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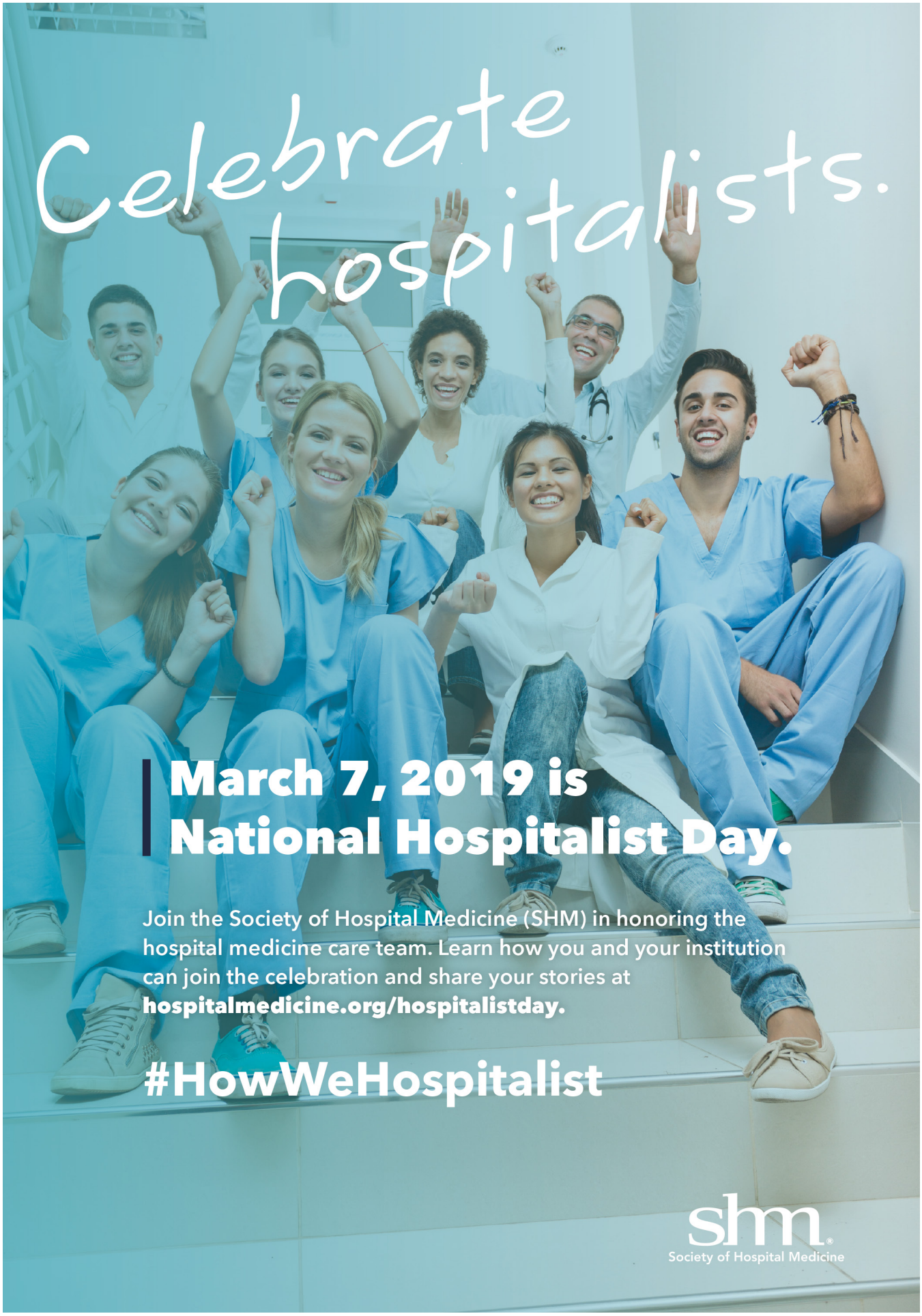
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CLINICAL CARE CONUNDRUM

PERSPECTIVES IN HOSPITAL MEDICINE

EDITORIALS

Introducing Leadership & Professional Development: A New Series in JHM

Vineet Chopra, MD, MSc

Division of Hospital Medicine, University of Michigan Health System, Ann Arbor, Michigan.

"I cannot say whether things will get better if we change; what I can say is they must change if they are to get better."

—Georg C. Lichtenburg

Leading change is never easy. Many a physician has joined a committee, hired a promising project manager, assumed responsibility for an operational or clinical task—only to have it painfully falter or agonizingly fail. Unfortunately, some of us become disillusioned with the process, donning our white coats to return to the safe ensconce of clinical work rather than take on another perilous change or leadership task. But ask those that have tried and failed and those that have succeeded and they will tell you this: the lessons learned in the journey were invaluable.

Academic medical centers and healthcare organizations are increasingly turning to hospitalists to assume a myriad of leadership roles. With very little formal training, many of us jump in to improve organizational culture, financial accountability, and patient safety, literally building the bridge as we walk on it. The practical knowledge and know-how gleaned in efforts during these endeavors are perhaps just as important as evidence-based medicine. And yet, few venues to share and disseminate these insights currently exist.

This void represents the motivation behind the new Journal series entitled, "Leadership & Professional Development" or "LPD." In these brief excerpts, lessons on leadership/followership, mentorship/menteeship, leading change and professional development will be shared using a conversational and pragmatic tone. Like a clinical case, pearls to help you navigate development and organizational challenges will be shared. The goal is simple: read an LPD and walk away with an "a-ha," a new tool, or a strategy that you can use ASAP. For example, in the debut LPD—Hire Hard[1]—we emphasize a cardinal rule for hiring: wait for the right person. Waiting is not easy, but it is well worth it in the long run—the right person will make your job that much better. Remember the aphorism: A's hire A's while B's hire C's.

Many other nuggets of wisdom can fit an LPD model. For example, when it comes to stress, a technique that brings mindfulness to your day—one you can practice with every patient encounter—might be the ticket.[2] Interested in mentoring? You'll need to know the Six Golden Rules.[3] And don't forget about emotional intelligence, tight-loose-tight management or the tree-climbing monkey! Don't know what these are? Time to read an LPD or two to find out!

As you might have guessed—some of these pieces are already written. They come from a book that my colleague, Sanjay Saint and I have been busy writing for over a year. The book distills much of what we have learned as clinicians, researchers and administrators into a collection we call, "Thirty Leadership Rules for Healthcare Providers." But LPD is not an advert for the book; rather, our contributions will only account for some of the series. We hope this venue will become a platform in where readers like you can offer "pearls" to the broader community. The rules are simple: coin a rule/pearl, open with an illustrative quote, frame it in 650 words with no more than five references, and write it so that a reader can apply it to their work tomorrow. And don't worry—we on the editorial team will help you craft them if the message makes sense. Interested? Send us an email at lpd.series@umich.edu with an idea and watch your Inbox—an invitation for an LPD might be in your future.

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The socio-adaptive (or "nontechnical") aspects of healthcare including leadership, followership, mentorship, culture, teamwork, and communication are not formally taught in medical training. Yet, they are critical to our daily lives as Hospitalists. The LPD series features brief "pearls of wisdom" that highlight these important lessons.

Hire Hard, Manage Easy

Vineet Chopra, MD, MSc[1,2]*; Sanjay Saint, MD, MPH[2,1]

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"If you can hire people whose passion intersects with the job, they won't require any supervision at all. They will manage themselves better than anyone could ever manage them. Their fire comes from within, not from without."

—Stephen Covey

When you initiate a quality or performance improvement project, you want to find someone who can help you do the necessary work and find that someone quickly. But be warned: leaders must learn to go slow when hiring for their team. Do not settle on whoever has available time or interest—they may have time to give or be eager for a reason.

We see this unfold in several ways. For example, individuals are sometimes "offered" up for a role: "This person has experience reviewing charts and abstracting data—and they have some time available. Would you like to hire them?" Similarly, eager students or faculty may be willing to jump on a project with you—"I am looking to join a project," or "Yes, I can help with that," are all too often heard in this context. Both scenarios share in common one truth: easy availability and willingness to help make it tempting to say, "Sure."

While some of these individuals might be ideal, many are not. When hiring, you have to think hard about the role and an individual's skill set that makes them well suited for it. Based on experience, we can tell you that once you go "soft" by selecting a suboptimal candidate, you are in trouble for at least three reasons. First, hiring the right people is the key to achieving success for your initiative. And success in your project reflects directly on you. People will make inferences about you based on the people you surround yourself with: if they are terrific, the assumption—right or wrong—is that you are as well. Second, we tend to compensate for underperforming employees, often at great cost to ourselves or others. When data collection for a project does not go well, we have found ourselves behind the screen filling in various portions of a data collection form. For example, a colleague once told us, "I hired this person to help, but they ended up needing so much assistance that it was often easier for me and others to do the work. The environment quickly became toxic."

Third, it is often difficult to remove an underperforming employee or have them change positions. Health organizations (especially universities or other public institutions) can be rigid that way. An infection prevention leader told us of waiting a whole year to fill a crucial vacancy before she found the right person. It was ultimately the right decision, she said, adding, "My life is so much better."

How can you be sure you have found the right person? Regardless of whether you are hiring for a permanent or temporary position, staff or faculty member, we recommend the following:

- Ensure recruits meet with several people. The more eyes on a candidate, the better. Often, someone will catch something you may not—and having many people involved helps get the team invested in the success of your hire.
- Standardize and solicit feedback. For example, we use a standardized template to garner feedback on administrative recruits, project managers, and faculty. This way, we all are evaluating potential colleagues through the same structured approach.
- Ensure skills match the role. For example, an ethnographic study would benefit from someone skilled in qualitative methods. Similarly, a project manager experienced in clinical trials would be best suited for patient recruitment and managing investigators at several sites. Identifying what is clearly needed in the role is a key step in hiring.

Management guru Jim Collins writes: "The moment you feel the need to tightly manage someone, you've made a hiring mistake. The best people don't need to be managed. Guided, taught, led—yes. But not tightly managed."[1] True in management, and true in the world of healthcare. Hire Hard. In the long run, you will be able to manage easy.

Disclosures: Drs. Chopra and Saint are co-authors of the upcoming book, "Thirty Rules for Healthcare Leaders," from which this article is adapted. Both authors have no other relevant conflicts of interest.

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Association of Weekend Admission and Weekend Discharge with Length of Stay and 30-Day Readmission in Children's Hospitals

Jessica L Markham, MD, MSc[1]*; Troy Richardson, PhD[1,2]; Matthew Hall, PhD[1,2]; Christopher P Bonafide, MD, MSCE[3]; Derek J Williams, MD, MPH[4]; Katherine A. Auger, MD, MSc[5,6]; Karen M Wilson, MD, MPH[7]; Samir S Shah, MD, MSCE[5,6]; on behalf of the Pediatric Research in Inpatient Settings (PRIS) Network.

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BACKGROUND: Worse outcomes among adults presenting for/receiving care on weekends (ie, "the weekend effect") have been observed for many diseases. However, little is known about the overall impact of the weekend effect in hospitalized children.

OBJECTIVE: To determine the association between weekend admission and length of stay (LOS) and between weekend discharge and 30-day all-cause readmission.

METHODS: We conducted a retrospective, cross-sectional study of children hospitalized between October 1, 2014 and September 30, 2015 using the Pediatric Health Information System. Birth hospitalizations and planned procedures were excluded. We used generalized linear mixed modeling to assess the independent association between weekend admission and LOS and weekend discharge and readmission risk.

RESULTS: Among 390,745 hospitalizations across 43 hospitals, the median LOS was 41 hours (interquartile range [IQR] 24-71) and the 30-day readmission rate was 8.2% (IQR 7.2-9.4). We observed no association between weekend admission and LOS (adjusted LOS [95% CI] weekend 63.70 [61.01-66.52] hours vs weekday 63.40 [60.73-66.19] hours, $P = .112$). Weekend discharge was associated with slightly increased odds of readmission compared with weekday discharge (adjusted probability of readmission [95% CI]: weekend 0.13 [0.12-0.13] vs weekday 0.11 [0.11-0.12]; $P < .001$) but was variable among individual hospitals. Patient characteristics (ie, number of chronic conditions) were more strongly associated with LOS and readmission risk than weekend admission or discharge.

CONCLUSIONS: Patient-level factors (ie, clinical and demographic characteristics) are more indicative of longer LOS and readmission risk than weekend admissions or discharges. The overall impact of the weekend effect across children's hospitals was minimal. *Journal of Hospital Medicine* 2019;14:75-82. © 2019 Society of Hospital Medicine

Increasingly, metrics such as length of stay (LOS) and readmissions are being utilized in the United States to assess quality of healthcare because these factors may represent opportunities to reduce cost and improve healthcare delivery.[1-8] However, the relatively low rate of pediatric readmissions,[9] coupled with limited data regarding recommended LOS or best practices to prevent readmissions in children, challenges the ability of hospitals to safely reduce LOS and readmission rates for children.[10–12]

In adults, weekend admission is associated with prolonged LOS, increased readmission rates, and increased risk of mortality.[13-21] This association is referred to as the "weekend effect." While the weekend effect has been examined in children, the results of these studies have been variable, with some studies supporting this association and others refuting it.[22-31] In contrast to patient demographic and clinical characteristics that are known to affect LOS and readmissions,[32] the weekend effect represents a potentially modifiable aspect of a hospitalization that could be targeted to improve healthcare delivery.

With increasing national attention toward improving quality of care and reducing LOS and healthcare costs, more definitive evidence of the weekend effect is necessary to prioritize resource use at both the local and national levels. Therefore, we sought to determine the association of weekend admission and weekend discharge on LOS and 30-day readmissions, respectively, among a national cohort of children. We hypothesized that children admitted on the weekend would have longer LOS, whereas those discharged on the weekend would have higher readmission rates.

METHODS

Study Design and Data Source

We conducted a multicenter, retrospective, cross-sectional

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study. Data were obtained from the Pediatric Health Information System (PHIS), an administrative and billing database of 46 free-standing tertiary care pediatric hospitals affiliated with the Children's Hospital Association (Lenexa, Kansas). Patient data are de-identified within PHIS; however, encrypted patient identifiers allow individual patients to be followed across visits. This study was not considered human subjects research by the policies of the Cincinnati Children's Hospital Institutional Review Board.

Participants

We included hospitalizations to a PHIS-participating hospital for children aged 0-17 years between October 1, 2014 and September 30, 2015. We excluded children who were transferred from/to another institution, left against medical advice, or died in the hospital because these indications may result in incomplete LOS information and would not consistently contribute to readmission rates. We also excluded birth hospitalizations and children admitted for planned procedures. Birth hospitalizations were defined as hospitalizations that began on the day of birth. Planned procedures were identified using methodology previously described by Berry et al.[9] With the use of this methodology, a planned procedure was identified if the coded primary procedure was one in which >80% of cases (eg, spinal fusion) are scheduled in advance. Finally, we excluded data from three hospitals due to incomplete data (eg, no admission or discharge time recorded).

Main Exposures

No standard definition of weekend admission or discharge was identified in the literature.[33] Thus, we defined a weekend admission as an admission between 3:00 PM Friday and 2:59 PM Sunday and a weekend discharge as a discharge between 3:00 PM Friday and 11:59 PM Sunday. These times were chosen by group consensus to account for the potential differences in hospital care during weekend hours (eg, decreased levels of provider staffing, access to ancillary services). To allow for a full 30-day readmission window, we defined an index admission as a hospitalization with no admission within the preceding 30 days. Individual children may contribute more than one index hospitalization to the dataset.

Main Outcomes

Our outcomes included LOS for weekend admission and 30-day readmissions for weekend discharge. LOS, measured in hours, was defined using the reported admission and discharge times. Readmissions were defined as a return to the same hospital within the subsequent 30 days following discharge.

Patient Demographics and Other Study Variables

Patient demographics included age, gender, race/ethnicity, payer, and median household income quartile based on the patient's home ZIP code. Other study variables included presence of a complex chronic condition (CCC),[34] technology dependence,[34] number of chronic conditions of any complexity, admission through the emergency department, intensive care unit (ICU) admission, and case mix index. ICU admission and case mix index were chosen as markers for severity of illness. ICU admission was defined as any child who incurred ICU charges at any time following admission. Case mix index in PHIS is a relative weight assigned to each discharge based on the All-Patient Refined Diagnostic Group (APR-DRG; 3M) assignment and APR-DRG severity of illness, which ranges from 1 (minor) to 4 (extreme). The weights are derived by the Children's Hospital Association from the HCUP KID 2012 database as the ratio of the average cost for discharges within a specific APR-DRG severity of illness combination to the average cost for all discharges in the database.

Statistical Analysis

Continuous variables were summarized with medians and interquartile ranges, while categorical variables were summarized with frequencies and percentages. Differences in admission and discharge characteristics between weekend and weekday were assessed using Wilcoxon rank sum tests for continuous variables and chi-square tests of association for categorical variables. We used generalized linear mixed modeling (GLMM) techniques to assess the impact of weekend admission on LOS and weekend discharge on readmission, adjusting for important patient demographic and clinical characteristics. Furthermore, we used GLMM point estimates to describe the variation across hospitals of the impact of weekday versus weekend care on LOS and readmissions. We assumed an underlying log-normal distribution for LOS and an underlying binomial distribution for 30-day readmission. All GLMMs included a random intercept for each hospital to account for patient clustering within a hospital. All statistical analyses were performed using SAS v.9.4 (SAS Institute, Cary, North Carolina), and P values <.05 were considered statistically significant.

RESULTS

We identified 390,745 hospitalizations that met inclusion criteria (Supplementary Figure 1). The median LOS among our cohort was 41 hours (interquartile range [IQR] 24-71) and the median 30-day readmission rate was 8.2% (IQR 7.2-9.4).

Admission Demographics for Weekends and Weekdays

Among the included hospitalizations, 92,266 (23.6%) admissions occurred on a weekend (Supplementary Table 1). Overall, a higher percentage of children <5 years of age were admitted on a weekend compared with those admitted on a weekday (53.3% vs 49.1%, $P < .001$). We observed a small but statistically significant difference in the proportion of weekend versus weekday admissions according to gender, race/ethnicity, payer, and median household income quartile. Children with medical complexity and those with technology dependence were admitted less frequently on a weekend. A higher proportion of children were admitted through the emergency department on a weekend and a higher frequency of ICU utilization was observed for children admitted on a weekend compared with those admitted on a weekday.

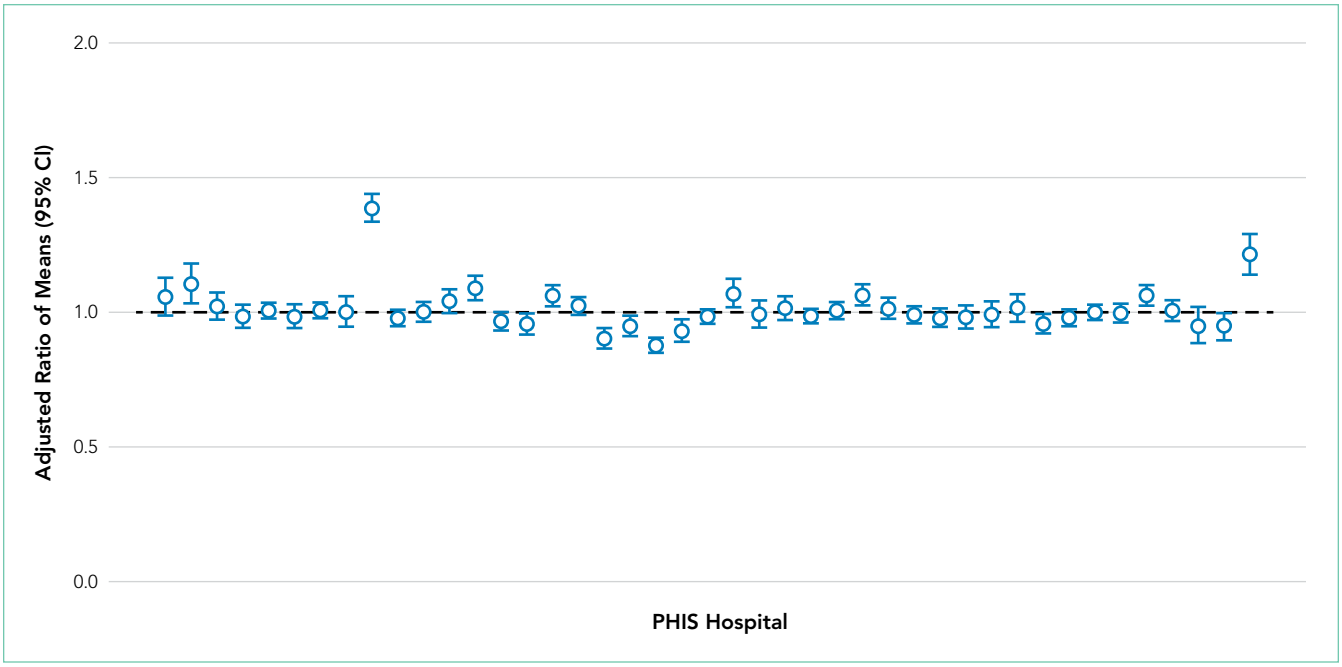

FIG 1. Comparison of adjusted length of stay (LOS) for weekend versus weekday admissions across 43 Pediatric Health Information System (PHIS) hospitals. Data are presented as adjusted ratios of means with 95% CI. Values >1.0 are observed for hospitals where weekend admissions were associated with longer length of stay (LOS), while values <1.0 are observed for hospitals where weekend admissions were associated with shorter LOS.

Association Between Study Variables and Length of Stay

In comparing adjusted LOS for weekend versus weekday admissions across 43 hospitals, not only did LOS vary across hospitals ($P < .001$), but the association between LOS and weekend versus weekday care also varied across hospitals ($P < .001$) (Figure 1). Weekend admission was associated with a significantly longer LOS at eight (18.6%) hospitals and a significantly shorter LOS at four (9.3%) hospitals with nonstatistically significant differences at the remaining hospitals.

In adjusted analyses, we observed that infants ≤30 days of age, on average, had an adjusted LOS that was 24% longer than that of 15- to 17-year-olds, while children aged 1-14 years had an adjusted LOS that was 6%-18% shorter (Table 1). ICU utilization, admission through the emergency department, and number of chronic conditions had the greatest association with LOS. As the number of chronic conditions increased, the LOS increased. No association was found between weekend versus weekday admission and LOS (adjusted LOS [95% CI]: weekend 63.70 [61.01-66.52] hours versus weekday 63.40 [60.73-66.19] hours, $P = .112$).

Discharge Demographics for Weekends and Weekdays

Of the included hospitalizations, 127,421 (32.6%) discharges occurred on a weekend (Supplementary Table 2). Overall, a greater percentage of weekend discharges comprised children <5 years of age compared with the percentage of weekday discharges for children <5 years of age (51.5% vs 49.5%, $P < .001$). No statistically significant differences were found in gender, payer, or median household income quartile between those children discharged on a weekend versus those discharged on a weekday. We found small, statistically significant differences in the proportion of weekend versus weekday discharges according to race/ethnicity, with fewer non-Hispanic white children being discharged on the weekend versus weekday. Children with medical complexity, technology dependence, and patients with ICU utilization were less frequently discharged on a weekend compared with those discharged on a weekday.

Association between Study Variables and Readmissions

In comparing the adjusted odds of readmissions for weekend versus weekday discharges across 43 PHIS hospitals, we observed significant variation ($P < .001$) in readmission rates from hospital to hospital (Figure 2). However, the direction of impact of weekend care on readmissions was similar ($P = .314$) across hospitals (ie, for 37 of 43 hospitals, the readmission rate was greater for weekend discharges compared with that for weekday discharges). For 17 (39.5%) of 43 hospitals, weekend discharge was associated with a significantly higher readmission rate, while the differences between weekday and weekend discharge were not statistically significant for the remaining hospitals.

In adjusted analyses, we observed that infants <1 year were more likely to be readmitted compared with 15- to 17-year-olds, while children 5-14 years of age were less likely to be readmitted (Table 2). Medical complexity and the number of chronic conditions had the greatest association with readmissions, with increased likelihood of readmission observed as the number of chronic conditions increased. Weekend discharge

TABLE 1. **Association between Patient Demographic and Clinical Characteristics and Length of Stay**

	Ratio of Means (95% CI)	Adjusted LOS in Hours (95% CI)	*P* Value
Day of Admission			
Weekend	1.00 (1.00,1.01)	63.70 (61.01,66.52)	.112
Weekday	Reference	63.40 (60.73,66.19)	
Age Group			
0-30 days	1.24 (1.23,1.26)	81.91 (78.35,85.62)	<.001
31-365 days	1.00 (0.99,1.01)	65.88 (63.08,68.80)	.288
1-4 years	0.82 (0.81,0.82)	53.83 (51.56,56.21)	<.001
5-9 years	0.84 (0.83,0.85)	55.21 (52.87,57.65)	<.001
10-14 years	0.94 (0.93,0.94)	61.62 (59.01,64.36)	<.001
15-17 years	Reference	65.90 (63.09,68.84)	
Gender			
Female	1.05 (1.04,1.05)	65.10 (62.35,67.97)	<.001
Male	Reference	62.04 (59.43,64.78)	
Race/Ethnicity			
Non-Hispanic White	Reference	61.42 (58.88,64.06)	
Non-Hispanic Black	1.00 (1.00,1.01)	61.63 (59.07,64.31)	.345
Hispanic	1.02 (1.01,1.03)	62.50 (59.90,65.21)	<.001
Asian	1.02 (1.01,1.04)	62.75 (60.01,65.61)	.008
Native American	1.14 (1.08,1.20)	69.73 (65.21,74.56)	<.001
Other	1.04 (1.03,1.05)	63.66 (60.98,66.46)	<.001
Payer			
Government	1.04 (1.03,1.05)	64.83 (62.13,67.66)	<.0001
Other	1.02 (1.00,1.04)	63.54 (60.63,66.59)	.059
Commercial	Reference	62.31 (59.70,65.03)	
Median Household Income Quartile			
Q1	1.02 (1.01,1.03)	64.14 (61.43,66.98)	<.001
Q2	1.02 (1.01,1.02)	63.77 (61.07,66.59)	<.001
Q3	1.01 (1.00,1.02)	63.53 (60.84,66.34)	.001
Q4	Reference	62.78 (60.12,65.56)	
Any CCC			
Yes	1.01 (1.01,1.02)	63.97 (61.27,66.78)	.001
No	Reference	63.14 (60.47,65.94)	
Any Technology Dependence			
Yes	0.97 (0.96,0.98)	62.66 (59.98,65.47)	<.001
No	Reference	64.46 (61.75,67.29)	
Number of Chronic Conditions			
0	Reference	46.81 (44.82,48.88)	
1	1.16 (1.15,1.17)	54.29 (51.99,56.70)	<.001
2	1.36 (1.35,1.37)	63.51 (60.81,66.33)	<.001
3	1.49 (1.47,1.51)	69.71 (66.72,72.84)	<.001
4	1.58 (1.56,1.60)	73.83 (70.62,77.18)	<.001
5+	1.69 (1.67,1.72)	79.32 (75.91,82.89)	<.001
Admitted through ED			
Yes	1.21 (1.20,1.21)	69.82 (66.88,72.89)	<.001
No	Reference	57.85 (55.41,60.41)	
ICU Stay			
Yes	1.67 (1.65,1.68)	82.06 (78.56,85.72)	<.001
No	Reference	49.22 (47.15,51.38)	

Abbreviations: CCC; complex chronic conditions; CI, confidence interval; ED, emergency department; ICU, intensive care unit; LOS, length of stay.

TABLE 2. **Association between Patient Demographic and Clinical Characteristics and Readmissions.**

	Odds Ratio (95 % CI)	Adjusted Probability of Readmission (95% CI)	*P* Value
Day of Discharge			
Weekend	1.12 (1.09,1.14)	0.13 (0.12,0.13)	<.001
Weekday	Reference	0.11 (0.11,0.12)	
Age Group			
0-30 days	1.21 (1.13,1.30)	0.14 (0.12,0.15)	<.001
31-365 days	1.39 (1.33,1.45)	0.15 (0.14,0.16)	<.001
1-4 years	0.97 (0.93,1.02)	0.11 (0.11,0.12)	.223
5-9 years	0.85 (0.81,0.89)	0.10 (0.09,0.11)	<.001
10-14 years	0.97 (0.93,1.02)	0.11 (0.10,0.12)	<.001
15-17 years	Reference	0.12 (0.12,0.13)	
Gender			
Female	1.01 (0.98,1.03)	0.12 (0.11,0.13)	.485
Male	Reference	0.12 (0.11,0.13)	
Race/Ethnicity			
Non-Hispanic White	Reference	0.12 (0.11,0.13)	<.001
Non-Hispanic Black	0.94 (0.90,0.97)	0.11 (0.11,0.12)	.831
Hispanic	1.00 (0.96,1.03)	0.12 (0.11,0.13)	.031
Asian	1.09 (1.01,1.17)	0.13 (0.12,0.14)	.164
Native American	1.18 (0.93,1.50)	0.14 (0.11,0.17)	<.001
Other	0.88 (0.84,0.93)	0.11 (0.10,0.11)	
Payer			
Government	1.04 (1.01,1.07)	0.11 (0.11,0.12)	.010
Commercial	Reference	0.11 (0.10,0.12)	
Other	1.25 (1.14,1.37)	0.13 (0.12,0.15)	<.001
Median Household Income Quartile			
Q1	0.95 (0.91,0.98)	0.12 (0.11,0.12)	.005
Q2	1.01 (0.97,1.05)	0.12 (0.11,0.13)	.547
Q3	1.00 (0.96,1.03)	0.12 (0.11,0.13)	.875
Q4	Reference	0.12 (0.11,0.13)	
Any CCC			
Yes	1.26 (1.22,1.30)	0.13 (0.12,0.14)	<.001
No	Reference	0.11 (0.10,0.12)	
Any Technology Dependence			
Yes	1.15 (1.11,1.20)	0.13 (0.12,0.14)	<.001
No	Reference	0.11 (0.11,0.12)	
Number of Chronic Conditions			
0	Reference		
1	1.71 (1.65,1.78)	0.05 (0.04,0.05)	<.001
2	2.70 (2.58,2.82)	0.08 (0.07,0.08)	<.001
3	3.64 (3.46,3.83)	0.12 (0.11,0.13)	<.001
4	4.38 (4.13,4.64)	0.15 (0.14,0.16)	<.001
5+	5.93 (5.62,6.27)	0.18 (0.17,0.19)	<.001
Admitted through ED			
Yes	0.93 (0.91,0.96)	0.12 (0.11,0.12)	<.001
No	Reference	0.12 (0.12,0.13)	
ICU Stay			
Yes	0.95 (0.91,0.99)	0.12 (0.11,0.13)	.017
No	Reference	0.12 (0.12,0.13)	

Abbreviations: CCC; complex chronic conditions; CI, confidence interval; ED, emergency department; ICU, intensive care unit.

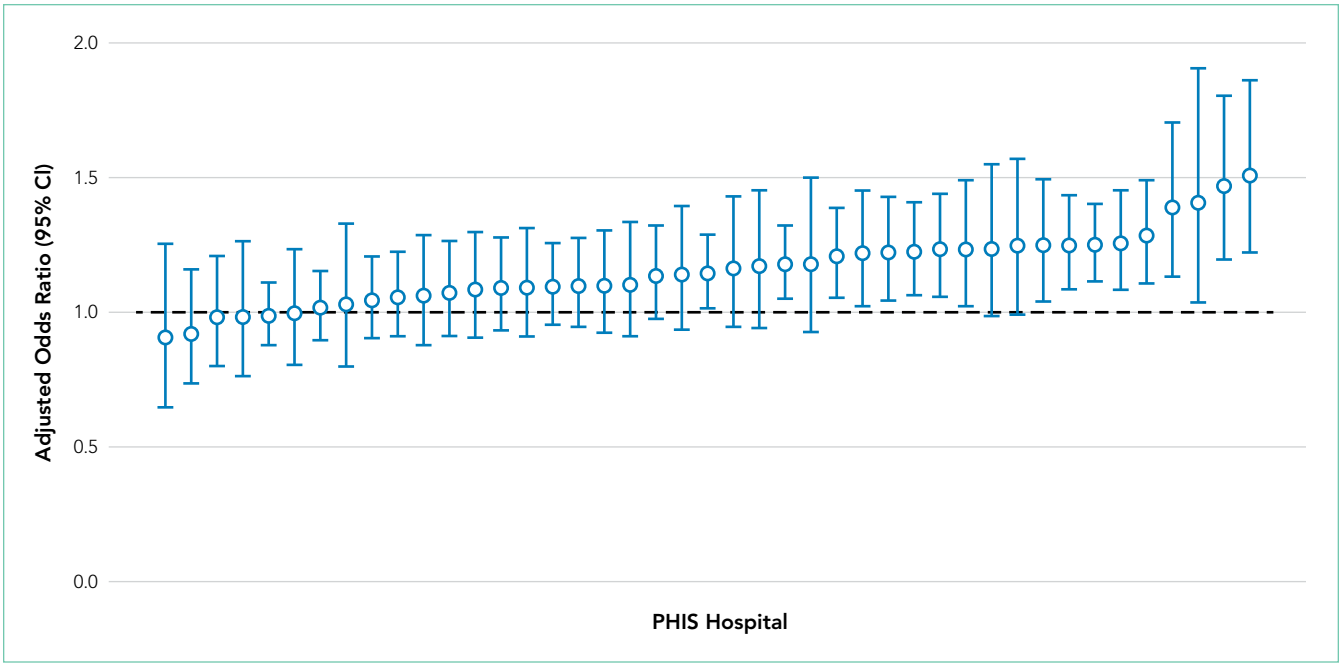

FIG 2. Comparison of adjusted odds of readmission for weekend versus weekday discharges across 43 Pediatric Health Information System (PHIS) hospitals. Data are presented as adjusted odds ratios with 95% CI. Values >1.0 are observed for hospitals where weekend discharges were associated with higher readmission rates, while values <1.0 are observed for hospitals where weekend discharges were associated with lower readmission rates.

was associated with increased probability of readmission compared with weekday discharge (adjusted probability of readmission [95% CI]: weekend 0.13 [0.12-0.13] vs weekday 0.11 [0.11-0.12], $P < .001$).

DISCUSSION

In this multicenter retrospective study, we observed substantial variation across hospitals in the relationship between weekend admission and LOS and weekend discharge and readmission rates. Overall, we did not observe an association between weekend admission and LOS. However, significant associations were noted between weekend admission and LOS at some hospitals, although the magnitude and direction of the effect varied. We observed a modestly increased risk of readmission among those discharged on the weekend. At the hospital level, the association between weekend discharge and increased readmissions was statistically significant at 39.5% of hospitals. Not surprisingly, certain patient demographic and clinical characteristics, including medical complexity and number of chronic conditions, were also associated with LOS and readmission risk. Taken together, our findings demonstrate that among a large sample of children, the degree to which a weekend admission or discharge impacts LOS or readmission risk varies considerably according to specific patient characteristics and individual hospital.

While the reasons for the weekend effect are unclear, data supporting this difference have been observed across many diverse patient groups and health systems both nationally and internationally.[13-27,31] Weekend care is thought to differ from weekday care because of differences in physician and nurse staffing, availability of ancillary services, access to diagnostic testing and therapeutic interventions, ability to arrange outpatient follow-up, and individual patient clinical factors, including acuity of illness. Few studies have assessed the effect of weekend discharges on patient or system outcomes. Among children within a single health system, readmission risk was associated with weekend admission but not with weekend discharge.[22] This observation suggests that if differential care exists, then it occurs during initial clinical management rather than during discharge planning. Consequently, understanding the interaction of weekend admission and LOS is important. In addition, the relative paucity of pediatric data examining a weekend discharge effect limits the ability to generalize these findings across other hospitals or health systems.

In contrast to prior work, we observed a modest increased risk for readmission among those discharged on the weekend in a large sample of children. Auger and Davis reported a lack of association between weekend discharge and readmissions at one tertiary care children's hospital, citing reduced discharge volumes on the weekend, especially among children with medical complexity, as a possible driver for their observation.[22] The inclusion of a much larger population across 43 hospitals in our study may explain our different findings compared with previous research. In addition, the inclusion/exclusion criteria differed between the two studies; we excluded index admissions for planned procedures in this study (which are more likely to occur during the week), which may have contributed to the differing conclusions. Although Auger and Davis suggest that differences in initial clinical management may be responsible for the weekend effect,[22] our observations suggest that discharge planning practices may also contribute to readmission risk. For example, a family's inability to access

compounded medications at a local pharmacy or to access primary care following discharge could reasonably contribute to treatment failure and increased readmission risk. Attention to improving and standardizing discharge practices may alleviate differences in readmission risk among children discharged on a weekend.

Individual patient characteristics greatly influence LOS and readmission risk. Congruent with prior studies, medical complexity and technology dependence were among the factors in our study that had the strongest association with LOS and readmission risk.[32] As with prior studies[22], we observed that children with medical complexity and technology dependence were less frequently admitted and discharged on a weekend than on a weekday, which suggests that physicians may avoid complicated discharges on the weekend. Children with medical complexity present a unique challenge to physicians when assessing discharge readiness, given that these children frequently require careful coordination of durable medical equipment, obtainment of special medication preparations, and possibly the resumption or establishment of home health services. Notably, we cannot discern from our data what proportion of discharges may be delayed over the weekend secondary to challenges involved in coordinating care for children with medical complexity. Future investigations aimed at assessing physician decision making and discharge readiness in relation to discharge timing among children with medical complexity may establish this relationship more clearly.

We observed substantial variation in LOS and readmission risk across 43 tertiary care children's hospitals. Since the 1970s, numerous studies have reported worse outcomes among patients admitted on the weekend. While the majority of studies support the weekend effect, several recent studies suggest that patients admitted on the weekend are at no greater risk of adverse outcomes than those admitted during the week.[35-37] Our work builds on the existing literature, demonstrating a complex and variable relationship between weekend admission/discharge, LOS, and readmission risk across hospitals. Notably, while many hospitals in our study experienced a significant weekend effect in LOS or readmission risk, only four hospitals experienced a statistically significant weekend effect for both LOS and readmission risk (three hospitals experienced increased risk for both, while one hospital experienced increased readmission risk but decreased LOS). Future investigations of the weekend effect should focus on exploring the differences in admission/discharge practices and staffing patterns of hospitals that did or did not experience a weekend effect.

This study has several limitations. We may have underestimated the total number of readmissions because we are unable to capture readmissions to other institutions by using the PHIS database. Our definition of a weekend admission or discharge did not account for three-day weekends or other holidays where staffing issues would be expected to be similar to that on weekends; consequently, our approach would be expected to bias the results toward null. Thus, a possible (but unlikely) result is that our approach masked a weekend effect that might have been more prominent had holidays been included. Although prior studies suggest that low physician/nurse staffing volumes and high patient workload are associated with worse patient outcomes,[38,39] we are unable to discern the role of differential staffing patterns, patient workload, or service availability in our observations using the PHIS database. Moreover, the PHIS database does not allow for any assessment of the preventability of a readmission or the impact of patient/family preference on the decision to admit or discharge, factors that could reasonably contribute to some of the observed variation. Finally, the PHIS database contains administrative data only, thus limiting our ability to fully adjust for patient severity of illness and sociodemographic factors that may have affected clinical decision making, including discharge decision making.

CONCLUSION

In a study of 43 children's hospitals, children discharged on the weekend had a slightly increased readmission risk compared with children discharged on a weekday. Wide variation in the weekend effect on LOS and readmission risk was evident across hospitals. Individual patient characteristics had a greater impact on LOS and readmission risk than the weekend effect. Future investigations aimed at understanding which factors contribute most strongly to a weekend effect within individual hospitals (eg, differences in institutional admission/discharge practices) may help alleviate the weekend effect and improve healthcare quality.

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Deimplementation of Routine Chest X-rays in Adult Intensive Care Units

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BACKGROUND: *Choosing Wisely*® is a national initiative to deimplement or reduce low-value care. However, there is limited evidence on the effectiveness of strategies to influence ordering patterns.

OBJECTIVE: We aimed to describe the effectiveness of an intervention to reduce daily chest X-ray (CXR) ordering in two intensive care units (ICUs) and evaluate deimplementation strategies.

DESIGN: We conducted a prospective, nonrandomized study with control data from a historical period. Qualitative evaluation was guided by the Consolidated Framework for Implementation Research.

SETTING: The study was performed in the medical intensive care unit (MICU) and cardiovascular intensive care unit (CVICU) of an academic medical center in the United States from October 2015 to June 2016.

PARTICIPANTS: The initiative included the staff of the MICU and CVICU (physicians, surgeons, nurse practitioners, fellows, residents, medical students, and X-ray technologists).

INTERVENTION COMPONENTS: We utilized provider education, peer champions, and weekly data feedback of CXR ordering rates.

MEASUREMENTS: We analyzed the CXR ordering rates and factors facilitating or inhibiting deimplementation.

RESULTS: Segmented linear time-series analysis suggested a small but statistically significant decrease in CXR ordering rates in the CVICU ($P < .001$) but not in the MICU. Facilitators of deimplementation, which were more prominent in the CVICU, included engagement of peer champions, stable staffing, and regular data feedback. Barriers included the need to establish goal CXR ordering rates, insufficient intervention visibility, and waning investment among medical residents in the MICU due to frequent rotation and competing priorities.

CONCLUSIONS: Intervention modestly reduced CXRs ordered in one of two ICUs evaluated. Understanding why adoption differed between the two units may inform future interventions to deimplement low-value diagnostic tests. *Journal of Hospital Medicine* 2019;14:83-89. © 2019 Society of Hospital Medicine

Despite increased awareness of *Choosing Wisely* (CW)® recommendations to reduce low-value care,[1] there is limited published data about strategies to implement these guidelines or evidence that they have influenced ordering patterns or reduced healthcare spending.[2-6] Implementation science seeks to accelerate the translation of evidence-based interventions into clinical practice and the deimplementation of low-value care.[7-9] Based on established principles of implementation science, we used a prospective, nonrandomized study design to assess a CW intervention to reduce chest X-ray (CXR) ordering in adult intensive care units (ICUs).[10]

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In ICUs, CXR ordering strategies may be routine (daily) or on-demand (with clinical indication). The former strategy's principal advantage is the potential to detect life-threatening situations that may otherwise escape diagnosis.[11] Disadvantages include cost, radiation exposure, patient inconvenience, false-positive workups, and low diagnostic and therapeutic value.[12,13] On-demand strategies may safely reduce CXR ordering by 32% to 45%.[11-17] Based on this evidence, the Critical Care Societies Collaborative and the American College of Radiology have recommended on-demand CXR ordering.[18,19] Here, we describe the effectiveness of an intervention to reduce CXR ordering in two ICUs while evaluating the deimplementation strategies using a validated framework.

METHODS

Setting and Design

Vanderbilt University Medical Center (VUMC) is an academic referral center in Nashville, Tennessee. The cardiovascular ICU (CVICU) has 27 beds and the medical ICU (MICU) has 34 beds. Acute care nurse practitioners (ACNPs) and two critical care physicians staff the CVICU; cardiology fellows, anesthesia critical

care fellows, and transplant and cardiac surgeons are also active in patient care. The MICU is staffed by two critical care physicians who supervise one team of ACNPs and two teams of medical residents who rotate through the unit every two weeks. Each MICU team is assigned a fellow in pulmonary and critical care.

We conducted a prospective, nonrandomized study in these units from October 2015 to June 2016. The VUMC Institutional Review Board approved the intervention as a quality improvement (QI) activity, waiving the requirement for informed consent.

Intervention

Following the top CW recommendation of the Critical Care Societies Collaborative—"Don't order diagnostic tests at regular intervals (such as every day), but rather in response to specific clinical questions."[19]—the VUMC resident-led CW Steering Committee designed a multifaceted approach to reduce ordering of routine CXRs in ICUs. The intervention included a didactic session on CW and proper CXR ordering practices, peer champions, data audits, and feedback to providers through weekly e-mails (see Supplemental Materials, 1 – Resident Presentation and 2 – CXR Flyer). [20]

In September 2015, CVICU and MICU teams received a didactic session highlighting CW, current CXR ordering rates, and the plan for reducing CXR ordering. On October 5, 2015, teams began receiving weekly e-mails with ordering rates defined as CXRs ordered per patient per day and a brief rationale for reducing unnecessary CXRs. To encourage friendly competition, we provided weekly rates to the MICU teams, allowing for transparent benchmarking against one another. A similar competition strategy was not used in the CVICU due to the lack of multiple teams.

In the CVICU, two ACNPs volunteered as peer champions. These champions coordinated data feedback and advocated for the intervention among their colleagues. In the MICU, three internal medicine residents volunteered as peer champions and fulfilled similar roles.

To facilitate deimplementation, we conducted two Plan-Do-Study-Act (PDSA) cycles, the first from November to mid-December 2015 and the second from mid-December 2015 to mid-January 2016. During these cycles, we tailored our deimplementation strategy based on barriers identified by the peer champions and ICU leaders (described in the Qualitative Results section). Peer champions and the CW Steering Committee generated potential solutions by conversing with stakeholders and using the Expert Recommendations for Implementing Change (ERIC).[20] Interventions included disseminating promotional flyers, holding meetings with stakeholders, and providing monthly CXR ordering rates. After the PDSA cycles, we continued reexamining the deimplementation efforts by reviewing ordering rates and soliciting feedback from ICU leaders and peer champions. However, no significant changes to the intervention were made during this time.

Quantitative Evaluation

We extracted data from VUMC's Enterprise Data Warehouse during the intervention period (October 5, 2015 to May 24, 2016) and a historical control period (October 1, 2014 to October 4, 2015). Within each ICU, descriptive statistics were used to compare patient cohorts in the baseline and intervention periods by age, sex, and race.

The primary outcome was CXRs ordered per patient per day by hospital unit (CVICU or MICU). The baseline period included all data between October 1, 2014 and September 15, 2015. To account for priming of providers from didactic education, we allowed a washout period from September 16, 2015 to October 4, 2015. As a preliminary analysis, we compared CXR rates in the baseline and intervention periods using Wilcoxon rank-sum tests. We then conducted interrupted time-series analyses with segmented linear regression to assess differences in linear trends in CXR rates over the two periods. To account for different staffing models in the MICU, we stratified the impact of the intervention by team—medical resident (physician) or ACNP. R version 3.4.0 was used for statistical analysis.[21]

Qualitative Evaluation

Our qualitative evaluation consisted of embedded observation and semistructured interviews with stakeholders. The qualitative portion was guided by the Consolidated Framework for Implementation Research (CFIR), a widely used framework for design and evaluation of improvement initiatives that helped us to determine major facilitators and barriers to implementation.[22,23]

Embedded Observation

From November 2015 to January 2016, we observed morning rounds in the CVICU and MICU one to two times weekly to understand factors facilitating and inhibiting uptake of the intervention. Observations were recorded and organized using a CFIR-based template and directed toward understanding interactions among team members (eg, the decision-making process hierarchy), team workflows and decision-making processes, process of ordering CXRs, and providers' knowledge and perceptions of the CXR intervention (see Supplemental Material, 3 – CFIR Table).[22,23] After rounds, ICU team members were invited to share suggestions for improving the intervention. All observations occurred during and shortly following morning rounds when the vast majority of routine CXRs are ordered; we did not evaluate night or evening workflows. In the spirit of continuous improvement, we evaluated data in real-time.

Semistructured Interviews

Based on the direct observations, we developed semistructured interview questions to further evaluate provider perspectives (eg, "Do you believe ICU patients need a daily CXR?") and constructs aligning with CFIR (eg, "intervention source—internally vs externally developed;" see Supplemental Material, 4 – Interview Questions).

Stakeholders from both ICUs were recruited through e-mail and in-person requests to participate in semistructured interviews. In the CVICU, we interviewed critical care physicians, anesthesia critical care fellows, and ACNPs. In the MICU, we

TABLE 1. **Patient Characteristics During the Baseline and Intervention Periods in the CVICU and MICU from October 1, 2014 to May 24, 2016**

	CVICU			MICU		
	Baseline n = 1,180	Intervention n = 847	*P* Value	Baseline n = 2,378	Intervention n = 1,524	*P* Value
Age in years (median)	63.0	62.0	.917[1]	59.0	58.0	.068[1]
Days in ICU (median)	3.0	3.0	.0831	2.0	2.0	.1711
Sex: male	66.2%	64.6%	.453[2]	52.4%	53.1%	.694[2]
Race			.001[2]			.371[2]
White	82.9%	84.1%		76.7%	76.2%	
Black	10.2%	6.0%		16.6%	15.8%	
Other	1.3%	2.4%		1.6%	2.2%	
Unknown	5.7%	7.6%		5.0%	5.8%	
In-hospital mortality	6.6%	4.4%	.031[2]	19.4%	20.9%	.273[2]

Note: Tests used include the [1]Wilcoxon rank-sum test and [2]Pearson chi-square test.

Abbreviations: CVICU, cardiovascular intensive care unit; MICU, medical intensive care unit.

TABLE 2. **Average Number of Chest X-rays per Patient per Day During the Baseline and Intervention Periods**

	Baseline				Intervention				
	25th Percentile	Median	75th Percentile	Mean ± SD	25th Percentile	Median	75th Percentile	Mean ± SD	*P* Value
CVICU	1.06	1.16	1.28	1.17 ± 0.18	0.94	1.07	1.21	1.08 ± 0.22	<.001
MICU: MD Care Team	0.48	0.60	0.73	0.61 ± 0.18	0.50	0.62	0.74	0.63 ± 0.19	.353
MICU: ACNP Care Team	0.21	0.39	0.57	0.41 ± 0.29	0.20	0.38	0.56	0.39 ± 0.26	.572

Test used: Wilcoxon rank-sum test.

Abbreviations: ACNP, acute care nurse practitioner; CVICU, cardiovascular intensive care unit; MICU, medical intensive care unit; MD, medical doctor; SD Standard Deviation.

interviewed medical students, interns, residents, critical care fellows, attending intensivist physicians, and ACNPs. We also interviewed X-ray technologists who routinely perform portable films in the units.

RESULTS

Quantitative Results

We analyzed CXR ordering data from a period of 86 weeks, comprising 50 weeks of baseline data, three weeks of washout period, and 33 weeks following the introduction of the intervention. In both ICUs, patient characteristics were similar in the baseline and intervention periods (Table 1).

Cardiovascular Intensive Care Unit

The median baseline CXR ordering rate in the CVICU was 1.16 CXRs per patient per day, with interquartile range (IQR) 1.06-1.28. During the intervention period, the rate dropped to 1.07 (IQR 0.94-1.21; $P < .001$; Table 2). The time-series analysis suggested an essentially flat trend during the baseline period, followed by a small but significant drop in ordering rates during the intervention period ($P < .001$; Table 3 and Figure 1). Ordering rates appeared to increase slightly over the course of the intervention period, but this slight upward trend was not significantly different from the flat trend seen during the baseline period.

Medical Intensive Care Unit

For both physician and ACPN teams, the median baseline CXR ordering rates in the MICU were much lower than the baseline rate in the CVICU (Table 2). For the MICU physician care team, the baseline CXR ordering rate was 0.60 CXRs per patient per day (IQR 0.48-0.73). For the ACNP team, the median rate was 0.39 CXRs per patient per day (IQR 0.21-0.57). Both rates stayed approximately the same during the intervention period (Table 2). The time-series analysis suggested a statistically significant but very slight downward trend in CXR ordering rates during the baseline period, in the physician ($P = .011$) and ACNP ($P = .022$) teams (Table 3, Figure 2). Under this model,

TABLE 3. **Results of Segmented Linear Regression Analyzing the Impact of Intervention on Chest X-ray Ordering Rates**

	CVICU			MICU: MD Team			MICU: ACNP Team		
	Est.	95% CI	*P* Value	Est.	95% CI	*P* Value	Est.	95% CI	*P* Value
Intercept in baseline period	1.17	1.13, 1.20	<.001	0.65	0.61, 0.68	<.001	0.46	0.40, 0.52	<.001
Baseline trend[a]	0.00	0.00, 0.00	.653	0.00	0.00, 0.00	.011	0.00	0.00, 0.00	.022
Level change associated with intervention period	–0.13	–0.19, –0.06	.001	0.07	0.02, 0.12	.010	0.08	0.00, 0.15	.055
Trend change associated with intervention period	0.00	0.00, 0.00	.479	0.00	0.00, 0.00	.557	0.00	0.00, 0.00	.491

[a]Change in rate of x-rays per patient per day.
Abbreviations: ACNP, acute care nurse practitioner; CVICU, cardiovascular intensive care unit; MICU, medical intensive care unit; MD, medical doctor.

a small increase in CXR ordering initially occurred during the intervention period for both physician and ACNP teams (P = .010 and P = .055, respectively), after which the rates declined slightly. Trends in ordering rates during the intervention period were not significantly different from the slight downward trends seen during the baseline period.

Qualitative Results

We identified 25 of 39 CFIR constructs as relevant to the initiative (see Supplemental Materials, 3 – CFIR Table.) We determined the major facilitators of deimplementation to be peer champion discussions about CXR ordering on rounds and weekly data feedback, particularly if accompanied by in-person follow-up.

Major differences between the units pertained to the "inner setting" domain. Compared with the CVICU, which is staffed by a stable group of ACNPs, two of the three MICU teams are staffed by resident physicians who rotate on and off service. CVICU providers and ACNPs in the MICU reported significant investment in the CXR and other QI interventions. Conversely, resident physicians, who complete two- to four-week MICU rotations, reported less investment as well as greater fatigue and competing priorities. Some MICU residents began ignoring weekly feedback, citing "e-mail fatigue" and the lack of in-person follow-up or didactic sessions associated with the reports.

We also noted differences in CXR ordering rationales and decisions between the units. Generally, residents in the MICU and ACNPs in the CVICU made decisions to order CXRs. However, decisions were influenced by the expectations of attending physicians. While CVICU providers tended to order CXRs reflexively as part of morning labs, MICU providers—in particular, ACNPs who had been trained on indications for proper CXR ordering—generally ordered CXRs for specific indications (eg, worsening respiratory status). Of note, MICU ACNPs reported the use of bedside ultrasound as an alternate imaging modality and a reason for their higher threshold to order CXRs.

Deimplementation barriers in both units included the need to identify goal CXR ordering rates and the intervention's limited visibility. To address these barriers, we conducted PDSA cycles and used the CFIR and ERIC to generate potential solutions.[24] We established a goal of a 20% absolute reduction in the CVICU, added monthly CXR rates to weekly e-mail reports to better account for variations in patient populations and ordering practices, and circulated materials to promote on-demand CXR ordering. Promotional materials contained guidelines on CXR ordering and five "Frequently Held Misconceptions" about ordering practices with succinct, evidence-based explanations (see Supplemental Material, 2 – CXR Flyer).

Approximately four months after the start of intervention, some CVICU physicians became concerned that on-demand CXR ordering might be inappropriate for high-risk surgical patients, including those who are undergoing or have undergone heart transplants, lung transplants, or left-ventricular assist device placement. This concern arose following two adverse outcomes, which were not attributed to the CXR initiative, but which heightened concerns about patient safety. A rise in CXR ordering then occurred, and CVICU providers requested that we perform an analysis of these high-risk groups. While segmented linear regression in this subgroup suggested that average daily CXR ordering rates did decrease among the high-risk group at the start of the intervention period (P = .001), the difference between the rates in the two periods was not significant using the Wilcoxon rank-sum test. Exclusion of these patients from the main analysis did not alter the interpretation of the findings reported above for the CVICU.

DISCUSSION

A deimplementation intervention using provider education, peer champions, and data feedback was associated with fewer CXRs in the CVICU (P < .001) but not in the MICU. The CFIR-guided qualitative analysis was valuable for evaluating our deimplementation strategy and for identifying differences between the two ICUs.

Relatively few studies have demonstrated effective interventions that address CW recommendations.[25-28] However, three population-level analyses of insurance claims show mixed results.[3,4,29] Experts have thus proposed using implementation science to improve uptake of CW recommendations.[2,3,7,8] Our study demonstrates the effectiveness of this approach. As expected, providers largely endorsed an on-demand CXR ordering strategy. Using the CFIR, however, we discovered barriers (eg, concern that data feedback did not reflect variations in

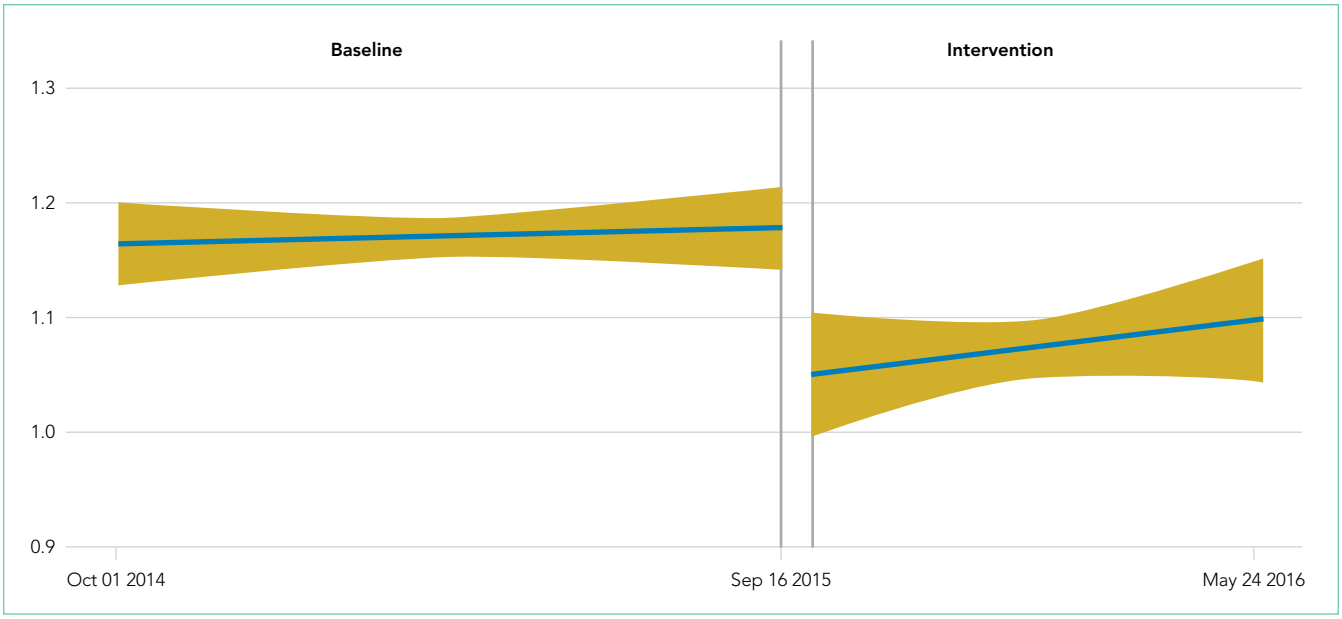

FIG 1. Model-based estimates with 95% confidence intervals: chest x-rays per patient per day in the cardiovascular intensive care unit from October 2014 to May 2016.

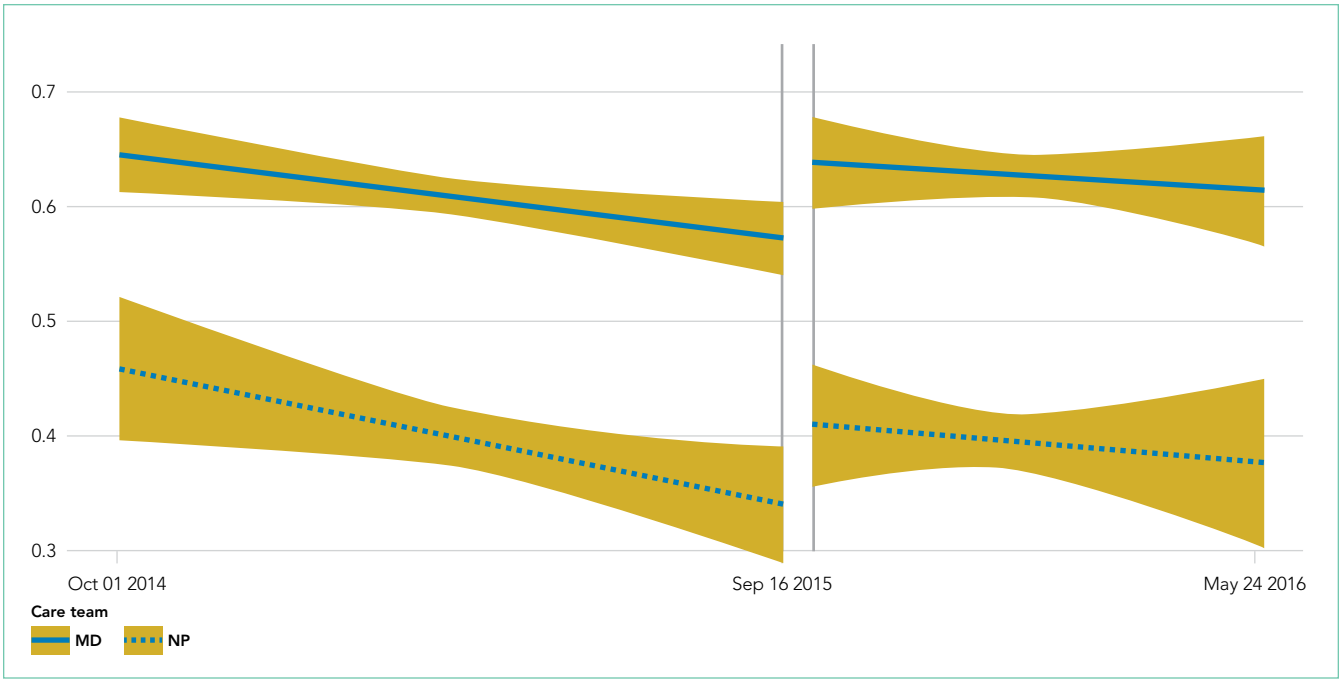

FIG 2. Model-based estimates with 95% confidence intervals: chest x-rays per patient per day in the medical intensive care unit from October 2014 to May 2016.

patients' needs). Using methods from implementation science allowed us to diagnose and tailor our approaches.

Our qualitative evaluation suggested that the intervention was ineffective mostly due to CFIR's "inner setting" constructs, including resident fatigue, competing priorities, and decreased investment in QI projects because of the rotating nature of providers in training. Baseline CXR ordering rates in the MICU were also considerably lower than in the CVICU. We observed that CVICU providers ordered many CXRs following the placement of lines or tubes and that ACNPs in the MICU had received education on appropriate CXR ordering practices and had access to an alternate imaging modality in ultrasound. These factors may partially explain the difference in baseline rates.

As noted in a study of cardiac stress testing guidelines, the existence of high-value care recommendations does not mean overuse.[30] Indeed, the lack of significant CXR over-ordering in the MICU highlights the importance of baseline measurement and partnering with information technology departments to create the best possible data feedback systems.[30-32] Our ex-

perience shows that these systems should provide sufficient pre-implementation data (ideally >1 year), such that teams selecting QI projects can ensure that a project is a good use of institutional resources and change capital.

To inform future work, we informally assessed program costs and savings. We estimate the initiative cost $1,600, including $1,000 for curriculum development and teaching time, $300 for educational materials, and $300 for CXR tracking dashboard development. Hospital charges and reimbursements for CXR vary widely.[33] We calculated savings using a range of rates, from a conservative $23 (the Medicare reimbursement rate for single-view CXR, CPT code 71010, global fee) to $50 (an approximate blended reimbursement rate across payers).[34,35] In the CVICU, we estimate that 51 CXRs were avoided each month, saving $1,173-$2,550 per month or $9,384-$20,400 over eight months of follow-up. Annualizing these figures, we estimate net savings of $12,476-$29,000 in the first year in a 27-bed ICU. Costs to continue the program include education of new employees, booster training, and dashboard maintenance for an estimated annual cost of $1,000. It is difficult to estimate effectiveness over time, but if we conservatively assume that 30 CXRs were avoided each month, then the projected savings would be $8,280-$18,000 per year or an annual net savings of $7,280-$17,000 in the ICU. Although these amounts are modest, providing trainees with experiential learning opportunities in high-value care is valuable in its own right, meets curricular goals, may result in spill-over effects to other diagnostic and therapeutic decisions, and may influence long-term practice patterns. Institutional decisions to pursue projects such as this should take into account these potential benefits.

This evaluation is not without limitations. First, the study was conducted in a single tertiary-care hospital, potentially limiting its generalizability.[36] Second, the study design lacked a concurrent control group, and observed outcomes may have been influenced by broader CXR utilization trends, increased awareness of low-value care generally or from previous CW projects at VUMC, seasonal effects, or the Hawthorne effect. Third, the study outcome was all CXRs ordered, rather than CXRs that were unnecessary or not clinically indicated. We chose all CXRs because it was more pragmatic, did not require clinical case review, and could be incorporated promptly into dashboards, enabling timely performance feedback. Other performance measures have taken a similar tack (eg, tracking all-cause readmissions rather than preventable readmissions). Given this approach, we did not track clinical indications for CXRs (eg, central line placement). Fourth, although we compared resident and APRN orders, we did not collect data on other provider characteristics such as years in/out of training or board certification status. These considerations should be addressed in future research.

Finally, the increase in CVICU CXR ordering at the end of the intervention period, which occurred following two adverse events, raises concerns about sustainability. While unrelated to CXR orders, the events resulted in increased ordering of diagnostic tests and showed the difficulty of deimplementation in ICUs. Indeed, some CVICU providers argued that on-demand CXR ordering represented minimal potential cost savings and had not been studied among heart and lung transplant patients. Subsequently, Tonna et al. have shown that on-demand CXR ordering can be safely implemented among such patients.[37] Also similar to our study, Tonna et al. observed an initial decrease in CXR ordering, followed by a gradual increase toward baseline ordering rates. These findings highlight the need for sustained awareness and interventions and for the careful selection of high-value projects.

In conclusion, our study shows that a deimplementation intervention based on CW recommendations can reduce CXR ordering and that ongoing evaluation of contextual factors provides insights for both real-time modifications of current interventions and the design of future interventions. We found that messaging about reducing unnecessary tests works well when discussions are framed at the unit level but may be counterproductive if used to question individual ordering decisions.[38] Additional lessons learned include the value of participation on rounds to build trust among stakeholders, the utility of monthly rather than weekly statistics for feedback, stakeholder input and peer champions, and differences in approach with physician and ACNP audiences.

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Patient, Caregiver, and Clinician Perspectives on Expectations for Home Healthcare after Discharge: A Qualitative Case Study

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BACKGROUND: Patients discharged from the hospital with skilled home healthcare (HHC) services have multiple comorbidities, high readmission rates, and multiple care needs. In prior work, HHC nurses described that patients often express expectations for services beyond the scope of skilled HHC.

OBJECTIVE: The objective of this study is to evaluate and compare expectations for HHC from the patient, caregiver, and HHC perspectives after hospital discharge.

DESIGN/PARTICIPANTS: This was a descriptive qualitative case study including HHC patients, caregivers, and clinicians. Patients were discharged from an academic medical center between July 2017 and February 2018.

RESULTS: The sample (N = 27) included 11 HHC patients, eight caregivers, and eight HHC clinicians (five nurses and three physical therapists). Patient mean age was 66 years and the majority were female, white, and had Medicare. We observed main themes of clear and unclear expectations for HHC after discharge. Clear expectations occur when the patient and/or caregiver have expectations for HHC aligned with the services received. Unclear expectations occur when the patient and/or caregiver expectations are uncertain or misaligned with the services received. Patients and caregivers with clear expectations for HHC frequently described prior experiences with skilled HHC or work experience within the healthcare field. In most cases with unclear expectations, the patient and caregiver did not have prior experience with HHC.

CONCLUSIONS: To improve HHC transitions, we recommend actively engaging both patients and caregivers in the hospital and HHC settings to provide education about HHC services, and assess and address additional care needs. *Journal of Hospital Medicine* 2019;14:90-95. © 2019 Society of Hospital Medicine

Patients who are discharged from the hospital with home healthcare (HHC) are older, sicker, and more likely to be readmitted to the hospital than patients discharged home without HHC.[1-3] Communication between clinicians in different settings is a key factor in successful transitions. In prior work, we focused on communication between primary care providers, hospitalists, and HHC nurses to inform efforts to improve care transitions.[4,5] In one study, HHC nurses described that patients frequently have expectations beyond the scope of what skilled HHC provides,[5] which prompted us to also question experiences of patients and caregivers after discharge with skilled HHC (eg, nursing and physical therapy).

In a prior qualitative study by Foust and colleagues, HHC patients and caregivers described disparate experiences around preparation for hospital discharge—patients expressed knowing about the timing and plans for discharge, and the caregivers frequently felt left out of this discussion.[6] In other studies, caregivers of recently discharged patients have described feeling excluded from interactions with clinicians both before and after discharge.[7,8] In another recent qualitative study, caregivers described uncertainty about their role compared with the HHC role in caring for the patient.[9]

As of 2016, a majority of states had passed the Caregiver Advise, Record, and Enable (CARE) Act, which requires hospitals to (1) record a family caregiver in the medical record, (2) inform this caregiver about discharge, and (3) deliver instructions with education about medical tasks that they will need to complete after discharge.[10] In the context of the CARE Act, hospitals are encouraged to increase caregiver engagement to prepare for

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TABLE 1. **Demographics for Patients, Caregivers, and Home Healthcare (HHC) Clinicians**

	Patient (n = 11)	Caregiver (n = 8)	HHC Clinician (n = 8)
Age, average (years)	66	61	40
Female	82%	100%	50%
Race/Ethnicity			
White	73%	—	—
Hispanic	18%	—	—
Asian	9%	—	—
Insurance			
Medicare	73%	—	—
Medicaid	9%	—	—
Private	9%	—	—
Other	9%	—	—

discharge, but it is unclear whether this engagement is occurring for patients in general and HHC patients in particular. Because more than 80% of HHC patients have a primary caregiver outside of HHC, caregiver engagement around the time of discharge could be a key factor in care transitions.[11]

The objective of this study is to evaluate and compare expectations for HHC from the patient, caregiver, and HHC perspectives after hospital discharge. By combining all three groups into a case study, we aim to build on our prior work with HHC nurses to explore how expectations for HHC compare within and across cases of patients, caregivers, and HHC clinicians.

METHODS

Study Design

In this qualitative descriptive case study, we interviewed HHC patients, an involved caregiver, and the HHC clinician completing the first HHC visit within 7-14 days following hospital discharge. We chose this timeframe to allow patients to receive one or more HHC visits following hospital discharge.

Population

A convenience sampling strategy was employed to recruit a sample that would reflect a national sample of Medicare HHC patients based on age, sex, race, and ethnicity. Because a majority of HHC users in the United States are Medicare beneficiaries ≥65 years old,[12] eligibility was initially limited to patients ≥65 years old. Due to recruitment challenges, the age range was broadened to ≥50 years old in October 2017. Because our goal was to better understand the experience of general medicine patients with multiple comorbidities, we recruited patients from one general medicine unit at an academic hospital in Colorado. Patients on this unit were screened for eligibility Monday-Friday (excluding weekends and holidays) based on research assistant availability.

Criteria included are as follows: HHC referral, three or more comorbidities, resides in the community prior to admission (ie, not in a facility), cognitively intact, English speaking, and able to identify a caregiver participating in their care. Eligible patients were approached for written consent prior to discharge to allow us to contact them 7-14 days after discharge for an interview by phone or in their home, per their preference. At the time of consent, patients provided contact information for their informal caregiver. Caregiver eligibility criteria included the following: age ≥18 years and provides caregiving at least one hour a week before hospital discharge. HHC clinicians approached for interviews had completed the first HHC visit for the patient following discharge. Both caregivers and HHC clinicians provided verbal consent for interviews. All participants received a $25 gift card for participation in the study.

Framework and Data Collection

Our interview guides were organized by the Agency for Healthcare Research and Quality Care Coordination Framework, an approach we have taken in prior work.[4,5,13] We added questions about patient preparation and self-management support to build on findings from a prior study with HHC nurses and on prior work by Coleman and colleagues.[5,14] Sample questions from the interview guides for patients, caregivers, and HHC clinicians within key analysis domains are included in Appendix 1. The patient and caregiver interviews were completed by an individual with prior experience in social work and healthcare (SS). The HHC clinician interviews were completed by either this individual (SS) or a physician-researcher with experience in qualitative methods (CJ). Patients and caregivers could choose to be interviewed individually or together. All interviews were digitally recorded and transcribed verbatim.

Analysis

This study aimed to evaluate the clarity of expectations related to HHC after discharge within and across cases. We primarily explored domains of patient preparation, assessing needs and goals, and creating a plan of care for skilled HHC from patient and caregiver perspectives. Because qualitative work had been completed previously with HHC clinicians, HHC perspectives were used primarily for triangulation of perspectives

TABLE 2. **Clear and Unclear Expectations within and across Cases: Quotes from Patients, Caregivers, and Home Healthcare Clinicians**

Case #	Patient	Caregiver	HHC Clinician
Clear Expectations across Cases			
1	Patient: In home care, you're in your own home… You're comfortable. They'll recommend how you should have your home so you don't feel afraid and I think that's important.	NA	HHC RN: Oh yes… she's very prepared for it (HHC). She has had a wound …for over ten years we've been trying to get healed... So she knows home healthcare well. She prefers home healthcare just because she's more comfortable in her own home.
2	Patient: I think it (the transition to HHC) was made fairly easy for me. Of course myself being in the health field, my daughter being in the health field …helps a lot too because, you know, we both know what to expect. We both, you know, know what we should be doing.	Caregiver: …yeah, my role is pretty well defined and as a family we've all got our roles pretty well defined as well so that helps… they do like physical therapy and those types of things and we take care of everything else so it's been a great relationship.	HHC PT: …I think (the patient is) very prepared of what's coming… she knows what's ahead of her.
3	Interviewer: …have you been surprised at all by what home health is able to help you with or not able to help you with? Patient: Not really. I'm so…it's cool. I like it.	Caregiver: I don't know…I can't look at his leg and say this is the appropriate color of red or it's not…or it's too swollen… Only a nurse can. So if I know (the HHC nurse) is coming to check on it, it does make me feel better knowing that I don't have to worry quite so much about it being, you know, beyond my control.	HHC RN: …I think he's adjusting well. He has the support of his (caregiver) for sure but, you know … she works a full time job so I think …his expectations are realistic.
Unclear Expectations across Cases			
4	Patient: Well, um…I don't know…I didn't expect it to happen but um… Interviewer: You didn't expect home health to happen? Patient: Yeah.	Caregiver: Well, one of the things that I was wondering about is that whether she would help her with her shower. …I think one of the things is that we don't know exactly what the home healthcare is supposed to do.	HHC RN: …I don't feel like (the patient) was totally clear on why we were there in the first place so… I don't think she really had any expectations.
5	Patient: And so they (the HHC agency) find out I'm in the hospital so as soon as I come home, I get all kind of telephone calls. They say …I'm physical therapist. I'm going to come and see you and I say, 'For what? We just talked to you at hospital' so I didn't know what to do.	NA	HHC PT: …you know, she kind of didn't seem like she knew like, you know, why I was there and this and … it took her a long time when I was in the house to just sit down and get started…
6	Patient: …I had never had home healthcare before. It was very reassuring. I was a little uncertain, like it was designed for someone in more of a chronic debilitated state than me but I think I just didn't know much about it, you know, so I thought wow, I don't need these people coming forever, but indeed they're not coming forever.	NA	HHC RN: You know, she didn't quite know what I was going to do. She knew I was coming. Actually she did… I take it back, she did kind of know that I was going to be there to show her what to do, how's that?

Abbreviations: HHC, home healthcare; RN, registered nurse; NA, not applicable; PT, physical therapist.

about expectations where possible. The analysis team was composed of the two interviewers (SS and CDJ) and a qualitative methods expert (JJ). We used our established team-based inductive approach to develop themes around patient expectations and preparation for HHC, with deductive connections to the framework as applicable.[15,16] Two team members completed the initial coding after every one to three interviews to ensure the themes were developing iteratively. Group discussions including the third team member were used to resolve discrepancies and to complete a team-based iterative analysis until informational saturation for expectations after discharge was reached from the patient and caregiver perspectives (ie, no new codes were identified).[17] Once the team reached informational saturation with codes, we recruited three additional patients to ensure no new codes were identified in key domains before concluding recruitment. ATLAS.ti version 7.5.17 (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) was used to facilitate coding and analysis. This study was approved by the Colorado Multiple Institutional Review Board (protocol 17-0553).

RESULTS

Between July 2017 and February 2018, patients were recruited for participation in this study. Because the discharge destination plans could change multiple times in a hospitalization, the eligibility of patients for the study could change throughout hospitalization. To give further context about patients on this unit during the study timeframe, we completed a retrospective review of the 1,024 patient discharges from the unit and found that 38 patients met the eligibility criteria. Overall, 15 patients provided written consent (11 women and four men), and 11 completed interviews. The remaining four were unable to complete interviews due to a change in postdischarge plans that no longer included HHC (two patients) and hospital readmissions prior to interviews (two patients). In total, interviews were completed with 27 individuals: 11 patients, eight caregivers, and eight HHC clinicians (five nurses and three physical therapists). For five of the interviews, the patient and the caregiver requested to be interviewed together. In four cases, interviews were missing from the caregiver (one case), the HHC clinician (one case), or both the caregiver and the HHC clini-

cian (two cases). Overall, perspectives were available from the complete triad of patients, caregivers, and HHC clinicians in seven cases, and perspectives were available from the patient and at least one other individual (ie, caregiver or HHC clinician) in two additional cases.

Patient interviews lasted an average of 43 minutes, caregiver interviews an average of 41 minutes, and HHC clinician interviews an average of 25 minutes. Patients were on average 66 years old (range 52-85 years), and most were women and white. Six of the patients had prior experience with HHC services, and five were new HHC patients. Primary diagnoses for patients included the following: sepsis (three cases), urinary tract or kidney infections (two cases), bone/hardware infections (two cases), *Clostridium difficile* infection (one case), acute respiratory failure with hypoxia (one case), aortic stenosis (one case), and acute pancreatitis (one case). For caregivers, the average age was 61 years, all were women, and they had a spouse or other family member in six cases and a nonfamily caregiver in two cases. HHC clinicians were an average of 40 years old, half were women, and the average time providing HHC was 4.4 years (Table 1).

We observed the two main themes of clear and unclear expectations for HHC after discharge. Clear expectations occur when the patient and/or caregiver have expectations for HHC that align with the services they receive. Unclear expectations occur when the patient and/or caregiver expectations are either uncertain or misaligned with the services they receive. Although not all interviews yielded codes about clear or unclear expectations, patients described clear expectations in five cases and unclear expectations in another five cases.

In nine cases with more than one perspective available, expectations were compared within cases and found to be clear (three cases), unclear (three cases), or discordant (three cases) across perspectives. For the discordant cases, the description of clear and unclear expectations differed between patients and either their caregiver or their HHC clinician. Patients and caregivers with clear expectations for HHC frequently described prior experiences with skilled HHC or work experience within the healthcare field. In most cases with unclear expectations, the patient and caregiver did not have prior experience with HHC. In addition, the desire for assistance with personal care for patients such as showering and housekeeping was described by caregivers with unclear expectations. The results are organized into clear, unclear, and discordant expectations from the perspectives of patients, caregivers, and HHC clinicians within cases.

Clear Expectations within Cases

Clear expectations for HHC were identified across perspectives in three cases, with sample quotes provided in Table 2. In the case of patient 1, the patient and HHC nurse had known each other for over two years because the patient had a wound requiring long-term HHC services. A caregiver did not complete an interview in this case. With patient 2, the patient, caregiver, and HHC physical therapist (PT) all describe that the patient had clear expectations for HHC. In this case, the patient and caregiver describe feeling prepared because of previously receiving HHC, prior work experience in the healthcare field, and a caregiver with experience working in HHC. In the case of patient 3, the patient had previously received HHC from the same HHC nurse.

Unclear Expectations across Cases

For the three cases in which unclear expectations were described across perspectives, two of the patients described being new to HHC, with representative quotes in Table 2. Patient 4 and her caregiver are new to HHC and describe unclear expectations for both the HHC referral and the HHC role, which was also noted by the HHC clinician. Of note, the caregiver for patient 4 further described that she was unable to be present for the first HHC visit. In the case of patient 5, although the patient had previously received HHC, the patient describes not knowing why the HHC PT needs to see her after discharge, which is also noted by the HHC PT. Finally, both patient 6 and her HHC PT describe that the patient was not sure about their expectations for HHC and that HHC was a new experience for them.

Discordant Expectation Clarity across Cases

In three of the cases, the description of clear and unclear expectations was discrepant across roles. In case 7, the caregiver and patient are new to HHC and express different perspectives about expectations for HHC. The HHC clinician, in this case, did not complete an interview. The caregiver describes not being present for the first HHC visit and no awareness that the patient was being discharged with HHC:

> **Caregiver:** Well, we didn't even know she had home health until she got home.

The same caregiver also expresses unclear expectations for HHC:

> **Caregiver:** It's pretty cloudy. They (the HHC clinicians) don't help her with her laundry, they don't help with the housekeeping, they don't help… with her showers so somebody is there when she showers. They don't do anything. The only two things like I said is the…home healthcare comes in on Wednesdays to see what she needs and then the therapy comes in one day a week.

However, the patient expresses more clear expectations that are being met by HHC.

> **Patient:** They (HHC) have met my expectations. They come in twice a week. They do vitals, take vitals and discuss with me, you know, what my feelings are, how I'm doing and I know they have met my expectations.

In case 8, although the patient describes knowing about the HHC PT involvement in her care, she expresses some unclear expectations about an HHC nurse after discharge.

> **Patient:** As far as home health, I didn't have a real … plan there at the hospital… They knew about (the HHC PT) coming once a week but as far as, you know, a nurse coming by to check on me, no.

However, the HHC PT describes feeling that the patient had clear expectations for HHC after discharge:

Interviewer: Can you reflect on whether she was prepared to receive home healthcare?
HHC PT: Yeah, she was ready.
Interviewer: …do you feel like she was prepared to know what to expect from you?
HHC PT: Yeah, but I think that comes from being a previous patient also.

Finally, in case 9, the patient describes clear expectations for HHC even though they were new to HHC:

Patient: …I knew what the PT was going to do and …I still need her because I've lost so much weight so she's been really good, instrumental, at giving me exercises… Occupational therapist…she's going to teach me how to shave, she's going to teach me how to get ready for the day.

The HHC PT describes that although the patient knew the PT role, they reflect that the patient may have been somewhat unclear about expectations for the first HHC visit:

HHC PT: He knew all that it entailed with the exception of he didn't really know what the first day was going to be like and the first day I don't usually do treatment because it does take a long time to get all the paperwork signed, to do the evaluation and the fact that it takes two hours to do that note.

DISCUSSION

In this qualitative case study with HHC patients, caregivers, and clinicians, the participants described varying levels of expectation clarity for HHC after discharge. We triangulated across and within cases and found three cases with clear expectations and three cases with unclear expectations for HHC across perspectives. In three additional cases, we found discordant expectations across perspectives: patients and HHC clinician expectations differed in two of the cases and a patient and caregiver differed in one case. Of interest, in all three cases of clear expectations across perspectives, the patients and/or caregivers had prior HHC or healthcare work experience. In contrast, in the cases of two caregivers with unclear expectations, neither had prior HHC experience and both described expectations for assistance with personal care or housekeeping. Our findings suggest the need to improve caregiver engagement in HHC decision-making and care delivery, even in the time following the passage of the CARE Act. In addition, our findings suggest that patients and caregivers with unclear expectations for HHC may benefit from enhanced education about HHC services.

Prior studies in this area have included a qualitative study HHC patients, caregivers, and clinicians by Foust and colleagues in which multiple caregivers described finding out about the discharge from the patient or other caregivers, rather than being actively engaged by clinicians.[6] In another recent qualitative study by Arbaje and colleagues, a majority of caregivers described "mismatched expectations" about HHC services, in which caregivers were unclear about their role compared with the HHC role in caring for the patient.[9] Of interest, HHC clinicians in the Arbaje study described one of their key tasks to be "expectation management" for receipt of HHC services.[9] In our study, the caregivers who described unclear expectations were not able to be present for the first HHC visit, which may have been a missed opportunity for the HHC clinician to clarify and manage expectations. Overall, findings from each of these studies support that consistent engagement and education from the hospital and HHC clinicians are needed to prepare patients and caregivers to know what to expect from HHC.

When caregivers have unclear expectations for HHC, they could be expressing the need for more support after hospital discharge, which suggests an active role for hospital teams to assess and address additional support needs with the patients and caregivers. For example, if the patient or caregiver request additional personal care services, a home health aide could help to reduce caregiver burden and improve the support network for the patient. In a prior study in which patients were asked what would help them to make informed decisions about postacute care options, the patients described wanting to receive practical information that could describe how it would apply to their specific situation and perceived needs.[18] To provide this for patients and caregivers, it would follow that hospitals could provide information about skilled HHC nursing and therapies and information about services that could meet additional needs, such as home health aides.

In the context of the CARE Act, in which hospitals are encouraged to increase family caregiver engagement to prepare for discharge, findings from this and other studies suggest an opportunity to improve caregiver partnership in HHC transitions. As a result of this work, we recommend intentionally engaging and including caregivers in addition to patients in both the hospital and HHC settings to clarify expectations. Steps to clarify expectations with both patients and caregivers should include the following: (1) providing education and clear expectations for HHC through verbal interactions and written materials, and (2) assessing and addressing additional needs (eg, personal care) that patients and caregivers may have. To support these efforts, multidisciplinary teams could use previously studied interventions and tools for guidance as they engage caregivers throughout care transitions processes.[10,19]

Limitations of this study include that it was a small qualitative case study of patients, caregivers, and HHC clinicians from one medical unit at one academic medical center. Most patients in this study had Medicare insurance, were 65 years and older, white, and female. A recent analysis of Medicare HHC users found that 63% were female and 75% were white, which shows that females were overrepresented in our study.[1,2,11] The perspective of Black and non-English speaking patients are missing from our study. Finally, we only interviewed individuals in three roles of complex transitions to HHC, and there are likely many additional perspectives on each of these transitions, which could provide additional insights. Results are not generalizable or transferable beyond this context.

In conclusion, to improve care transitions for HHC patients and their caregivers, emphasizing engagement of caregivers is key to ensure that they are educated about HHC, provided with additional support as needed, and included in initial HHC

visits once the patients are at home. Even though patients and caregivers with prior HHC experience often had clear expectations for HHC, a strategy to uniformly engage caregivers across a range of experience can ensure caregivers have all the information and support needed to optimize care transitions to HHC.

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Identifying Observation Stays in Medicare Data: Policy Implications of a Definition

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Observation stays are increasingly common, yet no standard method to identify observation stays in Medicare claims is available, including events with status change. To determine the claims patterns of Medicare observation stays, define comprehensive claims-based methodology for future Medicare observation research and data reporting, and identify policy implications of such definition, we identified potential observation events in a 2014 20% random sample of Medicare beneficiaries with both Part A and B claims and at least one acute care stay (1,667,660 events). Observation revenue center (ORC) and Healthcare Common Procedure Coding System codes occurring within 30 days of an inpatient hospitalization were recorded. A total of 125,920 (7.6%) events had an ORC code, and 75,502 (4.5%) were in the outpatient revenue center. Claims patterns varied tremendously, and almost half (47.3%, 59,529) of the ORC codes were associated with an inpatient claim, indicating status change and demonstrating a need for clarity in observation policy. The proposed University of Wisconsin method identified 72,858 of 75,502 (96.5%) events with ORC codes as observation stays, and provides a comprehensive, reproducible methodology.

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Medicare observation stays are increasingly common. From 2006 to 2012, Medicare observation stays increased by 88%,[1] whereas inpatient discharges decreased by 13.9%.[2] In 2012, 1.7 million Medicare observation stays were recorded, and an additional 700,000 inpatient stays were preceded by observation services; the latter represented a 96% increase in status change since 2006.[1] Yet no standard research methodology for identifying observation stays exists, including methods to identify and properly characterize "status change" events, which are hospital stays where initial and final inpatient or outpatient (observation) statuses differ.

With the increasing number of hospitalized patients classified as observation, a standard methodology for Medicare claims research is needed so that observation stays can be consistently identified and potentially included in future quality measures and outcomes. Existing research studies and government reports use widely varying criteria to identify observation stays, often lack detailed methods on observation stay case finding, and contain limited information on how status changes between inpatient and outpatient (observation) statuses are incorporated. This variability in approach may lead to omission and/or miscategorization of events and raises concern about the comparability of prior work.

This study aimed to determine the claims patterns of Medicare observation stays, define comprehensive claims-based methodology for future Medicare observation research and data reporting, and identify policy implications of such definition. We are poised to do this work because of our access to the nationally generalizable Centers for Medicare & Medicaid Services (CMS) linked Part A inpatient and outpatient data sets for 2013 and 2014, as well as our prior expertise in hospital observation research and Medicare claims studies.

METHODS

General Methods and Data Source

A 2014 national 20% random sample Part A and B Medicare data set was used. In accordance with the Centers for Medicare & Medicaid (CMS) data use agreement, all included beneficiaries had at least one acute care inpatient hospitalization. Included beneficiaries were enrolled for 12 months prior to their first 2014 inpatient stay. Those with Medicare Advantage or railroad benefits were excluded because of incomplete data per prior methods.[3] The University of Wisconsin Institutional Review Board approved this study.

Comparison of Methods

The PubMED query "Medicare AND (observation OR observation unit)," limited to English and publication between January

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TABLE. **Medicare Hospital Events Associated With Observation Revenue Center Codes**

	Total Events (n = 125,920)[a]	Inpatient DRG (n = 59,529, 47.3%)	HCPCS G0378 (n = 39,408, 31.3%)[b]	HCPCS G0379[c]**
Inpatient Revenue Center	*50,418*	*50,418 (100.0)*	*155 (0.3)*	**
0760 only	623 (1.2)	623 (1.2)	**	0 (0.0)
0761 only	22,037 (43.7)	22,037 (43.7)	0 (0.0)	0 (0.0)
0762 only	25,057 (49.7)	25,057 (49.7)	**	**
0769 only	304 (0.6)	304 (0.6)	0 (0.0)	0 (0.0)
2 different codes	2,379 (4.7)	2,379 (4.7)	16 (0.0)	**
3 different codes	18 (0.0)	18 (0.0)	0 (0.0)	0 (0.0)
Outpatient Revenue Center	*75,502*	*9,111 (12.1)[d]*	*39,253 (52.0)*	*1,577 (2.1)*
0760 only	343 (0.5)	63 (0.1)	51 (0.1)	**
0761 only	34,732 (46.0)	2,983 (4.0)	**	0 (0.0)
0762 only	36,996 (49.0)	5,499 (7.3)	36,074 (47.8)	1,338 (1.8)
0769 only	200 (0.3)	**	**	0 (0.0)
2 different codes	3,181 (4.2)	544 (0.7)	3,070 (4.1)	**
3 different codes	50 (0.1)	**	**	19 (0.0)

[a]125,920 events represent 7.6% of 1,667,669 total hospitalizations, with 50,418 (3.0%) in the inpatient revenue center and 75,502 (4.5%) in the outpatient revenue center.

[b]Of potential observation events with HCPCS G0378, 5,959 were also associated with a DRG (155 in the inpatient revenue center and 5,804 in the outpatient revenue center).

[c]Of potential observation events with HCPCS G0379, less than ten** occur without G0378.

[d]Of 9,111 observation revenue center codes associated with inpatient claims, 6,467 (71.0%) had at least one code found in Category 4. The remaining codes were found in Category 1 (1,088, 11.9%), 2 (925, 10.2%), 3 (328, 3.6%) or two or more codes in Category 1,2, and 3 (303, 3.3%).

**Information suppressed to adhere to CMS cell size suppression policy. All are number (%). 0760: Treatment or observation room-general classification; 0761: Treatment or observation room-treatment room; 0762: Treatment or observation room-obervation room; 0769: Treatment or observation room-other; G0378: Hospital observation service, per hour; G0379: Direct referral of patient for hospital observation care.

1, 2010 and October 1, 2017, was conducted to determine the universe of prior observation stay definitions used in research for comparison (Appendix).[4-20] The Office of Inspector General report,[21] the Research Data Assistance Center (ResDAC),[22] and Medicare Claims Processing Manual (MCPM)[23] were also included. Methods stated in each publication were used to extrapolate observation stay case finding to the study data set.

Observation Stay Case Finding

Inpatient and outpatient revenue centers were queried for observation revenue center (ORC) codes identified by ResDAC,[22] including 0760 (Treatment or observation room - general classification), 0761 (Treatment or observation room - treatment room), 0762 (Treatment or observation room – observation room), and 0769 (Treatment or observation room – other) occurring within 30 days of an inpatient stay. Healthcare Common Procedure Coding System (HCPCS) codes G0378 (Hospital observation service, per hour) and G0379 (Direct referral of patient for hospital observation care) were included per MCPM.[23] A combination of these ORC and HCPCS codes was also used to identify observation stays in every Medicare claims observation study since 2010. When more than one ORC code per event was found, each ORC was recorded as part of that event. Presence of HCPCS G0378 and/or G0379 was determined for each event in association with event ORC(s), as was association of ORC codes with inpatient claims. In this manuscript, "observation stay" refers to an observation hospital stay, and "event" refers to a hospitalization that may include inpatient and/or outpatient (observation) services and ORC codes.

Status Change

All ORC codes found in the inpatient revenue center were assumed to represent status changes from outpatient (observation) to inpatient, as ORC codes may remain in claims data when the status changes to inpatient.[24] Therefore, all events with ORC codes in the inpatient revenue center were considered inpatient hospitalizations.

For each ORC code found in the outpatient revenue center and also associated with an inpatient claim, timing of the ORC code in the inpatient claim was grouped into four categories to determine events with the final status of outpatient (observation stay). ResDAC defines the "From" date as "…the first day on the billing statement covering services rendered to the beneficiary."[24] For most hospitals, this is a three-day period prior to an inpatient admission where outpatient services are included in the Part A claim.[25] We defined Category 1 as ORC codes occurring prior to claim "From" date; Category 2 as ORC codes on the inpatient "From" date, between the inpatient "From" date and admission date, or on the admission date; Category 3 as ORC codes between admission and discharge dates; and Category 4 as ORC codes occurring on or after the discharge date. Given that Category 4 represents the final hospitalization status, we considered Category 4 ORC codes in the outpatient revenue center associated with inpatient claims to be observation stays that had undergone a status change from inpatient to outpatient (observation).

University of Wisconsin Method

After excluding ORC codes in the inpatient revenue center as true inpatient hospitalizations, we defined an observation stay as 0760 and/or 0761 and/or 0762 and/or 0769 in the outpatient

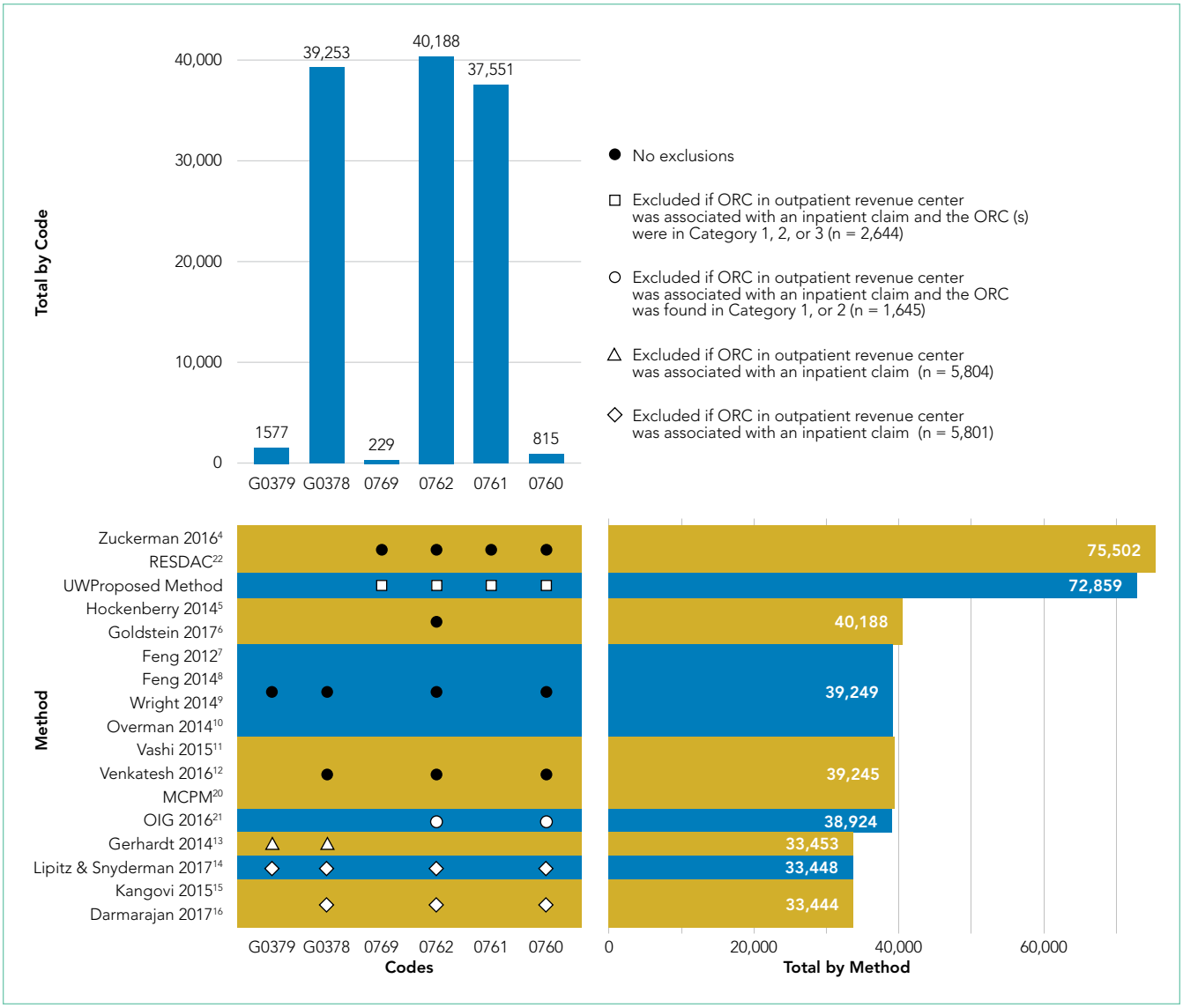

FIG. Extrapolation of Methods for Observation Stay Identification by Publication Source (n = 75,502). We assumed that studies with access to Part A claims excluded ORC codes in the inpatient revenue center as inpatient stays. We also assumed that multiple ORCs in a single event were counted as a single observation stay. Five out of 20 sources contained no information on codes used to identify observation stays. For 1 of the 5,[4] methods were obtained via personal communication with the first author. The remaining 4 sources[17-20] were not included. Of the remaining 16 sources, 5 mentioned status change criteria, with methods extrapolated above (see also Appendix). Status change extrapolation was based on methods interpretation, limited by specifics available in each source. All methods using ORC 0760 or 0762 and HCPCS G0378 or G0379 required that the ORC code be accompanied with an HCPCS code for inclusion.[7-12,14-16,23] Additional criteria listed for non-Medicare and/or commercial data[5,10] were not utilized (see Appendix).

Abbreviations: 0760, Treatment or observation room-general classification; 0761, Treatment or observation room-treatment room; 0762, Treatment or observation room-observation room; 0769, Treatment or observation room-other; G0378, Hospital observation service, per hour; G0379, Direct referral of patient for hospital observation care; HCPCS: Healthcare Common Procedure Coding System; MCPM, Medicare Claims Processing Manual; OIG, Office of Inspector General; ORC, Observation Revenue Center; RESDAC, Research Data Assistance Center.

revenue center and having no association with an inpatient claim. To address a status change from inpatient to outpatient (observation), for those ORC codes in the outpatient revenue center also associated with an inpatient claim, claims with ORC codes in Category 4 were also considered observation stays.

RESULTS

Of 1,667,660 hospital events, 125,920 (7.6%) had an ORC code within 30 days of an inpatient hospitalization, of which 50,418 (3.0%) were found in the inpatient revenue center and 75,502 (4.5%) were from the outpatient revenue center. A total of 59,529 (47.3%) ORC codes occurred with an inpatient claim (50,418 in the inpatient revenue center and 9,111 in the outpatient revenue center), 5,628 (4.5%) had more than one ORC code on a single hospitalization, and more than 90% of codes were 0761 or 0762. These results illustrated variability in claims submissions as measured by the claims themselves and demonstrated a high rate of status changes (Table).

Observation stay definitions varied in the literature, with different methods capturing variable numbers of observation

stays (Figure, Appendix). No methods clearly identified how to categorize events with status changes, directly addressed ORC codes in the inpatient revenue center, or discussed events with more than one ORC code. As such, some assumptions were made to extrapolate observation stay case findings as detailed in the Figure (see also Appendix). Notably, reference 4 methods were obtained via personal communication with the manuscript's first author. The University of Wisconsin definition offers a comprehensive definition that classifies status change events, yielding 72,858 of 75,502 (96.5%) potential observation events as observation stays (Figure). These observation stays include 66,391 stays with ORC codes in the outpatient revenue center without status change or relation to inpatient claim, and 6,467 (71.0%) of 9,111 events with ORC codes in the outpatient revenue center were associated with an inpatient claim where ORC code(s) is located in Category 4.

CONCLUSIONS

This study confirmed the importance of a standard observation stay case finding methodology. Variability in prior methodology resulted in studies that may have included less than half of potential observation stays. In addition, most studies did not include, or were unclear, on how to address the increasing number of status changes. Others may have erroneously included hospitalizations that were ultimately billed as inpatient, and some publications lacked sufficient detailed methodology to extrapolate results with absolute certainty, a limitation of our comparative results. Although excluding some ORC codes in the outpatient revenue center associated with inpatient claims may possibly miss some observation stays, or including certain ORC codes, such as 0761 (treatment or observation room - treatment room), may erroneously include a different type of observation stay, the proposed University of Wisconsin method could be used as a comprehensive and reproducible method for observation stay case finding, including encounters with status change.

This study has other important policy implications. More than 90% of ORC codes were either 0761 or 0762, and in almost one in 20 claims, two or more distinct codes were identified. Given the lack of clinical relevance of terms "treatment" or "observation" room, and the frequency of more than one ORC code per claim, CMS may consider simplification to a single ORC code. Studies of observation encounter length of stay by hour may require G0378 in addition to an ORC code to define an observation stay, but doing so eliminates nearly half of observation claims. Additionally, G0379 adds minimal value to G0378 in case finding.

Finally, this study illustrates overall confusion with outpatient (observation) and inpatient status designations, with almost half (47.3%) of all hospitalizations with ORC codes also associated with an inpatient claim, demonstrating a high status change rate. More than 40% of all nurse case manager job postings are now for status determination work, shifting duties from patient care and quality improvement.[26] We previously demonstrated a need for 5.1 FTE combined physician, attorney, and other personnel to manage the status, audit, and appeals process per institution.[27] The frequency of status changes and personnel needed to maintain a two-tiered billing system argues for a single hospital status.

In summary, our study highlights the need for federal observation policy reform. We propose a standardized and reproducible approach for Medicare observation claims research, including status changes that can be used for further studies of observation stays.

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Negative Urinalyses in Febrile Infants Age 7 to 60 Days Treated for Urinary Tract Infection

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The role of the urinalysis (UA) in the management of young, febrile infants is controversial. To assess how frequently infants are treated for urinary tract infection (UTI) despite having normal UA values and to compare the characteristics of infants treated for UTI who have positive versus negative UAs, we reviewed 20,570 well-appearing febrile infants 7-60 days of age evaluated at 124 hospitals in the United States who were included in a national quality improvement project. Of 19,922 infants without bacteremia and meningitis, 2,407 (12.1%) were treated for UTI, of whom 2,298 (95.5%) had an initial UA performed. UAs were negative in 337/2,298 (14.7%) treated subjects. The proportion of infants treated for UTI with negative UAs ranged from 0%-35% across hospitals. UA-negative subjects were more likely to have respiratory symptoms and less likely to have abnormal inflammatory markers than UA+ subjects, indicating that they are mounting less of an inflammatory response to their underlying illness and/or might have contaminated specimens or asymptomatic bacteriuria. *Journal of Hospital Medicine* 2019;14:101-104. © 2019 Society of Hospital Medicine

The sensitivity of the urinalysis (UA) in young infants has been reported to be in the 75% to 85% range.[1-4] This suboptimal sensitivity has prevented a widespread adoption of the UA as a true screening test for urinary tract infection (UTI). Although infants with a positive urine culture and a negative UA may have asymptomatic bacteriuria (AB) or contamination,[5-7] they are often treated for UTI.

Due to these concerns, the American Academy of Pediatrics (AAP) recommended in their 2011 UTI Practice Guidelines that UA criteria should be incorporated into the definition of UTI.[1] However, these guidelines were intended for the 2-24 month age range, leaving a gap in our understanding of the appropriate management of infants <2 months. It is unknown how UA results influence the current management of UTI in young, febrile infants. Using data from a large, nationally representative quality improvement project surrounding the management of febrile infants, this investigation aimed to examine how frequently infants are treated for UTI despite having normal UAs and to determine whether infant and hospital characteristics are different in infants treated for UTI with a positive UA as compared to those treated for UTI with a negative UA.

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METHODS

Subjects and Setting

This is a secondary analysis of the AAP's Reducing Excessive Variability in the Infant Sepsis Evaluation (REVISE) project that involved 20,570 well-appearing infants 7-60 days of age evaluated in the emergency department and/or inpatient setting for fever ≥38°C without a source between September 2015 and November 2017 at 124 community- and university-based hospitals in the United States. Data were collected via chart review and entered into a standardized tool for the project. This project was deemed exempt by the AAP Institutional Review Board. Because all data were de-identified, some sites did not require Institutional Review Board approval while others required data sharing agreements.

Variables and Definitions

A positive UA was defined as having any leukocyte esterase, positive nitrites, or >5 white blood cells (WBCs) per high power field. Treatment for UTI was defined using the question "*Did the urine culture grow an organism that was treated as a pathogen with a full course of antibiotics*?" Subjects treated for meningitis or bacteremia were excluded in order to focus on uncomplicated UTI. "Abnormal inflammatory markers" were defined as having a WBC count <5,000 or >15,000 cells/mm^3, an absolute band count ≥ 1,500 cells/mm^3, a band to neutrophil ratio of >0.2, cerebrospinal fluid (CSF) WBC count of >8/mm^3, a positive CSF gram stain, or an elevated C-reactive protein or procalcitonin level, as defined by the institutional range. Although technically not an "inflammatory

TABLE. **Characteristics of 2,298 Febrile Infants Treated for Urinary Tract Infection**

Characteristics	Treated for UTI, UA-Negative (n = 337)	Treated for UTI, UA-Positive (n = 1,961)	aOR for Treatment of UTI with Negative UA (95% Confidence Interval)[a]	Adjusted *P* Value
Subjects				
Age				
7 to 30 days	154 (45.7%)	810 (41.3%)	1.3 (1.02-1.7)	.04
31 to 60 days	183 (54.3%)	1,151 (58.7%)	Referent[b]	
Sex				
Boy	222 (65.9%)	1,193 (60.8%)	1.2 (0.9-1.6)	
Girl	115 (34.1%)	768 (39.2%)	Referent[b]	.17
Abnormal inflammatory marker[c]				
Yes	123 (38.4%)	1,242 (65.6%)	0.3 (0.3-0.4)	<.001
No	197 (61.6%)	652 (34.4%)	Referent[b]	
Respiratory symptoms				
Yes	93 (27.6%)	344 (17.5%)	1.7 (1.3-2.3)	<.001
No	244 (72.4%)	1,617 (82.5%)	Referent[b]	
Hospitals				
University-affiliated				
Yes	219 (65.0%)	1,338 (68.2%)	0.9 (0.6-1.3)	.63
No	118(35.1%)	623 (31.8%)	Referent[b]	
Urban setting				
Yes	240(71.2%)	1,455 (74.2%)	0.8 (0.6-1.2)	.32
No	97(28.8%)	506 (25.8%)	Referent[b]	
Annual volume of febrile infants				
<50	12 (3.6%)	115 (5.9%)	Referent[b]	.23
51-100	84 (24.9%)	442 (22.5%)	1.9 (0.9-4.1)	
101-200	47 (14.0%)	334 (17.0%)	1.4 (0.6-3.2)	
201-300	56 (16.6%)	289 (14.7%)	2.2 (0.9-5.0))	
>300	138 (41.0%)	781 (39.8%)	2.0 (0.9-4.4)	
Region				
South	137 (40.7%)	725 (37.0%)	Referent[b]	.002
Midwest	77 (22.9%)	460 (23.5%)	0.9 (0.6-1.4)	
Northeast	71 (21.1%)	280 (14.3%)	1.4 (0.9-2.3)	
West	52 (15.4%)	496 (25.3%)	0.5 (0.3-0.8)	

[a]Mixed-effects model was used to adjust for clustering by site. Due to missing inflammatory marker data for 84 (3.7% of 2,298) children, the adjusted odds ratios were generated from 2,214 children.

[b]Referent odds for a 31 to 60-day old girl without elevated inflammatory markers or respiratory symptoms, who was cared for in an urban, university-affiliated hospital in the south with an annual volume of less than 50 febrile infants was 0.15 (95% CI 0.06 to 0.35).

[c]Defined as white blood cell count < 5,000 or >15,000 cells/mm^3; cerebrospinal fluid white blood cell count >8/mm3; positive cerebrospinal fluid gram stain; or elevated C-reactive protein or procalcitonin per institutional range. Inflammatory markers were missing for 17 (5.0%) children with UA-negative UTI and 67 (3.4%) children with UA-positive UTI (*P*-value = 0.14 for difference in proportion).

Abbreviations: aOR, adjusted odds ratio; UA, urinalysis; UTI, urinary tract infection.

marker," CSF gram stain was included in this composite variable because in the rare cases that it is positive, the result would likely influence risk stratification and immediate management. Infants' ages were categorized as either 7-30 days or 31-60 days. Hospital length-of-stay (LOS) was recorded to the nearest hour and infants who were not hospitalized were assigned a LOS of 0 hours. Hospital characteristics were determined through a survey completed by site leads.

Statistics

Proportions were compared using chi-square test. We used multilevel mixed-effects logistic regression to determine associations between patients and hospital characteristics and UA-positivity in subjects treated for UTI. We accounted for the hospital clustering effect with a random effect that did not vary with patient characteristics. We "marginalized" the regression coefficients to reflect the average effect across hospitals.[8,9] We

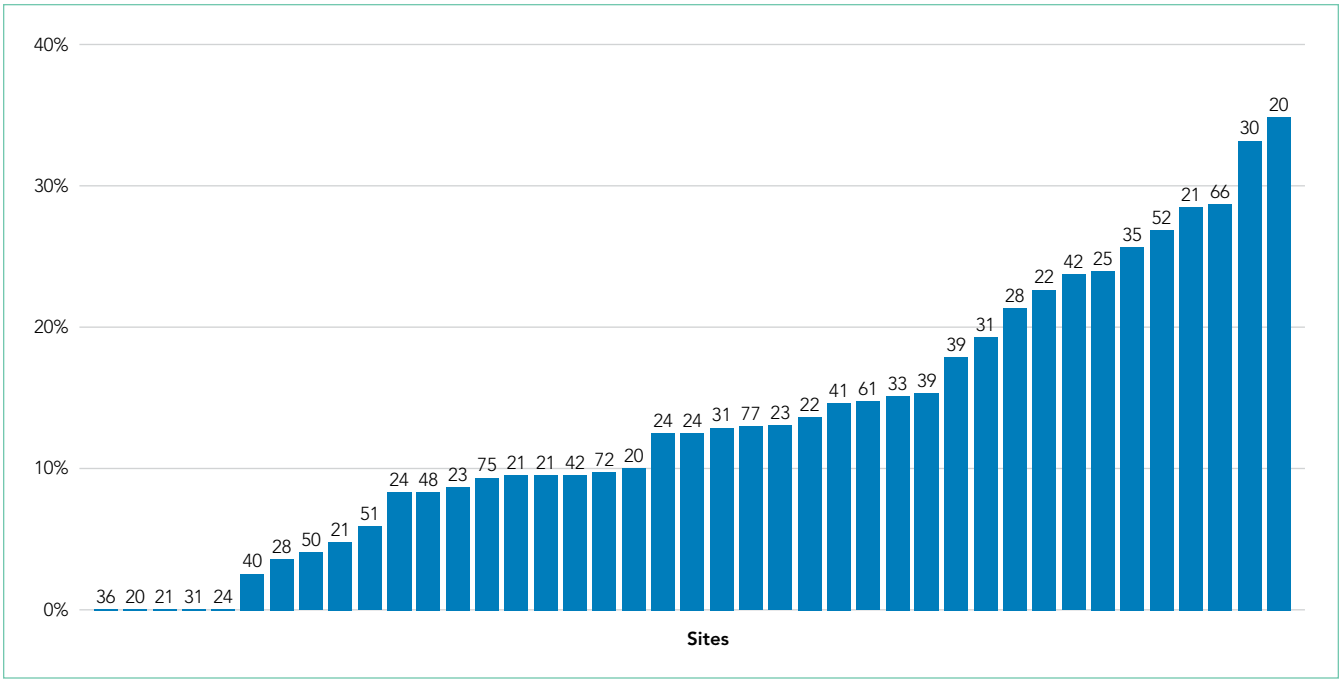

FIG. Proportion of Febrile Infants 7 to 60 Days Old Treated Having a UTI with Negative Urinalysis at 41 Sites with 20 or More UTI Cases

tested the overall importance of the hospital clustering effect on the treatment by comparing our multilevel model to a single-level model without hospital random effects using the likelihood ratio test.

RESULTS

A total of 20,570 infants from 124 hospitals were enrolled in the REVISE project, and 648 (3.2%) were treated for bacteremia and/or meningitis. Of the remaining 19,922 infants, 2,407 (12.1%) were treated for UTI, of whom 2,298 (95.5%) had an initial UA performed. Urine cultures were obtained by catheterization or suprapubic aspirate in 90.3% and "other/unknown" in 9.7% of these 2,298 subjects.

UAs were negative in 337/2,298 (14.7%) treated subjects. UA-negative subjects were more likely to be 7-30 days old (adjusted odds ratio [aOR] 1.3, 95% CI 1.02-1.7) and have upper respiratory symptoms (aOR 1.7, 95% CI 1.3-2.3) and were less likely to have abnormal inflammatory markers (aOR 0.3, 95% CI 0.3-0.4) than UA+ subjects (Table). Even after accounting for the hospital characteristics depicted in the Table, treatment of UA-negative UTI was affected by the hospital ($P < .001$), and the intraclass correlation coefficient was 6% (95% CI, 3% to 14%). The Figure illustrates substantial site variability in the proportion of infants treated for UTIs that were UA-negative, ranging from 0% to 35% in hospitals with ≥20 UTI cases.

There was no significant difference in the proportion of catheterized specimens in infants treated for UTIs with negative versus positive UAs (90% vs 92%, $P = .26$). The median hospital (interquartile range) LOS in infants treated for UTI with positive UAs was 58 (45-78) hours, compared to 54 (38-76) hours in infants treated for UTI with negative UAs and 34 (0-49) hours in infants who were not treated for UTI, meningitis, or bacteremia.

DISCUSSION

In this large, nationally representative sample of febrile infants 7-60 days of age, we demonstrate that nearly 15% of young febrile infants who are treated for UTIs have normal UAs. This proportion varied considerably among hospitals, suggesting that there are institutional differences in the approach to the UA. Infants treated for UA-negative UTIs were more likely to have respiratory symptoms and less likely to have abnormal inflammatory markers than infants treated for UA-positive UTIs, indicating that these infants are either developing a milder inflammatory response to their underlying illness and/or might not have true UTIs (eg due to AB or contamination).

The AAP recently updated their UTI practice parameter to recommend inclusion of UA results as diagnostic criteria for UTI.[1] However, the fact that these guidelines do not include infants <2 months creates a gap in our understanding of the appropriate diagnostic criteria in this age group, as reflected by the site variability demonstrated in our investigation. The fact that up to 35% of infants treated for UTI at these different sites have normal UAs suggests that many practitioners continue to treat positive urine cultures regardless of UA values.

Several prior studies provide insight into the clinical significance of a positive urine culture in the absence of pyuria. Wettergren et al.[6,7,10] reported growth from suprapubic aspirate in 1.4% of infants who were screened periodically with urine cultures obtained by bag at well-child checks over the course of the first year (with a point prevalence as high as 1.5% in boys aged 0.25 to 1.9 months).[10] These infants were not more likely to have subsequent UTIs[7] or renal damage[6] than infants without asymptomatic growth, leading the authors to conclude that this growth likely represented AB. These findings empha-

size that the probability of a positive urine culture in any infant, even asymptomatic infants, is not insignificant.

Hoberman et al.[11] demonstrated that dimercaptosuccinic acid scans did not reveal signs of pyelonephritis in 14/15 children < 2 years of age with urine cultures growing >50,000 CFU/mL but no pyuria on UA, and concluded that AB was the most likely explanation for this combination of findings. Schroeder et al.[5] and Tzimenatos et al.[12] examined infants <2-3 months with UTI and bacteremia caused by the same organism (and hence a true infection that cannot be explained by AB or contamination) and demonstrated that the UA sensitivity in this population was 99.5% and 100%, respectively, suggesting that the prior lower estimates of UA sensitivity in UTI in general, may have been biased by inclusion of positive urine cultures that did not represent UTI.

On the other hand, Shaikh et al.[13] recently demonstrated that the sensitivity of the UA appears to vary by organism, with lower reported sensitivity in non-*Escherichia coli* organisms, leading the authors to conclude that this variability is evidence of suboptimal UA sensitivity. However, an alternative explanation for their findings is that non-*E coli* organisms may be more likely to cause AB or contamination.[14] The fact that follow-up suprapubic aspirates on infants with untreated catheterized cultures yielding these organisms are often negative supports this alternative explanation.[15]

The median LOS in infants with UA-negative UTI was nearly one day longer than infants not treated for serious bacterial infection. These infants may have also undergone urinary imaging and possibly prophylactic antibiotics, indicating high resource burden created by this subgroup of infants. Expanding AAP UTI guidelines to infants <2 months of age would likely reduce resource utilization, but continued research is needed to assess the safety of this approach. Young infants have immature immune systems and may not develop a timely inflammatory response to UTI, which raises concerns about missing bacterial infections.

Our investigation has several strengths, including the large, nationally representative sample that includes both children's and non-children's hospitals. Similar febrile infant investigations of this size have previously been possible only using administrative databases, but our investigation required chart review for all enrolled infants, ensuring that the subjects were febrile, well-appearing, and were treated for UTI. However, our findings are limited in that data were collected primarily as part of a quality improvement initiative, and some of our thresholds for "abnormal" laboratory values might be controversial. For example, urine WBC thresholds differ across studies, and our CSF WBC threshold of >8/mm^3 may be somewhat low given prior reports that values slightly above this threshold might be normal in infants under one month of age.[16] The original intent of the inflammatory marker composite variable was to aid in risk stratification, but we were unable to collect granular data for all potentially relevant variables. In planning the REVISE project, we attempted to create straightforward, unambiguous variables to facilitate the anticipated high volume of chart reviews. Although patients categorized as having UTI might not have had true UTIs, by linking the "UTI" variable to practitioner management (rather than UA and microbiologic definitions), our data reflect real-world practice.

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Outpatient Parenteral Antimicrobial Therapy in Vulnerable Populations—People Who Inject Drugs and the Homeless

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Outpatient parenteral antimicrobial therapy (OPAT) programs can provide high-value care but may be challenging in people who inject drugs (PWID) and homeless individuals. We conducted a single-center, retrospective, cohort study of adults who received OPAT at an urban, public health hospital from January 1, 2015 to April 30, 2016, grouped by PWID and housing status. Outcomes included clinical cure, length of stay, secondary bacteremia, line-tampering, and readmission. A total of 596 patients (homeless PWID (9%), housed PWID (8%), homeless non-PWID (8%), and housed non-PWID (75%), received OPAT. Assuming that patients lost to follow-up failed therapy, homeless PWID were least likely to achieve cure compared with housed non-PWID, (odds ratio [OR] = 0.33, 95% CI 0.18-0.59; $P < .001$). Housed PWID were also less likely to achieve cure (OR = 0.37, 95% CI 0.20-0.67; $P = .001$). Cure rates did not differ in patients not lost to follow-up. OPAT can be effective in PWID and the homeless, but loss to follow-up is a significant barrier. *Journal of Hospital Medicine* 2019;14:105-109. © 2019 Society of Hospital Medicine

Outpatient parenteral antimicrobial therapy (OPAT) programs allow patients to receive antibiotic therapy at home or in other settings.[1-3] Bacterial infections among people who inject drugs (PWID) and the homeless are common, leading to complicated treatment strategies. Those with opioid dependence have frequent hospitalizations.[4] Bacteremia and endocarditis frequently require intravenous (IV) antibiotics[5-7] and may be difficult to treat. Creating outpatient treatment plans for PWID and the homeless is challenging, and there is a paucity of data on OPAT effectiveness in these groups as they are often excluded from OPAT services.[1,2,8]

We evaluated treatment outcomes in PWID and the homeless in our OPAT program.

METHODS

We conducted a retrospective cohort study of hospitalized adults discharged from Harborview Medical Center (HMC) with OPAT from January 1, 2015 to April 30, 2016. HMC is a county hospital in Seattle, Washington, affiliated with the University of Washington (UW). Infectious disease specialists supervise our OPAT program and provide follow-up care. We partner with a medical respite facility, a discharge option for homeless patients.[9] Respite is staffed by HMC nurses, mental health specialists, and case managers.

Patients aged ≥18 years were enrolled in OPAT if they were discharged with >2 weeks of IV therapy or required laboratory monitoring while on oral antibiotics. Patients with multiple hospitalizations were included for their initial OPAT encounter only. PWID discharged to respite were instructed not to use their vascular access to inject drugs, but drug abstinence was not required. A tamper-evident sticker was placed over lines that nurses evaluated daily. Patients violating line-tampering restrictions were discharged from respite, and OPAT providers developed alternative antibiotic plans.

The two primary exposures evaluated were patient-reported injection drug use and housing status, and our primary exposure measure was the four-category combination: (1) housed non-PWID, (2) housed PWID, (3) homeless non-PWID, and (4) homeless PWID. Current drug use was defined as use within three months of hospitalization. Homelessness was defined as lack of stable housing. Patients receiving chemotherapy, prolonged steroids, biologic agents, or those with organ transplant were considered immunocompromised.

The primary outcome was clinical cure, defined as completion of antibiotic therapy and resolution of infection, determined by OPAT providers. Patients who were placed on oral suppressive antibiotics or died before treatment completion were considered not cured. Unknown status, including care transfer and lost to follow-up, were noted separately. Lost to follow-up was assumed if patients did not return for care, their

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care was not formally transferred, and no other medical information was available.

Secondary outcomes included hospital length of stay (LOS), secondary bacteremia, line-tampering, and 30-day readmissions. Secondary bacteremia was defined as bacteremia with a different pathogen from the index illness, which occurred during the initial treatment course. Readmission included readmissions related to OPAT (ie, recurrent or worsening infection, treatment-related toxicities, line-tampering, secondary bacteremia, and line-associated complications).

Data collection was performed using REDCap, a data-capturing software program linked to the electronic medical record (EMR).[10] Hospitalization dates and demographics were electronically populated from the EMR. Details regarding drug use, homelessness, comorbidities, diagnosis, discharge complications, clinical cure, and lost to follow-up were manually entered.

Statistical Analysis

Statistical calculations were performed using SAS (v. 9.4). Chi-square testing and analysis of variance were conducted to assess group differences in demographics, infection types, and clinical outcomes.

Primary and secondary outcomes were further evaluated by univariable logistic regression and presented as odds ratios, with the non-PWID housed group serving as the reference. Given the large number of PWID and homeless patients lost to follow-up, sensitivity analyses were conducted using the assumption that patients with unknown clinical outcomes did not achieve cure (ie, chronic infection or death). Multivariable regression was performed on the outcomes of cure and 30-day readmission to OPAT using backward elimination to select a final model, initially including potential confounders of age, sex, and relevant comorbidities (DM and HIV). We assumed that those lost to follow-up were not cured (or readmitted). Other secondary outcomes were either rare events or those of uncertain relevance (eg, hospital LOS) to be evaluated in the multivariable analysis.

Our study did not meet the definition of research by the UW's institutional review board. It was a quality improvement project funded by a UW Medicine Patient Safety Innovations Program Grant.

RESULTS

Overall, 596 patients received OPAT over 16 months. OPAT patients were categorized into groups as follows: homeless PWID (9%, n = 53), housed PWID (8%, n = 48), homeless non-PWID (8%, n = 45), and housed non-PWID (75%, n = 450).

PWID were younger than non-PWID, and the majority of patients in all groups were men (Table 1). PWID were more likely to have hepatitis C. Non-PWID appeared more likely to have diabetes and be immunosuppressed.

Patients had a total of 960 types of infection (Table 1). Bacteremia was the most common infection among PWID. Osteomyelitis was the most frequent infection in non-PWID.

Discharge location varied widely ($P < .001$; Table 1). The majority of patients with housing (housed PWID 60.4%, housed non-PWID 59.1%) were discharged to home, although 36.7% of housed non-PWID went to nursing facilities. Among homeless patients, 58.5% of PWID and 42.2% of non-PWID were discharged to respite; 10 patients were discharged to a shelter or street. Data specific to transition from IV to oral therapy were not recorded.

Cure rates among participants with known outcomes did not differ by group (Table 1; $P = .85$). In a sensitivity analysis of clinical cure, assuming those with unknown outcomes were not cured, housing status and drug use were significantly associated with cure (Table 1; $P < .001$, in the overall test), with rates lower among housed and homeless PWID groups (50.0% and 47.2%, respectively) compared with housed and homeless non-PWID groups (73.1% and 82.2%, respectively). In the multivariable analysis after backward elimination of noninfluential measures, only PWID and housing status were associated with cure; PWID, whether housed (OR = 0.37) or not (OR = 0.33), had lower odds of cure relative to housed non-PWID (Table 2).

Secondary outcomes, evaluated on all patients regardless of cure, differed by group (Table 1). Mean LOS appeared to be shortest for homeless PWID (15.5 days versus ≥18.0 for other groups; $P < .001$ for overall test). Homeless PWID patients appeared more likely to have secondary bacteremia (13.2% versus <4.2% in other groups; $P < .001$ for overall test), line tampering (35.9% versus <2.2% in other groups; $P < .001$), and 30-day readmission related to OPAT (26.4% versus <16.7% in other groups; $P = .004$). Compared with housed non-PWID using logistic regression, homeless PWID had a higher risk of secondary bacteremia (OR = 12.9; 95% CI 3.8-37.8; $P < .001$), line tampering (OR 88.4; 95% CI 24.5-318.3; $P < .001$), and readmission for OPAT (OR 2.4; 95% CI 1.2-4.6; $P = .007$). After adjusting for age, sex, and comorbidities, readmission for OPAT remained elevated in homeless PWID (OR = 2.4; 95% CI 1.2-4.6). No significant differences in secondary outcomes were found between housed non-PWID and also between housed PWID and homeless non-PWID.

Among homeless persons, discharge to respite care was not associated with improved outcomes, assuming those lost to follow-up did not achieve cure. Among non-PWID discharged to respite, the cure rate was 74% (14/19) compared with 88% (23/26) discharged elsewhere ($P = .20$). Among PWID, 48% (15/31) discharged to respite were cured compared with 45% (10/22) discharged elsewhere ($P = .83$).

DISCUSSION

Our study compares the outcomes of 596 OPAT patients, including PWID and the homeless. Among those retained in care, PWID achieved similar rates of cure compared with non-PWID groups. When assuming that all lost to follow-up had poor outcomes, the cure rates were markedly lower for PWID, with no difference noted by housing status.

Data on PWID and homeless enrolled in OPAT programs are limited.[5,11,12] Few studies have reported the outcomes of infections in PWID and the homeless, as these populations often experience significant loss to follow-up due to transiency, lack of care continuity, and effective means of communication.

TABLE 1. **OPAT Patient Characteristics (N = 596)**

	Homeless PWID n = 53 (%)	Housed PWID n = 48 (%)	Homeless Non-PWID n = 45 (%)	Housed Non-PWID n = 450 (%)	*P* Value[a]
Mean Age (years)	38.8	41.6	49.4	53.9	<.001
Sex					
Male	33 (62.3)	36 (75.0)	37 (82.2)	290 (64.4)	.05
Race					
White	44 (83.0)	38 (79.2)	25 (55.6)	330 (73.3)	<.001
Black	5 (9.4)	6 (12.5)	15 (33.3)	46 (10.2)	
Other[b]	4 (7.6)	4 (8.4)	5 (11.1)	77 (17.1)	
Medical Comorbidities					
ESRD on HD	1 (1.9)	4 (8.3)	2 (4.4)	24 (5.3)	.53
Diabetes Mellitus	4 (7.6)	4 (8.3)	8 (17.8)	131 (29.1)	<.001
Immunosuppressed	0	0	0	25 (5.6)	.04
HIV/AIDS	2 (3.8)	3 (6.3)	1 (2.2)	9 (2.0)	.31
Hepatitis C	39 (73.6)	32 (66.7)	6 (13.3)	45 (10.0)	<.001
Discharge Location					
Respite	31 (58.5)	1 (2.1)	19 (42.2)	1 (0.2)	<.001
Home	4 (7.6)	29 (60.4)	10 (22.2)	266 (59.1)	
Inpatient/SNF	6 (9.5)	14 (29.2)	12 (26.7)	165 (36.7)	
Shelter/street	8 (15.1)	1 (2.1)	2 (4.4)	1 (0.2)	
Other	4 (7.5)	3 (6.3)	2 (4.4)	17 (3.8)	
Infection Types[c]					
Bacteremia	31 (58.5)	26 (54.2)	18 (40.0)	90 (20.0)	<.001
Endocarditis	17 (32.1)	12 (25.0)	4 (8.9)	20 (4.4)	<.001
Septic arthritis	9 (17.0)	6 (12.5)	1 (2.2)	36 (8.0)	.04
Pulmonary	11 (20.8)	3 (6.3)	7 (15.6)	21 (4.7)	<.001
Osteomyelitis	20 (37.7)	23 (47.9)	26 (57.8)	282 (62.7)	.002
Central nervous system	8 (15.1)	12 (25.0)	7 (15.6)	89 (19.8)	.56
Skin/soft tissue	15 (28.3)	11 (22.9)	12 (26.7)	93 (20.7)	.52
Genitourinary	0	1 (2.1)	1 (2.2)	19 (4.2)	.38
Intra-abdominal	0	1 (2.1)	1 (2.2)	27 (6.0)	.14
Total Infection Types	111	95	77	677	
Mean Infection Types per Encounter	2.2	2.0	1.8	1.5	.02
Clinical Cure (Excluding Unknown)					
Yes	25 (89.3)	24 (92.7)	37 (92.5)	329 (88.7)	.85
No	3 (10.7)	2 (7.7)	3 (7.5)	42 (11.3)	
Unknown[d]	25	22	5	79	
Clinical Cure					
Yes	25 (47.2)	24 (50.0)	37 (82.2)	329 (73.1)	<.001
No[e]	28 (52.8)	24 (50.0)	8 (17.8)	121 (26.9)	
Hospital Length of Stay	15.5	21.8	18.2	18.0	<.001
Secondary bacteremia	7 (13.2)	2 (4.2)	1 (2.2)	6 (1.3)	<.001
Line Tampering	19 (35.9)	1 (2.1)	1 (2.2)	3 (0.7)	<.001
30-Day Readmission	21 (39.6)	10 (20.8)	10 (22.2)	107 (23.8)	.07
Related to OPAT	14 (26.4)	8 (16.7)	4 (8.9)	59 (13.1)	.004

[a]*P* values indicate an overall test of association between the measure and the four groups of drug use by housing status. Pairwise comparisons were not performed.
[b]Other race includes Asian, Native American/American Indian, Pacific Islander, and Hispanic
[c]Percentage calculations based on persons per group, not total infections per group
[d]Unknown clinical cure excluded from primary analysis
[e]Assumes all unknown outcomes did not achieve cure
Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; OPAT, outpatient parenteral antimicrobial therapy; PWID, people who inject drugs, SNF, skilled nursing facility.

TABLE 2. **Univariable and Multivariable Assessment of Factors Related to Cure. All 596 Persons are Included**[a]

Characteristic	Odds Ratio (95% CI)	*P* Value	Adjusted Odds Ratio (95% CI)	*P* Value
Drug use and housing status				
Homeless PWID	0.33 (0.18, 0.59)	<.001	0.33 (0.18, 0.59)	<.001
Housed PWID	0.37 (0.20, 0.67)	.001	0.37 (0.20, 0.67)	.001
Homeless non-PWID	1.70 (0.77, 3.76)	.19	1.70 (0.77, 3.76)	.19
Housed non-PWID	Reference		Reference	
Age in years	1.0 (0.99, 1.01)	.41	—	
Sex				
Women	Reference			
Men	0.81 (0.56, 1.18)	.28	—	
Comorbidities				
Diabetes Mellitus	1.23 (0.81, 1.85)	.34	—	
HIV	1.21 (0.38, 3.84)	.75	—	

[a]Those lost to follow-up prior to cure observation were included as "not cured."
Abbreviation: PWID, people who inject drugs

Cure was achieved in less than half of PWID, when lack of cure was assumed for unknown outcomes. This rate was substantially less than that for non-PWID groups. The assumption that those lost to follow-up did not achieve cure dramatically alters the inference; the truth may lie somewhere between the primary and sensitivity analyses. Homeless PWID remained at the highest risk for lost to follow-up, secondary bacteremia, line-tampering, and 30-day readmission related to OPAT.

PWID have traditionally been considered as a high-risk group for OPAT,[1,2,8] but to completely restrict PWID from OPAT may not be appropriate. Ho et al. studied 29 PWID who were selectively enrolled to receive OPAT, and 28 completed IV therapy without any instances of line-tampering, death, or unknown clinical status.[6] Recent literature suggests that some candidates can succeed with OPAT, despite drug use.[13,14]

Homelessness is also considered a barrier to OPAT.[1,8] Medical respite is a harm-reduction model implemented for patients who require subacute care.[9] In our study, among homeless patients, PWID status was the primary determinant of whether therapy was successful, rather than respite care.

Our study may have limited generalizability to other populations. We are a single-center facility in a large, urban city. PWID and housing status were self-reported but were verified before discharge. Most of our patients were men and white; thus, outcomes may differ for others. Due to the nature of the data, cost effectiveness could not be directly calculated. LOS and readmissions serve as proxy measures.

When patients remain engaged in care, PWID and the homeless achieved comparable clinical cure rates to those of housed non-PWID. Moving forward, OPAT can be more effective in PWID and the homeless with careful patient selection and close clinical support. Access to medication-assisted therapy, such as methadone or buprenorphine,[15] may improve follow-up rates and linkage to outpatient care. Additional treatment strategies to improve retention in and adherence to care may promote successful outcomes in these vulnerable populations.

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Things We Do for No Reason: Prescribing Docusate for Constipation in Hospitalized Adults

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The "Things We Do for No Reason" (TWDFNR) series reviews practices that have become common parts of hospital care but which may provide little value to our patients. Practices reviewed in the TWDFNR series do not represent "black and white" conclusions or clinical practice standards but are meant as a starting place for research and active discussions among hospitalists and patients. We invite you to be part of that discussion.

CASE PRESENTATION

An 80-year-old woman with no significant past medical history presents with a mechanical fall. X-rays are notable for a right hip fracture. She is treated with morphine for analgesia and evaluated by orthopedic surgery for surgical repair. The hospitalist recognizes that this patient is at high risk for constipation and orders docusate for prevention of constipation.

BACKGROUND

Constipation is a highly prevalent problem in all practice settings, especially in the hospital, affecting two out of five hospitalized patients.[1] Multiple factors in the inpatient setting contribute to constipation, including decreased mobility, medical comorbidities, postsurgical ileus, anesthetics, and medications such as opioid analgesics. Furthermore, the inpatient population is aging in parallel with the general population and constipation is more common in the elderly, likely owing to a combination of decreased muscle mass and impaired function of autonomic nerves.[2] Consequently, inpatient providers frequently treat constipation or try to prevent it using stool softeners or laxatives.

One of the most commonly prescribed agents, regardless of medical specialty, is docusate, also known as dioctyl sulfosuccinate or by its brand name, Colace. A study from McGill University Health Centre in Montreal, Canada reported that docusate was the most frequently prescribed laxative, accounting for 64% of laxative medication doses, with associated costs approaching $60,000 per year.[3] Direct drug costs accounted for a quarter of the expenses, and the remaining three quarters were estimated labor costs for administration. Medical and surgical admissions shared similar proportions of usage, with an average of 10 doses of docusate per admission across 17,064 admissions. Furthermore, half of the patients were prescribed docusate upon discharge. The authors extrapolated their data to suggest that total healthcare spending in North America on docusate products likely exceeds $100,000,000 yearly. A second study from Toronto found that 15% of all hospitalized patients are prescribed at least one dose of docusate, and that one-third of all new inpatient prescriptions are continued at discharge.[4]

WHY YOU THINK DOCUSATE MIGHT BE HELPFUL FOR CONSTIPATION

Docusate is thought to act as a detergent to retain water in the stool, thereby acting as a stool softener to facilitate stool passage. Physicians have prescribed docusate for decades, and attendings have passed down the practice of prescribing docusate for constipation to medical trainees for generations. The initial docusate studies showed promise, as it softened the stool by increasing its water content and made it easier to pass through the intestines.[5] One of the earliest human studies compared docusate to an unspecified placebo in 35 elderly patients with chronic atonic constipation and found a decreased need for enemas.[6] Some other observational studies also reported a decreased need for manual disimpactions and enemas in elderly populations.[7,8] One randomized, controlled trial from 1968 showed an increased frequency of bowel movements compared to placebo, but it excluded half of the enrolled patients because they had a positive placebo response.[9] Since those early studies from the 1950s and 1960s, docusate remains widely accepted as an effective stool softener with positive endorsements from hospital formularies and order sets and patient information sheets such as the JAMA Patient Page.[10] Furthermore, the World Health Organization lists docusate as an "essential medicine," reinforcing the notion that it is effective.[11]

WHY THERE IS NO REASON TO PRESCRIBE DOCUSATE FOR CONSTIPATION

Despite common practice, the efficacy of docusate as a stool softener has not been borne out by rigorous scientific data. On the contrary, multiple randomized controlled trials have failed to show any significant efficacy of this drug over placebo (Table).

The initial trial in 1976 studied 34 elderly patients on a general medical ward for prophylaxis of constipation.[12] They random-

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TABLE. **Summary of Randomized Controlled Trials Studying Docusate**

First Author	Year Published	Sample Size (n)	Patient Population	Intent of Therapy	Site of Care	Docusate Dose	Comparator	Duration	Brief Summary	Comments
Hyland[9]	1968	15	Geriatric patients in hospital with chronic constipation	Treatment	Hospital	Docusate sodium 100 mg tid	Placebo with crossover	Four weeks, then four weeks crossover	Increase in bowel movements with treatment	19 patients excluded because of placebo response
Goodman[12]	1976	34	Prophylaxis for Inpatients on "chronic medical service"	Prophylaxis	Hospital	Docusate sodium 100 mg bid	Control	26 days	No difference in frequency of quality of bowel movements	
Fain[13]	1978	46	Institutionalized patients with chronic constipation	Treatment	Nursing home	Docusate sodium 100 mg daily, docusate sodium 100 mg bid, docusate calcium 240 mg daily	Placebo period for each arm	Two weeks placebo, three weeks treatment	An increase in frequency of bowel movements with docusate calcium 240 mg, but no change in quality. Increase in bowel movements in other arms did not meet statistical significance	
Chapman[14]	1985	12	Healthy patients with ileostomies and healthy controls	Prophylaxis	Ambulatory	Docusate sodium 100 mg tid	Control with crossover	Four days	No difference in stool weight, frequency, water content, or transit time	
Castle[15]	1991	15	Elderly veterans in nursing home on bowel regimen	Treatment	Nursing home	Docusate calcium 240 mg bid	Placebo with crossover	Three weeks then two weeks crossover	No difference in stool frequency, need for additional laxatives, or patient's subjective experience	
McRorie[17]	1998	170	Chronic idiopathic constipation	Treatment	Ambulatory	Docusate sodium 100 mg bid	Psyllium 5.1g bid	Two weeks placebo, two weeks treatment	Psyllium increased stool water content and frequency; docusate had no change	Industry sponsored
Tarumi[18]	2013	74	Hospice patients	Prophylaxis and treatment	Inpatient hospice	Docusate sodium 200 mg bid	Placebo	10 days	No difference in stool frequency, volume, or consistency	All patients received sennosides

ized patients to 100 mg twice daily of docusate sodium versus a control group that did not receive any type of laxative. The number of bowel movements and their character served as the measured outcomes. The study demonstrated no statistically significant differences in the frequency and character of bowel movements between the docusate and placebo groups. Even at that time, the authors questioned whether docusate had any efficacy at all: "[w]hether the drug actually offers anything beyond a placebo effect in preventing constipation is in doubt."

Another trial in 1978 studied 46 elderly, institutionalized patients with chronic functional constipation.[13] All patients underwent a two-week placebo period followed by a three-week treatment period with three arms of randomization: docusate sodium 100 mg daily, docusate sodium 100 mg twice daily, or docusate calcium 240 mg daily. Patients received enemas or suppositories if required. All three arms showed an increase in the average number of natural bowel movements when compared to each patient's own placebo period, but only the arm with docusate calcium reached statistical significance ($P < .02$). According to the authors, none of the therapies appeared to have a significant effect on stool consistency. The authors hypothesized that the higher dose given to the docusate calcium arm may have been the reason for the apparent efficacy in this cohort. As such, studies with higher doses of docusate calcium would be reasonable.

A third study in 1985 compared docusate sodium 100 mg three times daily versus placebo in six healthy patients with ileostomies and six healthy volunteers.[14] Therapy with docusate "had no effect on stool weight, stool frequency, stool water, or mean transit time."

Another study in 1991 evaluated 15 elderly nursing home residents with a randomized, double-blind crossover design.[15] Subjects received 240 mg twice daily of docusate calcium versus placebo for three weeks and then crossed over to other arm after a two-week wash-out period. The investigators found no difference in the number of bowel movements per week or in the need for additional laxatives between the two study periods. There were also no differences in the patients' subjective experience of constipation or discomfort with defecation.

Larger studies were subsequently initiated in more recent years. In 1998, a randomized controlled trial in 170 subjects with chronic idiopathic constipation compared psyllium 5.1 g twice daily and docusate sodium 100 mg twice daily with a corresponding placebo in each arm for a treatment duration of two weeks after a two-week placebo baseline period.[16] Psyllium was found to increase stool water content and stool water weight over the baseline period, while docusate essentially had no effect on stool water content or water weight. Furthermore, by treatment week 2, psyllium demonstrated an increase in the frequency of bowel movements, whereas docusate did not. It should be noted that this study was funded by Procter & Gamble, which manufactures Metamucil, a popular brand of psyllium.

Lastly, the most recent randomized controlled trial was published in 2013. It included 74 hospice patients in Canada,

comparing docusate 200 mg and sennosides twice daily versus placebo and sennosides for 10 days. The study found no difference in stool frequency, volume, or consistency between docusate and placebo.[17]

A number of systematic reviews have studied the literature on bowel regimens and have noted the paucity of high-quality data supporting the efficacy of docusate, despite its widespread use.[18-22] With these weak data, multiple authors have advocated for removing docusate from hospital formularies and using hospitalizations as an opportunity to deprescribe this medication to reduce polypharmacy. [3,4,23]

Although docusate is considered a benign therapy, there is certainly potential for harm to the patient and detrimental effects on the healthcare system. Patients commonly complain about the unpleasant taste and lingering aftertaste, which may lead to decreased oral intake and worsening nutritional status.[23] Furthermore, docusate may impact the absorption and effectiveness of other proven treatments.[23] Perhaps the most important harm is that providers needlessly wait for docusate to fail before prescribing effective therapies for constipation. This process negatively impacts patient satisfaction and potentially increases healthcare costs if hospital length of stay is increased. Another important consideration is that patients may refuse truly necessary medications due to the excessive pill burden.

Costs to the healthcare system are increased needlessly when medications that do not improve outcomes are prescribed. Although the individual pill cost is low, the widespread use and the associated pharmacy and nursing resources required for administration create an estimated cost for docusate over $100,000,000 per year for North America alone.[3] The staff time required for administration may prevent healthcare personnel from engaging in other more valuable tasks. Additionally, every medication order creates an opportunity for medical error. Lastly, bacteria were recently found contaminating the liquid formulation, which carries its own obvious implications if patients develop iatrogenic infections.[24]

WHAT YOU SHOULD DO INSTEAD

Instead of using docusate, prescribe agents with established efficacy. In 2006, a systematic review published in the *American Journal of Gastroenterology* graded the evidence behind different therapies for chronic constipation.[21] They found good evidence (Grade A) to support the use of polyethylene glycol (PEG), while psyllium and lactulose had moderate evidence (Grade B) to support their use. All other currently available agents that were reviewed had poor evidence to support their use. A more recent study in people prescribed opioids similarly found evidence to support the use of polyethylene glycol, lactulose, and sennosides.[25] Lastly, the 2016 guidelines from the American Society of Colon and Rectal Surgeons do not mention docusate, though they comment on the paucity of data on stool softeners. Their recommendations for laxative therapy are similar to those of the previously discussed reviews.[26] Ultimately, the choice of therapy, pharmacological and nonpharmacological, should be individualized for each patient based on the clinical context and cause of constipation. Nonpharmacologic treatments include dietary modification, mobilization, chewing gum, and biofeedback. If pharmacotherapy is required, use laxatives with the strongest evidence.

RECOMMENDATIONS

- In patients with constipation or at risk for constipation, use laxatives with proven efficacy (such as polyethylene glycol, lactulose, psyllium, or sennosides) for treatment or prophylaxis of constipation instead of using docusate.
- Discuss de-prescription for patients using docusate prior to admission.
- Remove docusate from your hospital formulary.

CONCLUSION

Docusate is commonly used for the treatment and prevention of constipation in hospitalized patients, with significant associated costs. This common practice continues despite little evidence supporting its efficacy and many trials failing to show benefits over placebo. Decreased utilization of ineffective therapies such as docusate is recommended. Returning to the case presentation, the hospitalist should start the patient on alternative therapies, instead of docusate, such as polyethylene glycol, lactulose, psyllium, or sennosides, which have better evidence supporting their use.

Do you think this is a low-value practice? Is this truly a "Thing We Do for No Reason?" Share what you do in your practice and join in the conversation online by retweeting it on Twitter (#TWDFNR) and liking it on Facebook. We invite you to propose ideas for other "Things We Do for No Reason" topics by emailing TWDFNR@hospitalmedicine.org.

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Things We Do For No Reason: Sliding-Scale Insulin as Monotherapy for Glycemic Control in Hospitalized Patients

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The "Things We Do for No Reason" (TWDFNR) series reviews practices that have become common parts of hospital care but may provide little value to our patients. Practices reviewed in the TWDFNR series do not represent "black and white" conclusions or clinical practice standards but are meant as a starting place for research and active discussions among hospitalists and patients. We invite you to be part of that discussion.

A CLINICAL SCENARIO

A 60-year-old man with a past medical history of obesity and type 2 diabetes presented to the emergency department with one week of myalgias and fever up to 103.5°F (39.7°C). Other vital signs were normal. He had no localizing symptoms, and physical examination was unrevealing, except for a small scab from a tick bite sustained two weeks prior to symptom onset. Before admission, he had been managing his diabetes with metformin 1,000 mg twice a day, and on arrival, his blood sugar level was 275 mg/dL. The admitting provider decided to hold the patient's metformin and replace it with insulin per a sliding scale. Is monotherapy with sliding-scale insulin the best inpatient management option for this patient's type 2 diabetes?

WHY YOU MIGHT THINK SLIDING-SCALE INSULIN AS MONOTHERAPY IS HELPFUL

The basic premise of sliding-scale insulin (SSI) is to correct hyperglycemia through the frequent administration of short-acting insulin dosed according to a patient's blood glucose level with the help of a prespecified rubric. When blood glucose levels are low, patients receive little or no insulin, and when blood glucose levels are high, higher doses are given. This approach to inpatient blood glucose management was first popularized by Joslin in 1934,[1] and it remains a common strategy today. For example, a 2007 survey of 44 hospitals in the United States showed that approximately 43% of all noncritically ill patients with hyperglycemia were treated with SSI alone.[2] More recently, a single-center study showed that 30% of clinicians continued to use SSI as monotherapy even after the implementation of order sets designed to limit this practice.[3]

The rationale for SSI as monotherapy appears to have two components. First, guidelines suggest that certain patients should be screened periodically in the hospital for hyperglycemia (blood glucose persistently greater than 180 mg/dL) and that, if identified, hyperglycemia should be treated.[4] By pairing finger-stick glucose monitoring with SSI, the diagnosis and treatment—although not the prevention—of hyperglycemia can be accomplished simultaneously. Second, inpatient providers do not want to cause harm in the form of hypoglycemia. SSI as monotherapy is sometimes viewed as a cautious approach in this regard as insulin is administered only if the blood sugar level is high.

Convenience is probably another key contributor to the enduring use of SSI as monotherapy. Several hospitals have ready-made order sets for SSI that are easier to prescribe than a patient-specific regimen including both short- and long-acting insulin. In at least one single-center survey, physicians and staff were found to favor convenience over perceived efficacy when asked about their attitudes toward inpatient glycemic control.[5] Although efforts at individual hospitals to change practice patterns among residents have shown promise,[6] reform on a broader scale remains elusive.

WHY SSI AS MONOTHERAPY IS NOT HELPFUL

SSI administration does not attempt to replicate normal pancreatic physiology, which involves basal insulin secretion to impair hepatic gluconeogenesis and meal-associated insulin spikes to promote uptake into glucose-avid tissues. SSI is a reactive strategy, not a proactive one, and perhaps unsurprisingly, to our knowledge, it has never been shown to prevent hyperglycemia in hospitalized patients, an impression corroborated by a systematic review of the topic between 1964 and 2003.[7] More recently, one multicenter trial analyzed the effect of adding SSI to oral antihyperglycemic medications in hospitalized diabetics and found no differences in rates of hyperglycemia.[8] Another study found that 84% of administered SSI doses failed to correct hyperglycemia.[9]

However, does adding basal insulin to SSI raise a patient's risk of hypoglycemia? When basal insulin is dosed carefully, the answer appears to be no. In a trial in which diabetic long-term care residents who were receiving SSI at baseline were randomized to either continued SSI or basal-bolus insulin, the investigators found that the basal-bolus group experienced significantly lower average blood glucose levels without an increase in adverse

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glycemic events.[10] Perhaps the most significant milestone to date, however, was the RABBIT 2 multicenter trial, published in 2007, that randomized hospitalized, insulin-naïve diabetics to either a weight-based regimen of basal and prandial insulin or SSI only.[11] Rates of hypoglycemia and length of stay did not differ between the groups, and 66% of patients receiving basal-prandial insulin achieved their glycemic control target as opposed to just 38% of patients in the SSI-only group. The SSI group also required more total insulin. A weight-based, basal-bolus strategy was later proven to be similarly effective, without causing severe hypoglycemia, for patients undergoing surgery who could not maintain consistent oral alimentation.[12] Basal-bolus insulin was associated with fewer surgical complications, and it produced a cost savings of $751 per day as determined by a *post hoc* comparative effectiveness study.[13]

Prolonged use of SSI as monotherapy may be not only ineffective but also harmful. Clearly, the absence of basal insulin will harm type 1 diabetics, who need basal insulin to prevent diabetic ketoacidosis. However, even for type 2 diabetics and nondiabetics, hyperglycemia has been established as a marker for adverse outcomes among hospitalized patients,[14] and SSI monotherapy has been associated with a three-fold higher risk of hyperglycemia compared with the use of a sliding scale plus other forms of insulin.[15] At least one other study has also linked this practice with a significantly increased length of stay compared with patients who were receiving insulin proactively.[16] We believe that the potential for harm is difficult to disregard, especially because safer alternatives are available. Ultimately, it can be stated that in hospitalized patients with persistent hyperglycemia who require insulin, SSI alone should not be the preferred treatment choice regardless of whether the patient carries a known diagnosis of diabetes mellitus or has used insulin previously.

WHEN YOU MIGHT CONSIDER USING SSI AS MONOTHERAPY

As discussed above, there is no known clinical scenario in which SSI as monotherapy has been proven to be effective; however, the use of SSI as monotherapy as a short-term approach has not been well studied. Hospitalized patients who are at risk for adverse glycemic events should be monitored with periodic finger-stick blood glucose draws per guidelines. In the first 24 hours, it may be reasonable to withhold basal insulin for insulin-naive patients, particularly if the medication reconciliation or other key components of the history are in doubt or if there are risk factors for hypoglycemia such as a history of bariatric surgery. The amount of insulin received in the first 24 hours of such monitoring may inform subsequent insulin dosing, but this method of "dose finding" has not been validated in the literature.

Uncertain or interrupted alimentation status or stress hyperglycemia may complicate the assessment of a patient's insulin needs. One of the insights from the RABBIT 2 surgery trial is that even with interrupted alimentation, patients on a weight-based, long-acting insulin regimen did not experience severe hypoglycemia. Nevertheless, if a patient without type 1 diabetes is felt to be at high risk for a severe hypoglycemic event, it may be prudent to withhold long-acting insulin. However, in that situation, adding SSI to finger-stick monitoring is unlikely to be beneficial. Cases of stress hyperglycemia in nondiabetics can also be challenging, as the persistence of hyperglycemia can be difficult to predict. Guidelines state that if hyperglycemia is persistent, then insulin therapy should be initiated and that this therapy is best accomplished in the form of a basal-prandial regimen.[17]

WHAT YOU SHOULD DO INSTEAD

Current guidelines from the American Diabetes Association[17] and the American Association of Clinical Endocrinologists[18] for hospitalized patients with hyperglycemia who require insulin recommend against the prolonged use of SSI as monotherapy (category A recommendation) and support the use of basal plus correctional insulin with the addition of nutritional insulin for patients with consistent oral intake (category A recommendation). Although a complete discourse on the determination of the appropriate starting dose of insulin is outside of the scope of this case presentation, the basic approach begins with calculating a weight-based total daily dose of insulin, approximately half of which can be given as basal insulin with the remainder given with meals along with correctional insulin as needed to account for premeal hyperglycemia.[4] For example, the protocol used in the RABBIT 2 trial, which involved known type 2 diabetics, started insulin based on a total daily dose of 0.4 units/kg for patients presenting with blood sugar levels ≤200 mg/dL and 0.5 units/kg for those with higher initial glucose levels.[7] Half of the total daily dose was given as basal insulin, and the other half was divided among meals. Caution with insulin dosing may be required in patients aged >70 years, in those with impaired renal function, and in situations in which steroid doses are fluctuating. The Society of Hospital Medicine has formulated an online subcutaneous insulin order implementation guideline, eQUIPS, that can be a helpful resource to centers that are interested in changing their practice patterns.[19]

RECOMMENDATIONS

- Instead of using SSI monotherapy for hospitalized patients who require insulin, add basal and prandial insulin, using a weight-based approach if necessary for insulin-naive patients.
- Engage with leadership at your center to learn how inpatient hyperglycemia protocols and blood sugar management teams can help provide evidence-based and individualized treatment plans for your patients.
- If no infrastructure exists at your center, the Society of Hospital Medicine offers training and guidance through its eQUIPS inpatient hyperglycemia management program.

CONCLUSION

In the case presentation, the hyperglycemic patient whose metformin was on hold should have been started on a combination of basal and prandial insulin as determined by his weight and current renal function as opposed to monotherapy with SSI. Using SSI as monotherapy for hyperglycemia is a

common practice, and although well-intentioned, it is an ineffective and possibly dangerous approach. Continued efforts must be made to address the gap between guidelines and suboptimal practice patterns locally and nationally.

Do you think this is a low-value practice? Is this truly a "Thing We Do for No Reason?" Share what you do in your practice and join in the conversation online by retweeting it on Twitter (#TWDFNR) and liking it on Facebook. We invite you to propose ideas for other "Things We Do for No Reason" topics by emailing TWDFNR@hospitalmedicine.org.

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A Protean Protein

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This icon represents the patient's case. Each paragraph that follows represents the discussant's thoughts.

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A 39-year-old man presented to a neurologist with three weeks of progressive leg weakness associated with numbness in his feet and fingertips. His medical history included hypertriglyceridemia, hypogonadism, and gout. He was taking fenofibrate and colchicine as needed. There was no family history of neurologic issues. He did not smoke or drink alcohol.

The patient appeared well with a heart rate of 76 beats per minute, blood pressure 133/72 mm Hg, temperature 36.6°C, respiratory rate 16 breaths per minute, and oxygen saturation 100% on room air. His cardiopulmonary and abdominal examinations were normal. His skin was warm and dry without rashes. On neurologic examination, upper extremity strength and sensation was normal. Bilateral hip flexion, knee flexion, and knee extension strength was 4/5; bilateral ankle dorsiflexion and plantar flexion strength was 3/5. Reflexes were trace in the arms and absent at the patellae and ankles. He had symmetric, length-dependent reduction in vibration, pinprick, and light touch sensation in his legs.

Peripheral neuropathy presenting with ascending symmetric motor and sensory deficits progressing over three weeks raises the suspicion of an acquired inflammatory demyelinating polyneuropathy (AIDP), a variant of Guillain-Barre Syndrome. Alternative causes of acute polyneuropathy include thiamine (B1) deficiency, vasculitis, sarcoidosis, or malignancy, particularly lymphoma and multiple myeloma. Further evaluation should include electromyography, nerve conduction studies, lumbar puncture with cerebrospinal fluid (CSF) protein, glucose, and cell count differential. Follow-up laboratory testing based on results of the above may include serum protein electrophoresis (SPEP), serum free light chains (sFLC), vitamin B12, human immunodeficiency virus (HIV), hepatitis B and C testing, antinuclear antibody, and erythrocyte sedimentation rate.

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Electromyography and nerve conduction studies revealed a sensorimotor mixed axonal/demyelinating polyneuropathy in all extremities. CSF analysis found one white cell per mm^3, glucose of 93 mg/dL, and protein of 313 mg/dL. Magnetic resonance imaging (MRI) of the spine without contrast showed normal cord parenchyma. The vitamin B12 level was 441 pg/mL (normal >200 pg/mL). Antibodies to HIV-1, HIV-2, hepatitis C virus, and Borrelia burgdorferi were negative. Serum protein electrophoresis (SPEP) and immunofixation were normal.

The patient received two courses of intravenous immunoglobulin (IVIG) for suspected AIDP. His weakness progressed over the next several weeks to the point that he required a wheelchair.

Progression of symptoms beyond three weeks and lack of response to IVIG are atypical for AIDP. Alternate diagnoses for a sensorimotor polyneuropathy should be considered. Causes of subacute or chronic demyelinating polyneuropathy include inflammatory conditions (chronic inflammatory demyelinating polyneuropathy [CIDP], connective-tissue disorders), paraprotein disorders (myeloma, amyloidosis, lymphoplasmacytic lymphoma), paraneoplastic syndromes, infectious diseases (HIV, Lyme disease), infiltrative disorders (sarcoidosis), medications or toxins, and hereditary disorders. Of these etiologies, the first three seem the most likely given the history and clinical course, the negative HIV and Lyme testing, and the absence of exposures and family history. Normal SPEP and immunofixation make paraprotein disorders less likely, but sFLC testing should be sent to evaluate for a light chain-only paraprotein. A paraneoplastic antibody panel and a CT of the chest, abdomen, and pelvis should be ordered to evaluate for sarcoidosis, lymphoma, or other malignancies. Although a peripheral nerve biopsy would further classify the polyneuropathy, it is of low diagnostic yield in patients with subacute and chronic distal symmetric polyneuropathies and is associated with significant morbidity. In the absence of history or physical exam findings to narrow the differential diagnosis for polyneuropathy, testing for paraneoplastic antibodies and imaging is appropriate.

The patient tested negative for antiganglioside GM1 and antimyelin-associated glycoprotein antibodies.

Urine arsenic, lead, and mercury levels were normal. Tests for serum antinuclear antibody, rapid plasmin reagin, and a paraneoplastic neuropathy panel including amphiphysin antibody, CV2 antibody, and Hu auto-antibody were negative. Repeat electrodiagnostic testing was consistent with CIDP. The patient received prednisone 60 mg daily for six weeks and was then tapered to 30 mg daily over six weeks. Concurrently, he underwent twelve cycles of plasma exchange. His strength improved, and he could walk with a cane; however, weakness recurred when steroids were further tapered.

He was maintained on prednisone 50 mg daily. Over the next year, the patient's lower extremities became flaccid and severely atrophied. He developed hyperpigmented patches on his trunk, severe gastroesophageal reflux disease (GERD), dysphonia, and gynecomastia. He had lost 60 pounds since symptom onset. He was prescribed levothyroxine for subclinical hypothyroidism (thyroid stimulating hormone 12.63 μIU/mL [normal 0.10-5.50 μIU/mL], free thyroxine 0.8 ng/dL [0.8-1.7 ng/dL]).

At this point, the diagnosis of CIDP should be questioned, and additional investigation is warranted. Although improvement was initially observed with plasma exchange and steroids, subsequent progression of symptoms despite prednisone suggests a nonimmune-mediated etiology, such as a neoplastic or infiltrative process. Conversely, negative serologic testing for paraneoplastic antibodies may be due to an antibody that has not been well characterized.

While prednisone could explain GERD and gynecomastia, the weight loss, dysphonia, and subclinical hypothyroidism may offer clues to the diagnosis underlying the neurological symptoms. Weight loss raises suspicion of a hypercatabolic process such as cancer, cachexia, systemic inflammation, heart failure, or chronic obstructive pulmonary disease. Causes of dysphonia relevant to this presentation include neurologic dysfunction related to malignant invasion of the vagus nerve or demyelinating disease. Subclinical hypothyroidism due to chronic autoimmune thyroiditis seems most likely in the absence of a medication effect or thyroid injury, yet infiltrative disorders of the thyroid (eg, amyloidosis, sarcoidosis, lymphoma) should also be considered. A diagnosis that unifies the neurologic and nonneurologic findings would be desirable; lymphoma with paraneoplastic peripheral neuropathy manifesting as CIDP seems most likely. As of yet, CT of the chest, abdomen, and pelvis or an 18-Fluoro-deoxyglucose positron emission tomography (FDG-PET) scan have not been obtained and would be helpful to evaluate for underlying malignancy. Further evaluation for a paraprotein disorder that includes sFLC is also still indicated to rule out a paraneoplastic disorder that may be associated with polyneuropathy.

Repeat SPEP and serum immunofixation were normal. sFLC assay showed elevated levels of both kappa and lambda light chains with a ratio of 0.61 (reference range: 0.26-1.25). Urine protein electrophoresis (UPEP) from a 24-hour specimen showed a homogenous band in the gamma region, but urine immunofixation demonstrated polyclonal light chains. The plasma vascular endothelial growth factor (VEGF) level was 612 pg/mL (reference range, 31-86 pg/mL).

CT imaging of the chest, abdomen, and pelvis with contrast demonstrated an enlarged liver and spleen and possible splenic infarcts. A skeletal survey and whole-body FGD-PET scan were normal. The patient declined bone marrow biopsy.

Polyneuropathy secondary to a monoclonal protein was previously considered, and an SPEP was normal. Full evaluation for a monoclonal protein additionally requires sFLC testing. If clinical suspicion remains high after a negative result, 24-hour UPEP and urine immunofixation should be obtained. Normal results in this case argue against the presence of a monoclonal protein.

The presence of a monoclonal protein and polyneuropathy are mandatory diagnostic criteria for POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), a plasma cell proliferative disorder. Major diagnostic criteria include osteosclerotic bone lesions, Castleman's disease, and markedly elevated VEGF levels. Castleman's disease is a lymphoproliferative disorder characterized by angiofollicular lymphoid hyperplasia that results in lymphadenopathy in one or multiple lymph node regions. Imaging studies reveal organomegaly, one of many minor criteria, but not bone lesions or lymphadenopathy. A diagnosis of POEMS syndrome requires the presence of both mandatory, one major, and one minor criteria. Since only one of two of the mandatory criteria are met at this point, a diagnosis of POEMS syndrome cannot be made.

Eighteen months after symptom onset, the patient presented to the emergency department with dyspnea, orthopnea, and lower extremity edema. B-type natriuretic peptide was 1564 pg/mL. Transthoracic echocardiography showed a severely dilated and hypertrophied left ventricle. Left ventricular ejection fraction was 20%. A furosemide infusion was initiated. Angiography of the coronary vessels was not performed. Congo red stain of an abdominal adipose biopsy was negative for amyloid.

On hospital day five, he developed gangrenous changes in his right first toe. CT angiography of the abdomen and lower extremities demonstrated patent three vessel runoff to the foot with an infrarenal aortic thrombus. Heparin infusion was started. On hospital day 10, the patient developed expressive aphasia and somnolence, prompting intubation for airway protection. MRI and MR angiography (MRA) of the brain and cerebral vessels revealed multiple bilateral acute ischemic strokes (Figure 1) without flow limiting stenosis in cerebral vessels.

These clinical developments lead to an important opportunity to rethink this patient's working diagnosis. The new diagnosis of heart failure in this young patient with polyneuropathy raises suspicion for an infiltrative cardiomyopathy such as amyloidosis, sarcoidosis, or Fabry disease. Of these, Fabry disease is the least likely because it is typically characterized by a painful burning sensation in response to specific triggers. Although

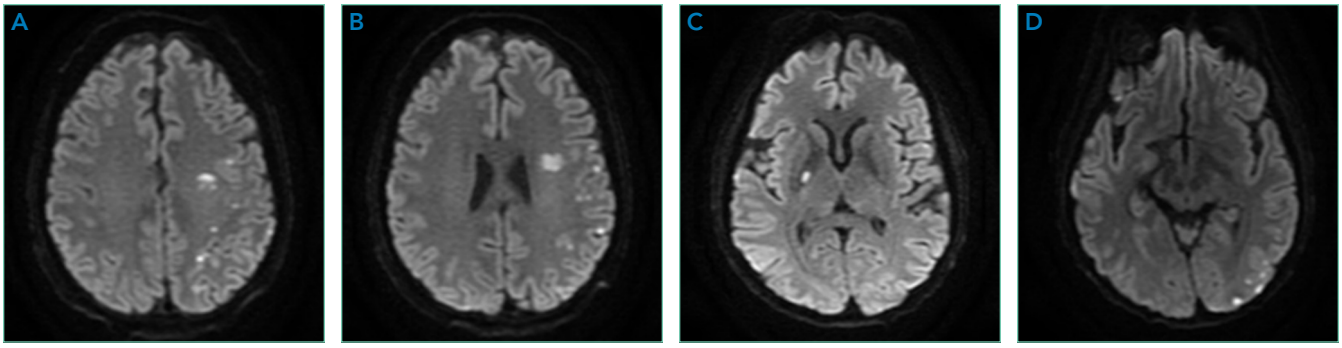


FIG 1. MRI images of reduced diffusion with associated fluid-attenuated inversion recovery (FLAIR) hyperintensity prominently involving the left hemisphere in left middle cerebral artery (A, B), right basal ganglia (C), and left posterior cerebral artery (D) distributions, read as numerous punctate acute infarcts involving multiple vascular territories.

polyneuropathy and heart failure may be concurrently observed with both sarcoidosis and amyloidosis, the absence of an apparent arrhythmia make amyloidosis the more likely of these two diagnoses. The development of an arterial thrombus and multiple strokes may represent emboli from a cardiac thrombus.

Cardiac imaging and tissue biopsy of the heart or other affected organs would distinguish between these diagnostic possibilities. An abdominal adipose biopsy negative for amyloid does not rule out amyloidosis, as the test is approximately 80% sensitive when cardiac amyloidosis is present and varies depending on the etiology of the amyloid protein (ie, light chain vs transthyretin). Evaluation of cardiac amyloid in the setting of peripheral neuropathy should include echocardiography (as was performed here) and repeat testing for a monoclonal protein.

If clinical suspicion of a paraprotein-associated disorder remains high and both SPEP and sFLC are normal, it is important to obtain a 24-hour UPEP and immunofixation. A monoclonal protein can be overlooked by SPEP and serum immunofixation if the monoclonal protein is composed only of a light chain or if the monoclonal protein is IgD or IgE. In these rare circumstances, sFLC analysis or 24-hour UPEP and immunofixation should mitigate the potential for a falsely negative SPEP/IFE. These studies are normal in this case, which argues against the presence of a monoclonal protein.

Transesophageal echocardiography showed grade IV atheromatous plaque within the descending thoracic aorta with mobile elements suggesting a superimposed thrombus; there was no intracardiac shunt or thrombus. MRA of the neck and great vessels was normal.

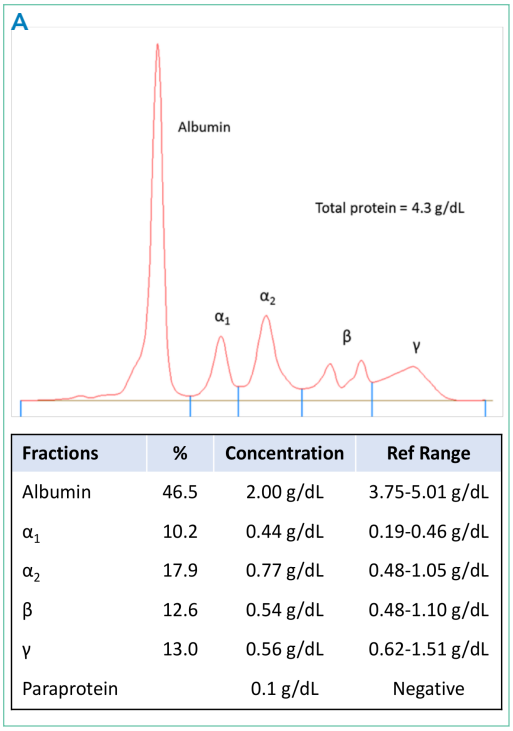
Testing for heparin-induced thrombocytopenia (HIT) was sent due to thrombocytopenia and the presence of thrombosis. An immunoassay for antiheparin-platelet factor 4 (anti-PF4) antibodies was substantially positive (optical density 2.178); however, functional testing with a washed platelet heparin-induced platelet activation assay was negative. Anticoagulation was changed to argatroban due to concern for HIT. Dry gangrenous changes developed in all distal toes on the right foot and three toes on the left foot. A right radial artery thrombus formed at the site of a prior arterial line.

Thrombocytopenia that develops between the fifth and tenth day following heparin exposure in a patient with new thromboses is consistent with HIT. However, the patient's infrarenal aortic thrombus preceded the initiation of heparin, and negative functional testing undermines the diagnosis of HIT in this case. Therefore, the arterial thromboses may be related to an underlying unifying diagnosis.

A third SPEP showed a 0.1 g/dL M-spike in the gamma region, but standard immunofixation did not reveal a monoclonal protein (Figure 2). However, a specific request for immunofixation testing using IgD antisera detected an IgD heavy chain. A lambda chain comprising 3% of urine protein was detected on 24-hour urine immunofixation but was not detectable by serum immunofixation. Bone marrow biopsy demonstrated plasma cells comprising 5% of bone marrow cellularity (Figure 3); flow cytometry of the aspirate demonstrated an abnormal lambda-restricted plasma cell population.

When a monoclonal protein is identified but does not react with standard antisera to detect IgG, IgM, and IgA, immunofixation with IgD and IgE antisera are necessary to rule out a monoclonal IgD or IgE protein. The underlying IgD isotype coupled with its low abundance made detection of this monoclonal protein especially challenging. With the discovery of a monoclonal protein in the context of polyneuropathy, the mandatory criteria of POEMS syndrome are met. The elevated VEGF level and hypothyroidism meet major and minor criteria, respectively. Arterial thromboses and heart failure are other features that may be observed in cases of POEMS syndrome.

POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes) was diagnosed. Prednisone was continued, and weekly cyclophosphamide was initiated. After six weeks, the VEGF level remained elevated, and a neurologic examination showed minimal improvement. Due to poor respiratory muscle strength and difficulty managing secre-



Fractions	%	Concentration	Ref Range
Albumin	46.5	2.00 g/dL	3.75-5.01 g/dL
α_1	10.2	0.44 g/dL	0.19-0.46 g/dL
α_2	17.9	0.77 g/dL	0.48-1.05 g/dL
β	12.6	0.54 g/dL	0.48-1.10 g/dL
γ	13.0	0.56 g/dL	0.62-1.51 g/dL
Paraprotein		0.1 g/dL	Negative

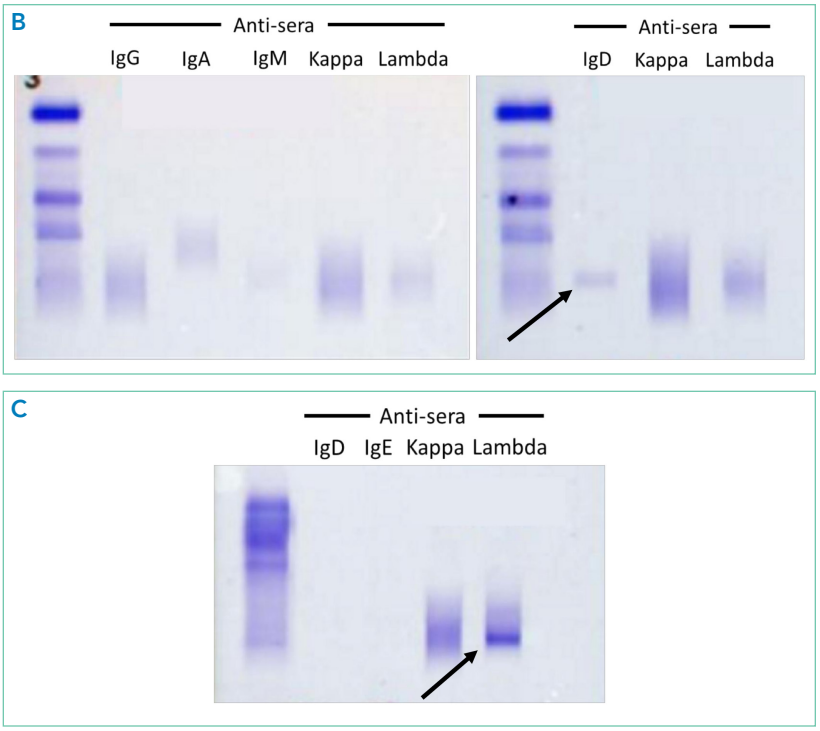


FIG 2. (A) Serum protein electrophoresis demonstrating a faint monoclonal peak in the gamma region and a detectable paraprotein. (B) Serum immunofixation electrophoresis did not detect a monoclonal protein with anti-sera against IgG, IgA, or IgM. However, additional testing against IgD revealed a monoclonal protein (marked with arrow). (C) Urine immunofixation electrophoresis detected a lambda chain (marked with arrow).

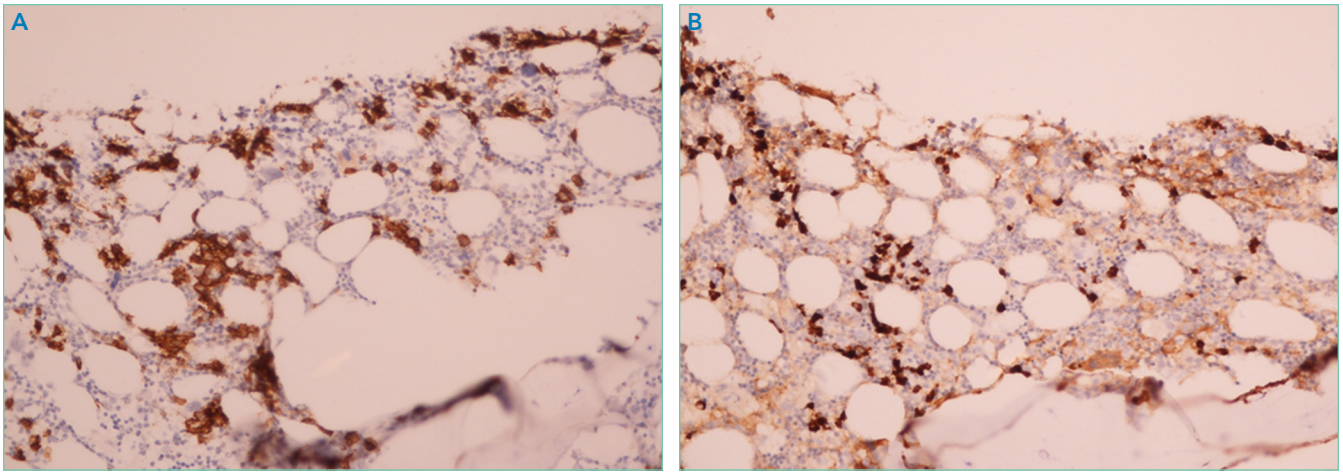


FIG 3. (A) Immunostaining for CD138, a plasma cell marker, on the bone marrow biopsy specimen highlighting ~5% of cells. (B) Lambda light chain predominance was demonstrated using a lambda specific immunostain. Flow cytometry was definitive for light chain restriction, confirming the presence of a monoclonal plasma cell disorder.

tions, he underwent percutaneous tracheostomy and gastrostomy tube placement. Unfortunately, his condition further deteriorated and he subsequently died of sepsis from pneumonia.

An autopsy revealed acute bronchopneumonia and multiple acute and subacute cerebral infarctions. There was extensive peripheral mixed axonal/demyelinating neuropathy, hepatosplenomegaly, atrophy of the thyroid and adrenal glands, hyperpigmented patches and thickened integument, and severe aortic and coronary atherosclerotic disease with a healed myocardial infarction.

DISCUSSION

POEMS syndrome[1] is a rare constellation of clinical and laboratory findings resulting from an underlying plasma cell proliferative disorder. This paraneoplastic syndrome is characterized by the chronic overproduction of proinflammatory and proangiogenic cytokines, including VEGF, which are postulated to drive its manifestations,[2] though the exact pathogenesis is not understood. Some of the disease's most common features are summarized by its name: polyneuropathy, organomegaly, endocrinopathy, monoclonal plasma cell disorder, and skin changes.[3]

TABLE. **International Myeloma Working Group (IMWG) Diagnostic Criteria for POEMS Syndrome**[1]

POEMS syndrome[a]	**Both of the following mandatory criteria:**
	Polyneuropathy
	Monoclonal plasma cell proliferative disorders (almost always λ-restricted)
	Any one of the following three major criteria:
	Sclerotic bone lesions
	Castleman's disease
	Elevated levels of VEGF[b]
	Any one of the following six minor criteria:
	Organomegaly (splenomegaly, hepatomegaly, or lymphadenopathy)
	Extravascular volume overload (edema, pleural effusion, or ascites)
	Endocrinopathy (adrenal, thyroid, pituitary, gonadal, parathyroid, pancreatic)
	Skin changes (hyperpigmentation, hypertrichosis, glomeruloid hemangiomata, acrocyanosis, flushing, white nails)
	Papilledema
	Thrombocytosis/polycythemia

[a]The diagnosis is confirmed when both of the mandatory, one of the three major, and one of the six minor criteria are met. However, not every patient meeting these criteria will have POEMS syndrome; the features should have a temporal association with each other and no other attributable cause

[b]IMWG suggest that VEGF measured in the serum be at least 3 to 4 times higher than the normal reference range to be regarded as a major criterion

Abbreviations: IMWG, International Medical Working Group; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes; VEGF, vascular endothelial growth factor.

The International Myeloma Working Group (IMWG) diagnostic criteria[1] (Table) require the presence of both mandatory criteria (polyneuropathy and monoclonal plasma cell proliferation), plus at least one major and one minor criterion. Delayed diagnosis or misdiagnosis of this protean disorder is often driven by its rarity and clinical overlap with other paraprotein-associated polyneuropathies. These include amyloidosis, cryoglobulinemia, and monoclonal gammopathy of undetermined significance (MGUS), which can all produce antibodies directed against neural antigens. In addition, polyneuropathy is often the first and most striking manifestation of POEMS syndrome, fostering confusion with CIDP as both disorders are subacute, symmetric, motor-dominant, mixed axonal/demyelinating polyneuropathies.[4]

IgD and IgE monoclonal gammopathies are extremely rare. IgD myeloma, for instance, accounts for 2% of multiple myeloma cases, and IgE myeloma has been reported fewer than 50 times.[5] IgD is secreted only in very small amounts, ordinarily representing 0.25% of the immunoglobulins in serum, while the majority is found in the plasma membranes of mature B-cells.[6] These monoclonal gammopathies often escape detection for two reasons: (1) the very low paraprotein concentration produces undetectable or small M-protein levels on electrophoresis,[5] and (2) immunofixation is routinely performed without antisera against IgD and IgE heavy chains.[7]

While this case depicts a rare manifestation of a rare disease, the principles underlying its elusive diagnosis are routinely encountered. Recognition of the specific limitations of the SPEP, UPEP, sFLC, and immunofixation tests, outlined below, can assist the hospitalist when suspicion for paraproteinemia is high.

First, low levels of monoclonal proteins may be associated with a normal SPEP. Accordingly, suspicion of a plasma cell dyscrasia should prompt serum immunofixation, even when the electrophoretic pattern appears normal.[8]

Second, laboratories routinely perform immunofixation with antisera against IgG, IgA, and IgM heavy chains and kappa and lambda light chains, whereas testing with IgD or IgE antisera must be specifically requested. Thus, clinicians should screen for the presence of IgD and IgE in patients with an apparently free monoclonal immunoglobulin light chain in the serum or with a monoclonal serum protein and negative immunofixation. In this case, the paraprotein was not detected on the first two serum electrophoreses, likely due to a low serum concentration, then missed on immunofixation due to a lack of IgD antiserum. On admission to the hospital, this patient had a very low paraprotein concentration (0.1 g/dL) on SPEP, and the lab initially reported negative immunofixation. When asked to test specifically for IgD and IgE, the lab ran a more comprehensive immunofixation revealing IgD heavy chain paraprotein.

Third, this case illustrates the limitations of the sFLC assay. IMWG guidelines specify that sFLC assay in combination with SPEP and serum immunofixation is sufficient to screen for monoclonal plasma cell proliferative disorders other than light chain amyloidosis (which requires all the serum tests as well as 24-hour urine immunofixation).[9] Though the sFLC assay has been demonstrated to be more sensitive than urine analysis for detecting monoclonal free light chains,[10] it is still subject to false negatives. Polyclonal gammopathy or reduced renal clearance with accumulation of free light chains in the serum may mask the presence of low levels of monoclonal sFLC,[11] the latter of which likely explains why the sFLC ratio was repeatedly normal in this case. In these circumstances, monoclonal free light chains can be identified by urine studies.[11] In this case, 24-hour urine immunofixation detected the excess light chain that was not evident on the sFLC assay. Even with these pitfalls in mind, there is still no evident explanation as to why the 24-hour urine studies done prior to the patient's hospital admission did not reveal a monoclonal light chain.

This case also highlights the thrombotic diathesis in POEMS syndrome. Although the patient was treated with argatroban

for suspected HIT, it is likely that the HIT antibody result was a false positive, and his thrombi were better explained by POEMS syndrome in and of itself. Coronary, limb, and cerebral artery thromboses have been linked to POEMS syndrome,[12,13] all of which were present in this case. Laboratory testing for HIT involves an immunoassay to detect circulating HIT antibody and a functional assay to measure platelet activity in the presence of patient serum and heparin. The immunoassay binds anti-PF4/heparin complex irrespective of its ability to activate platelets. The presence of nonspecific antibodies may lead to cross-reactions with the immunoassay test components, which has been demonstrated in cases of MGUS.[14] In this case, elevated production of monoclonal antibodies by plasma cells may have led to false-positive results. With moderate to high clinical suspicion of HIT, the combination of a positive immunoassay and negative functional assay (as in this case) make the diagnosis of HIT indeterminate.[15]

TEACHING POINTS

- If a monoclonal protein is suggested by SPEP but cannot be identified by standard immunofixation, request immunofixation for IgD or IgE. Screen patients for IgD and IgE paraproteins before making a diagnosis of light chain multiple myeloma.
- Polyclonal gammopathy or reduced renal clearance with accumulation of free light chains in the serum may mask the presence of low levels of monoclonal FLC and result in a normal sFLC ratio.
- Thrombosis is a less-recognized but documented feature of POEMS syndrome which may be mediated by the overproduction of proinflammatory and proangiogenic cytokines, though the precise pathogenesis is unknown.

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Ethical Considerations in the Care of Hospitalized Patients with Opioid Use and Injection Drug Use Disorders

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"Lord have mercy on me, was the kneeling drunkard's plea."
—*Johnny Cash*

The Diagnostic and Statistical Manual of the American Psychiatric Association defines opioid-use disorder (OUD) as a problematic pattern of prescription and/or illicit opioid medication use leading to clinically significant impairment or distress.[1] Compared with their non-OUD counterparts, patients with OUD have poorer overall health and worse health service outcomes, including higher rates of morbidity, mortality, HIV and HCV transmission, and 30-day readmissions.[2] With the rate of fatal overdoses from opioids at crisis levels, leading scientific and professional organizations have declared OUD to be a public health emergency in the United States.[3]

The opioid epidemic affects hospitalists through the rising incidence of hospitalization, not only as a result of OUD's indirect complications, but also its direct effects of intoxication and withdrawal.[4] In caring for patients with OUD, hospitalists are often presented with many ethical dilemmas. Whether the dilemma involves timing and circumstances of discharge or the permission to leave the hospital floor, they often involve elements of mutual mistrust. In qualitative ethnographic studies, patients with OUD report not trusting that the medical staff will take their concerns of inadequately treated pain and other needs seriously. Providers may mistrust the patient's report of pain and withhold treatment for OUD for nonclinical reasons.[5] Here, we examine two ethical dilemmas specific to OUD in hospitalized patients. Our aim in describing these dilemmas is to help hospitalists recognize that targeting issues of mistrust may assist them to deliver better care to hospitalized patients with OUD.

DISCHARGING HOSPITALIZED PATIENTS WITH OUD

In the inpatient setting, ethical dilemmas surrounding discharge are common among people who inject drugs (PWID). These patients have disproportionately high rates of soft tissue and systemic infections, such as endocarditis and osteomyelitis, and subsequently often require long-term, outpatient parenteral antibiotic therapy (OPAT).[6] From both the clinical and ethical perspectives, discharging PWID requiring OPAT to an unsupervised setting or continuing inpatient hospitalization to prevent a potential adverse event are equally imperfect solutions.

These patients may be clinically stable, suitable for discharge, and prefer to be discharged, but the practitioner's concerns regarding untoward complications frequently override the patient's wishes. Valid reasons for this exercise of what could be considered soft-paternalism are considered when physicians unilaterally decide what is best for patients, including refusal of community agencies to provide OPAT to PWID, inadequate social support and/or health literacy to administer the therapy, or varying degrees of homelessness that can affect timely follow-up. However, surveys of both hospitalists and infectious disease specialists also indicate that they may avoid discharge because of concerns the PWID will tamper with the intravenous (IV) catheter to inject drugs.[7] This reluctance to discharge otherwise socially and medically suitable patients increases length of stay,[7] decreases patient satisfaction, and could lead to misuse of limited hospital resources.

Both patient mistrust and stigmatization may contribute to this dilemma. Healthcare professionals have been shown to share and reflect a long-standing bias in their attitudes toward patients with substance-use disorders and OUD, in particular.[8] Studies of providers' attitudes are limited but suggest that legal concerns over liability and professional sanctions,[9] reluctance to contribute to the development or relapse of addiction,[10] and a strong psychological investment in not being deceived by the patient[11] may influence physicians' decisions about care.

Closely supervising IV antibiotic therapy for all PWID may not reflect current medical knowledge and may imply a moral assessment of patients' culpability and lack of will power to resist using drugs.[12] No evidence is available to suggest that inpatient parenteral antibiotic treatment offers superior adherence, and emerging evidence showing that carefully selected patients with an injection drug-use history can be safely and effectively treated as outpatients has been obtained.[13,14] Ho et al. found high rates of treatment success in patients with adequate housing, a reliable guardian, and willingness to comply with appropriate IV catheter use.[13] Although the study by Buehrle et al. found higher rates of OPAT failure among PWIDs, 25% of these

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failures were due to adverse drug reactions and only 2% were due to documented line manipulations.[14] This research suggests that disposition to alternative settings for OPAT in PWID may be feasible, reasonable, and deserving of further study. Rather than treating PWIDs as a homogenous group of increased risk, contextualizing care based on individual risk stratification promotes more patient-centered care that is medically appropriate and potentially more cost efficient. A thorough risk assessment includes medical evaluation of remote versus recent drug use, other psychiatric comorbidities, and a current willingness to avoid drug use and initiate treatment for it.

Patient-centered approaches that respond to the individual needs of patients have altered the care delivery model in order to improve health services outcomes. In developing an alternative care model to inpatient treatment in PWID who required OPAT, Jafari et al.[15] evaluated a community model of care that provided a home-like residence as an alternative to hospitalization where patients could receive OPAT in a medically and socially supportive environment. This environment, which included RN and mental health staff for substance-use counseling, wound care, medication management, and IV therapy, demonstrated lower rates of against medical advice (AMA) discharge and higher patient satisfaction compared with hospitalization.[15]

MOBILITY OFF OF THE HOSPITAL FLOOR FOR HOSPITALIZED PATIENTS WITH OUD

Ethical dilemmas may also arise when patients with OUD desire greater mobility in the hospital. Although some inpatients may be permitted to leave the floor, some treatment teams may believe that patients with OUD leave the floor to use drugs and that the patient's IV will facilitate such behavior. Nursing and medical staff may also believe that, if they agree to a request to leave the floor, they are complicit in any potential drug use or harmful consequences resulting from this use. For their part, patients may have a desire for more mobility because of the sometimes unpleasant constraints of hospitalization, which are not unique to these patients[16] or to distract them from their cravings. Patients, unable to tolerate the restriction emotionally or believing they are being treated unfairly, even punitively, may leave AMA rather than complete needed medical care. Once more, distrust of the patient and fear of liability may lead hospital staff to respond in counterproductive ways.

Addressing this dilemma depends, in part on creating an environment where PWID and patients with OUD are treated fairly and appropriately for their underlying illness. Such treatment includes ensuring withdrawal symptoms and pain are adequately treated, building trust by empathically addressing patients' needs and preferences,[17] and having a systematic (ie, policy-based) approach for requests to leave the floor. The latter intervention assures a transparent, referable standard that providers can apply and refer to as needed.

Efforts to adequately treat withdrawal symptoms in the hospital setting have shown promise in maintaining patient engagement, reducing the rate of AMA discharges, and improving follow up with outpatient medical and substance-use treatment.[18] Because physicians consistently cite the lack of advanced training in addiction medicine as a treatment limitation,[12] training may go a long way in closing this knowledge and skill gap. Furthermore, systematic efforts to better educate and train hospitalists in the care of patients with addiction can improve both knowledge and attitudes about caring for this vulnerable population,[19] thereby enhancing therapeutic relationships and patient centeredness. Finally, institutional policies promoting fair, systematic, and transparent guidance are needed for front-line practitioners to manage the legal, clinical, and ethical ambiguities involved when PWID wish to leave the hospital floor.

ENHANCING CARE DELIVERY TO PATIENTS WITH OUD

In addressing the mistrust some staff may have toward the patients described in the preceding ethical dilemmas, the use of universal precautions is an ethical and efficacious approach that balances reliance on patients' veracity with due diligence in objective clinical assessments.[20] These universal precautions, which are grounded in mutual respect and responsibility between physician and patient, include a set of strategies originally established in infectious disease practice and adapted to the management of chronic pain particularly when opioids are used.[21] They are based on the recognition that identifying which patients prescribed opioids will develop an OUD or misuse opioids is difficult. Hence, the safest and least-stigmatizing approach is to treat all patients as individuals who could potentially be at risk. This is an ethically strong approach that seeks to balance the competing values of patent safety and patient centeredness, and involves taking a substance-use history from all patients admitted to the hospital and routinely checking state prescription-drug monitoring programs among other steps. Although self-reporting, at least of prescription-drug misuse, is fairly reliable,[22] establishing expectations for mutual respect when working with patients with OUD and other addictive disorders is more likely to garner valid reports and a positive alliance. Once this relationship is established, the practitioner can respond to problematic behaviors with clear, compassionate limit setting.

From a broader perspective, a hospital system and culture that is unable to promote trust and adequately treat pain and withdrawal can create a "risk environment" for PWID.[23] When providers are inadequately trained in the management of pain and addiction, or there is a shortage of addiction specialists, or inadequate policy guidance for managing the care of these patients, this can result in AMA discharges and reduced willingness to seek future care. Viewing this problem more expansively may persuade healthcare professionals that patients alone are not entirely responsible for the outcomes related to their illness but that modifying practices and structure at the hospital level has the potential to mitigate harm to this vulnerable population.

As inpatient team leaders, hospitalists have the unique opportunity to address the opioid crisis by enhancing the quality of care provided to hospitalized patients with OUD. This

enhancement can be accomplished by destigmatizing substance-use disorders, establishing relationships of trust, and promoting remedies to structural deficiencies in the healthcare system that contribute to the problem. These approaches have the potential to enhance not only the care of patients with OUD but also the satisfaction of the treatment team caring for these patients.[24] Such changes will ideally allow physicians to better treat the illness, address ethical and clinical concerns when they arise, and promote enhanced participation in treatment planning.

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Optimizing Well-being, Practice Culture, and Professional Thriving in an Era of Turbulence

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In 2010, the *Journal of Hospital Medicine* published an article proposing a "talent facilitation" framework for addressing physician workforce challenges.[1] Since then, continuous changes in healthcare work environments and shifts in relevant policies have intensified a sense of clinician workforce crisis in the United States,[2,3] often described as an epidemic of burnout. Unfortunately, hospital medicine remains among the specialties most impacted by high burnout rates and related turnover.[4-6]

THE HEALTHCARE TALENT IMPERATIVE

Despite efforts to address the sustainability of careers in hospital medicine, common approaches remain mostly reactive. Existing research on burnout is largely descriptive, focusing on the magnitude of the problem,[3] the links between burnout and diminished productivity or turnover,[7] and the negative impact of burnout on patient care.[8,9] Improvement efforts often focus on rescuing individuals from burnout, rather than prevention.[10] While evidence exists that both individually targeted interventions (eg, mindfulness-based stress reduction) and institutional changes (eg, improvements in the operation of care teams) can reduce burnout, efforts to promote individuals' resilience appear to have limited impact.[11,12]

Given our field's reputation for innovation, we believe hospitalist groups must lead the way in developing practical solutions that enhance the well-being of their members, by doing more than exhorting clinicians to "heal themselves" or imploring executives to fix care delivery systems. In this article, we describe an approach to increase resilience and well-being in a large, academic hospital medicine practice and offer an emerging list of best practices.

FROM BURNOUT TO WELL-BEING—A PARADIGM SHIFT

Maslach et al. demonstrated that burnout reflects an individual's experience of emotional exhaustion, depersonalization of human interactions, and decreased sense of accomplishment at work.[13] Updated frameworks emphasize that well-being and lower burnout arise from workflow efficiency, a surrounding culture of wellness, and attention to individual resilience.[14] Emerging evidence suggests that burnout and well-being are, in part, a collective experience.[15] As outlined in the recently published "Charter on Physician Well-being,"[16] this realization creates an opportunity for clinical groups to enhance collective well-being—or thriving—rather than asking individuals to take personal responsibility for resilience or waiting for a top-down system redesign to fix drivers of burnout.

APPLYING THE NEW PARADIGM TO HOSPITAL MEDICINE

In 2013, our academic hospital medicine group set a new vision: To become the best in the nation by being an outstanding place to work. We held an inclusive divisional strategic planning retreat, which focused on clarifying the group's six core values and exploring how to translate the values into structures, processes, and behaviors that reinforced, rather than undermined, a positive work environment. We used these initial themes to create 16 novel interventions from 2014-2017 (Figure).

Notably, we pursued this work without explicit support or interference from senior leaders in our institution. There were no competing organizational efforts addressing hospitalist efficiency, turnover, or burnout until 2017 (Excellence in Communication, described below). Furthermore, we avoided individually targeted resilience efforts based on feedback from our group that "requiring resilience activities is like blaming the victim." Intervention participation was not mandatory, out of respect for individual choice and to avoid impeding hospitalists' daily work.

Before designing interventions, we created a measurement tool to assess our existing culture and track evolution over time (available upon request). We utilized the instrument to provoke emotional responses, surface paradoxes, uncover assumptions, and engage the group in iterative dialog that informed and calibrated interventions. The instrument itself drew from validated elements of existing tools to quantify perceptions across nine domains: meaningful work, autonomy, professional development, logistical support, health, fulfillment outside of work, collegiality, organizational learning, and safety culture.

Several subsequent interventions focused on the emotional experience of work. For example, we developed a formal mechanism (Something Awesome) for members to share the

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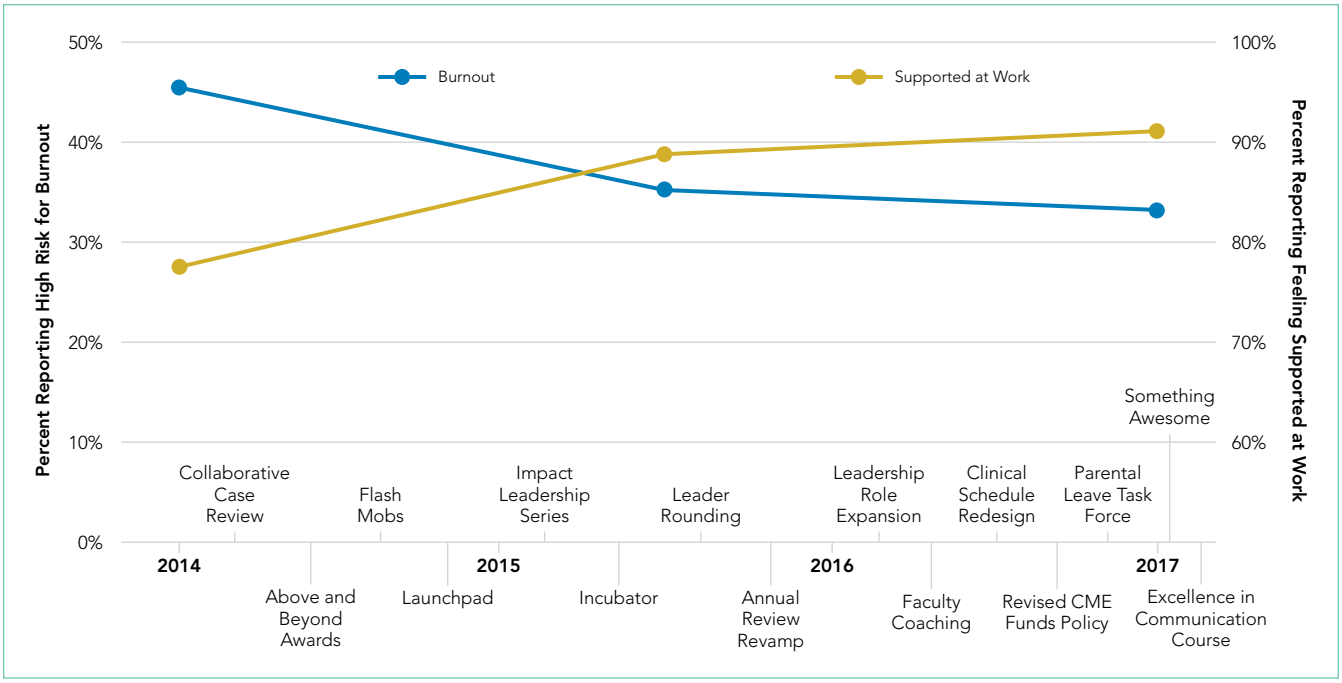

FIG. Interventions Made over Time to Enhance Resilience, Well-being, and Burnout.

experience of positive emotions during daily work (eg, gratitude and awe) for five minutes at monthly group meetings. We created a Collaborative Case Review process, allowing members to submit concerning cases for nonpunitive discussion and coaching among peers. Finally, we created Above and Beyond Awards, through which members' written praise of peers' extraordinary efforts were distributed to the entire group.

We also pursued interventions designed to increase empathy and translate it to action. These included leader rounding on our clinical units, which sought to recognize and thank individuals for daily work and to uncover exigent needs, such as food or assistance with conflict resolution between services. We created "Flash Mobs" or group conversations, which are facilitated by a leader and convened in the hospital, in order to hear from people and discuss topics of concern in real time, such as increased patient volumes. Likewise, we established "The Incubator," a half-day meeting held four to six times annually when selected clinical faculty applied design thinking techniques to create, test, and implement ideas to enhance workplace experience (eg, supplying healthy food to our common work space at low cost).

Another key focus was professional development for group members. Examples included a three-year development program for new faculty (LaunchPad), increasing the number of available leadership roles for aspiring leaders, modifying annual reviews to focus on increasing individuals' strengths-based work rather than solely grading performance, and creating a peer-support coaching program for newly hired members. In 2017, we began offering members a full shift credit to attend the hospital's four-hour Excellence in Communication course, which covers six high-yield skills that increase efficiency, efficacy, and joy in practice.

Finally, we revised a number of structures and operational processes within our group's control. We created a task force to address the needs of new parents and acquired a lactation room in the hospital. Instead of only covering offsite conference attendance (our old policy), we enhanced autonomy regarding use of continuing education dollars to allow faculty to fund any activity supporting their clinical practice. Finally, we applied quality improvement methodology to redesign the clinical schedule. This included blending value-stream mapping, software solutions, and a values-based framework to analyze proposed changes through the lens of waste elimination, IT feasibility, *and* whether the proposed changes aligned with the group's core values.

IMPACT ON GROUP CULTURE AND WELL-BEING

We examined the impact of these tactics on workplace experience over a four-year period (Figure). In 2014, 30% of group members reported psychological safety, 24% had become more callous toward people in their current job, and 45% were experiencing burnout. By 2017, 59% felt a sense of psychological safety (69% increase), 15% had become more callous toward people (38% decrease), and 33% were experiencing burnout (27% decrease). Average annual turnover in the five years before the first survey was 13.2%; turnover declined during the intervention period to 6.6% (adjusted for increased number of positions). While few comprehensive models exist for calculating well-being program return on investment, the American Medical Association's calculator[17] demonstrated our group's cost of burnout plus turnover in 2013 was $464,385 per year (assumptions in Appendix 1). We spent $343,517 on the 16 interventions between 2013 and 2017, representing an aver-

age annual cost of $86,000: $190,094 to buy-down clinical time for new leadership roles, $133,023 to fund time for the Incubator, $2,500 on gifts and awards, $4,900 on program supplies, and $10,000 on leadership training.

BEST PRACTICES FOR HOSPITALIST GROUPS

Based on the current literature and our experience, hospital medicine groups seeking to improve culture, resilience, and well-being should:

- Collaborate to define the group's sense of purpose. Mission and vision are important, but most of the focus should be on surfacing, naming, and agreeing upon the group's essential core values—the beliefs that inform whether hospitalists see the workplace as attractive, fair, and sustainable. Utilizing an expert, neutral facilitator is helpful.
- Assess culture—including, but not limited to, individual burnout and well-being—using preexisting questions from validated instruments. As culture is a product of systems, team climate, and leadership, measurement should include these domains.
- Monitor and share anonymous data from the assessment regularly (at least annually) as soon as possible after survey results are available. The data should drive inclusive, open, nonjudgmental dialog among group members and leaders in order to clarify, explore, and refine what the data mean.
- Undertake improvement efforts that emerge from the steps above, with a balanced focus on the three domains of well-being: efficiency of practice, culture of wellness, and personal resilience. Modify the number and intensity of interventions based on the group's readiness and ability to control change in these domains. For example, some groups may have more excitement and ability to work on factors impacting the efficiency of practice, such as electronic health record templates, while others may wish to enhance opportunities for collegial interaction during the workday.
- Strive for codesign. Group members must be an integral part of the solution, rather than simply raise complaints with the expectation that leaders will devise solutions. Ideally, group members should have time, funding, or titles to lead improvement efforts.
- Opportunities to improve resilience and well-being should be widely available to all group members, but should not be mandatory.

CONCLUSION

The healthcare industry will continue to grapple with high rates of burnout and rapid change for the foreseeable future. We believe significant improvements in burnout rates and workplace experience can result from hospitalist-led interventions designed to improve experience of work among hospitalist clinicians, even as we await broader and necessary systematic efforts to address structural drivers of professional satisfaction. This work is vital if we are to honor our field's history of productive innovation and navigate dynamic change in healthcare by attracting, engaging, developing, and retaining our most valuable asset: our people.

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Admittedly Simple? The Quest for Clarity in Medicare Claims Data

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Every reader of a certain age will recognize this acronym: ADCVANDIML. In simpler times, we "admitted" to a location: medical intensive care unit, bone marrow transplant unit. At some point, admission orders changed from a synonym for "hospitalize" to chart evidence necessary for inpatient payment to the hospital. In the billing and payment world, "inpatient" and "outpatient" hospitalizations are paid at different rates. Observation stays are one type of "outpatient hospitalization," a confusing and contradictory term to physicians and patients alike. In their article published in this month's *Journal of Hospital Medicine*, Sheehy and colleagues attempt the herculean task of defining a reproducible methodology to identify observation hospital stays using Medicare claims data.[1] They highlight the complexity of claims data, the variability of revenue codes used, and the probable high frequency of status changes from outpatient observation to inpatient, and vice-versa, during a single hospitalization. They also argue for reform to simplify payment policy for hospitalized patients.

In October 2013, the Center for Medicare and Medicaid Services (CMS) changed the definition of "inpatient" in the Hospital Inpatient Prospective Payment System rule.[2] This change is known colloquially as the "two-midnight rule" and occurred on the heels of several years of Recovery Audit contractor (RAC) retroactive denials of short-stay inpatient payments to hospitals around the country. These denials appear to have been based solely on the visit status under which a claim was billed, rather than a dispute over the actual medical care delivered.[3] The RAC audits alleged billions of dollars of improper payment to hospitals and resulted in a log-jam of hundreds of thousands of cases in the federal appeal system.[4] The two-midnight rule altered the subjective characterization of an inpatient from patient-based (severity of illness) and physician-based (intensity of service) to an objective, time-based payment definition. For the hospital to submit a claim to Medicare Part A, a medical provider with admitting privileges should expect that the patient will need, for medically necessary reasons, a hospitalization that will span at least two midnights of hospital care. Notable exceptions to the rule include patients undergoing a procedure on the Medicare Inpatient Only list and hospitalizations that include an unplanned mechanical intubation. To receive payment for observation (an outpatient service billed under Part B) the physician must place an observation order in addition to other requirements. At its core, the two-midnight rule is a payment rule, not a patient care rule.

This change in the criteria for an inpatient hospitalization from a subjective to a more objective and measurable time-based criterion might lead us to believe that the process for determining the correct visit status would now be simple. Unfortunately, we are dealing with a messy real-world scenario, where doctors can make different judgments and patients can have an unpredictable hospital course. Physicians are familiar with the issues surrounding the choice of the "correct" admission order. In many hospitals, the Medicare patients in "observation" and those with an "inpatient" order can be on the same floor and even share the same room. From a hospital resource, nurse's, and physician's standpoint, the patients are often indistinguishable. While some facilities have observation units often associated with their emergency departments, the elderly and those patients with certain comorbidities can be excluded from these units based on protocols designed to improve outcomes and patient safety.

Additionally, most patients who spend at least one night in the hospital for medical treatment would not think that they could be an "outpatient." To address this, CMS has produced specific beneficiary information[5] and now requires hospitals to provide patients with the Medicare outpatient observation notice (MOON) if patients spend more than 24 hours in observation status.[6] Beneficiaries must sign this notice, but unlike those admitted as inpatients, Medicare observation patients have no appeal rights. Recent articles in the lay press highlight the interplay between observation status, out-of-pocket expenses, and impact on postacute care.[7,8]

Following the implementation of the two-midnight rule, CMS directed the regional Medicare Administrative Contractors to perform audits in every hospital in the country. This has led to system-based processes at most facilities directing the "proper" visit class orders for our patients: direct education to providers, electronic medical record fixes and hard-stops, and real-time communications from the utilization review nurses and staff. These processes, based on a payment rule are burdensome to patients, physicians, and hospital support staff.

It's not surprising to see that the billing of hospital-based observation care is also a quagmire. The methods and results sections of Sheehy et al.'s article reads like a calculus textbook written in a foreign language on first pass, even to an expert.

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Adding to an already complex issue, since October 2013, a hospital's Utilization Review physicians can also "self-deny" Medicare inpatient stays that do not meet the two-midnight rule payment criteria and still bill for most of Part B charges. These cases are sometimes referred to as "Part A to B rebills" and may or may not have been captured in the claims data reported by CMS and reviewed by Sheehy et al. These cases represent another important status change that should be tracked.

There is a multitude of opinions on the pros and cons of observation care as a payment policy, and the data presented by Sheehy et al. is further evidence that the line between inpatient and observation hospitalizations remains blurred and mutable. The authors demonstrate the need for a consistent methodology to define observation stays and ultimately to study them using claims-based data. Simplicity may be the answer, but first, we must know what we are doing, then we can have a debate on whether or not it needs to change.

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Should the Diagnosis of UTI in Young Febrile Infants Require a Positive Urinalysis?

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Reduction of antibiotic overuse is an important goal for improving the quality of care for children and is highlighted in many of the *Choosing Wisely*® recommendations across disciplines.[1-3] However, the evidence supporting these recommendations vary widely and many are derived from expert opinion and clinical practice guidelines rather than from original research studies.[2] In this issue of the *Journal of Hospital Medicine*, Schroeder and colleagues identify a potential area of antibiotic overuse among young febrile infants with possible urinary tract infection (UTI).[4] A wide variation in antibiotic treatment rates (0%-35%) was observed across 124 hospitals in the United States for febrile infants 7-60 days of age with uropathogen detection by urine culture but a negative urinalysis (UA). Treated infants with a negative UA were more likely to be younger (7-30 days), have respiratory symptoms, and were less likely to have abnormal inflammatory markers than infants with a positive UA.

Clinicians faced with the decision of whether or not to treat a febrile infant with uropathogen detection in the setting of a negative UA must weigh the potential benefits and harms of antibiotic use in this population. Withholding antibiotics for a young infant with UTI may increase the risk of recurrent UTI and renal scarring,[5,6] while antibiotic treatment in young infants can lead to the disruption of the gut microbiome, resulting in long-term consequences that are only beginning to be understood.[7-10]

The American Academy of Pediatrics (AAP) UTI practice parameter requires a positive UA to establish the diagnosis of UTI in children 2-24 months of age.[11] This recommendation is based primarily on studies demonstrating that uropathogen detection in the setting of a negative UA commonly represents asymptomatic bacteriuria or contamination rather than true infection.[12-14] This is supported by research showing that the UA demonstrates near perfect (>99%) sensitivity for UTI in children with bacteremic UTI,[12,15] and studies demonstrating lower rates of subsequent urinary infections and renal injury among infants with uropathogen detection and a negative UA compared with those with uropathogen detection and a positive UA.[13,14,16]

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An important question is whether febrile infants within the first two months of life with uropathogen detection should be treated with antimicrobials regardless of UA findings or specifically in the setting of a negative UA. The AAP practice guideline[11] deliberately omits these young infants, recognizing that evidence derived from studies of older infants and children may not be applicable to this young age group, as they may not mount as robust an inflammatory response and thus may not demonstrate pyuria in the setting of a bacterial urinary infection. Schroeder et al. demonstrate lower rates of abnormal inflammatory markers in UA negative compared with UA positive infants, a finding the authors argue supports the possibility of asymptomatic bacteriuria or contamination rather than true infection.[4] The counterargument is that young infants may not mount a significant inflammatory response to true infections.

The authors appropriately highlight the paucity of literature to help differentiate true infection from asymptomatic bacteriuria or contamination in infants less than two months of age. As infants in this age group are usually treated with antibiotics for a positive urine culture regardless of UA result, robust data on short- and long-term outcomes of untreated infants are lacking. Much of the existing literature evaluates the test performance of the UA for UTI using the urine culture as the reference standard, which presents inherent limitations with incorporating the results of the UA into the definition of UTI using these data. Additionally, reported test performance of the UA for UTI varies by uropathogen type,[17] fever duration,[18] associated bacteremia,[19] and urine concentration,[20] which are important considerations when applying a strict definition of UTI that includes the UA in this age group. Conversely, more recent studies have demonstrated improved sensitivity of the dipstick and microscopic UA for the detection of UTI.[15,20,21] The improved test performance may not only enhance the use of the UA as a screen for UTI in this high-risk population but also allow its potential inclusion into the definition of UTI as the authors suggest, as previous false-negative UTIs would be less frequent with improved UA testing modalities.

Ultimately, what's missing from the equation is whether treatment of young febrile infants with uropathogen detection in the setting of a negative UA affects either short-term or long-term complications of UTI. Unfortunately, limited information exists to help inform the decision to initiate antibiotic treatment for these infants. Ideally, this question can only be answered by either an observational study evaluating outcomes of untreated infants or a randomized trial of antibiot-

ics for infants less than two months of age with uropathogen detection in the setting of a negative UA. Until then, we may continue to observe a wide variation in antibiotic treatment rates for febrile young infants with uropathogen detection in the setting of a negative UA.

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