we become better people, clinicians, and leaders.







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ChatGPT and AI: How Does Health Care Handle 1.0?

The rapid rise of the most popular large-language model chatbot has hospitalists —and health care—taking caution to use the new technology properly in clinical care

By Richard Quinn

ealth care, including hospital medicine, isn't exactly known as the professional land of early adopters—and for good reason.

The regulations that govern the care of hospitalized patients can't allow just every new application, website, or technology to get its hands on patient information. And hospitalists can't just rely on Google searches to come up with the right approach to a particularly difficult diagnosis.

But can it help? Can hospital medicine embrace the latest technology in real time?

Well, ChatGPT is a test case. The large-language model-based chatbot has taken the world by storm over the past year and it has hospitalists asking each other, "What are the real use cases in clinical care, their pros and cons, and rules of the still-being-built road?"

"Like all new technology, there is

a lot of hype that goes with it," said Vineet Arora, MD, MAPP, MHM, (@FutureDocs), dean for medical education at the Pritzker



Dr. Arora

School of Medicine at the University of Chicago. "I think of other technologies that have come, that people have hyped up in health care, and I think this one is one we're looking at the version 1.0 for a large language model."

Not yet ready for primetime

For the technologically uninitiated, ChatGPT stands for Chat Generative Pre-trained Transformer. It is an artificial intelligence (AI) technology that uses available content online to generate answers in response to questions posed by users. It mimics interpersonal dialogue as closely as it can, to make back-and-forth communication more akin to conversation. Multiple companies have similar technology, so there are different chatbots available for use online.

Generative AI technology, like when the first iPhone was delivered in 2007, remains in its earliest phases, but—again like the iPhone—it has already begun pushing its way into everyday societal use faster than anyone but its creators could foresee.

Just not quite in health care yet. "It's not ready for health care primetime," Dr. Arora said. "In contrast, Google has released Med-Palm as an alternative specific for health care. It has a more limited release so they can make it ready for healthcare primetime but looks promising given the early results."

"I think everyone is excited

about (ChatGPT), and it's slowly starting to sneak into clinical work in a couple of different



hospitalist Dr. Airan-Javia Subha Airan-Javia, MD, FAMIA, (@ subhaairan), who practices at Hospital of the University of Pennsylvania in Philadelphia. But "I think it's far from widespread right now."

Dr. Airan-Javia, a former associate chief medical informatics officer, says the most immediate use for ChatGPT in its current iteration is more as a resource than an end tool. In clinical decision making, she sees the opportunity potentially to streamline thought processes—to use it as a reference or resource to help find key information about a diagnosis, symptom, or contraindication. And it doesn't require integration into your clinical systems—another plus.

"Additionally, when using it as a reference, you don't need to enter any patient health infor-

mation, which of course keeps things simpler from a security and compliance perspective," she said. "For example, one can say, 'I have a patient with this background and these symptoms. What diagnoses should I be thinking of?' I have used it multiple times a day while I'm on service to help think through certain scenarios or diagnoses that I might not be as familiar with, and once it gives me that first pass, I then go and dig deeper, cross-checking with other sources such as UptoDate. Dr. Peter Lee from Microsoft says, 'Trust, but verify.' That is a good motto to go by when first starting with ChatGPT."

Dr. Airan-Javia says a recent example for her was a patient presenting with bacteremia.

"The patient had a fairly atypical organism growing in their blood culture. I wasn't sure where or what the source was, and it was an organism I wasn't as familiar with," she said. "So to get me started, I asked ChatGPT, 'Can this particular organism be seen as a contaminant, or does it tend to come from a particular source in the body? And what should I be thinking about?"

ChatGPT gave an answer, and Dr. Airan-Javia fed it a few more details and got an even more tailored response. She didn't view the AI-generated answers as the endpoint of research, but more like a waypoint to see which path to head down next. "That was really helpful," she said. "I then went and researched a few more details in more typical sources and knew what to do next. But that initial step with ChatGPT summed up a large amount of research in a few paragraphs that helped get me started."

That last step—a doctor verifying by doing more diagnostic homework—is key, particularly in the still-early days of ChatGPT.

Beth Israel Deaconess Medical Center (BIDMC) professionals published a study in the summer of 2023 that assessed the ability of one generative AI to provide accurate medical diagnoses.¹ The AI selected the correct diagnosis 39% of the time and provided the correct diagnosis in its list of potential diagnoses in 64% of challenging cases, according to a BIDMC announcement.

"While chatbots cannot replace the expertise and knowledge of a trained medical professional, generative AI is a promising potential adjunct to human cognition in diagnosis," first author Zahir Kanjee, MD, FACP, MPH, a hospitalist at BIDMC and assistant professor of medicine at Harvard Medical School in Boston, said in the press release.

"It has the potential to help physicians make sense of complex medical data and broaden or refine our diagnostic thinking. We need more research on the optimal uses, benefits, and limits of this technology, and a lot of privacy issues



need sorting out, but these are exciting findings for the future of diagnosis and patient care."²

Garbage in, garbage out

Dr. Arora notes that—similarly to what happened when WebMD debuted—one of the first interactions for many hospitalists with ChatGPT will be patients using it in conversation with them.

"Absolutely, it's like Google," Dr. Arora said. "My search engine now has ChatGPT in enabled searches at the top. I do think it's going to be part of health care in the sense that patients are using it, just like they're using 'Dr. Google.""

But that concerns Dr. Arora as some patients may not come to the hospital armed with the right information. And in the context of physical exams, how patients describe what is happening to them—or what they think ChatGPT is telling them happened to them—can cause downstream issues.

"More importantly, it's about misinformation," Dr. Arora said. "It's garbage in, garbage out. There's a lot of garbage out there that ChatGPT can learn on. And that's dangerous. It goes back to credible sources. So, yeah, you should be asking your patients what they are learning from. What are they finding out? Trying to be proactive.

"We don't dismiss empowered patients looking around for things. That's important. But it's also important that we highlight the pitfalls and how to process the information with the right degree of skepticism, if you will."

Dr. Arora's skepticism is mostly based on the technology's use in clinical care. She sees burgeoning uses for ChatGPT in academic circles, where it can act almost as a teaching assistant. Similarly, she could envision a multitude of coding and billing applications to streamline that process for practitioners.

Government regulations for privacy and health care will also limit how fast ChatGPT is adapted for clinical use.

"One thing to keep in mind is, in all technology innovations, the health care sector has usually lagged behind because of regulations and because of our unique privacy issues and our unique data and billing issues," Dr. Arora said. "The focus on tech-based conversation—it's the currency of our field. How we make a diagnosis is conversation."

Skepticism, appropriately

One concern many hospitalists have about ChatGPT is the fear of getting left behind. Like cell phone users who clung to non-touch screens, not embracing generative AI technology is likely going to leave some practitioners behind as the years pass.

Dr. Airan-Javia cautions against worrying too much about that, though.

"The rate of change is exponential," Dr. Airan-Javia said. "I think we'll get there faster than we'd normally think. But, for the use cases of actually going through a chart and finding the information and trusting it...we have a lot more work and research to do, to ensure that the information we get from these models is accurate."

In addition, Dr. Arora notes that "an appropriate amount of skepticism" is diligent for now. She looks at electronic health records (EHR) systems as an example, where early mistakes caused problems that lasted for longer than they needed to.

"If you have a bad process, and you automate it, you can really hurt a lot of people in health care," she said. "What I have seen a lot of right now is the testing. Does ChatGPT, can it take tests? Can it

cation

make diagnoses? And it is kind of all over the place. That obviously gives everyone pause when it's not consistent."

"Trust is going to play a huge part in how people rely on, or don't rely on, tools that use generative AI," said Dr. Airan-Javia, chief executive officer of CareAlign, an EHR workflow application created at Penn Medicine in Philadelphia. "We are okay with humans making mistakes, but when a machine makes even a tenth of the mistakes, we don't accept that.

"We expect to see a much higher accuracy with any GenAI model. Whether that's appropriate or not, that's where we are currently across the board, and what we will need before we can use it more actively to interpret patient-specific data and charts."

Richard Quinn is a freelance writer in New Jersey.

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Dr. Kaboli's telemedicine set up enables rounding via video, seeing patients and reviewing charts or writing order simultaneously, and covering one or more rural hospitals.

Hospitalists Explore Evolving Roles in Telemedicine

By Larry Beresford

hen the COVID-19 pandemic struck in March 2020, health care providers had to learn in a hurry how to navigate telemedicine and virtual, distant encounters with patients—using technologies that were well-established but not as widely used. Hospitalists were no exception. Sometimes their pandemic virtual visit was just down the hall to a hospitalized COVID-19 patient in isolation. Other times it was helping other clinicians in need of expert medical support during patient surges across the state or the country.

Now that COVID-19 has become more endemic, hospitalists are still trying to clarify their roles and responsibilities, with an eye to the future and the evolving definition of a hospitalist. Will that include hospital at home, the range of post-acute settings where some hospitalists are finding new roles, or new post-discharge transitional follow-up programs?¹ Could telemedicine help with other kinds of surges, crises, and natural disasters in hospitals?

In 2018, hospitalists Michael K. Ong, MD, FACP,

PhD, and Daniel Brotman, MD, MHM, penned an editorial in the Journal of Hospital Medicine entitled The Virtual Hospitalist: The Future is Now.² Acknowledging that medicine traditionally has been slower than some other industries to "embrace the



Dr. Ong

digital age," they suggested that new applications of the electronic health record (EHR), and digital tools such as video or remote sensor technology, were becoming increasingly important An option to increase value of care

in medicine—and for hospitalists.

Dr. Ong, who practices at the Veterans Administration Greater Los Angeles Healthcare System as well as at the University of California Los Angeles's hospitals, was recently asked where hospitalists are today relative to these virtual applications. "Some of the technological changes during the pandemic that we might have expected in how we conduct inpatient care haven't really happened yet (in hospital medicine)," he said. "But as we continue to innovate in terms of staffing models and how we manage patients, my guess is that we will see much more of what we've already seen with intensive care units (ICU) and tele-ICU programs."

Some of the new tools haven't been incorporated into routine medical practice for reasons ranging from cost, to security and privacy concerns, to reimbursement. But regulatory limitations remain the biggest barrier, he says, along with the challenges of obtaining privileges at a given hospital. "In the future, we likely will be triaging more complex patients, ideally moving them more quickly to the facilities that have the diagnostic tools they need," Dr. Ong said.

Rural links lead the way

The best-known application of telemedicine is the professional support of distant hospitalists to small, rural, isolated, understaffed, or critical-access hospitals that, for varied reasons, are unable to deploy sufficient physician coverage in person 24-7 for their acutely ill patients. According to a 2018 article in the *Journal of Hospital Medicine*, telemedicine "virtual hospitalists" may expand critical-access hospital capabilities at a fraction of the cost, and the intervention is well-received by staff at the rural hospital and by its patients.³ A follow-up study in rural Veterans Affairs

(VA) hospitals from 2021 confirmed that rural hospital administrators perceived tele-hospitalist models as a viable option to address their staffing needs and improve quality of care.⁴ According to VA hospitalist Peter J. Kaboli, MD, FACP, SFHM, executive



Dr. Kaboli

director of the VA Office of Rural Health, professor of medicine at the University of Iowa Carver College of Medicine in Iowa City, Iowa, and one of the authors of the latter study, the Tomah VA Medical Center, a small rural VA hospital in Tomah, Wisc., (population 9,570) did not have enough physicians or hospital staff to cover its patients 24-7. So the Iowa City VA Medical Center, 200 miles away, offered hospital medicine coverage as a telemedicine service with an advanced practice practitioner (APP) holding down the onsite coverage.

"Having someone physically present in the room with the patient and family is important," Dr. Kaboli said. "We work with them so they can do the physical exam and be available to respond to emergencies. Then we round together by video as a team." Similar initiatives, depending on local geography, are underway in other VA regions, he said. "We need to have more of those services available for small hospitals. That way their practitioners don't end up feeling professionally isolated and they can have expert help when they need it."

How does the telemedicine link work functionally? These joint interactions use a computer on wheels with a camera and a microphone, wheeled to the patient's hospital room. "You don't have to buy a high-priced robot to do this.

PRACTICE MANAGEMENT

We feel like we can provide the level of care that's needed, using our expertise as hospitalists," Dr. Kaboli said.

"I can be sitting at my computer in my office with three screens and the EHR, so I can be seeing the patient as well as reviewing the chart, or writing orders, or chatting with my team." Plus, for the 10 to 20 minutes the doctor spends talking with the patient, there might be 30 minutes before and after, taking care of a myriad of other details. "I can be very efficient sitting at my computer doing all of the things in the EHR that need to be done. I could be covering one or more rural hospitals." And the tele-hospitalist can be physically located anywhere, say, at a ski resort in Colorado, fresh off the slopes.

Not just for rural hospitals

Brian Carpenter, MD, SFHM, chief medical

officer for telemedicine at Tacoma, Wash.-based national hospitalist chain Sound Physicians, started as a practicing hospitalist trained in med-peds, but took on various leadership roles when he joined Sound Physicians in 2014. "I've been here since the birth of



Dr. Carpenter

telemedicine at Sound Physicians, predating the pandemic. We started with four or five hospitals and are now up to 30 that we cover across the country."

There is a belief that telemedicine is primarily for rural hospitals, which is true enough, Dr. Carpenter said. "But our footprint covers anywhere from critical access-sized to large, inner-city hospitals." Sound employs about 45 physicians on its tele-hospitalist service, with several service-delivery options for the contracting hospitals.

The first is a true tele-hospitalist who is on call, covering the facility at night-doing everything from video-enabled admissions to rapid response like a traditional in-person nocturnist. Where the hospital requires a bootson-the-ground hospitalist to attend to patients admitted from the emergency department, the tele-hospitalist can handle cross-coverage calls. Somewhere in between is for hospitals staffed at night with APPs, although their hospital bylaws still require some level of physician oversight and support for the APP. That is where the tele-hospitalist can be leveraged to provide peer-to-peer support to the in-house APPs, Dr. Carpenter says.

Sound Physicians staffs its telemedicine by divisions or pods, with each division comprising between five and 12 hospitals. "We have to be strategic in how we align our physician pods to states and hospitals since both state licensure and hospital credentialing can take months to complete," Dr. Carpenter said.

The Interstate Medical Licensure Compact helps expedite state licensure for qualified physicians, but it still takes time to get a physician credentialled by a given hospital. Another limiting factor is how many EHRs the hospitalist needs to log in and out of during a shift because they can be cumbersome.

"We opted not to go with a 'bunker' model for the tele-hospitalist service, because it would limit our ability to recruit," he said. "So, we went with a work-from-home model. We send them the equipment, two monitors, a desktop, and a headset, and we partner with a platform that processes all the requests for consultation from the hospitals electronically and routes them to the doctor who is on the schedule."

Tele-hospitalist applications skyrocketed during the COVID-19

pandemic, after simmering in the background, said Mark Shen, MD, FAAP, SFHM, a one-time pediatric hospitalist, digital health pioneer, and current CEO of two small surgical hospitals in Austin, Texas. "Sure, the technology is getting easier,



Dr. Shen

with more integration with the EHR, and that's a benefit. But what really changed adoption was the pandemic, with the result that the concept of video visits has been integrated more permanently into many doctors' workflows. What makes sense, as we continue down the path to value in health care, is that we pair telemedicine workflows to the movement toward hospital at home," he said.

"That's where there's a real opportunity, with a movement that's still relatively young but growing quickly. A hospital-at-home program based in a hospital system doesn't need its doctors to be out driving all over town. Other team members can be out on the road and in the home and the hospitalist can connect with them via the technology."

Dr. Shen also appreciates the opportunities for his hospital's physicians to connect virtually with medical specialists. For small, independent hospitals like his, that may mean a relationship with a national telemedicine company. "Say we need a neurology consult. They have a big network and can plug us into a consultation with a neurologist who can help us, eliminating the need to contract directly with specialists who have to be on call for infrequent needs," he said.

New applications of telemedicine

During the pandemic, New York-Presbyterian/ Weill Cornell Medical Center in New York City actively deployed hospitalists virtually to help with issues such as high patient census and acuity, limited access to personal protective equipment, and increased communication challenges due to visitor restrictions.

An article about this deployment in the Journal of General Internal Medicine noted that primary palliative care was another application, incorporating virtual, advance-care, planning discussions with patients and families.⁵ Another need was how to take advantage of the skills of practitioners who were eager to help in the crisis but needed to work from home due to pregnancy, comorbidities, exposure to COVID-19, or recovery from illness. Initially, 15 experienced

hospitalists were assigned to work virtually. They also helped train physicians from other specialties who were redeployed in the hospital during COVID-19 surges.

"Historically, hospital medicine has been defined by our setting. We have a particular set of skills processing a lot of clinical data and dealing with patient acuity with creativity and flexibility. We can actually apply these skills in different settings, including beyond the hospital walls," said Kimberly Bloom-Feshbach, MD, a hospitalist at Weill

Cornell, director of its virtual hospitalist program and lead author of the article about its

Dr. Bloom-

Feshbach

Dr. Berger

COVID-19 tele-hospitalist pilot. She and colleagues, including hospitalist Rebecca Berger, MD, are leading the way on another application in collaboration with Westchester Behavioral Health Center, Weill Cornell's affiliated psychiatric hospital 22 miles away in White Plains, N.Y.

"We adapted our COVID-19 model to medical consultations for a psychiatric hospital," Dr. Berger said. "We're not practicing telemedicine in the same way that many other physicians are practicing it. The majority of our work is not directly patient-facing, but consulting with other clinicians," she said. "The model is about maximizing the expertise of the hospitalist working virtually, supporting our on-site team members."

There need to be clinicians on-site, typically at least one internist during the day plus APPs, with one hospitalist joining virtually, 24-7. The in-person and virtual hospitalists divide up tasks but also come together to discuss cases. The hospitalist doesn't need to be physically present to review every patient's history and physical or do chart reviews and medication reconciliations.

Battling burnout

Telemedicine models are an exciting development given widespread concerns about the sustainability of hospital medicine as a longterm career—with its shifts, hours, and all the walking around. "We're finding it can be physically more sustaining for hospitalists who don't have to come in person to work every day," Dr. Bloom-Feshbach said. "Bringing this option to them can be very helpful for their well-being in their jobs, and they say they enjoy it. It's the flexibility of working from home with a different pace of work and the unique clinical challenges."

Dr. Bloom-Feshbach said she's surprised at how well she's taken to the model of the virtual hospitalist. "I'm someone who really loves direct contact with patients, you know, sitting by the bedside, holding someone's hand when conveying serious news. It has been humbling and exciting for me to learn how we can use technology to enhance what are already great skills of hospitalists," she said.

"There will never be a replacement for some of the things that we all love about bedside medicine. But how can we extend ways to deliver humanistic care through these virtual technologies-always viewing it as a complement, not a replacement?"

"I recommend it to my colleagues—something to try, to see if they like it, but also to see the limits to what we can do by telemedicine," Dr. Kaboli said. "I only do it for a few weeks out of the year, but it's a way to add variety into how we provide patient care as hospitalists."

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

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SIG Spotlight: Night Medicine

Overcoming the "stepping-stone" stigma

By Richard Quinn

hen hospitalist Neil Desai, MD, started as a night doctor, he would get the same question for years. It came from colleagues and family members alike—and no one meant anything by it.

They just didn't understand.

"When are you going to be promoted to a day position?" they'd ask.

Dr. Desai

response was always the same: "No, no,

Dr. Desai's

no, this is what I love doing. I love night medicine. I'm a night owl. This is what I plan on doing for the rest of my career."

The perception that working the overnight shift as a hospitalist is just a start—a stepping-stone to better hours or a better position could be seen as a microcosm of how misunderstood the subspecialty is. And it's just one of the reasons that the Night Medicine Special Interest Group (SIG) led by Dr. Desai is important.

"It's not just the perception in the hospital, but outside the hospital as well," he said.

Dr. Desai, who helped start the SIG in 2019 and is now its chair,

says the group serves as a voice for night doctors who are often underrepresented. The group has 364 members, according to SHM.

"We didn't have a place where we could turn to our colleagues and ask, 'Hey, what's going on at your university or your hospital?" Dr. Desai said. "To be able to communicate with one another, to be able to network with one another, to ask questions that were very difficult to get information from. We didn't have that place."

The SIG helps link people with questions that other subspecialties have for years been sharing, in part because those cohorts are larger and have received more attention in the past.

"For example, a lot of night people were asking, 'What are your responsibilities? What is your compensation? How do you get promoted?" said Dr. Desai, director of the hospitalist night program and the oncology night program at Mount Sinai School of Medicine in New York. "This put us in touch with one another, and we were able to help grow our programs and our professional lives by talking to one another. This was a very big thing for the night doctors across the nation."

One area of particular importance for hospitalists specializing in overnight medicine is building lines of communication with physicians on other shifts. "It's definitely very important to have that communication with our day counterparts," Dr. Desai said. "That's one thing we've all talked about. Sometimes, nights can be overlooked, and that's a common theme we've heard from different night docs in the network."

The SIG uses virtual events to help promote discussions on how best to approach day counterparts and perhaps more importantly the C-suite administrators, who all tend to work during times night docs don't.

"People can feel isolated from the day team, and a lot of the heavy-hitter administrators are there during days, and it's hard to advance outside of doing your clinical work," Dr. Desai said. "What's so great about having this network, is that we've given people and people have given me—ideas on how to do that.

"To talk to your day administrators, to get involved. It's very important to let them know we're doing A, B, and C. It's not that we're just keeping the patients alive. We're pretty much covering the entire hospital at night. We're doing admissions. We're overseeing nurse practitioners, physician assistants, and residents. Handling renal replacement therapies, codes, X, Y, and Z."

The communication is working, Dr. Desai says.

"As time has progressed, most hospitals have realized the importance of maintaining a good night staff," he said. "A lot of hospitals consider night starting at 5 p.m. We're covering from 5 p.m. until 8 a.m. We're taking care of patients the majority of the day ... as long as we were communicating what we're doing, the vocalization of that, we're getting more and more support with that."

One of the more tangible results of the SIG is a published survey on facts and figures for night doctors, as well as a budding webinar series. The first session was on wellness, a hot topic in a post-COVID-19 world.

There is also an educational program called "Chalk Talk" that aims to connect hospitalists with a useful curriculum specific to night issues. The goal there—via a subgroup of chapter members—is to create a distributable series of talks that night doctors can use for their residents and others.

Every initiative the SIG works on, Dr. Desai says, is aimed at helping grow the group to reach more night hospitalists who could benefit from the shared thoughts.

"We're on a different time schedule than everybody else is," he said. "So, being able to have this (group) is invaluable. ... this has created that kind of close-knit community."

Richard Quinn is a freelance writer in New Jersey.

SHM



Chapter Spotlight: Iowa

Making connections with everyone in the tent

By Richard Quinn

very SHM chapter likes to focus on the so-called bigtent philosophy, the idea that a group's success is enhanced by having members who aren't just hospitalists, but who are in the hospital medicine orbit.

Not every chapter has a pharmacist for a chapter leader, but Iowa does.

"Everyone has their areas of

expertise and areas of experience that have made them the person they are," said Iowa Chapter president T. Michael



Dr. Farley

Farley, PharmD, FHM. "We get together and work as a team for patient care, but also work as a team to learn and collaborate and grow as practitioners and individuals."

So how does a pharmacist take over the top spot at an SHM chapter?

Dr. Farley had been working with a group of hospitalists for years at Mercy Hospital Iowa City in Iowa City and there was interest in launching a state chapter. That started in 2014 and in the years since, he stayed involved as he saw the value in "forwarding the teambased approach, working together with things in terms of continuing

education, building networks."

Perhaps nothing exemplifies that approach more than Progress 2023: Learning Together in the 21st Century. The event, held in October in Coralville, Iowa, was put on by the SHM Iowa Chapter, the American College of Physicians' statewide chapter, and the University of Iowa Carver College of Medicine and its College of Pharmacy.

"It speaks to the collaborative approach, the teamwork approach, the big-tent approach we try to have," said Dr. Farley, a clinical associate professor at the University of Iowa College of Pharmacy and a clinical pharmacy specialist on Mercy Hospital's hospitalist team. It's "getting together and learning together, which I think has been a positive thing for working relationships in the region and the state."

Dr. Farley is conscious that too much of a big-tent philosophy can border on noise.

"Sometimes, you do get too many cooks in the kitchen, especially in the context of patient care," he said. "But in the context of the team and bringing different knowledge to the table ... I think when we have different perspectives, we get more nuance in our understanding of how to do things well.

"Obviously, from a patient-safety perspective, having a number of different eyes with different perspectives allows you to catch things that someone with a certain perspective might miss."

Dr. Farley calls it "the Swiss cheese model" where different knowledge areas help everyone fill in each other's gaps.

"Together, we make a better product," he said.

As it relates to the 130-member chapter, it's working.

Quite well.

The Iowa outpost won a Platinum Excellence Award in 2022 and he credits past presidents Martin Izakovic, MD, FACP, MHA, PhD, SFHM, Melinda Johnson, MD, FACP, SFHM, and Dianna Edwards, MD, FHM, as well as the current leadership team of president-elect Daniel Leary, MD, PhD, membership director Kristen Followwill, DO, secretary Ethan Kuperman, MD, SFHM, treasurer Matthew Bauer, MD, and chapter advisory board member Melinda Johnson, MD, FACP, SFHM.

"I attribute the success of the chapter to the past leaders setting a high bar and trying to continue that with the current leadership team," Dr. Farley said. "Looking at how we can grow, refine things, and make it better.'

In a move that should surprise no one given the chapter's inclusive philosophy, growth to Dr. Farley means an even bigger tent.

"One of the things we're trying to do with the chapter going forward is involving residents at a higher level," he said. "We have a poster session that a lot of residents are involved in at the

progress meeting, but we're also looking at how we can further that and get them more involved as the future of our chapter. We're thinking about job fairs, keeping them engaged with topics of interest that they might have. Thinking about contracts, thinking about how they might have a good work-life balance.'

In a statewide chapter where members can be hours apart geographically, Dr. Farley says one key to success is a mix of in-person and virtual events. By moving physical meetings around the state, the chapter makes it easier to broaden its reach—and by embracing Zoom meetings and other technology that became much more accepted in the years since the COVID-19 pandemic started, that reach stays broader.

But meeting people where they are isn't just a function of geography.

It's Dr. Farley's view on how to engage members.

"We want to supply our members with things they think are valuable, experiences they think are valuable," he said. "We want to make connections with everyone in the tent and get that positive experience, which is ultimately why people are involved in these organizations. They want to have a good experience, they want to be engaged, they want to be involved in moving things forward."

Richard Quinn is a freelance writer in New Jersey.

Questions Remain About the Impact of Nirsevimab

Hospitalists offer insight

By Ruth Jessen Hickman, MD

he new monoclonal antibody nirsevimab may radically change incidence and outcomes for respiratory syncytial virus (RSV) infections in young pediatric patients, especially when combined with the impact of the new RSV vaccine approved in pregnancy. However, many questions remain about the implementation of nirsevimab in the 2023-24 RSV season and its more long-term impacts.

Current impact of pediatric RSV

"RSV is the most common diagnosis pediatric

hospitalists see over the winter months," said Samir S. Shah, (@SamirShahMD), MD, MSCE, MHM, vice chair of clinical affairs and education at Cincinnati Children's Hospital in Ohio, editor-in-chief of the Journal of Hospital Medi-



cine, and pediatric hospital

medicine and infectious diseases physician. "RSV typically occurs in infants and children less than two years of age, with the most severe illness occurring in infants less than six months."

No direct treatment is available, but very young children with severe disease may require hospitalization for supportive care such as oxygen and intravenous (IV) fluids to prevent mortality. In most of the U.S., the RSV season runs from the beginning of October through the end of March.

Andrea R. Hadley, (@AndreaHadleyMD), MD,

FAAP, FHM, is chief of acute care pediatric medicine at Cornell Health/Helen DeVos Children's Hospital in Grand Rapids, Mich. She pointed out that pediatric RSV infections can significantly strain hospital resources and contribute to staff burnout, especially



Dr. Hadley

combined with the concurrent impacts of SARS-CoV-2 and influenza. She said, "Especially since COVID-19, pediatric inpatient beds and resources like pediatric nurses have been decreasing around the country for a variety of reasons. That has made it even more difficult for the children's and community hospitals to handle these big surges of patients."

Until recently the only therapy available to help prevent pediatric RSV was the monoclonal antibody palivizumab. However, it has an onerous administration schedule, requiring five monthly shots. Because of this and its high price (\$1,500 or more per shot), the American Academy of Pediatrics and the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommended it only for those with certain preexisting medical conditions which put them at risk of poor outcomes from RSV, which is less than 5% of infants.1

Like palivizumab, nirsevimab is a monoclonal antibody, but one that clinicians can administer in a single shot. Like palivizumab, nirsevimab is not a vaccine in the traditional sense, in that it does not provoke active immunity. Instead, the monoclonal antibodies themselves provide



fast-acting and direct protection against disease for at least five months.² The recombinant long-acting monoclonal antibody binds the F1 and F2 regions of the RSV fusion protein, locking the protein in place and thereby blocking viral entry into host cells.³

Russell McCulloh, (@RMcCulloh), MD, a professor in the divisions of hospital medicine and infectious diseases and vice president for research at the University of Nebraska Medical Center in Omaha. said, "Nirsevimab is much more effective in its binding than palivizumab, and consequently has better

activity in reducing symptom severity. Based on studies looking at the anticipated effect on hospitalizations, it looks to be far more cost-effective than palivizumab." A global trial showed that a single injection of nirsevimab reduced the incidence of RSV infections requiring medical attention by about 75% in otherwise healthy infants.3

Dr. McCulloh explained that because of these differences, the ACIP recommended that all infants born during RSV season receive nirsevimab, as well as infants less than eight months old when entering the season. They also recommended that older children, aged 8 to 19 months, also receive the vaccine if they are at risk for severe RSV disease.² Dr. Shah also pointed out that nirsevimab has only shown mild adverse events in clinical trials, and that it had no differences in terms of serious side effects compared with palivizumab.

Dr. Hadley added, "The number needed to treat to prevent hospitalizations is in the 50s. So, if we can distribute it in the way we hope, that's a lot of hospitalizations prevented, and that is going to have a huge impact on pediatric access to hospital beds and resources."3

Nirsevimab implementation and availability

It's unclear how widely health care practitioners will be able to deploy nirsevimab this season, but it will be covered under the federal Vaccine for Children Program (VFC), which provides vaccines at no cost to children who might not be vaccinated due to the inability to pay. The product is available at \$395 via the VFC and for \$495 through the private sector.4

Dr. Hadley said, "Some insurance companies have already said that they're going to reimburse for it, but a lot haven't yet. We're waiting eagerly to hear that information."

Dr. Hadley explained that ideally most eligible patients would receive nirsevimab at their primary-care home, and this will likely be how it is mostly administered in future seasons. However, she also pointed out that it may be financially challenging for some small practices to take on this uncertainty and financial risk, given that reimbursement for the current RSV season is still unclear.

"The great debate is how we can best get as many shots into kids across the country as possible," she said. Some hospital systems may try to make nirsevimab available to qualifying patients, e.g., those born during the current RSV season, or perhaps to a subset of patients, e.g., higher-risk infants or those who qualify for the VFC program. Dr. Hadley speculated, "It may be that for a short window, we give it in the nurseries to try and get it to as many babies as we can until the private offices start ordering it."

However, this will likely differ among institutions, and hospitals face barriers to practical implementation and reimbursement. Due to current payment structures, hospitals would not receive similar reimbursement for nirsevimab compared to current vaccinations given in the nursery such as hepatitis B.

Dr. McCulloh also pointed out that carrying costs for VFC could be very high for health systems outside of clinics, and it can be logistically difficult to manage VFC versus non-VFC administration. He suspects that most hospitals will not opt to stock nirsevimab, particularly those that don't exclusively treat pediatric patients. Only 10% of birthing hospitals have traditionally participated in the VFC program.4

Supply issues have also been a challenge. Ordering through the VFC program was put on hold in October, although it is expected to resume with preference to providers who have not previously ordered. The maker of nirsevimab, Sanofi, reported higher-than-expected demand for nirsevimab, especially for the 100-mg dose, used for infants of 5 kg or more. This formulation is not currently available for ordering through Sanofi, and using two 50-mg doses instead has not been studied.4

"It's going to be imperative that pediatric nursery and hospital clinicians work closely with their pharmacy and therapeutics committees to understand what's going to be available, even if that's not in the hospital, to maximize equitable access post-discharge from the nursery," Dr. McCulloh said. "You've got to be able to provide some information to patients."

Maternal RSV vaccine

Another complicating factor for systems administration is that the mother's vaccination status must be considered. In September, ACIP recommended that pregnant women receive a dose of the new adult RSV vaccine (Abrysvo) at 32 to 36 weeks of pregnancy, giving at least some protection to infants for approximately 3 to 6 months after birth.⁵



Dr. McCulloh

According to guidelines from the American Academy of Pediatrics, infants whose mothers received an RSV vaccine should not receive nirsevimab unless the mother received it less than two weeks before delivery.² Dr. Shah explained that trials showed a statistically nonsignificant difference in preterm births in pregnant people who received the RSV vaccine at 24 weeks or later, compared to placebo. Thus, out of caution, the current recommendation is to give the vaccine to the patient at 32 weeks to 36 weeks gestational age.6

"We know that the hospital is an opportune place to talk about vaccines for adults as well as children," Dr. McCulloh said. "If you are seeing a pregnant adult, you should be surveilling for the COVID-19 vaccine, the flu vaccine, Tdap, the RSV vaccine. Because all of those are associated with the reduced risk for acute illness, disability, and death in pregnant people, and all have downstream positive impacts on their child's risk of infection and illness."

Looking forward

It's unclear how the availability of these new products will affect the current RSV season. Dr. Hadley said, "We're still going to see a surge. We're forced to brace for the worst just because of so many unknowns."

By fall 2024, more of the infrastructure for administering nirsevimab should be in place, such

as order sets and decision aids for clinicians. In terms of implementation this season, health disparities are likely in terms of who gets access to nirsevimab, as more educated parents proactively seek it out. "Despite good solid efforts from public health officials and providers, I think this first rollout will be more inequitable and hitchy this year compared to next," Dr. McCulloh said.

Even though nirsevimab is not a vaccine in the traditional sense, another potential barrier is vaccine hesitancy. However, Dr. McCullough notes that in his experience, patients have been more open to RSV vaccines compared to SARS-CoV-2, which has a less than 10% coverage rate in children under five years. He asked, "Is our coverage going to be around mid-40s like we see for seasonal flu? We're not sure."

Long term, it will also be important for health care systems to consider and plan for the potential impact of these new preventative measures on hospital volumes and income. Dr. Shah noted that the impact may ultimately be similar to that of the rotavirus vaccine, which has radically decreased what had been a relatively common hospitalization in infants.

"This is a good thing for individual children and their families, for the community," Dr. McCulloh said. "For health systems, it may mean they have to watch this closely and adapt to changes moving forward."

Ruth Jessen Hickman is a graduate of the

Indiana University School of Medicine in Indianapolis. She is a freelance medical writer living in Bloomington, Ind.

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$\ensuremath{\mathsf{REBYOTA}}\xspace^\circ$ (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. <u>Limitation of Use</u>: 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 1×10^8 and 5×10^{10} colony forming units (CFU) per mL of fecal microbes including >1x10⁵ 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.

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 matter 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 (\geq 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 \geq 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.

<u>Serious Adverse Reactions</u> - 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 <u>www.FDA.gov/medwatch</u>, or call 1-800-332-1088.

Manufactured for Ferring Pharmaceuticals by Rebiotix, Inc. Roseville, MN 55113



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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-V2 Where dysbiosis once left the gut microbiome in ruin,

RISE ABOVE RECURRENT C. DIFFICILE INFECTION

and restore hope with **REBYOTA**°

DEDICATED J-CODE (J1440) EFFECTIVE JULY 1, 2023

The first and only single-dose microbiota-based live biotherapeutic approved to prevent recurrence of *C. difficile* infection starting at first recurrence.^{1,2,a}



Scan to

^aIn the pivotal phase 3 trial, 32.8% of patients were treated at first recurrence of CDI following antibiotic treatment of CDI.¹

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 (\geq 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.



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