INDICATION
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.

IMPORTANT SAFETY INFORMATION

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

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

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

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 5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

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

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

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

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

Helped reduce progression to more severe disease, an additional secondary endpoint

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

Adverse reaction frequency was comparable between VEKLURY and placebo

- 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%)‡

VEKLURY 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.

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 total 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 breastfed 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.


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

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

Renal Impairment: 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 dilution intravenously without any other medication.

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

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

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

CONTRAINDICATIONS [Also see Warnings and Precautions]:

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

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

Hypersensitivity, Including Infusion-related and Anaphylactic Reactions: Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diarrhea, 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 >10×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 with chloroquine or hydroxychloroquine is not recommended.

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 NIAD 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 <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.

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 (8%, n/a, n/a), and 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 (8%, 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 Precautions]:

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 is 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 preterm delivery, 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 breastfeeding 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 ≥28 days old and weighing ≥3 kg. Use in this age group is supported by the following:
- Trials in adults
- An open-label trial (Study GS-US-540-5823) in 53 hospitalized pediatric subjects

Geriatric Use

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

Renal Impairment

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.

OVERDOSE

There is no human experience of acute overdose 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.

GILEAD

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Lessons for All Hospitalists from the Pediatric Hospital Medicine (PHM) Community

By Anika Kumar, MD, FAAP, FHM

In August 2023, the Pediatric Hospital Medicine (PHM) community celebrated 20 years of hosting the Pediatric Hospital Medicine Conference. The milestone was marked by highlighting the field’s past, present, and future through plenaries.

Dr. Mary Ottolini and Ken Roberts covered the past in their plenary. They discussed how the field of PHM has grown, highlighting key milestones along the way, like the creation of a section within the American Academy of Pediatrics (AAP), the first PHM Conference, the inaugural PHM fellow, and the American Board of Pediatrics’ recognition of PHM as a pediatric subspecialty.

Rev. Krista Gregory and Dr. Kenya McNeal-Trice discussed the current PHM landscape in their plenary. Rev. Gregory talked about restoring capacity as it relates to mental well-being and resiliency. She provided hospitalists with resources to improve their own resiliency. Dr. McNeal-Trice presented on health equity in PHM. She defined health equity and related principles, shared patient experiences, and ended with takeaways for hospitalists to address health equity in their practice.

PHM’s president, Dr. Kris Rehm, tackled the future of PHM in her presentation. She identified areas the PHM field is encountering currently and areas it will be required to address as it grows. Dr. Rehm shared leadership strengths that will now hospitalists to address challenges we encounter in clinical care, organizational development and leadership, and advocacy. She ended her plenary acknowledging her excitement for the field of pediatric hospital medicine.

The PHM Conference was first hosted in 2003, by the AAP’s Section on Hospital Medicine (AAP SoHM). The conference was designed for pediatricians caring for hospitalized children. In 2005, the AAP SoHM was joined by SHM and the Academic Pediatric Association to develop a three-society planning committee. Each year, one society takes the lead in planning the conference with planning committee representation from all three societies.

Along with the insightful article on electronic health records and the inspiring story of hospitalists who’ve served in the military, this issue features recaps of PHM Conference sessions. And, while these sessions were geared toward pediatric hospital medicine, there are topics and lessons to be learned for all hospitalists, including modeling empathy in difficult situations, health equity pitfalls to implement a protocol, multicenter research, and much more.

There are more session recaps online. You can find all our PHM 2023 coverage by scanning this QR code. 📆

Dr. Kumar

Dr. Kumar is a pediatric hospitalist at Cleveland Clinic’s and assistant professor of pediatrics at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. Dr. Kumar is also The Hospitalist’s pediatrics editor and an executive committee member of the SHM’s Pediatrics Special Interest Group.
Mr. Mutebi played football at a pretty competitive level. He was going to college to play football, and he figured he'd take that as far as he could and then become a doctor if that didn't pan out. Then he got the opportunity to attend Wayne State through its BS-MD program. "I spent a lot of time reflecting on the opportunity," he said, "I ended up coming here and hanging up the cleats."

His first experience in the health care setting as an undergrad became a pivotal moment in his journey. "I was volunteering in HIV testing at an emergency department," he said. "There was this young gentleman, pretty much the same age as me, from the same community as me. I performed the rapid HIV test and it was the first time I ever had a test come back positive and I had to go in and tell him. Seeing him, this young Black guy in Detroit, at that moment experiencing a lot of the anger, the fear, the confusion, the sadness—that brought home a lot of what I'd heard about in terms of health care disparities and the increased rates in Black communities. That's when it became more than just statistics for me. These are people. They are brothers. They are sons. They are mothers. They are friends. They are lovers. These are all people who are in my community and at that moment I knew it was important for me to be here not only to help people to navigate through their illness and care but to help change the narrative of what health care is in my community. At that moment it really became tangible."

As for what's next for Mr. Mutebi, the possibilities are endless. After med school, he hopes to complete his internal medicine residency and then potentially pursue a fellowship. He wants to serve the communities that have the most need and are most marginalized—the Black and brown communities—and he's drawn to health policies and innovative solutions to the upstream barriers that prevent equitable health care for all. "I'll be serving the communities I came to serve and helping to hopefully transform the culture of medicine wherever I end up," Mr. Mutebi said.
Secrets of Satisfied EHR Users

The work is worth the effort

By Larry Beresford

A report released earlier this year by KLAS Research identified more than 3,000 “highly satisfied” users of their hospital’s electronic health record (EHR), which has also been shown to be a contributor to job stress, dissatisfaction, and burnout for some clinicians. The report that teases out these highly satisfied clinicians, using survey data from December 2021 to December 2022 among 400,000 end users of the EHR in different countries, also highlighted several key traits distinguishing satisfied EHR users from those who are not.

“We measured physicians, advanced practice clinicians, nurses, and allied health professionals, gathering their responses to 11 core metrics of our Net EHR Experience Score,” said Anna Beyer, a Salt Lake City-based market analyst at KLAS—which works with practitioner members of the Arch Collaborative committed to improving their EHR experience through surveys and benchmarking.

Highly satisfied users agreed or strongly agreed that the EHR enables them to deliver high-quality care and makes them as efficient as possible, she said. A previous KLAS report found that satisfaction with the EHR is also important for job retention. These highly satisfied users may be outliers from the mass of working hospitalists, but they’ve learned lessons that could help point the field as a whole to a more efficient and productive relationship with this ubiquitous hospital tool while improving their satisfaction with their EHR.

“The most satisfied users pointed to personal accountability: taking ownership of their own EHR journey and learning the system to the best of their ability; the use of personalization tools to adapt the tool to their personal needs and practice style; and longer experience with the system combined with more ongoing training and education. They also shared the belief that their organization had implemented the EHR well that the initial training had prepared them well; and that they trusted the organization for how it supports them.

We use it, and we want it better

John Vazquez, MD, (@JohnVaz06707022) a hospitalist and director for the division of hospital medicine at Emory Healthcare in Atlanta, says he’s not aware of many colleagues who could actually say they love their EHR. “I would say we think it’s necessary, and we think it’s better and safer overall than what we used to have to do with paper charts. But would I say I love it? It’s more like I use it, and I want it to be better.”

Last October, Emory converted the health system to Epic from a previous EHR software vendor. “Everyone knew it was coming. We advertised that this is likely to be painful for a year. But we put in a ton of work to try to have a good product when it opened. Some issues were brought to the top that we needed to change quickly,” Dr. Vazquez said.

One solution to EHR frustrations is to make sure someone is really advocating for your group, your doctors, and your nurses, he said. “I think every hospital has an IT [information technology] team and usually has a chief information officer (CIO), but what I find is that they get told things by the software vendor, like ‘We can’t do that,’ or ‘Oh, well, this is just how we do things,’” he said.

“In our case, we formed a hospital medicine, division-specific, IT group that has the phone number of a hospital administrator who is going to respond, and that connects directly through the CIO and CMIO (chief medical information officer) to our advocates at Epic to report when we’re having trouble with a major safety issue, for example, losing patients off of team lists in the chart because the information was entered in the wrong order,” he said.

Sometimes tech people instruct physicians and nurses: “When you see something that’s not working, just click on this button and insert your complaint and concern, and that will be addressed,” Dr. Vazquez said. But clinicians typically don’t take the time to do that, because they’re too busy. So Emory had to find multiple pathways to make it easier for people to give those little examples of what could be done better and how to reorganize it.

“We did what we were here to do for some of our tech guys and the EHR guys from Epic. We just follow our doctors around (to see what isn’t working). We know that if you sit at the lunch table with a doctor, you’re going to get a lot of feedback. But if you tell them, ‘Call me when there’s a problem,’ well unless a fire has broken out, you’re not going to get that phone call. I say to our doctors: just send me a text that says ‘call me,’ and I will get back to them so they can tell me about it.”

Fanfare and promises

The EHR was rolled out with much fanfare and promise—for all the things it could do or facilitate or enhance medical care better, easier, safer, more efficient, and evidence-based. The promise was that it would serve the doctor with timely, essential alerts and easy access to vast amounts of data that could enhance clinical decision making. However, limitations to the EHR from the vantage point of physicians who use it have been widely described.

A 2017 survey of hospitalists conducted by hospitalist Zuzanna Czernecki, MD, and colleagues at Colorado University in Denver concluded that interventions to improve the EHR user interface could help mitigate hospitalist burnout. Surveyed physicians reported that their work-life balance was better with EHRs as opposed to paper, but the vast majority (85%) said they felt burned out often/very often or sometimes. The least burned-out physicians were more likely to state that the EHR improved their work/life balance, and those who said the EHR improved their work/life balance were more likely to report that it also improved their job satisfaction.

Bethany Grommesh, MD, a hospitalist with Park Nicollet Methodist Hospital in Minneapolis, also wears the title of “Epic Lead” for her department, for which she gets 35% protected time to work on IT issues. “I have physician ‘build’ status in Epic, but I don’t do any actual physician build. I basically know how everything works, but the IT experts are putting this together. I’m kind of a translator, explaining the clinical process and how it needs to work for the end user so it makes sense,” she said.

“I think you need to put pressure on your system to add resources to make it as efficient as possible,” Dr. Grommesh said. “Epic has a lot of different ways to do things, and to create efficiencies, for example, good order sets with preselects that are directing you toward the appropriate care, and smart phrases that can give you time and efficiency and help you with your documentation needs.”

Or a well-crafted best-practice alert that pops up at the time it’s really needed. “You can also do a preference list for things like problems (diagnoses) that are most commonly used, so people don’t have to go hunting for them.”

Dr. Grommesh said the biggest secret is the “build” of the software at the system level, the code that is ready to access by the user. “If you have a nice enough build, and it’s intuitive, you may not even need to do much education. People just go, ‘Oh, this is better.’ And that’s what I strive for—just to make stuff easier, where it’s obvious that it’s going to be better for the user.”

Figure 1: A hospitalist and director for the division of hospital medicine at Emory Healthcare in Atlanta, says he’s not aware of many colleagues who could actually say they love their EHR.
Dr. Patel offers the example of the manual filter in Epic. “That means when you hover over a note in the chart, you can choose the manual filter, which will show you what the person who did the note wrote manually. Why is that helpful? Well, when the patient’s been in the hospital a long time, and you’re getting recommendations from a consultant who may not be making many changes, you’re just looking for actionable insights—what is new today? What is the main recommendation?” he explained.

“I learned recently that Epic upgraded to allow us to not just copy other people’s order sets, but you can also ‘favorite’ someone else’s order sets. So if we were working together, you could say, ‘I’m going to favorite Sajan’s order sets,’ and you just have to click on my name and you’ll see your order set list and choose which ones you want.”

At UCSF, hospitalists can submit suggested enhancements or changes to the EHR, which then go through a governance committee that determines whether to follow through with them. Dr. Patel offered the example of a medication called sodium polystyrene sulfonate, used to reduce potassium in patients with dangerously high levels. It’s usually called Kayexalate by doctors, but you couldn’t order it by that name on Epic. “I submitted a ticket to our Apex Clinical Content Committee, which is the name for UCSF’s Epic (EHR) governance committee asking them to change Epic to make it possible to order it by the name Kayexalate.”

He keeps a running list of all the things that are bothering him about the EHR. “I’m obviously not trying to figure out everything on that list, but if I remember something, I’ll put it on the list and later I’ll come back to it.” Things that can save seconds per patient add up to minutes per day, which can add up to hours per week, even if some of these things take a little time to set up in the first place, he said.

“I am also our director of quality improvement, so I think of things like these in terms of quality and safety—always trying to improve them, thinking lean, how to reduce waste. So to me, enhancements to Epic can also have safety implications.”

Dr. Patel recommended getting the hospitalist group together to share their own efficiency practice tips. “You can learn a lot from other people’s tricks and hacks,” he said. “Write down your different sorts of little tasks, shortcuts, tips, and tricks, and then regularly share them with your colleagues.”

Emerging applications
Ron Li, MD, a hospitalist and clinical associate professor of medicine at Stanford School of Medicine in Stanford, Calif., as well as the medical informatics director for digital health at Stanford Health Care in Stanford, Calif., sees opportunities for hospitalists to get involved in enhancing the EHR in a couple of ways. One is to offer feedback on how things should be designed better in the EHR. The other way is to get involved in governance—the whole process of analyzing tradeoffs, and prioritizing what needs to be fixed.

“There are tons of opportunities to play a role in the design and enhancement of our medical tools, including the EHR. We don’t have to be engineers. But we should have some expertise in the technology,” he said. “For hospitalists, the EHR is part of the equipment we use to take care of our patients, so we should know how it works.”

Dr. Li founded and directs the Stanford Emerging Applications Lab (SEAL), at which Stanford clinicians can propose ideas for novel digital products and have them prototyped and tested for care delivery at Stanford. “Our thesis: Physicians should be the builders. We have plenty of faculty and physicians who are creative and motivated to build. But we’re also in the hospital, with opportunities to safely test those ideas (in real-world settings). We can take an idea from a clinician and turn it into an app within a couple of weeks and play around with all sorts of interfaces.”

Potentially, they might even go on to start their own software-based company, integrated with the EHR, to market the solution they thought of.

A new career opportunity
Some hospitalists may find it not very useful to the hospital that they do not know, as the studies have shown, that those who believe the EHR makes their work more efficient are likely to also say it improves their job satisfaction and work-life balance. But satisfaction is also reported for those who are actively engaged in improving the EHR for their hospital. Is that the pathway to the highly satisfied hospitalist?

“Some hospitalists get paid to do the work of improving the EHR,” said Dr. Vazquez. “I have an administrative role and so I consider it part of my job. But a lot of our local site hospitalists don’t get protected time to work on improving the EHR. They just do it because they want to have better patient care, and to have their days be more efficient,” he said.

Dr. Vazquez has noted that when someone is into helping and comes up with great ideas, they should bring them up on the chief medical information officer’s shortlist for leadership roles or even get protected time for information technology work. It has to be more than just showing up at the department’s information technology meetings; it means really taking an active role, he said. Suddenly that hospitalist has a new leadership position, which may signal a new career direction.

“With a little mentoring, and knowing who else to connect with and how to be seen, since there is such a hunger for good leadership everywhere, now they have a new job title. Or they’re presented with a great idea at the SHM annual meeting about how they arranged something in the computer system that improved patient care.”

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

References
Choosing Effective. Dutiful. Supportive.
Serving. Protective. Leading. Responsi-
ble. These words easily describe a hos-
pitalist or a soldier—and sometimes
both. In honor of Veteran’s Day, we talked with
four SHM members, working hospitalists, who
also have served, or currently serve, in the mili-
tary. While their paths differ, their commitment
to their patients and their country is the same.

By Lisa Casinger

In Service to Their Patients and Their Country
Hospitalists who’ve served or continue to serve in the U.S. armed forces or reserves

Jon Sweet, MD, FACP
(@jonmsweet)
Chair of medicine and senior vice president, Carilion Clinic, professor, Virginia Tech Carilion School of Medicine in Roanoke, Va., former major, United States Air Force

Dr. Sweet began his military career in the U.S. Air Force (USAF) as an internal medicine resi-
dent at the medical center at Wright-Patterson USAF Base in Ohio for all seven years. “I
had the opportunity to serve on two wartime operations during my military tenure but otherwise stayed in medical school with no educational debt. My stepfather, grandfather, and father-in-law all served, the latter as an Army physician for several years. They were all exemplars of humility, service, sacrifice, and honor.”

After his residency, he remained on staff at Wright-Patterson, first as the chief resident, and then as the site internal medicine clerkship di-
rector for medical students from the Uniformed Services University’s F. Edward Hebert School of Medicine in Bethesda, Md., and the Wright State University School of Medicine in Dayton, Ohio.

“My clinical role was as a traditional academic internist, seeing patients and teaching in both the inpatient and outpatient settings,” Dr. Sweet said. “I delighted in the opportunity to serve,” he said. “The HPSP program was a fantastic route to this service, which also allowed me to graduate from medical school with no educational debt. My stepfather, grandfather, and father-in-law all served, the latter as an Army physician for several years. They were all exemplars of humility, service, sacrifice, and honor.”

Dr. Sweet always had and enjoyed a teaching
role, starting with his year as chief resident. After leaving the USAF, he returned to Virginia with his family and joined Carilion Clinic. There, he became a core faculty member with the internal medicine residency program, before eventu-
ally serving as residency program director, chief
of hospital medicine, and eventually chair of the
department of medicine at Carilion’s integrated health system and affiliated medical school. For the past 15 years, he’s practiced exclusively as a hospitalist at the level 1 trauma center, a 750-bed flagship hospital in Roanoke, always with a team of residents, medical students, and pharmacists.

The first 15 years of his career were as a tradi-
tional general internist, both outpatient and in-
patient. “During my time as residency program
director, I transitioned completely to the hospi-
tal medicine role,” he said. “That allowed me to
focus on acute and stable patient care, with a strong focus more completely on graduate and under-
graduate medical education while advocating for and delivering high-value, patient-centered, quality, efficient, inpatient care to patients in our residency training program, along with pa-
tients in our vast integrated network of family medicine practices.”

Dr. Sweet says serving in the military not only had a positive influence on his career, it taught him lessons that stayed with him. “The military hard-wired service above self. I am grateful for this,” he said. Although the path to medicine is arduous and the days can be long, we have a truly just mission in improving the health of the patients and communities we serve. Many of us are physicians in America and are therefore wonderfully blessed by both our occupation and the country in which we are able to practice.”

He adds that military medicine is strong on mentorship and leadership training. Some of this is baked into the experiences of a military physician and is part of the promotion process. “I learned to show up, engage, take calculated
risks, and the importance of ‘deepening the
bench’ and succession planning,” he said.

Toward the end of his service, he went to the Uniformed Services University’s medical school every quarter and was mentored by Dr. Louis Pangaro and his teams. Dr. Sweet also took other leadership courses, including courses on medi-
cal-education faculty development, ranging from short workshops on precepting to the abbreviated Stanford Faculty Development Course, and says he leans on some of these lessons every week.

Dr. Sweet says one of his most meaningful ex-
periences while serving in the USAF was the pa-
tients themselves. “The patients we served were extraordinarily,” he said. “In one week, I recall caring first for a patient who presented me with a signed copy of his book about his experiences in the Bataan Death March, another who took live photographs of the bombing of Hiroshima from approximately 10,000 feet, and then caring for Gen. Paul Tibbets, pilot of the Enola Gay.”

Serving in the military as a physician “is a great opportunity to experience the best of both worlds—practicing medicine in a wonderful culture while serving one’s country and the men, women, and families who put themselves in harm’s way,” Dr. Sweet said. “I have always appreci-
ated my service and the opportunities it afforded.”

Jennifer E. Colella, MD
(@colella_jen)
Nebraska Medical Center/
University of Nebraska Medical Center, Omaha,
Neb., former captain, United States Air Force

When asked why she joined the military, Dr. Colella’s answer was simple. She felt called to serve. “During high school and college summers, I worked at my father’s medical office,” she said. “I also visited the VA clinic where my father was the chief medical officer and I enjoyed watching the interaction and bonds that formed between my father and his veteran patients. After college, I remembered the veterans and their sacrifices that my father tended to, and I decided to join the military before pursuing my career in medicine.”

Dr. Colella was a captain in the USAF, an electronic warfare officer (EWO) instructor (at a time when only about 4% of EWOs were female), and an evaluator and subject-matter expert on the EC-130H Compass Call aircraft in the USAF. “I was the test EWO on the new Block 35 Avionics System Upgrade and developed and authored the first manual for the upgraded elec-
tronic operating system and completed training of all individuals ahead of schedule,” she said. “I briefed members of Congress in Washington, D.C. on the aircraft’s capabilities. I completed four tours to Operation Enduring Freedom in Afghanistan and Uzbekistan and one tour to Operation Iraqi Freedom in Kuwait.”

“The bonds among soldiers who shared com-
mon experiences (especially deployed during wartime) is unmatched in any other experience,” she said. “I cherish these veteran friendships and look forward to our reunions.”

Dr. Colella says her seven years of active duty provided the most valuable lessons of her life. She honed her teamwork, leadership, and prob-
lem-solving skills, which enabled her to become a highly-regarded EWO, a successful govern-
ment contractor, and ultimately a physician.

She also credits one of her EWO instructors (one of the few females paving the way for others) with helping her understand the importance of fostering relationships with new colleagues and helping them engage in the workplace while understanding how the organization operated and how to fit in and be successful within the company culture.

“My leadership experience prepared me men-
tally and physically to face challenges, commu-
nicate effectively, and garner the full support of my teams,” Dr. Colella said. “Many life ex-
periences have given me confidence, motivation, and the ability to think critically. My passion for medicine and my lifelong belief in contin-

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Dr. Huang serves as a reservist in the Ohio National Guard (OHARNG) and is a hospitalist at OhioHealth Riverside Methodist Hospital, Columbus, Ohio. As a hospitalist, he is responsible for providing care to patients in the hospital's intensive care unit. Dr. Spaeth serves as a hospitalist at OhioHealth Riverside Methodist Hospital, and she is a member of the hospital's critical care team.

Dr. Spaeth has completed her residency in internal medicine at the University of Nebraska Medical Center in Omaha, Nebraska. She has since served in various roles within the hospital, including as a critical care nurse in the medical intensive care unit and as a staff physician in the emergency department. Dr. Spaeth has also been involved in various research projects and has served as a mentor to residents.

Dr. Huang has served in various roles within the military, including as a military physician and a hospitalist at OhioHealth Riverside Methodist Hospital. He has also served as a hospitalist at the Wexner Medical Center in Columbus, Ohio. Dr. Huang has been involved in various research projects and has served as a mentor to residents.

Dr. Spaeth has served in various roles within the military, including as a critical care nurse in the medical intensive care unit and as a staff physician in the emergency department. She has also been involved in various research projects and has served as a mentor to residents.
PHM Conference Celebrates 20th Anniversary

By Richard Quinn

The first national meeting of the Pediatric Hospital Medicine (PHM) Conference was held in 2003—and it’s now the largest meeting of its kind for pediatric hospitalists. It’s sponsored jointly by the American Academy of Pediatrics (AAP), the AAP Section on Hospital Medicine, the Academic Pediatric Association, and SHM.

The PHM Conference keynote, delivered by Mary Ottolini, MD, MPH, Med, FHM, and Ken Roberts, MD, recounted the challenges of building the PHM specialty and challenged pediatric hospitalists to fight the good fight for continued progress.

When Dr. Roberts was first hired in the 1970s, he was told that pediatric specialists couldn’t just be based in the hospital. "The job didn’t exist, so he just did it anyway. Though times have changed, he feel this was a good thing so they could focus then on consulting."

The arguments resonated pretty quickly as PCPs recognized they could spend more time in the office, financially do better, and have their patients cared for full time by people in the hospital.

Advancements in electronic health records, a growing research presence, and the birth of fellowships all coincided with the specialty’s evolution. Annual meetings grew from roughly 125 people back in 2003 to some 1,800 attendees before the COVID-19 pandemic.

By Richard Quinn

The Hospitalist

PHM 2024 will be in Minneapolis, July 31 to August 4, 2024. Richard Quinn is a freelance writer in New Jersey.
Next-generation Web-based Tools for Clinical Teachers

Presenters
Cody Clary, MD, and Emily Hopkins, MD

By David Fish, MD, SFHM

In this impactful session, Drs. Clary and Hopkins introduced web-based resources that they’ve used as effective teaching tools in their practice. Both presenters demonstrated their passion for education with examples of how they’ve used these tools during their recent pediatric hospital medicine fellowships and early careers where they are both currently working on their master’s degrees in medical education.

Web 2.0 tools were introduced as platforms that allow the user to read or write web content, including many forms of social media. Drs. Clary and Hopkins presented three separate web-based tools they’ve found to be successful in engaging trainees, allowing for collaboration between educators and learners, and improving efficiency in education. They demonstrated how these resources can be used in many different teaching settings, including at the bedside and in both synchronous and asynchronous teaching environments.

The first platform that was introduced was Padlet. An online tool and app that allows the user to organize their teaching material and share it with trainees. Ways to use this tool, including mapping out a teaching plan for the week as well as incorporating libraries for visual diagnoses, illness scripts, and evidence-based medicine were all demonstrated. This resource also allows the user to upload presentations as well as web-based surveys that can help facilitate discussion regarding expectations and feedback.

Two other platforms were also presented as effective teaching tools: Visme and Playposit. Visme is a resource that allows the user to create graphics as well as interactive handouts that can help engage learners. Playposit is a resource where the user can create interactive asynchronous materials including presentations with questions and surveys embedded within.

All the resources discussed have free options that the presenters stated they found effective in their teaching, but there are paid options as well that offer increased content. Videos demonstrating how to navigate each of these platforms were also provided (and presented seamlessly!) which were very helpful for audience members looking to explore these innovative teaching options.

Making a Fortune in Pediatrics

Presenters
Lisa Herrmann, MD, MEd, Tony Tarchichi, MD, and Matthew Molloy, MD, MPH

By Erin E. King, MD

Dr. Herrmann, Tarchichi, and Molloy discussed their approach to financial health, a concept important to anyone caring for children, as 76% of medical school graduates have an average debt of $200,000 and start retirement savings 10 years after peers. This is especially crucial for anyone in pediatrics as we rank second to last in medical specialty pay and have an average net worth of less than $500,000. Components of financial health include protecting yourself, mitigating debt, budgeting, and saving for the future.

Protecting yourself—Physicians are in a special employee class with unique skills and health needs. Having your own disability policy is important and many employer plans are only short-term. On average, it is recommended you spend 1-3% of your salary on disability insurance.

It is recommended to consider a life insurance policy that covers 10 to 12 times your salary if you have dependents and/or debts. Term insurance is the cheapest and time limited. Whole life is more expensive yet can have a cash value and/or be borrowed against. Either way, obtain this while you are young and healthy as it will cost less.

Mitigating debt—Consider the different types of debt you may have (federal, institutional, or private loans, credit cards, housing, etc.) and what your percent interest is on each of these. Prioritize your highest interest rates and/or consider refinancing when economic conditions change. If you have government loans, consider Public Service Loan Forgiveness. With Public Service Loan Forgiveness, after 150 payments, your remaining debt is forgiven. This requires employment verification (must be at a not-for-profit institution), consolidation to a direct loan, and an income-driven repayment plan. For a small amount of input, this strategy can have a large payoff.

Budgeting—The first step is to have one! Consider your savings goals and rank your priorities. This could be an emergency fund (three to six months of salary), cushion for gaps in employment, or planning for that home, vacation, vehicle, etc. Available tools include websites (banks, consumer.gov), apps (Mint, Goodbudget, EveryDollar, PocketGuard, Honeydue, NerdWallet, and You Need a Budget), and others (spreadsheet, ‘envelope’ system, etc.). Expenses should be categorized into fixed (paid every month) and variable. Consider combining your variable expenses and avoiding the “I’m a doctor” lifestyle until your finances are under control.

Saving for the future—Options for physicians include IRA accounts, Roth IRAs (with income limits), and employer 401k, 403b, or 457f accounts. All have different plans, and some are matched. It is recommended to get your full match and consider 10% of your income a minimum savings goal. Consider housing and other costs you may have during retirement. These may increase your need for additional savings. A Health Savings Account uses pre-tax dollars for health care expenses and can be invested. After age 65, this can also be used for non-health-related expenses.

The closing portion of this session focused on making your money grow. Remember that time is your friend in investing. The audience was encouraged to make their full employment match and shoot for an investment return of 7%. In simple terms, fund management is divided into active and passive strategies. Active implies taking your dollars and moving them from one place to another over time (i.e., buying and selling stocks). Account fees with this strategy are typically around 1%. Passive investments include items such as buying index funds (S&P Dow Jones, etc.) and sitting with them over time. Account fees for passive funds average 0.5%. With fees in consideration alone, a passive account will net a $30,000 difference over seven years. In any 15-year period, the US S&P index fund beats all money managers, with an average rate of 10.3% over the past 50 years, however, there is much year-to-year variability. Other investments to consider include bonds (safer, as they are secured by a government or company), real estate, precious metals, and art. If you seek out a financial advisor to help you craft your strategy, ensure they are a fiduciary and will work for you, not themselves.

Blogs recommended by this team include the White Coat Investor, The Nomad Partnership Letters, The Memo by Howard Marks, and Berkshire Hathaway Annual Reports. The session concluded with an active Q&A session and contacts shared by the presenting team.
A Prescription for Function: Expanding your Toolbox for Somatic Symptom Disorders

Presenters
Catherine Sullivan, MD, and Christina Giudice, MSN, APRN, CPNP-PC

By Lauren McIntosh, MD

Delirium is underrecognized in the pediatric acute care spaces. Both in the intensive care unit and on the general medical floors. Studies have reported that the incidence of pediatric delirium is 20% to 60% of pediatric intensive care unit (PICU) patients and 10% to 40% of all hospitalized children. Delirium is defined in the DSM-5 as a disturbance in attention and alertness, with an abrupt change from baseline, which fluctuates, is not explained by a pre-existing neurocognitive disorder, and has evidence of a cause. Delirium can present as hypoactive (listless, withdrawn, reduced activity or awareness), hyperactive (restless, agitated, inconstant), or mixed, motor sub-type.

In pediatric patients, risk factors for delirium include age (less than two years old), mechanical ventilation, intensive care stay longer than five days, major surgery, presence of medical co-morbidities, and underlying developmental disabilities. Precipitating factors include drugs and toxins (barbituates, benzodiazepines, antihistamines including diphenhydramine, narcotics, steroids, psychotropic meds, tricyclic antidepressants, etc.), infections, metabolic derangements, systemic organ failure, neurological disorders, and physical disorders. The presenters shared a helpful mnemonic: BRAIN MAPS to remember the causes:

• B: Bring oxygen: hypoxemia and anemia
• R: Reduce: remove deliriogenic drugs
• A: Atmosphere: lights, sounds, unknown people
• I: Infection, Immobilization or inflammation
• N: New organ dysfunction
• M: Metabolic disturbances
• A: Awake: sleep disturbances
• P: Pain
• S: Sedation

Delirium can affect patient outcomes. Length of stay, after controlling for illness severity, has been reported to be 2.3 times longer for patients with delirium, and studies have shown that pediatric delirium is independently associated with increased hospital costs and higher mortality risk. The observed behaviors of inconsolability, agitation, or reduced awareness can be distressing to caregivers, especially if not identified by the care team as delirium.

Identifying and treating delirium is crucial to improving outcomes. The Cornell Assessment of Pediatric Delirium is one option for a screening tool that can be used in the PICU and has been used in multiple institutions on the general care floors. This bedside assessment can be completed by nursing staff twice daily and charted for trending within the electronic health record. The mainstay of treatment is to identify and treat the underlying cause and remove risk factors as much as possible. Non-pharmacological treatment includes re-orienting the patient to a day/night schedule, removing lines and tubes as able, minimizing sleep disruptions, and encouraging mobility. Melatonin can be used to promote normal circadian rhythm and anti-psychotics may be required, but their use should be limited and ideally involve psychiatry if possible.

Given that pediatric delirium is underrecognized and can affect patient outcomes, pediatric intensivists and pediatric hospitalists need to understand the presentation, diagnosis, and treatment as outlined above. The presenters encourage the development of a multidisciplinary

Lifting the Shade on Pediatric Acute Care Delirium—an Underrecognized Problem

Presenters
Nicholas Beam, MD, Jeri Kessenich, MD, Jillian Bybee, MD, and Brett Leingang, MD

By Andrea Hadley, MD

Delirium is underrecognized in the pediatric acute care spaces. Both in the intensive care unit and on the general medical floors. Studies have reported that the incidence of pediatric delirium is 20% to 60% of pediatric intensive care unit (PICU) patients and 10% to 40% of all hospitalized children. Delirium is defined in the DSM-5 as a disturbance in attention and alertness, with an abrupt change from baseline, which fluctuates, is not explained by pre-existing neurocognitive disorders, and has evidence of a cause. Delirium can present as hypoactive (listless, withdrawn, reduced activity or awareness), hyperactive (restless, agitated, inconstant), or mixed, motor sub-type.

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Please see references online.
The Art of Lifelong LEARNing: How to Model Empathy in Difficult Situations

Presenters
Sarah Gustafson, MD, Lee Engelbreth, MD, and Mallory Logsdon, DO

By Patricia Tran, MD, MS, FAAP

This session focused on modeling empathy in difficult clinical situations. The presenters introduced a framework called LEARN to guide medical professionals in effectively demonstrating empathy when dealing with patients and families. LEARN stands for Listen, Empathize, Acknowledge, Respect, and Next Steps. The session opened with a discussion on the concept of the art of medicine and the challenge of understanding what makes certain patient interactions more successful than others. The presenters drew parallels between art and empathy, emphasizing the importance of forming emotional connections and bonds with patients. The definition of empathy was explored, going beyond a simple understanding of another’s feelings, to connecting with their emotions and using that understanding to guide actions.

The need for empathy in medical practice was highlighted, with its positive impact on patient outcomes, satisfaction, adherence to treatment plans, and even health care provider wellness. The presenters acknowledged that while empathy is important, it must be used thoughtfully, as overextending oneself can lead to negative consequences.

The LEARN framework was then introduced, with each step explained in detail using examples:

• **Listen**—stressed the importance of active listening, allowing silence for reflection, and using open-ended questions to encourage patients and parents to express their concerns.

• **Empathize**—emphasized understanding and validating patients’ and parents’ emotions, naming feelings, and sharing values.

• **Acknowledge**—encouraged acknowledging parent concerns, advocating for their child, and even apologizing for frustrations or challenges.

• **Respect**—involved showing respect for parents’ opinions, including cultural differences, and valuing their expertise as parents.

• **Next Steps**—focused on collaborating with patients and parents, involving them in the decision-making process, and reflecting with colleagues to ensure effective communication.

Throughout the session, the presenters engaged the audience with a case study involving a three-week-old baby experiencing failure to thrive and the hesitance of the parents regarding a nasogastric feeding tube. The attendees provided examples of how to apply the LEARN framework to effectively communicate empathy and address the family’s concerns.

The session concluded by inviting attendees to use the provided toolkit for further guidance and incorporating the LEARN framework into their medical practice. Attendees were encouraged to provide feedback to improve the toolkit and share their experiences with the framework’s implementation.

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Health Equity in Hospital Medicine

Presenters
Kenya McNeal-Trice, MD

By Vignesh Doraiswamy, MD

Dr. McNeal-Trice’s plenary was a tour-de-force at the 2023 PHM Conference. She effortlessly blended basic health equity definitions and principles, important historical contexts, intimate individual patient and practitioner experiences, and actionable takeaways to deliver a powerful message.

She started by defining health equity as a principle that all individuals, regardless of factors like race, gender, socioeconomic status, or location, should have equal access, opportunities, and resources to achieve their optimal level of health, and further described it as a state where everyone has a just and fair chance to attain their highest health potential.

She defined racism as a powerful force that operates in various levels of society both intentionally and unintentionally, and one that unfairly distributes opportunities and value based on physical appearance, resulting in advantages for some and marked disadvantage for others.

Dr. McNeal-Trice continued by introducing the crucial concept of the political determinants of health as the interconnected processes of structuring relationships, distributing resources, and wielding power, all of which simultaneously shape opportunities that can both promote health equity and exacerbate existing inequities.

These determinants encompass factors like poor environmental conditions, limited transportation, unsafe neighborhoods, and insufficient access to healthy food options. Understanding the origins and impact of these determinants is key to developing effective strategies that combat health disparities. To achieve justice in health care, hospitalists need a grasp of how politics functions and how it has influenced population health.

She shared with us the tragic historical stories and context that led to the closure of North Carolina institutions like St. Agnes Hospital and Leonard Medical School, local institutions that trained and cared for the Black residents of Raleigh. An August 2020 study in JAMA Network Open estimated that if the major institutions training Black physicians in the early 1900s had remained open, we would have had an additional 35,315 Black physicians in the U.S.

Dr. McNeal-Trice then moved on to share heartbreaking reflections on the experiences of hospitalized children and families, including the impact of being Black when living with a chronic condition or having a hospitalized family member. She showed the impact that racial stress and trauma have on our patients and their families, further affecting our patients’ care. She described the strategies and approaches families needed to take just so they could be taken seriously in the hospital and receive the care they needed. However, even those in positions of power and importance are not immune to the challenges of racism as she shared with us the experiences of physicians who were on the receiving end of racist behaviors.

Most importantly, she concluded her plenary with actionable takeaways that allow us to make actual changes in our practices. She described how not just hospitalists, but everyone in health care can recognize disparities, educate themselves, and ultimately advocate for the changes they wish to see and be.

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References

Creating a Therapeutic Environment for Adolescents with Behavioral Health Needs

Presenters
Cori Grant, MD, Purvi Patel, MD, and Molly Gleason, OTR/L

By Rebecca Cantu, MD, MPH

Recent states of mental health issues and suicide in children have been rising for at least a decade, but since the summer of 2020 there has been a significant increase in mental health patient volumes, an increase in the severity of symptoms, and less access to outpatient psychiatric resources—8% of U.S. states report a shortage of psychiatric beds. Patients with autism spectrum disorders (ASD) have significantly more psychiatric admissions than children without ASD and intellectual disability (ID) are the top two predictors for emergency department (ED) boarding. Typical pediatric inpatient psychiatric units do not meet the needs of children with ASD or ID. Models for best practice include an interdisciplinary team (including psychiatry, nursing, pediatrics, social work, board-certified behavioral analyst, speech therapy, and occupational therapy), autism-specific programming, and a specially designed milieu.

“Boarding” occurs when the decision has been made to admit a patient to inpatient psychiatry, but a bed is not currently available. The patient remains in an ED or acute medical facility. The average boarding time for youth has doubled, with more than half of patients boarding for more than two days (the Joint Commission recommends boarding times of fewer than four hours).

Ancillary providers such as occupational therapists (OTs) can work with hospitalists to help mediate disruptive behavior by understanding and modifying aspects of antecedents and triggers for the behavior and adapting to the environment. Examples of meeting sensory needs in the hospital environment include proprioception (weighted blankets), decreasing sensory input (quiet times, TV off, lighting), visual stimulation (tidying the visual space of wrappers and supplies), and mediating activities to avoid overstimulation. Sensory toolkits and giving space for physical activity can help. Involving an OT as part of the interdisciplinary team is key to evaluating each patient’s strengths and needs and determining interventions to best support their engagement in daily activities while in the hospital setting.

The creation of a safe environment also includes the physical environment, so room selection and preparation are important. Rooms should be cleared of ligature risks, ingestion hazards, and potential weapons. Rooms should be evaluated for proximity to elevators, stairs, and other patients and have appropriate availability and accessibility of security and trained staff. Behavioral-health-specific personal protective equipment is available and should be used to protect from injury and infection risk.

Communication is critical, especially during prolonged admissions with multiple providers. Inconsistent expectations can also be a trigger for unwanted behaviors in patients. Several strategies can help improve communication, including regular multidisciplinary care meetings, handoffs (including physician handoffs and handoffs between one-to-one observers), flags in the electronic health record indicating risk for workplace violence or presence of a behavioral health plan, admission and discharge checklists, and identification of primary hospitalists and psychiatrists who longitudinally follow a patient, even when they are not on service.

Top 10 Pitfalls to Implementing a Protocol in Your Hospital and How to Avoid Them

Presenters
Raymond Lejano, MD, Ha Nguyen, MD, and Pete Van Hoff, MD

By Julia Sparks, MD

A hospital protocol is a mandatory, specific set of decision-making processes or standards based on best practice. Protocols are important in the promotion of safe, efficient, consistent, and high-quality care while maintaining space for future improvement. Protocols are made through a generally universal set of stages including literature review, drafting, feedback and approval, implementation, monitoring, and adjustments. These are the 10 most common pitfalls to implementing a new protocol and how to avoid or resolve them:

1. Not being clear or concise enough when drafting the protocol. Avoid this pitfall by reviewing the scope during the writing stage.
2. Delayed feedback for the new protocol. Avoid this pitfall by identifying key shareholders early and setting clear deadlines for review or feedback, with frequent follow-up.
3. Delayed committee or departmental approval. Avoid this pitfall by confirming protocol approvals and meeting frequencies.
4. Lack of consensus on best practice amongst shareholders. Avoid this pitfall by identifying the “whys” surrounding the disagreement and reviewing relevant literature; consider making a clearly delineated exception to the protocol if a disagreement persists.
5. The protocol doesn’t align with your electronic health records (EHR) or resources. Avoid this pitfall by identifying an information technology liaison early and determining whether the protocol requires a third-party tool that may not be immediately compatible with your EHR.
6. Delayed EHR changes. Avoid this pitfall by staying in close contact with the information technology team and using flexible language so that the protocol can go live despite unanticipated EHR delays.
7. Unclear education of staff on the new protocol. Avoid this pitfall by including the reasoning for the practice change, assigning physician liaisons for different units, making the protocol easily accessible, and removing old or outdated policies.
8. Challenges in the maintenance of staff education. Avoid this pitfall through the use of pre-recorded education, online modules, and reminders at important department or unit meetings.
9. Inconsistent practice after the launch of the new protocol. Avoid this pitfall with close monitoring and review of process measures, making adjustments as needed.
Getting Started with Multicenter Research and QI: Lessons from EMO

Presenters
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By Rachel J. Peterson, MD, FHM

A team from Children’s Hospital of Philadelphia (CHOP) is leading a national multicenter project looking at ending monitoring overuse (EMO) in children with bronchiolitis. The CHOP EMO research team gained knowledge and insights through this project and shared this with the FHM 2023 Conference attendees.

The team first addressed the reasons for choosing a multicenter trial. Single-center sites have limitations that could prevent generalizability; whereas multisite projects can build on what single-site projects have started. It’s important to think through the improvements needed and questions remaining when moving from single-site to multisite studies.

Multisite studies also allow for larger sample sizes, and testing interventions, and are specifically geared toward implementation or (as in the case of EMO) de-implementation work. One issue the leaders of EMO noted is that when intervention (or study period) ceases, the change that was initiated often goes away as well.

Regulatory and financial aspects also impact the success of multisite studies. It’s important to have a skilled research staff. The clinical research assistants are vital, as they’re the face of the study. Project managers work closely with the principal investigators to keep track of budgeting and timeline projections and ensure these are in line with the aims of the overall project. Building partnerships with the collaborating sites allowed EMO to succeed. Collaborations include reliance agreements to allow for the institutional review board reviews to successfully move forward.

Engaging the hospitalists involved in EMO was another key aspect of its success. Leaders from CHOP discussed spoon-feeding communication and using a consistent but digestible amount of knowledge for each communication dissemination. Enthusiasm for the project from research staff is important for engaging hospitalists nationally. Additionally, allowing for flexibility for various sites within their needs allowed a greater breadth of engagement. Lastly, tracking everyone involved and every data piece keeps the study team on top of the current status and next steps. Rolling out multisite interventions requires thoughtful project management. Initiation, planning, execution, and monitoring all impact the end success.

Key Takeaways
- Multisite trials are useful for building on what is known from single-site trials and can be a great resource for implementation or de-implementation work.
- Engaging hospitalists at multiple sites requires great communication, enthusiasm, organization, agility, and data-driven focus in a research team.
- Ironing out the regulatory and financial aspects of a multisite trial can help ease hospitalists’ involvement.

Brief overview of the issue
Toxic alcohol ingestion should be suspected in patients with metabolic acidosis and an elevated osmolal gap. However, diagnosing such ingestions can be challenging as patients are often encephalopathic and unable to provide meaningful histories.

Gas chromatography is used to detect toxic alcohols, but it is time-consuming and not widely available. Methanol and ethylene glycol poisonings can cause serious injury and are potentially life-threatening.

Ethylene glycol is metabolized into glycolic and oxalic acids, possibly leading to acute renal failure (Figure 1). Methanol, on the other hand, is metabolized into formic acid, which can cause optic nerve damage and blindness (Figure 1). Toxic alcohols can also result in central nervous system (CNS) depression, coma, and seizures. The osmolal gap can serve as an early indicator of toxic ingestions, enabling prompt treatment decisions. The osmotically active particles in the blood include sodium, chloride, glucose, and urea. The calculated osmolality (cOsm) can be determined using the equation:

\[
cOsm = 2 \times [Na^+] + \frac{[glucose ]}{18} + \frac{[BUN ]}{2.8}
\]

If ethanol is present, \( + \frac{[ethanol ]}{3.7} \) can be added to the equation. Measured serum osmolality values also impact the success of multisite studies. It’s important to have a skilled research staff. The clinical research assistants are vital, as they’re the face of the study. Project managers work closely with the principal investigators to keep track of budgeting and timeline projections and ensure these are in line with the aims of the overall project. Building partnerships with the collaborating sites allowed EMO to succeed. Collaborations include reliance agreements to allow for the institutional review board reviews to successfully move forward. Engaging the hospitalists involved in EMO was another key aspect of its success. Leaders from CHOP discussed spoon-feeding communication and using a consistent but digestible amount of knowledge for each communication dissemination. Enthusiasm for the project from research staff is important for engaging hospitalists nationally. Additionally, allowing for flexibility for various sites within their needs allowed a greater breadth of engagement. Lastly, tracking everyone involved and every data piece keeps the study team on top of the current status and next steps. Rolling out multisite interventions requires thoughtful project management. Initiation, planning, execution, and monitoring all impact the end success.
(optic nerve damage, blindness)

**Ethylene Glycol**

1. **Alcohol dehydrogenase** inhibits
2. **Formaldehyde**
3. **Glycerol**
4. **Formic Acid**
5. **Glycolic Acid**
6. **Oxalic Acid**

**Application to case**

The range of potential osmotically active substances leading to an elevated osmolal gap is extensive, resulting in a comprehensive list for the differential diagnosis. Clinicians should be vigilant in identifying an osmolal gap exceeding 20 mOsm/L as it immediately raises suspicion for potential toxic alcohol ingestion.

Ethylene glycol and methanol have rapid gastrointestinal absorption with ethylene glycol achieving peak plasma levels in one to four hours and methanol in 30 minutes to one hour. When seriously suspecting ethylene glycol or methanol poisoning, it is imperative to act promptly. Recommended treatment includes supportive care with IV fluids, sodium bicarbonate, and fomepizole, an alcohol dehydrogenase inhibitor. It is encouraged to start Fomepizole right away because it stops toxic metabolite formation and can prevent end organ damage. If severe acidosis or renal failure occurs, then hemodialysis may be necessary to eliminate metabolites.

In this case, the patient received hemodialysis and there was less clinical suspicion for ingestion of ethylene glycol or methanol. It is commonly known that diabetic and alcoholic ketoacidosis states can raise the osmolal gap, but less often encountered is that IV benzodiazepines, which contain propylene glycol, and mannitol infusions can raise the osmolal gap. Two types of IV contrast frequently used are iso-osmolar contrast, which has equal osmolality to blood but a higher viscosity, and low osmolar contrast, which has about two to three times the osmolality of blood and can increase serum osmolality.

An elevated osmolal gap can also be seen in chronic renal failure, especially in dialysis-dependent patients. A combination of alcohol ingestion, IV contrast, and chronic renal disease contributed to this patient’s increased osmolal gap.

**Bottom line**

Interpreting the osmolal gap requires a good history, screening for toxic ingestions, and measuring serum alcohol, lactic acid, and glucose levels. Calculations can be confounded by IV contrast and renal failure.

**References**

Chapter Spotlight: Connecticut

A beacon of belonging for Nutmeggers

By Richard Quinn

N o one starts out as the president of an SHM chapter. In fact, it’s usually the opposite. Folks are recruited to join because someone sees potential in them, and they rise to the top as their work product shows they see the value and benefits that come from chapter engagement.

Meet Kelsey Cole, MMSc, PA-C, co-president of the Connecticut chapter of SHM. Brought into the fold roughly five years ago by former president, Dr. Rob Fogarty, she’s now building a succession plan. She’s kind of the chapter equivalent of “see one, do one, teach one.”

After a few years as a member, “I was working with hospitalist leadership at each of what we call delivery networks, our hospital locations, to help really break down our silos,” said Ms. Cole, a program manager at Yale New Haven Health System, New Haven, Conn. To “problem-solve together and learn from one another about multiple aspects of our best practices, and implementation of best practice recommendations for our patients.”

That collaborative work led to a phone call from a chapter executive, which led to a leadership role, which led to her current chapter title alongside co-president Dr. Agata Sajkiewicz.

Ms. Cole speaks highly of the value of the leadership lessons the chapter has taught her, and of the power of communal communication, not just in the walls of a hospital, but across the health care system of a state.

“Our own, individual wisdom is nothing compared to the collective wisdom of those who have been in the situation or have had other experiences similar to ours or different than ours,” she said. “Unless you get folks talking together, you may never have understood what they bring to the table or what that potential is.”

“I don’t think enough emphasis can be placed on the power of collective wisdom, and how much unnecessary effort you can go through trying to solve a problem when someone already has the key to the solution, and you didn’t know it or didn’t have the opportunity to be connected to that person.”

One approach to getting folks to share more is in-person events, which Ms. Cole says she favors over remote gatherings. In fact, she sees that as a recruitment tool.

“I would like to focus on the visibility of the professional development opportunities that are available in SHM, especially for some of our newer hospitalists and residents, where we have a lot of opportunities for increasing our membership,” she said.

Ms. Cole says growing the membership base is a key goal for the future. And that starts with early-career hospitalists and would-be hospitalists.

“This year, we have a really great resident liaison on our team, and we’re hoping to have a fun resident-focused event,” Ms. Cole said. “Something that they are interested in participating in that also serves as an opportunity to highlight the different special interest groups, committees, additional training, and all the leadership academies, etc., that SHM has to offer for those who are considering a career in hospital medicine.”

Ms. Cole has seen the value of expanding the leadership team, too. Past chapter president Dr. Jacqueline Rheiner came up with the idea for an event coordinator.

“Leadership succession is essential with the right people with the right skill set,” Ms. Cole said.

The tuck has been working, if the 2022 Platinum Chapter Excellence Award it earned is any way to judge.

Ms. Cole attributes the honor to “a really strong and collaborative leadership team of folks who are really engaged and bring great collective ideas to the table. Each of us has our role. Each of us has our responsibilities. Each of us has our contributions. And together, that causes a great brainstorm about where we can focus next, and who is going to do what in order to get different activities and initiatives off the ground.”

Sometimes that is presentations from the Connecticut Hospital Association, and sometimes it’s as simple as folks at hospitals a few miles away meeting for the first time. Either way, a key to chapter success is making sure events are well planned, important to the members, and, frankly, worth the time.

The chapter brings “people together who maybe wouldn’t have normally known of each other’s existence or each other’s knowledge on a certain topic,” Ms. Cole said. “After a meeting, I can get an email from someone that says, Hey, would you mind sharing so-and-so’s contact information with me so we can discuss this item that they brought up during the forum further.” That allows for that natural connection between people, and you just never know what opportunities and new ideas can come from fostering those types of connections.

“It’s a balance from having the agenda driven by our hospitalists…I always say if you have a topic you’d like to explore, we can do that and figure out how to bring people in or make sure the right people are at the meeting in order to discuss the question that you have.”

Richard Quinn is a freelance writer in New Jersey.
By Richard Quinn

The practice of medicine, particularly in the hospitalized setting, is viewed by some as bureaucracy at scale. The federal government, particularly in the hospitalized setting, could be described the same way.

In a sense, SHM’s Veterans Affairs (VA) Hospitalists Special Interest Group is arguably the best place for pearls, pitfalls, and practices to navigate the two hierarchies.

“Bureaucracy for the sake of bureaucracy has a well-deserved reputation for hindering efficiency,” said Mel Anderson, MD, MACP, past SIG chair and interim section chief of hospital medicine at the Rocky Mountain Regional VA Medical Center in Aurora, Colo. “And this is just the opposite. This is creating connections that didn’t exist before and creating opportunities that didn’t exist before.”

Dr. Anderson, one of the first backers of an SHM group to connect VA hospitalists, says he sees parallels between the VA and the nature of hospital medicine. Hospitalists across the country can feel isolated in their buildings and duties, despite the shared challenges and accomplishments across the specialty; and the SIG provides a chance for communication and collaboration.

“And as much as the VA is one system, we’re probably more accurately like 159 federated hospitals that have varying degrees of connection with one another,” he said. The SIG exists “to leverage expertise to support one another, to improve the care we deliver for patients, to advance professional careers, and to realize opportunities for scholarship.”

Dr. Anderson says the SIGs sense of community was evident during the COVID-19 pandemic.

“This is not just meeting each month on a Zoom call or FaceTime call, but that you actually know one another and have developed trust in one another and have an actual relationship,” he said. “That then lowers the bar for reaching out. And in this way, you know, a small VA somewhere knows that they’re a phone call away from Michelle who is a phone call away from me and 18 other networks...it’s an unrealized opportunity.”

SIG chair Jeffrey Bates, MD, FHM, says the group’s future is limited only by its ambition.

“The answer to that is about as broad as we can imagine,” said Dr. Bates, an associate professor at Baylor College of Medicine and section chief of consult medicine at the Michael E. DeBakey VA Medical Center, both in Houston. “And I mean that literally...we now have an infrastructure that will allow us to develop and communicate quality improvements and system improvement practices at scale in the largest integrated health care system in the U.S. affecting millions of patients.”

SIG vice chair Michelle Guidry, MD, FHM, says the breadth of the VA system means that hospitalists working within it see a combination of both unique situations and routine ones.

“I often get asked by my non-VA hospitalist colleagues, ‘What is different about taking care of veterans than taking care of non-veterans?’ or ‘What can I learn from you about taking care of veterans?’” said Dr. Guidry, an associate professor of medicine at Tulane University and section chief of hospital medicine at the Southeast Louisiana Veterans Healthcare System in New Orleans.

“There are unique constellations of clinical conditions that come with being a veteran that we have become experts in caring for. Examples include toxic exposures, TBI (traumatic brain injury), depression, moral injury, chronic pain, amputation, and PTSD (post-traumatic stress disorder).”

Dr. Guidry sees that experience as a chance to pass along that subject matter expertise, to others in the VA as well as to hospitalists in community and academic settings.

“We have an opportunity and maybe a responsibility to share more broadly,” Dr. Bates said. “Veterans are cared for across hospitals in our country, not just in the VA. I think those are things that would be important for us to share.”

Dr. Bates says he’s seen an increasing number of practitioners engaging with the SIG but, perhaps moreso than other groups, the lessons learned are just as applicable when brought back to VA centers nationwide.

“All of these other practitioners go out, take that back to the other places,” he said. “It’s got an exponential effect in terms of getting people otherwise engaged in the process. And so one of the things we want to do is make SHM a home for VA hospital medicine. And so we try to bring that part home to everyone. ‘Come to these groups and we’ll get you connected in the way that you want to be connected.’”

Drs. Anderson, Bates, and Guidry agree that the work they’ve put into the SIG—and the work all leadership committees put into their organizations—is only truly successful if it succeeds without them.

“These changes, at the leadership level, at the organizational level, are not about any particular person,” Dr. Anderson said. “It’s about building something that will outlast us and that is not dependent on us. And so I’m always thinking about working myself out of this job in that way. We’ve very much embrace the idea of servant leadership.”

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

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

Each 150mL dose of REBYOTA contains between 1x10⁸ and 5x10¹⁰ colony forming units (CFU) per mL of fecal microbes including >1x10⁷ 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 (≥ 3%) adverse reactions occurring in adults following a single dose of REBYOTA were abdominal pain, (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

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

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

**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.

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

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

For more information, visit www.REBYOTAHCP.com

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

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References