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Sound and Light Levels Are Similarly Disruptive in ICU and non-ICU Wards

Stuti J. Jaiswal, MD, PhD[1, 2*], Solana Garcia[1], Robert L. Owens, MD[3]

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BACKGROUND: Hospitalized patients frequently report poor sleep, partly due to the inpatient environment. In-hospital sound and light levels are not well described on non-intensive care unit (non-ICU) wards. Although non-ICU wards may have lower average and peak noise levels, sound level changes (SLCs), which are important in disrupting sleep, may still be a substantial problem.

OBJECTIVE: To compare ambient sound and light levels, including SLCs, in ICU and non-ICU environments.

DESIGN: Observational study.

SETTING: Tertiary-care hospital.

MEASUREMENTS: Sound measurements of 0.5 Hz were analyzed to provide average hourly sound levels, sound peaks, and SLCs ≥17.5 decibels (dB). For light data, measurements taken at 2-minute intervals provided average and maximum light levels.

RESULTS: The ICU rooms were louder than non-ICU wards; hourly averages ranged from 56.1 ± 1.3 dB to 60.3 ± 1.7 dB in the ICU, 47.3 ± 3.7 dB to 55.1 ± 3.7 dB on the telemetry floor, and 44.6 ± 2.1 dB to 53.7 ± 3.6 dB on the general ward. However, SLCs ≥ 17.5 dB were not statistically different (ICU, 203.9 ± 28.8 times; non-ICU, 270.9 ± 39.5; $P = 0.11$). In both ICU and non-ICU wards, average daytime light levels were <250 lux, and peak light levels occurred in the afternoon and early evening.

CONCLUSIONS: Quieter, non-ICU wards have as many SLCs as ICUs do, which has implications for quality improvement measurements. Efforts to further reduce average noise levels might be counterproductive. Light levels in the hospital (ICU and non-ICU) may not be optimal for maintenance of a normal circadian rhythm for most people. *Journal of Hospital Medicine* 2017;12:798-804. Published online first September 6, 2017. © 2017 Society of Hospital Medicine

The hospital environment fails to promote adequate sleep for acutely or critically ill patients. Intensive care units (ICUs) have received the most scrutiny, because critically ill patients suffer from severely fragmented sleep as well as a lack of deeper, more restorative sleep.[1-4] ICU survivors frequently cite sleep deprivation, contributed to by ambient noise, as a major stressor while receiving care.[5,6] Importantly, efforts to modify the ICU environment to promote sleep have been associated with reductions in delirium.[7,8] However, sleep deprivation and delirium in the hospital are not limited to ICU patients.

Sleep in the non-ICU setting is also notoriously poor, with 50%-80% of patients reporting sleep as "unsound" or otherwise subjectively poor.[9-11] Additionally, patients frequently ask for and/or receive pharmacological sleeping aids[12] despite little evidence of efficacy[13] and increasing evidence of harm.[14] Here too, efforts to improve sleep seems to attenuate risk of delirium,[15] which remains a substantial problem on general wards, with incidence reported as high as 20%-30%. The reasons for poor sleep in the hospital are multifactorial, but data suggest that the inpatient environment, including noise and light levels, which are measurable and modifiable entities, contribute significantly to the problem.[16]

The World Health Organization (WHO) recommends that nighttime baseline noise levels do not exceed 30 decibels (dB) and that nighttime noise peaks (ie, loud noises) do not exceed 40 dB[17]; most studies suggest that ICU and general ward rooms are above this range on average.[10,18] Others have also demonstrated an association between loud noises and patients' subjective perception of poor sleep.[10,19] However, when considering clinically important noise, peak and average noise levels may not be the key factor in causing arousals from sleep. Buxton and colleagues[20] found that noise quality affects arousal probability; for example, electronic alarms and conversational noise are more likely to cause awakenings compared with the opening or closing of doors and ice machines. Importantly, peak and average noise levels may also matter less for sleep than do sound level changes (SLCs), which are defined as the difference between background/baseline noise and peak noise. Using healthy subjects exposed to simulated ICU noise, Stanchina et al.[21] found that SLCs >17.5 dB were more likely to cause polysomnographic arousals from sleep regardless of peak noise level. This sound pressure change of approximately 20 dB would be perceived as 4 times louder, or, as an example, would be the difference between normal conversation between 2 people (~40 dB) that is then interrupted by the start of a vacuum cleaner (~60 dB). To our knowledge, no other studies have closely examined SLCs in different hospital environments.

Ambient light also likely affects sleep quality in the hos-

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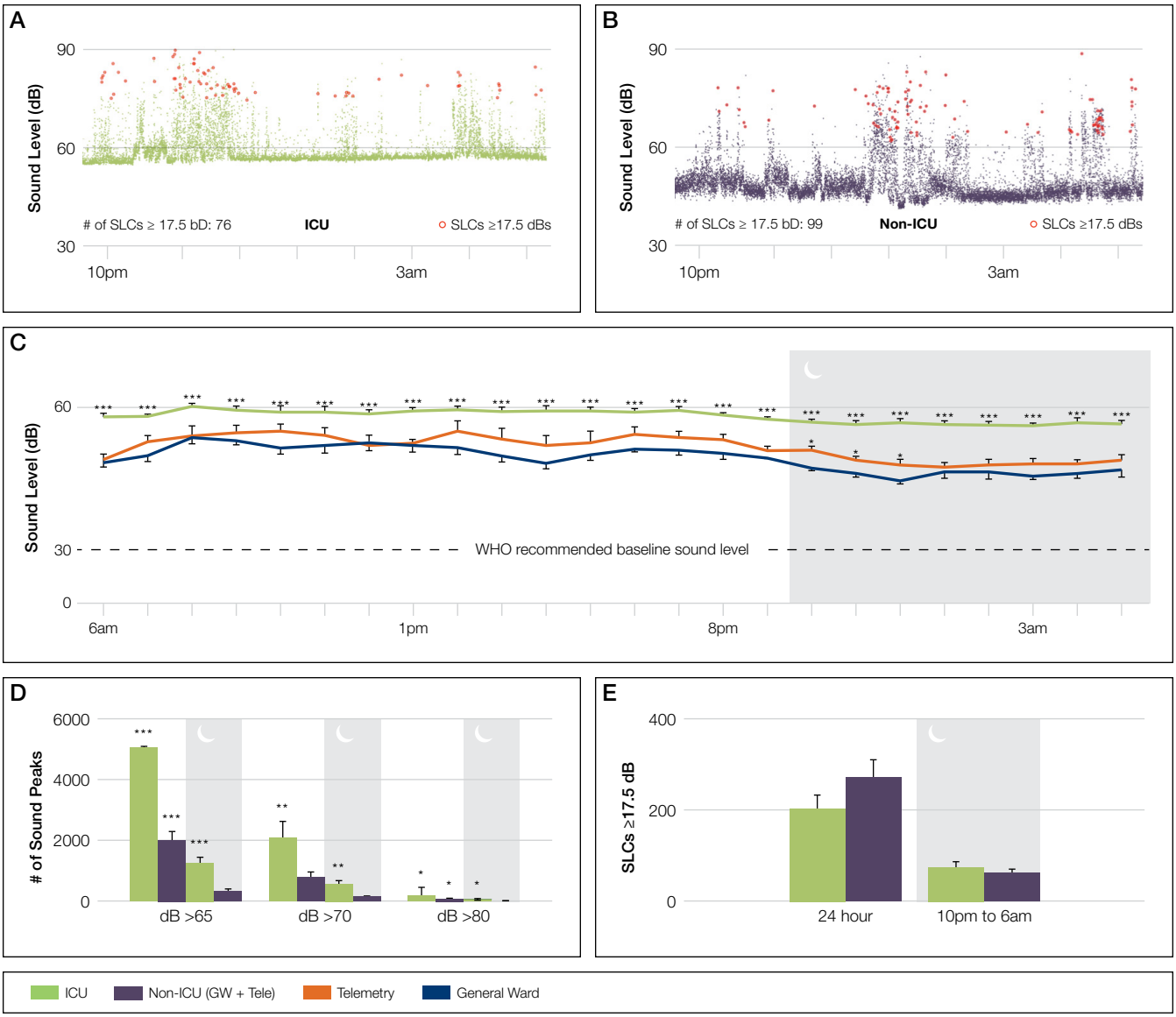

FIG 1. Sound-level findings. (A,B) Sample recordings overnight in 1 ICU and 1 non-ICU room. Plotted raw data points over the nighttime from the ICU (A) and a non-ICU floor (B); SLCs greater than 17.5 dB (red circles) occurred 76 times overnight in the ICU room (green) and 99 times in the non-ICU room (purple), despite a lower baseline sound level in the non-ICU room. (C) Hourly sound-level averages over 24 hours. Average ICU sound levels (±SE) remained higher throughout the day and night than both non-ICU floors (general ward and telemetry). The dashed line represents World Health Organization recommendation for baseline noise levels during the nighttime (30 dB). Asterisks above the green line represent statistical significance from a one-way ANOVA calculation between all 3 floors while asterisks above the orange line represent statistical significance from T-test calculation between the general ward and telemetry floor. Shaded area with moon symbol depicting nighttime hours. (D) Sound peak data. The ICU had statistically more average sound peaks during the daytime and nighttime for sound levels ≥65 dB, ≥70 dB, and ≥80 dB. (E) SLCs ≥ 17.5 dB. On average over the 24-hour day, SLCs greater than or equal to 17.5 dB occurred 203.9 ± 28.8 times on the ICU and 270.9 ± 39.5 times on the non-ICU floors, while nighttime values were 73.7 ± 11.3 times in the ICU and 62.6 ± 8.4 times on non-ICU floors; no statistical difference was found during either epoch.

NOTE: *** = $P < .001$; ** = $P < .01$; * = $P < .05$. Abbreviations: ANOVA, analysis of variance; dB, decibel; ICU, intensive care unit; SLC, sound level change.

pital. The circadian rhythm system, which controls the human sleep–wake cycle as well as multiple other physiologic functions, depends on ambient light as the primary external factor for regulating the internal clock.[22,23] Insufficient and inappropriately timed light exposure can desynchronize the biological clock, thereby negatively affecting sleep quality.[24,25] Conversely, patients exposed to early-morning bright light may sleep better while in the hospital.[16] In addition to sleep patterns, ambient light affects other aspects of patient care; for example, lower light levels in the hospital have recently been associated with higher levels of fatigue and mood disturbance.[26]

A growing body of data has investigated the ambient environment in the ICU, but fewer studies have focused on sound

and light analysis in other inpatient areas such as the general ward and telemetry floors. We examined sound and light levels in the ICU and non-ICU environment, hypothesizing that average sound levels would be higher in the ICU than on non-ICU floors but that the number of SLCs >17.5 dB would be similar. Additionally, we expected that average light levels would be higher in the ICU than on non-ICU floors.

METHODS

This was an observational study of the sound and light environment in the inpatient setting. Per our Institutional Review Board, no consent was required. Battery-operated sound-level (SDL600, Extech Instruments, Nashua, NH) and light-level (SDL400, Extech Instruments, Nashua, NH) meters were placed in 24 patient rooms in our tertiary-care adult hospital in La Jolla, CA. Recordings were obtained in randomly selected, single-patient occupied rooms that were from 3 different hospital units and included 8 general ward rooms, 8 telemetry floor rooms, and 8 ICU rooms. We recorded for approximately 24-72 hours. Depending on the geographic layout of the room, meters were placed as close to the head of the patient's bed as possible and were generally not placed farther than 2 meters away from the patient's head of bed; all rooms contained a window.

Sound Measurements

Sound meters measured ambient noise in dB every 2 seconds and were set for A-weighted frequency measurements. We averaged individual data points to obtain hourly averages for ICU and non-ICU rooms. For hourly sound averages, we further separated the data to compare the general ward telemetry floors (both non-ICU), the latter of which has more patient monitoring and a lower nurse-to-patient ratio compared with the general ward floor.

Data from ICU versus non-ICU rooms were analyzed for the number of sound peaks throughout the 24-hour day and for sound peak over the nighttime, defined as the number of times sound levels exceeded 65 dB, 70 dB, or 80 dB, which were averaged over 24 hours and over the nighttime (10 PM to 6 AM). We also calculated the number of average SLCs ≥17.5 dB observed over 24 hours and over the nighttime.

Light Measurements

Light meters measured luminescence in lux at a frequency of 120 seconds. We averaged individual data points to obtain hourly averages for ICU and non-ICU rooms. In addition to hourly averages, light-level data were analyzed for maximum levels throughout the day and night.

Statistical Analysis

Hourly sound-level averages between the 3 floors were evaluated using a 1-way analysis of variance (ANOVA); sound averages from the general ward and telemetry floor were also compared at each hour using a Student t test. Light-level data, sound-level peak data, as well as SLC data were also evaluated using a Student t test.

RESULTS

Sound Measurements

Examples of the raw data distribution for individual sound recordings in an ICU and non-ICU room are shown in Figure 1A and 1B. Sound-level analysis with specific average values and significance levels between ICU and non-ICU rooms (with non-ICU rooms further divided between telemetry and general ward floors for purposes of hourly averages) are shown in Table 1. The average hourly values in all 3 locations were always above the 30-35 dB level (nighttime and daytime, respectively) recommended by the WHO (Figure 1C). A 1-way ANOVA analysis revealed significant differences between the 3 floors at all time points except for 10 AM. An analysis of the means at each time point between the telemetry floor and the general ward floor showed that the telemetry floor had significantly higher sound averages compared with the general ward floor at 10 PM, 11 PM, and 12 AM. Sound levels dropped during the nighttime on both non-ICU wards but remained fairly constant throughout the day and night in the ICU.

Peak sound-level analysis in ICU versus non-ICU floors (Figure 1D) revealed that the ICU consistently had more sound peaks ≥65 dB, ≥70 dB, and ≥80 dB than non-ICU floors both over the 24-hour day and at nighttime (see Table 2 for averages and significance levels).

Importantly, despite average and peak sound levels showing that the ICU environment is louder overall, there were an equivalent number of SLCs ≥ 17.5 dB in the ICU and on non-ICU floors. The number of SLCs ≥ 17.5 dB is not statistically different when comparing ICU and non-ICU rooms either averaged over 24 hours or averaged over the nighttime (Figure 1E).

Light Measurements

Examples of light levels over a 24-hour period in an ICU and non-ICU room are shown in Figure 2A and 2B, respectively. Maximum average light levels (reported here as average value ± standard deviation to demonstrate variability within the data) in the ICU were 169.7 ± 127.1 lux and occurred at 1 PM, while maximum average light levels in the non-ICU rooms were 213.5 ± 341.6 lux and occurred at 5 PM (Figure 2C). Average light levels in the morning hours remained low and ranged from 15.9 ± 12.7 lux to 38.9 ± 43.4 lux in the ICU and from 22.3 ± 17.5 lux to 100.7 ± 92.0 lux on the non-ICU floors. The maximum measured level from any of the recordings was 2530 lux and occurred in a general ward room in the 5 PM hour. Overall, light averages remained low, but this particular room had light levels that were significantly higher than the others. A t test analysis of the hourly averages revealed only 1 time point of significant difference between the 2 floors; at 7 AM, the general ward floor had a higher lux level of 49.9 ± 27.5 versus 19.2 ± 10.7 in the ICU (P = 0.038). Otherwise, there were no differences between light levels in ICU rooms versus non-ICU rooms. Evaluation of the data revealed a substantial amount of variability in light lev-

TABLE 1. Hourly Sound Averages

Hourly Averages (day)	6 AM	7 AM	8 AM	9 AM	10 AM	11 AM	12 PM	1 PM
ICU	58.0 ± 0.8	57.9 ± 0.5	60.3 ± 0.6	59.4 ± 1.0	59.0 ± 1.3	59.0 ± 1.4	58.6 ±0.7	59.3 ± 0.5
Non-ICU								
Telemetry	48.9 ± 1.2	52.8 ± 1.4	54.0 ± 2.2	54.7 ± 1.6	55.1 ± 1.4	54.2 ± 1.7	52.2 ± 1.9	52.2 ± 1.2
General Ward	48.2 ± 0.9	50.0 ± 1.3	53.7 ± 1.3	53.1 ± 1.0	51.5 ± 1.4	52.0 ± 1.5	52.7 ± 2.0	52.2 ± 1.7
P value (1-way ANOVA)	8.6 x 10-7	.0002	.0052	.0019	.3153	.0051	.0124	.0003
P value (t test)	.6466	.1583	.9182	.3971	.0833	.3198	.8572	.9760
Hourly Averages (day)	**2 PM**	**3 PM**	**4 PM**	**5 PM**	**6 PM**	**7 PM**	**8 PM**	**9 PM**
ICU	59.6 ± 0.8	59.0 ± 1.1	59.2 ± 1.1	59.3 ± 0.8	59.0 ± 0.7	59.4 ± 0.8	58.4 ± 0.6	57.6 ± 0.3
Non-ICU								
Telemetry	55.0 ± 2.2	53.3 ± 2.3	52.0 ± 2.1	52.5 ± 2.6	54.2 ± 1.7	53.6 ± 1.5	53.2 ± 1.2	51.0 ± 0.9
General Ward	52.0 ± 1.6	49.6 ± 1.2	48.3 ± 1.2	49.8 ± 1.1	51.2 ± 0.6	50.9 ± 1.0	50.4 ± 1.4	49.4 ± 0.5
P value (1-way ANOVA)	.0004	.0011	.0001	.0014	.0002	.0001	.0001	2.4 x 10-8
P value (t test)	.2033	.1926	.1631	.3702	.1047	.1382	.1426	.1667
Hourly Averages (night)	**10 PM**	**11 PM**	**12 AM**	**1 AM**	**2 AM**	**3 AM**	**4 AM**	**5 AM**
ICU	56.9 ± 0.6	56.5 ± 0.7	56.9 ± 0.9	56.5 ± 0.8	56.3 ± 0.7	56.1 ± 0.5	56.8 ± 1.1	56.5 ± 0.9
Non-ICU								
Telemetry	50.9 ± 1.1	48.9 ± 0.9	48.0 ± 1.3	47.3 ± 1.3	48.0 ± 1.2	48.1. ± 1.3	48.0 ± 1.1	49.0 ± 1.0
General Ward	47.2 ± 0.7	46.1 ± 0.8	44.6 ± 0.8	46.4 ± 1.3	46.5 ± 1.6	45.60 ± 0.7	46.0 ± 0.9	46.7 ± 1.3
P value (1-way ANOVA)	1.1 x 10-7	3.54x 10-8	5.2 x 10-8	3.3 x 10-6	9.3 x 10-6	1.7 x 10-7	3.9 x 10-7	4.7 x 10-6
P value (t test)	.0128	.0418	.0375	.6162	.4570	.1228	.1936	.1823

NOTE: Raw data averages (±SE) showing sound levels (dB) throughout the day and night. A 1-way ANOVA test was used to compared sound between the ICU and both non-ICU floors (telemetry and general ward) while a Student t test was used to compare for differences between the telemetry and general ward floor. Abbreviations: ANOVA, analysis of variance; dB, decibels; ICU, intensive care unit.

TABLE 2. Sound Peak Averages

Sound Peak Averages	≥65 dB	≥70 dB	≥ 80dB
24 Hours			
ICU	5052.9 ± 555.5	2060.0 ± 280.0	161.4 ± 41.1
Non-ICU	1973.6 ± 301.0	777.6 ± 167.4	60.1 ± 23.2
P value (t test)	.0010	.0053	.0361
Nighttime			
ICU	1254.6 ± 172.2	556.8 ± 103.1	53.9 ± 14.7
Non-ICU	326.8 ± 54.1	133.2 ± 25.5	9.3 ± 4.6
P value (t test)	.0001	.0020	.0221

NOTE: Sound peaks ≥65 dB, ≥70 dB, and ≥ 80dB were averaged over the 24-hour day or over the nighttime and compared between both environments using a t test. Abbreviations: dB, decibels; ICU, intensive care unit.

els throughout the daytime hours. Light levels during the nighttime remained low and were not significantly different between the 2 groups.

DISCUSSION

To our knowledge, this is the first study to directly compare the ICU and non-ICU environment for its potential impact on sleep and circadian alignment. Our study adds to the literature with several novel findings. First, average sound levels on non-ICU wards are lower than in the ICU. Second, although quieter on average, SLCs >17.5 dB occurred an equivalent number of times for both the ICU and non-ICU wards. Third, average daytime light levels in both the ICU and non-ICU environment are low. Lastly, peak light levels for both ICU and non-ICU wards occur later in the day instead of in the morning. All of the above have potential impact for optimizing the ward environment to better aid in sleep for patients.

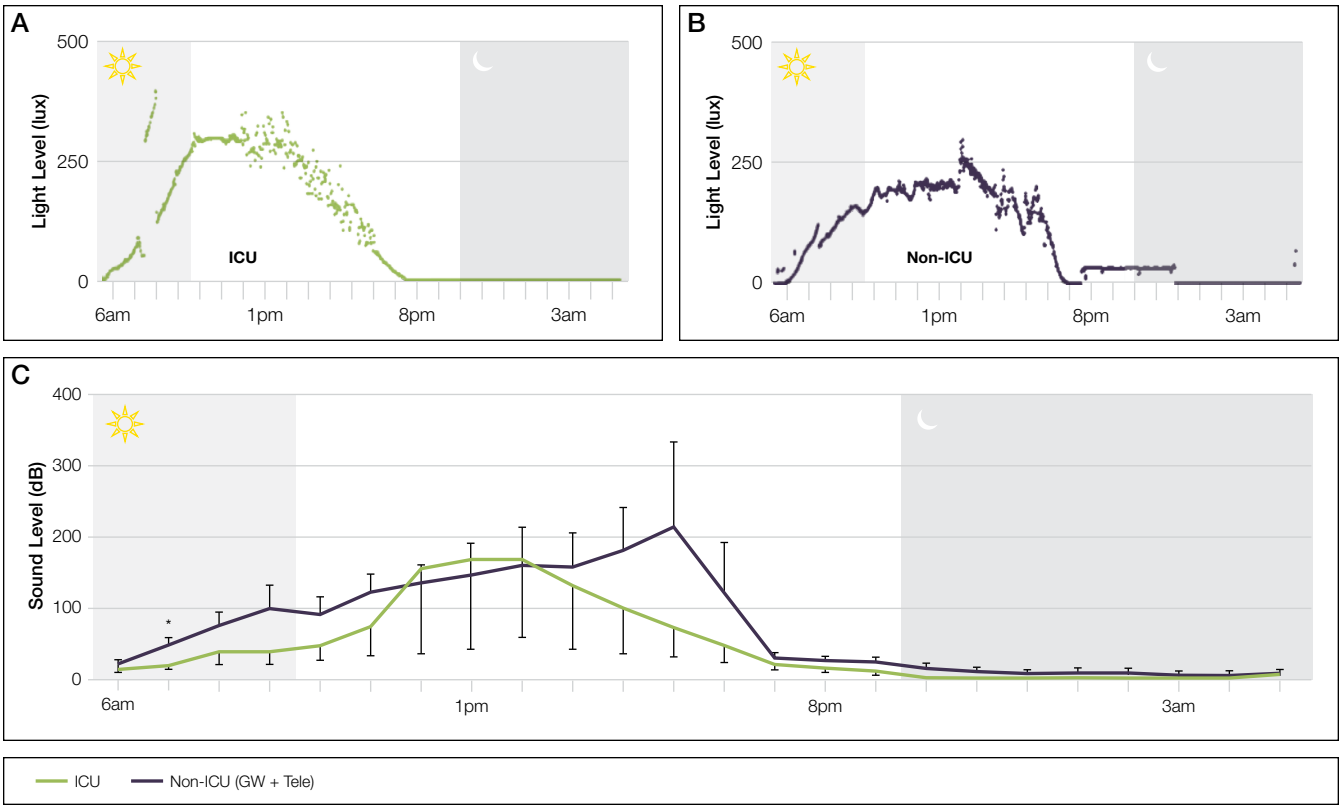

FIG 2. Light levels in ICU and non-ICU rooms. (A,B) Sample traces of light level over the 24-day in 1 ICU and 1 non-ICU room. Individuals data points were plotted to show the distribution of light levels throughout the day in an (A) ICU and (B) non-ICU room. Sun symbol indicates the 4-hour period designated as morning (6 AM-10 AM), when bright light levels are important for maintaining circadian rhythm. (C) Average hourly light levels. Average light levels (±SE) varied substantially throughout the day in both environments but consistently remained below 2500 lux on both floors. A t test showed that both ICU and non-ICU environments were not significantly different throughout the day except for the 7 AM hour, although this may not be clinically significant.

NOTE: Abbreviation: ICU, intensive care unit.

Sound-Level Findings

Data on sound levels for non-ICU floors are limited but mostly consistent with our findings; sound averages in our study ranged from 44.6 to 55.1 dB in non-ICU rooms, while others report averages ranging from 48 dB[19] to 63.5 dB,[10] although the latter measurement includes rooms occupied with 4 to 6 patients, which we expect would increase the noise levels. Others report average noise levels in the ICU similar to our values, which ranged from 56.1 to 60.3 dB.[18,27] Here, we show that average and peak sound levels on non-ICU wards are consistently lower than in the ICU. However, sound levels on the general ward and telemetry floors still remain quite high and potentially disruptive to patients, with average nighttime sound levels reaching the range of light outdoor traffic. The sleep environment could play an even larger role in sleep quality for non-ICU patients, as they do not typically receive sedation (though pharmacological sleeping-aid use is quite high, despite the risks)[28] and thus may be more sensitive to environmental factors that impact sleep.

Average and peak sound levels contribute to the ambient noise experienced by patients but may not be the source of sleep disruptions. Using polysomnography in healthy subjects exposed to recordings of ICU noise, Stanchina et al.[21] showed that SLCs from baseline and not peak sound levels determined whether a subject was aroused from sleep by sound. Accordingly, they also found that increasing baseline sound levels by using white noise reduced the number of arousals that subjects experienced. To our knowledge, other studies have not quantified and compared SLCs in the ICU and non-ICU environments. Our data show that patients on non-ICU floors experience at least the same number of SLCs, and thereby the same potential for arousals from sleep, when compared with ICU patients. The higher baseline level of noise in the ICU likely explains the relatively lower number of SLCs when compared with the non-ICU floors. Although decreasing overall noise to promote sleep in the hospital seems like the obvious solution, the treatment for noise pollution in the hospital may actually be more background noise, not less.

Recent studies support the clinical implications of our findings. First, decreasing overall noise levels is difficult to accomplish.[29] Second, recent studies utilized white noise in different hospital settings with some success in improving patients' subjective sleep quality, although more studies using objective data measurements are needed to further understand the im-

pact of white noise on sleep in hospitalized patients.[30,31] Third, efforts at reducing interruptions—which likely will decrease the number of SLCs—such as clustering nursing care or reducing intermittent alarms may be more beneficial in improving sleep than efforts at decreasing average sound levels. For example, Bartick et al. reduced the number of patient interruptions at night by eliminating routine vital signs and clustering medication administration. Although they included other interventions as well, we note that this approach likely reduced SLCs and was associated with a reduction in the use of sedative medications.[32] Ultimately, our data show that a focus on reducing SLCs will be one necessary component of a multipronged solution to improving inpatient sleep.[33]

Light-Level Findings

Because of its effect on circadian rhythms, the daily light-dark cycle has a powerful impact on human physiology and behavior, which includes sleep.[34] Little is understood about how light affects sleep and other circadian-related functions in general ward patients, as it is not commonly measured. Our findings suggest that patients admitted to the hospital are exposed to light levels and patterns that may not optimally promote wake and sleep. Encouragingly, we did not find excessive average light levels during the nighttime in either ICU or non-ICU environment of our hospital, although others have described intrusive nighttime light in the hospital setting.[35,36] Even short bursts of low or moderate light during the nighttime can cause circadian phase delay,[37] and efforts to maintain darkness in patient rooms at night should continue.

Our measurements show that average daytime light levels did not exceed 250 lux, which corresponds to low, office-level lighting, while the brightest average light levels occurred in the afternoon for both environments. These levels are consistent with other reports[26,35,36] as is the light-level variability noted throughout the day (which is not unexpected given room positioning, patient preference, curtains, etc). The level and amount of daytime light needed to maintain circadian rhythms in humans is still unknown.[38] Brighter light is generally more effective at influencing the circadian pacemaker in a dose-dependent manner.[39] Although entrainment (synchronization of the body's biological rhythm with environmental cues such as ambient light) of the human circadian rhythm has been shown with low light levels (eg, <100 lux), these studies included healthy volunteers in a carefully controlled, constant, routine environment.[23] How these data apply to acutely ill subjects in the hospital environment is not clear. We note that low to moderate levels of light (50-1000 lux) are less effective for entrainment of the circadian rhythm in older people (age >65 years, the majority of our admissions) compared with younger people. Thus, older, hospitalized patients may require greater light levels for regulation of the sleep-wake cycle.[40] These data are important when designing interventions to improve light for and maintain circadian rhythms in hospitalized patients. For example, Simons et al. found that dynamic light-application therapy, which achieved a maximum average lux level of <800 lux, did not reduce rates of delirium in critically ill patients (mean age ~65). One interpretation of these results, though there are many others, is that the light levels achieved were not high enough to influence circadian timing in hospitalized, mostly elderly patients. The physiological impact of light on the circadian rhythm in hospitalized patients still remains to be measured.

LIMITATIONS

Our study does have a few limitations. We did not assess sound quality, which is another determinant of arousal potential.[20] Also, a shorter measurement interval might be useful in determining sharper sound increases. It may also be important to consider A- versus C-weighted measurements of sound levels, as A-weighted measurements usually reflect higher-frequency sound while C-weighted measurements usually reflect low-frequency noise[18]; we obtained only A-weighted measurements in our study. However, A-weighted measurements are generally considered more reflective of what the human ear considers noise and are used more standardly than C-weighted measurements.

Regarding light measurements, we recorded from rooms facing different cardinal directions and during different times of the year, which likely contributed to some of the variability in the daytime light levels on both floors. Additionally, light levels were not measured directly at the patient's eye level. However, given that overhead fluorescent lighting was the primary source of lighting, it is doubtful that we substantially underestimated optic-nerve light levels. In the future, it may also be important to measure the different wavelengths of lights, as blue light may have a greater impact on sleep than other wavelengths.[41] Although our findings align with others', we note that this was a single-center study, which could limit the generalizability of our findings given inter-hospital variations in patient volume, interior layout and structure, and geographic location.

CONCLUSIONS

Overall, our study suggests that the light and sound environment for sleep in the inpatient setting, including both the ICU and non-ICU wards, has multiple areas for improvement. Our data also suggest specific directions for future clinical efforts at improvement. For example, efforts to decrease average sound levels may worsen sleep fragmentation. Similarly, more light during the day may be more helpful than further attempts to limit light during the night.

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Associations of Physician Empathy with Patient Anxiety and Ratings of Communication in Hospital Admission Encounters

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BACKGROUND: Responding empathically when patients express negative emotion is a recommended component of patient-centered communication.

OBJECTIVE: To assess the association between the frequency of empathic physician responses with patient anxiety, ratings of communication, and encounter length during hospital admission encounters.

DESIGN: Analysis of coded audio-recorded hospital admission encounters and pre- and postencounter patient survey data.

SETTING: Two academic hospitals.

PARTICIPANTS: Seventy-six patients admitted by 27 attending hospitalist physicians.

MEASUREMENTS: Recordings were transcribed and analyzed by trained coders, who counted the number of empathic, neutral, and nonempathic verbal responses by hospitalists to their patients' expressions of negative emotion. We developed multivariable linear regression models to test the association between the number of these responses and the change in patients' State Anxiety Scale (STAI-S) score pre- and postencounter and encounter length. We used Poisson regression models to examine the association between empathic response frequency and patient ratings of the encounter.

RESULTS: Each additional empathic response from a physician was associated with a 1.65-point decline in the STAI-S anxiety scale (95% confidence interval [CI], 0.48-2.82). Frequency of empathic responses was associated with improved patient ratings for covering points of interest, feeling listened to and cared about, and trusting the doctor. The number of empathic responses was not associated with encounter length (percent change in encounter length per response 1%; 95% CI, –8%-10%).

CONCLUSIONS: Responding empathically when patients express negative emotion was associated with less patient anxiety and higher ratings of communication but not longer encounter length. *Journal of Hospital Medicine* 2017;12:805-810. Published online first September 6, 2017. © 2017 Society of Hospital Medicine

Admission to a hospital can be a stressful event,[1,2] and patients report having many concerns at the time of hospital admission.[3] Over the last 20 years, the United States has widely adopted the hospitalist model of inpatient care. Although this model has clear benefits, it also has the potential to contribute to patient stress, as hospitalized patients generally lack preexisting relationships with their inpatient physicians.[4,5] In this changing hospital environment, defining and promoting effective medical communication has become an essential goal of both individual practitioners and medical centers.

Successful communication and strong therapeutic relationships with physicians support patients' coping with illness-associated stress[6,7] as well as promote adherence to medical treatment plans.[8] Empathy serves as an important building block of patient-centered communication and encourages a strong therapeutic alliance.[9] Studies from primary care, oncology, and intensive care unit (ICU) settings indicate that physician empathy is associated with decreased emotional distress,[10,11] improved ratings of communication,[12] and even better medical outcomes.[13]

Prior work has shown that hospitalists, like other clinicians, underutilize empathy as a tool in their daily interactions with patients.[14-16] Our prior qualitative analysis of audio-recorded hospitalist-patient admission encounters indicated that how hospitalists respond to patient expressions of negative emotion influences relationships with patients and alignment around care plans.[17] To determine whether empathic communication is associated with patient-reported outcomes in the hospitalist model, we quantitatively analyzed coded admission encounters and survey data to examine the association between hospitalists' responses to patient expressions of negative emotion (anxiety, sadness, and anger) and patient anxiety and ratings of communication. Given the often-limited time hospitalists have to complete admission encounters, we also examined the association between response to emotion and encounter length.

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TABLE 1. Patient Ratings of Communication: Items and Summary Statistics

Patient Communication Rating Items	Summary Statistics n = 76		
	Mean (SD)	Median (IQR)	Patients Rating Highest Score (10) n (%)
Enough time was allowed for information	8.9 (2.1)	10 (1)	49 (64)
The information was easy to understand	9.2 (1.7)	10 (1)	51 (67)
The information covered all the points of interest to me	8.8 (2.3)	10 (1)	50 (66)
The doctor listened to what I had to say	9.4 (1.7)	10 (0)	59 (78)
I felt this doctor cared about me	9.2 (1.8)	10 (1)	56 (74)
Overall, how well did talking with this doctor meet your needs?	8.8 (2.0)	10 (2)	39 (51)
All things considered, how much do you trust this doctor?	9.0 (1.8)	10 (1)	44 (58)

Note: Abbreviations: IQR, interquartile range; SD, standard deviation.

METHODS

We analyzed data collected as part of an observational study of hospitalist-patient communication during hospital admission encounters[14] to assess the association between the way physicians responded to patient expressions of negative emotion and patient anxiety, ratings of communication in the encounter, and encounter length. We collected data between August 2008 and March 2009 on the general medical service at 2 urban hospitals that are part of an academic medical center. Participants were attending hospitalists (not physician trainees), and patients admitted under participating hospitalists' care who were able to communicate verbally in English and provide informed consent for the study. The institutional review board at the University of California, San Francisco approved the study; physician and patient participants provided written informed consent.

Enrollment and data collection has been described previously.[17] Our cohort for this analysis included 76 patients of 27 physicians who completed encounter audio recordings and pre- and postencounter surveys. Following enrollment, patients completed a preencounter survey to collect demographic information and to measure their baseline anxiety via the State Anxiety Scale (STAI-S), which assesses transient anxious mood using 20 items answered on a 4-point scale for a final score range of 20 to 80.[10,18,19] We timed and audio-recorded admission encounters. Encounter recordings were obtained solely from patient interactions with attending hospitalists and did not take into account the time patients may have spent with other physicians, including trainees. After the encounter, patients completed postencounter surveys, which included the STAI-S and patients' ratings of communication during the encounter. To rate communication, patients responded to 7 items on a 0- to 10-point scale that were derived from previous work (Table 1)[12,20,21]; the anchors were "not at all" and "completely." To identify patients with serious illness, which we used as a covariate in regression models, we asked physicians on a postencounter survey whether or not they "would be surprised by this patient's death or admission to the ICU in the next year."[22]

As previously described, we professionally transcribed and coded the audio recordings.[17] Following past work,[15,16,23-25] we identified patient expressions of negative emotion and categorized the initial hospitalist response to each expression. Table 2 shows examples to illustrate the coding scheme. We considered an empathic response to be one that directed further discussion toward a patient's expressed negative emotion. A neutral response was one that directed discussion neither towards nor away from the expressed emotion, while a nonempathic physician response directed further discussion away from the patient's emotion.[15] To assess reliability, 2 coders independently coded a randomly selected 20% of encounters (n = 15); kappa statistics were 0.76 for patient expressions of emotion and 0.85 for physician responses, indicating substantial to almost perfect agreement.[26]

We used regression models to assess the association between the number of each type of physician response (empathic, neutral, nonempathic) in an encounter and the following variables: (1) the change in the patient's anxiety level, defined as the difference between the post- and preencounter STAI-S score (using linear regression); (2) patient ratings of the physician and encounter (using Poisson regression); and (3) encounter length (using linear regression). To assess each patient rating item, we utilized a single model that included frequencies for each type of physician response. For ratings of their encounters, most patients gave high ratings, resulting in a preponderance of 10/10 scores for several items. Thus, we focused on trying to understand "negativity," meaning the minority of less than completely positive reactions. To do this, we analyzed reflected outcomes (defined as 10 minus the patient's response) using zero-inflated Poisson regression models. This approach allowed us to distinguish between degrees of dissatisfaction and to determine whether additional change in ratings resulted from additional physician responses. Encounter length also demonstrated right skewness, which we addressed through log transformation;

TABLE 2. Overview and Examples of Coding Scheme for Hospitalists' Responses to Patients' Expressions of Negative Emotion[17]

Empathic Response: Focuses Toward Further Expression of Emotion
Explicitly encourages patient to speak further about their emotional experience; for example, by naming emotion, voicing understanding, or showing respect or support for patient.
Patient (*expression of emotion*): "I wouldn't say failure because it's not a failure. It's challenging, but I'm *having difficulty* climbing the wall [referring to cancer therapy]."
Physician (*voices understanding*): "Anytime that someone goes through treatment and … that cancer comes back is devastating. It's very, very difficult."
Neutral Response: Focuses Neither Toward nor Away From Emotion
Brief clarifications, acknowledgements, restatements, eg, "Mhmm," "Uh-huh," "Got it."
Patient (*expression of emotion*): "It's a *shock* and I don't want to be labeled. You have this [hepatitis B]. I didn't have it for a long time and all of the sudden I have it."
Physician (*brief acknowledgement*): "Right. Of course."
Nonempathic Response: Focuses Away From Emotion
Does not acknowledge emotion, changes topic, and/or asks for clinical information.
Patient (*expression of emotion*): "I got *scared* when they said I have a urinary tract infection."
Physician (*clinical question*): "Maybe. Did they check your urine again?"

results for this are reported as percent change in the encounter length per physician response.

We considered physician as a clustering variable in the calculation of robust standard errors for all models. In addition, we included in each model covariates that were associated with the outcome at $P \leq 0.10$, including patient gender, patient age, serious illness,[22] preencounter anxiety, encounter length, and hospital. We considered P values < 0.05 to be statistically significant. We used Stata SE 13 (StataCorp LLC, College Station, TX) for all statistical analyses.

RESULTS

We analyzed data from admission encounters with 76 patients (consent rate 63%) and 27 hospitalists (consent rate 91%). Their characteristics are shown in Table 3. Median encounter length was 19 minutes (mean 21 minutes, range 3-68). Patients expressed negative emotion in 190 instances across all encounters; median number of expressions per encounter was 1 (range 0-14). Hospitalists responded empathically to 32% (n = 61) of the patient expressions, neutrally to 43% (n = 81), and nonempathically to 25% (n = 48).

The STAI-S was normally distributed. The mean preencounter STAI-S score was 39 (standard deviation [SD] 8.9). Mean postencounter STAI-S score was 38 (SD 10.7). Mean change in anxiety over the course of the encounter, calculated as the postencounter minus preencounter mean was −1.2 (SD 7.6). Table 1 shows summary statistics for the patient ratings of communication items. All items were rated highly. Across the items, between 51% and 78% of patients rated the highest score of 10.

Across the range of frequencies of emotional expressions per encounter in our data set (0-14 expressions), each additional empathic hospitalist response was associated with a 1.65-point decrease in the STAI-S (95% confidence interval [CI], 0.48-2.82). We did not find significant associations between changes in the STAI-S and the number of neutral hospitalist responses (−0.65 per response; 95% CI, −1.67-0.37) or nonempathic hospitalist responses (0.61 per response; 95% CI, −0.88-2.10).

The Figure shows the adjusted relative effects (aREs) and 95% CIs from zero-inflated multivariate Poisson regression models of the association between physician response to patient expressions of negative emotion and reflected patient ratings of the encounters, defined as 10 minus the patient's response. Empathic hospitalist responses to patient expressions of emotion were associated with less negative patient ratings of communication in the encounter for 4 of 7 items: covering points of interest, the doctor listening, the doctor caring, and trusting the doctor. For example, for the item "I felt this doctor cared about me," each empathic hospitalist response was associated with an approximate 77% reduction in negative patient ratings (aRE: 0.23; 95% CI, 0.06-0.85).

In addition, nonempathic responses were associated with more negative ratings of communication for 5 of the 7 items: ease of understanding information, covering points of interest, the doctor listening, the doctor caring, and trusting the doctor. For example, for the item "I felt this doctor cared about me," each nonempathic hospitalist response was associated with a more than doubling of negative patient ratings (aRE: 2.3; 95% CI, 1.32-4.16). Neutral physician responses to patient expressions of negative emotion were associated with less negative patient ratings for 2 of the items: covering points of interest (aRE 0.68; 95% CI, 0.51-0.90) and trusting the doctor (aRE: 0.86; 95% CI, 0.75-0.99).

We did not find a statistical association between encounter length and the number of empathic hospitalist responses in the encounter (percent change in encounter length per response [PC]: 1%; 95% CI, −8%-10%) or the number of nonempathic responses (PC: 18%; 95% CI, −2%-42%). We did find a statistically significant association between the number of neutral responses and encounter length (PC: 13%; 95% CI, 3%-24%), corresponding to 2.5 minutes of

TABLE 3. Characteristics of Participating Patients and Hospitalist Physicians

Characteristic	Patients n = 76	Physicians n = 27
Age (years), mean (SD)	54 (19)	35 (5)
Gender, n (%) male	34 (45%)	11 (41%)
Ethnicity, n (%)		
Hispanic	3 (4%)	1 (4%)
Non-Hispanic	73 (96%)	26 (96%)
Race, n (%)		
White	55 (72%)	18 (67%)
Asian	5 (7%)	7 (26%)
African American	8 (11%)	0
Other	8 (11%)	2 (7%)
Serious Illness, n (%)		
Physician would not be surprised by death or ICU admission in next year	33 (43%)	
Encounter location, n (%)		
Hospital A (attendings & house staff)	62 (82%)	
Hospital B (attendings only)	14 (18%)	
Encounter length, minutes, median (range)	19 (3-68)	

NOTE: Abbreviations: ICU, intensive care unit; SD, standard deviation.

additional encounter time per neutral response for the median encounter length of 19 minutes.

DISCUSSION

Our study set out to measure how hospitalists responded to expressions of negative emotion during admission encounters with patients and how those responses correlated with patient anxiety, ratings of communication, and encounter length. We found that empathic responses were associated with diminishing patient anxiety after the visit, as well as with better ratings of several domains of hospitalist communication. Moreover, nonempathic responses to negative emotion were associated with more strongly negative ratings of hospitalist communication. Finally, while clinicians may worry that encouraging patients to speak further about emotion will result in excessive visit lengths, we did not find a statistical association between empathic responses and encounter duration. To our knowledge, this is the first study to indicate an association between empathy and patient anxiety and communication ratings within the hospitalist model, which is rapidly becoming the predominant model for providing inpatient care in the United States.[4,5]

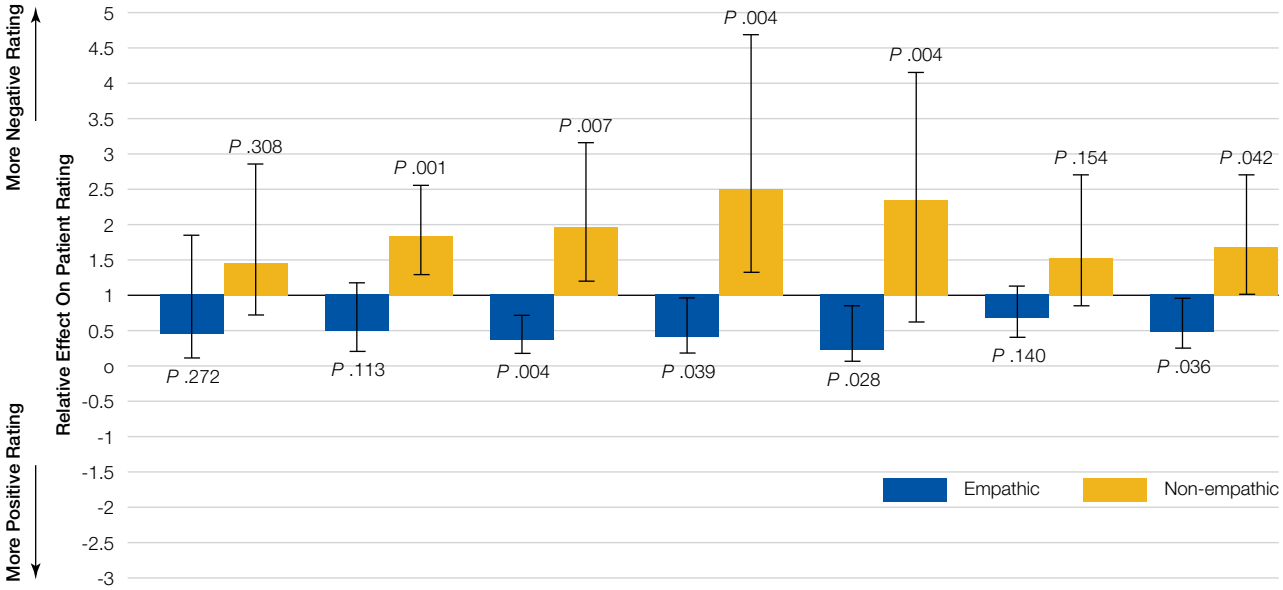
As in oncologic care, anxiety is an emotion commonly confronted by clinicians meeting admitted medical patients for the first time. Studies show that not only do patient anxiety levels remain high throughout a hospital course, patients who experience higher levels of anxiety tend to stay longer in the hospital.[1,2,27-30] But unlike oncologic care or other therapy provided in an outpatient setting, the hospitalist model does not facilitate "continuity" of care, or the ability to care for the same patients over a long period of time. This reality of inpatient care makes rapid, effective rapport-building critical to establishing strong physician-patient relationships. In this setting, a simple communication tool that is potentially able to reduce inpatients' anxiety could have a meaningful impact on hospitalist-provided care and patient outcomes.

In terms of the magnitude of the effect of empathic responses, the clinical significance of a 1.65-point decrease in the STAI-S anxiety score is not precisely clear. A prior study that examined the effect of music therapy on anxiety levels in patients with cancer found an average anxiety reduction of approximately 9.5 units on the STAIS-S scale after sensitivity analysis, suggesting a rather large meaningful effect size.[31] Given we found a reduction of 1.65 points for each empathic response, however, with a range of 0-14 negative emotions expressed over a median 19-minute encounter, there is opportunity for hospitalists to achieve a clinically significant decrease in patient anxiety during an admission encounter. The potential to reduce anxiety is extended further when we consider that the impact of an empathic response may apply not just to the admission encounter alone but also to numerous other patient-clinician interactions over the course of a hospitalization.

A healthy body of communication research supports the associations we found in our study between empathy and patient ratings of communication and physicians. Families in ICU conferences rate communication more positively when physicians express empathy,[12] and a number of studies indicate an association between empathy and patient satisfaction in outpatient settings.[8] Given the associations we found with negative ratings on the items in our study, promoting empathic responses to expressions of emotion and, more importantly, stressing avoidance of nonempathic responses may be relevant efforts in working to improve patient satisfaction scores on surveys reporting "top box" percentages, such as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). More notably, evidence indicates that empathy has positive impacts beyond satisfaction surveys, such as adherence, better diagnostic and clinical outcomes, and strengthening of patient enablement.[8]

Not all hospitalist responses to emotion were associated with patient ratings across the 7 communication items we assessed. For example, we did not find an association between how physicians responded to patient expressions of negative emotion and patient perception that enough time was spent in the visit or the degree to which talking with the doctor met a patient's overall needs. It follows logically, and other research supports, that empathy would influence patient ratings of physician caring and trust,[32] whereas other communication factors we were unable to measure (eg, physician body language, tone, and use of jargon and patient health literacy and primary language) may have a more significant association with patient ratings of the other items we assessed.

In considering the clinical application of our results, it is important to note that communication skills, including respond-



	There was not enough time	Information difficult to understand	Information did not cover points of interest	Doctor did not listen to me	Doctor did not care about me	Overall, meeting did not meet needs	Distrust of this doctor
Nonempathic aRE [95% CI]	1.44 [072-2.87]	1.82 [1.29-2.56]	1.95 [1.20-3.17]	2.5 [1.33-4.69]	2.34 [1.32-4.16]	1.52 [0.85-2.70]	1.66 [1.02-2.70]
Empathic aRE [95% CI]	0.46 [0.11-1.85]	0.5 [0.21-1.18]	0.36 [0.18-0.72]	0.41 [0.18-0.96]	0.23 [0.06-0.85]	0.68 [0.41-1.14]	0.49 [0.25-0.95]

FIG. Associations between hospitalists' responses to patient emotional expressions in admission encounters and patients' ratings of communication in the encounter. Following the admission encounter with the attending hospitalist, patients rated each item above on a 0-10 point scale with anchors "not at all" and "completely." Patient ratings of communication were high and positively skewed so we analyzed reflected outcomes, defined as 10 minus the patient's response, using zero-inflated Poisson regression models. The figure shows the adjusted relative effect, 95% confidence intervals, and associated p-value for each item. Relative effect is the percent relative change in rating for each additional empathic or non-empathic physician response. A greater number of empathic responses during an encounter was associated with more positive patient ratings (relative effect less than 1) and a greater number of non-empathic responses was associated with more negative patient ratings (relative effect greater than 1).

ing empathically to patient expressions of negative emotion, can be imparted through training in the same way as abdominal examination or electrocardiogram interpretation skills.[33-35] However, training of hospitalists in communication skills requires time and some financial investment on the part of the physician, their hospital or group, or, ideally, both. Effective training methods, like those for other skill acquisition, involve learner-centered teaching and practicing skills with role-play and feedback.[36] Given the importance of a learner-centered approach, learning would likely be better received and more effective if it was tailored to the specific needs and patient scenarios commonly encountered by hospitalist physicians. As these programs are developed, it will be important to assess the impact of any training on the patient-reported outcomes we assessed in this observational study, along with clinical outcomes.

Our study has several limitations. First, we were only able to evaluate whether hospitalists verbally responded to patient emotion and were thus not able to account for nonverbal empathy such as facial expressions, body language, or voice tone. Second, given our patient consent rate of 63%, patients who agreed to participate in the study may have had different opinions than those who declined to participate. Also, hospitalists and patients may have behaved differently as a result of being audio recorded. We only included patients who spoke English, and our patient population was predominately non-Hispanic white. Patients who spoke other languages or came from other cultural backgrounds may have had different responses. Third, we did not use a single validated scale for patient ratings of communication, and multiple analyses increase our risk of finding statistically significant associations by chance. The skewing of the communication rating items toward high scores may also have led to our results being driven by outliers, although the model we chose for analysis does penalize for this. Furthermore, our sample size was small, leading to wide CIs and potential for lack of statistical associations due to insufficient power. Our findings warrant replication in larger studies. Fourth, the setting of our study in an academic center may affect generaliz-

ability. Finally, the age of our data (collected between 2008 and 2009) is also a limitation. Given a recent focus on communication and patient experience since the initiation of HCAHPS feedback, a similar analysis of empathy and communication methods now may result in different outcomes.

In conclusion, our results suggest that enhancing hospitalists' empathic responses to patient expressions of negative emotion could decrease patient anxiety and improve patients' perceptions of (and thus possibly their relationships with) hospitalists, without sacrificing efficiency. Future work should focus on tailoring and implementing communication skills training programs for hospitalists and evaluating the impact of training on patient outcomes.

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A Concise Tool for Measuring Care Coordination from the Provider's Perspective in the Hospital Setting

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BACKGROUND: To support hospital efforts to improve coordination of care, a tool is needed to evaluate care coordination from the perspective of inpatient healthcare professionals.

OBJECTIVES: To develop a concise tool for assessing care coordination in hospital units from the perspective of healthcare professionals, and to assess the performance of the tool in measuring dimensions of care coordination in 2 hospitals after implementation of a care coordination initiative.

METHODS: We developed a survey consisting of 12 specific items and 1 global item to measure provider perceptions of care coordination across a variety of domains, including teamwork and communication, handoffs, transitions, and patient engagement. The questionnaire was distributed online between October 2015 and January 2016 to nurses, physicians, social workers, case managers, and other professionals in 2 tertiary care hospitals.

RESULTS: A total of 841 inpatient care professionals completed the survey (response rate = 56.6%). Among respondents, 590 (75%) were nurses and 37 (4.7%) were physicians. Exploratory factor analysis revealed 4 subscales: (1) Teamwork, (2) Patient Engagement, (3) Handoffs, and (4) Transitions (Cronbach's alpha 0.84-0.90). Scores were fairly consistent for 3 subscales but were lower for patient engagement. There were minor differences in scores by profession, department, and hospital.

CONCLUSION: The new tool measures 4 important aspects of inpatient care coordination with evidence for internal consistency and construct validity, indicating that the tool can be used in monitoring, evaluating, and planning care coordination activities in hospital settings. *Journal of Hospital Medicine* 2017;12:811-817. Published online first August 23, 2017. © 2017 Society of Hospital Medicine

Care Coordination has been defined as "…the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of healthcare services."[1] The Institute of Medicine identified care coordination as a key strategy to improve the American healthcare system,[2] and evidence has been building that well-coordinated care improves patient outcomes and reduces healthcare costs associated with chronic conditions.[3-5] In 2012, Johns Hopkins Medicine was awarded a Healthcare Innovation Award by the Centers for Medicare & Medicaid Services to improve coordination of care across the continuum of care for adult patients admitted to Johns Hopkins Hospital (JHH) and Johns Hopkins Bayview Medical Center (JHBMC), and for high-risk low-income Medicare and Medicaid beneficiaries receiving ambulatory care in targeted zip codes. The purpose of this project, known as the Johns Hopkins Community Health Partnership (J-CHiP), was to improve health and healthcare and to reduce healthcare costs. The acute care component of the program consisted of a bundle of interventions focused on improving coordination of care for all patients, including a "bridge to home" discharge process, as they transitioned back to the community from inpatient admission. The bundle included the following: early screening for discharge planning to predict needed postdischarge services; discussion in daily multidisciplinary rounds about goals and priorities of the hospitalization and potential postdischarge needs; patient and family self-care management; education enhanced medication management, including the option of "medications in hand" at the time of discharge; postdischarge telephone follow-up by nurses; and, for patients identified as high-risk, a "transition guide" (a nurse who works with the patient via home visits and by phone to optimize compliance with care for 30 days postdischarge).[6] While the primary endpoints of the J-CHiP program were to improve clinical outcomes and reduce healthcare costs,

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we were also interested in the impact of the program on care coordination processes in the acute care setting. This created the need for an instrument to measure healthcare professionals' views of care coordination in their immediate work environments.

We began our search for existing measures by reviewing the Coordination Measures Atlas published in 2014.[7] Although this report evaluates over 80 different measures of care coordination, most of them focus on the perspective of the patient and/or family members, on specific conditions, and on primary care or outpatient settings.[7,8] We were unable to identify an existing measure from the provider perspective, designed for the inpatient setting, that was both brief but comprehensive enough to cover a range of care coordination domains.[8]

Consequently, our first aim was to develop a brief, comprehensive tool to measure care coordination from the perspective of hospital inpatient staff that could be used to compare different units or types of providers, or to conduct longitudinal assessment. The second aim was to conduct a preliminary evaluation of the tool in our healthcare setting, including to assess its psychometric properties, to describe provider perceptions of care coordination after the implementation of J-CHiP, and to explore potential differences among departments, types of professionals, and between the 2 hospitals.

METHODS

Development of the Care Coordination Questionnaire

The survey was developed in collaboration with leaders of the J-CHiP Acute Care Team. We met at the outset and on multiple subsequent occasions to align survey domains with the main components of the J-CHiP acute care intervention and to assure that the survey would be relevant and understandable to a variety of multidisciplinary professionals, including physicians, nurses, social workers, physical therapists, and other health professionals. Care was taken to avoid redundancy with existing evaluation efforts and to minimize respondent burden. This process helped to ensure the content validity of the items, the usefulness of the results, and the future usability of the tool.

We modeled the Care Coordination Questionnaire (CCQ) after the Safety Attitudes Questionnaire (SAQ),[9] a widely used survey that is deployed approximately annually at JHH and JHBMC. While the SAQ focuses on healthcare provider attitudes about issues relevant to patient safety (often referred to as safety climate or safety culture), this new tool was designed to focus on healthcare professionals' attitudes about care coordination. Similar to the way that the SAQ "elicits a snapshot of the safety climate through surveys of frontline worker perceptions," we sought to elicit a picture of our care coordination climate through a survey of frontline hospital staff.

The CCQ was built upon the domains and approaches to care coordination described in the Agency for Healthcare Research and Quality Care Coordination Atlas.[3] This report identifies 9 mechanisms for achieving care coordination, including the following: Establish Accountability or Negotiate Responsibility; Communicate; Facilitate Transitions; Assess Needs and Goals; Create a Proactive Plan of Care; Monitor, Follow Up, and Respond to Change; Support Self-Management Goals; Link to Community Resources; and Align Resources with Patient and Population Needs; as well as 5 broad approaches commonly used to improve the delivery of healthcare, including Teamwork Focused on Coordination, Healthcare Home, Care Management, Medication Management, and Health IT-Enabled Coordination.[7] We generated at least 1 item to represent 8 of the 9 domains, as well as the broad approach described as Teamwork Focused on Coordination. After developing an initial set of items, we sought input from 3 senior leaders of the J-CHiP Acute Care Team to determine if the items covered the care coordination domains of interest, and to provide feedback on content validity. To test the interpretability of survey items and consistency across professional groups, we sent an initial version of the survey questions to at least 1 person from each of the following professional groups: hospitalist, social worker, case manager, clinical pharmacist, and nurse. We asked them to review all of our survey questions and to provide us with feedback on all aspects of the questions, such as whether they believed the questions were relevant and understandable to the members of their professional discipline, the appropriateness of the wording of the questions, and other comments. Modifications were made to the content and wording of the questions based on the feedback received. The final draft of the questionnaire was reviewed by the leadership team of the J-CHiP Acute Care Team to ensure its usefulness in providing actionable information.

The resulting 12-item questionnaire used a 5-point Likert response scale ranging from 1 = "disagree strongly" to 5 = "agree strongly," and an additional option of "not applicable (N/A)." To help assess construct validity, a global question was added at the end of the questionnaire asking, "Overall, how would you rate the care coordination at the hospital of your primary work setting?" The response was measured on a 10-point Likert-type scale ranging from 1 = "totally uncoordinated care" to 10 = "perfectly coordinated care" (see Appendix). In addition, the questionnaire requested information about the respondents' gender, position, and their primary unit, department, and hospital affiliation.

Data Collection Procedures

An invitation to complete an anonymous questionnaire was sent to the following inpatient care professionals: all nursing staff working on care coordination units in the departments of medicine, surgery, and neurology/neurosurgery, as well as physicians, pharmacists, acute care therapists (eg, occupational and physical therapists), and other frontline staff. All healthcare staff fitting these criteria was sent an e-mail with a request to fill out the survey online using Qualtrics™ (Qualtrics Labs Inc., Provo, UT), as well as multiple follow-up reminders. The participants worked either at the

JHH (a 1194-bed tertiary academic medical center in Baltimore, MD) or the JHBMC (a 440-bed academic community hospital located nearby). Data were collected from October 2015 through January 2016.

Analysis

Means and standard deviations were calculated by treating the responses as continuous variables. We tried 3 different methods to handle missing data: (1) without imputation, (2) imputing the mean value of each item, and (3) substituting a neutral score. Because all 3 methods produced very similar results, we treated the N/A responses as missing values without imputation for simplicity of analysis. We used STATA 13.1 (Stata Corporation, College Station, Texas) to analyze the data.

To identify subscales, we performed exploratory factor analysis on responses to the 12 specific items. Promax rotation was selected based on the simple structure. Subscale scores for each respondent were generated by computing the mean of responses to the items in the subscale. Internal consistency reliability of the subscales was estimated using Cronbach's alpha. We calculated Pearson correlation coefficients for the items in each subscale, and examined Cronbach's alpha deleting each item in turn. For each of the subscales identified and the global scale, we calculated the mean, standard deviation, median and interquartile range. Although distributions of scores tended to be non-normal, this was done to increase interpretability. We also calculated percent scoring at the ceiling (highest possible score).

We analyzed the data with 3 research questions in mind: Was there a difference in perceptions of care coordination between (1) staff affiliated with the 2 different hospitals, (2) staff affiliated with different clinical departments, or (3) staff with different professional roles? For comparisons based on hospital and department, and type of professional, nonparametric tests (Wilcoxon rank-sum and Kruskal-Wallis test) were used with a level of statistical significance set at 0.05. The comparison between hospitals and departments was made only among nurses to minimize the confounding effect of different distribution of professionals. We tested the distribution of "years in specialty" between hospitals and departments for this comparison using Pearson's χ^2 test. The difference was not statistically significant ($P = 0.167$ for hospitals, and $P = 0.518$ for departments), so we assumed that the potential confounding effect of this variable was negligible in this analysis. The comparison of scores within each professional group used the Friedman test. Pearson's χ^2 test was used to compare the baseline characteristics between 2 hospitals.

RESULTS

Among the 1486 acute care professionals asked to participate in the survey, 841 completed the questionnaire (response rate 56.6%). Table 1 shows the characteristics of the participants from each hospital. Table 2 summarizes the item response rates, proportion scoring at the ceiling, and weighting from the factor analysis. All items had completion rates of 99.2% or higher, with N/A responses ranging from 0% (item 2) to 3.1% (item 7). The percent scoring at the ceiling was 1.7% for the global item and ranged from 18.3% up to 63.3% for other individual items.

Factor analysis yielded 3 factors comprising 6, 3, and 2 items, respectively. Item 7 did not load on any of the 3 factors, but was retained as a subscale because it represented a distinct domain related to care coordination. To describe these domains, factor 1 was named the "Teamwork" subscale; factor 2, "Patient Engagement"; factor 3, "Transitions"; and item 7, "Handoffs." Subscale scores were calculated as the mean of item response scale scores. An overall scale score was also calculated as the mean of all 12 items. Average inter-item correlations ranged from 0.417 to 0.778, and Cronbach alpha was greater than 0.84 for the 3 multi-item subscales (Table 2). The pairwise correlation coefficients between the four subscales ranged from 0.368 (Teamwork and Handoffs) to 0.581 (Teamwork and Transitions). The correlation coefficient with the global item was 0.714 for Teamwork, 0.329 for Handoffs, 0.561 for Patient Engagement, 0.617 for Transitions, and 0.743 for overall scale. The percent scoring at the ceiling was 10.4% to 34.0% for subscales.

We used the new subscales to explore the perception of inpatient care coordination among healthcare professionals that were involved in the J-CHiP initiative (n = 646). Table 3 shows scores for respondents in different disciplines, comparing nurses, physicians and others. For all disciplines, participants reported lower levels of coordination on Patient Engagement compared to other subscales ($P < 0.001$ for nurses and others, $P = 0.0011$ for physicians). The mean global rating for care coordination was 6.79 on the 1 to 10 scale. There were no significant differences by profession on the subscales and global rating.

Comparison by hospital and primary department was carried out for nurses who comprised the largest proportion of respondents (Figure). The difference between hospitals on the transitions subscale was of borderline significance (4.24 vs 4.05; $P = 0.051$), and was significant in comparing departments to one another (4.10, 4.35, and 4.12, respectively for medicine, surgery, and others; $P = 0.002$).

We also examined differences in perceptions of care coordination among nursing units to illustrate the tool's ability to detect variation in Patient Engagement subscale scores for JHH nurses (see Appendix).

DISCUSSION

This study resulted in one of the first measurement tools to succinctly measure multiple aspects of care coordination in the hospital from the perspective of healthcare professionals. Given the hectic work environment of healthcare professionals, and the increasing emphasis on collecting data for evaluation and improvement, it is important to minimize respondent burden. This effort was catalyzed by a multifaceted initiative to redesign acute care delivery and promote seamless transitions of care, supported by the Center for Medicare & Medicaid Innovation. In initial testing, this questionnaire

TABLE 1. Characteristics of the Respondents

Characteristics	Total	JHH (N = 612)	JHBMC (N = 229)
Department			
Medicine	330 (39.2%)	234 (38.2%)	96 (41.9%)
Surgery	248 (29.5%)	222 (36.3%)	26 (11.4%)
Neurology/Neurosciences	90 (10.7%)	62 (10.1%)	28 (12.2%)
Psychiatry	21 (2.5%)	14 (2.3%)	7 (3.1%)
Rehabilitation	38 (4.5%)	30 (4.9%)	8 (3.5%)
Other	60 (7.1%)	37 (6.0%)	20 (8.7%)
No response	54 (6.4%)	13 (2.1%)	41 (17.9%)
Position			
Nurse	590 (70.2%)	416 (68.0%)	174 (76.0%)
Physician	37 (4.4%)	23 (3.8%)	14 (6.1%)
Pharmacist	16 (1.9%)	9 (1.5%)	7 (3.1%)
Dietitian/Nutritionist	2 (0.2%)	2 (0.3%)	0
Physician Assistant	10 (1.2%)	10 (1.6%)	0
Acute Care therapist	35 (4.2%)	35 (5.7%)	0
Coordination staff[a]	71 (8.4%)	53 (8.7%)	18 (17.0%)
Other	22 (2.6%)	15 (2.5%)	7 (3.1%)
No response	58 (6.9%)	49 (8.0%)	9 (3.9%)
Gender			
Female	702 (83.5%)	515 (84.2%)	187 (81.7%)
Male	101 (12.0%)	75 (12.3%)	26 (11.4%)
No response	38 (4.5%)	22 (3.6%)	16 (6.9%)
Total years in specialty			
Less than 1 year	76 (9.0%)	55 (9.0%)	21 (9.2%)
1 to 5 years	353 (42.0%)	275 (44.9%)	78 (34.1%)
6 to 10 years	138 (16.4%)	93 (15.2%)	45 (20.0%)
11 years or more	248 (29.5%)	173 (28.3%)	75 (32.8%)
No response	26 (3.1%)	16 (2.6%)	10 (4.4%)

[a]Coordination staff includes Case manager, Customer service representative, home care coordinator, social worker, transition guide, patient access line nurse and care coordination management staff.

NOTE: Numbers are n (%). Abbreviations: JHH; Johns Hopkins Hospital, JHBMC; Johns Hopkins Bayview Medical Center.

has evidence for reliability and validity. It was encouraging to find that the preliminary psychometric performance of the measure was very similar in 2 different settings of a tertiary academic hospital and a community hospital.

Our analysis of the survey data explored potential differences between the 2 hospitals, among different types of healthcare professionals and across different departments. Although we expected differences, we had no specific hypotheses about what those differences might be, and, in fact, did not observe any substantial differences. This could be taken to indicate that the intervention was uniformly and successfully implemented in both hospitals, and engaged various professionals in different departments. The ability to detect differences in care coordination at the nursing unit level could also prove to be beneficial for more precisely targeting where process improvement is needed. Further data collection and analyses should be conducted to more systematically compare units and to help identify those where practice is most advanced and those where improvements may be needed. It would also be informative to link differences in care coordination scores with patient outcomes. In addition, differences identified on specific domains between professional groups could be helpful to identify where greater efforts are needed to improve interdisciplinary practice. Sampling strategies stratified by provider type would need to be targeted to make this kind of analysis informative.

The consistently lower scores observed for patient engagement, from the perspective of care professionals in all groups, suggest that this is an area where improvement is needed. These findings are consistent with published reports on the common failure by hospitals to include patients as a member of their own care team. In addition to measuring care processes from the perspective of frontline healthcare workers, future evaluations within the healthcare system would also benefit from including data collected from the perspective of the patient and family.

This study had some limitations. First, there may be more than 4 domains of care coordination that are important and can be measured in the acute care setting from provider perspective. However, the addition of more domains should be balanced against practicality and respondent burden. It may be possible to further clarify priority domains in hospital settings as opposed to the primary care setting. Future research should be directed to find these areas and to develop a more comprehensive, yet still concise measurement instrument. Second, the tool was developed to measure the impact of a

TABLE 2. Item Completion Rate and Distribution, Factor Loadings, and Reliability

Subscale	Item	Item Completion Rate	% Ceiling	Factor Loading	Reliability
Teamwork (Eigenvalue: 5.28)	1. Multidisciplinary rounds help to improve care coordination.	99.8%	63.3%	0.708	Average inter-item correlation: 0.476 Cronbach alpha: 0.845
	2. Members of the healthcare team share information that enables timely decision-making.	99.7%	41.6%	0.722	
	3. Our clinical leader alerts the healthcare team about situations that may affect patient care.	99.8%	49.1%	0.572	
	4. Members of the healthcare team meet to reevaluate the patient care plan when the patient's situation had changed.	99.7%	35.0%	0.619	
	5. The healthcare team uses input from multidisciplinary rounds to help determine the patient's care plan.	99.4%	52.9%	0.736	
	6. The healthcare team explains information to patients and their families in lay terms.	99.7%	31.9%	0.407	
Handoffs	7. My discipline has a clear protocol for sharing information during patient handoffs.	100%	49.7%	N/A	N/A
Patient Engagement (Eigenvalue: 0.85)	8. The patient and/or family know who the primary contact is on their healthcare team.	99.7%	19.7%	0.634	Average inter-item correlation: 0.657 Cronbach alpha: 0.852
	9. Patients are actively engaged in developing their plan of care.	98.6%	18.3%	0.864	
	10. Patients are actively engaged in developing their discharge plans.	99.4%	22.8%	0.804	
Transitions (Eigenvalue: 0.44)	11. Members of the healthcare team teach patients how to take care of themselves after they leave the hospital.	99.4%	39.8%	0.730	Average inter-item correlation: 0.644 Cronbach alpha: 0.856
	12. The healthcare team gives patients the tools they need for a safe transition from the hospital to home, or the next care setting.	99.5%	39.9%	0.714	

NOTE: % Ceiling for subscales; 14.7% (Teamwork), 10.4% (Patient Engagement), and 34.0% (Transitions)

TABLE 3. Subscale Scores by Respondent Profession

Scale	Total (N = 646)	Profession			*P* value
		Nurse (N = 422)	Physician (N = 36)	Others (N = 188)	
Teamwork	4.19 ± 0.71	4.18 ± 0.71	4.25 ± 0.69	4.19 ± 0.71	.856
Patient Engagement	3.47 ± 1.02	3.40 ± 1.05	3.65 ± 0.82	3.60 ± 0.95	.694
Transitions	4.14 ± 0.87	4.19 ± 0.85	3.99 ± 0.84	4.06 ± 0.89	.073
Handoffs	4.22 ± 0.99	4.29 ± 0.92	4.03 ± 1.27	4.12 ± 1.07	.316
Overall	4.01 ± 0.69	4.00 ± 0.70	4.05 ± 0.59	4.01 ± 0.68	.967
Global	6.79 ± 1.60	6.71 ± 1.61	6.83 ± 1.67	6.96 ± 1.57	.114

NOTE: Numbers are mean ± standard deviation. The scores for subscales range from 1 to 5, and the scores for global scale range from 1 to 10. Higher scores indicate better care coordination. *P* values are generated from Kruskal-Wallis test.

large-scale intervention, and to fit into the specific context of 2 hospitals. Therefore, it should be tested in different settings of hospital care to see how it performs. However, virtually all hospitals in the United States today are adapting to changes in both financing and healthcare delivery. A tool such as the one described in this paper could be helpful to many organizations. Third, the scoring system for the overall scale score is not weighted and therefore reflects teamwork more than other components of care coordination, which are represented by fewer items. In general, we believe that use of the subscale scores may be more informative. Alternative scoring systems might also be proposed, including item weighting based on factor scores.

For the purposes of evaluation in this specific instance, we only collected data at a single point in time, after the intervention had been deployed. Thus, we were not able to evaluate the effectiveness of the J-CHiP intervention. We also did not intend to focus too much on the differences between units, giv-

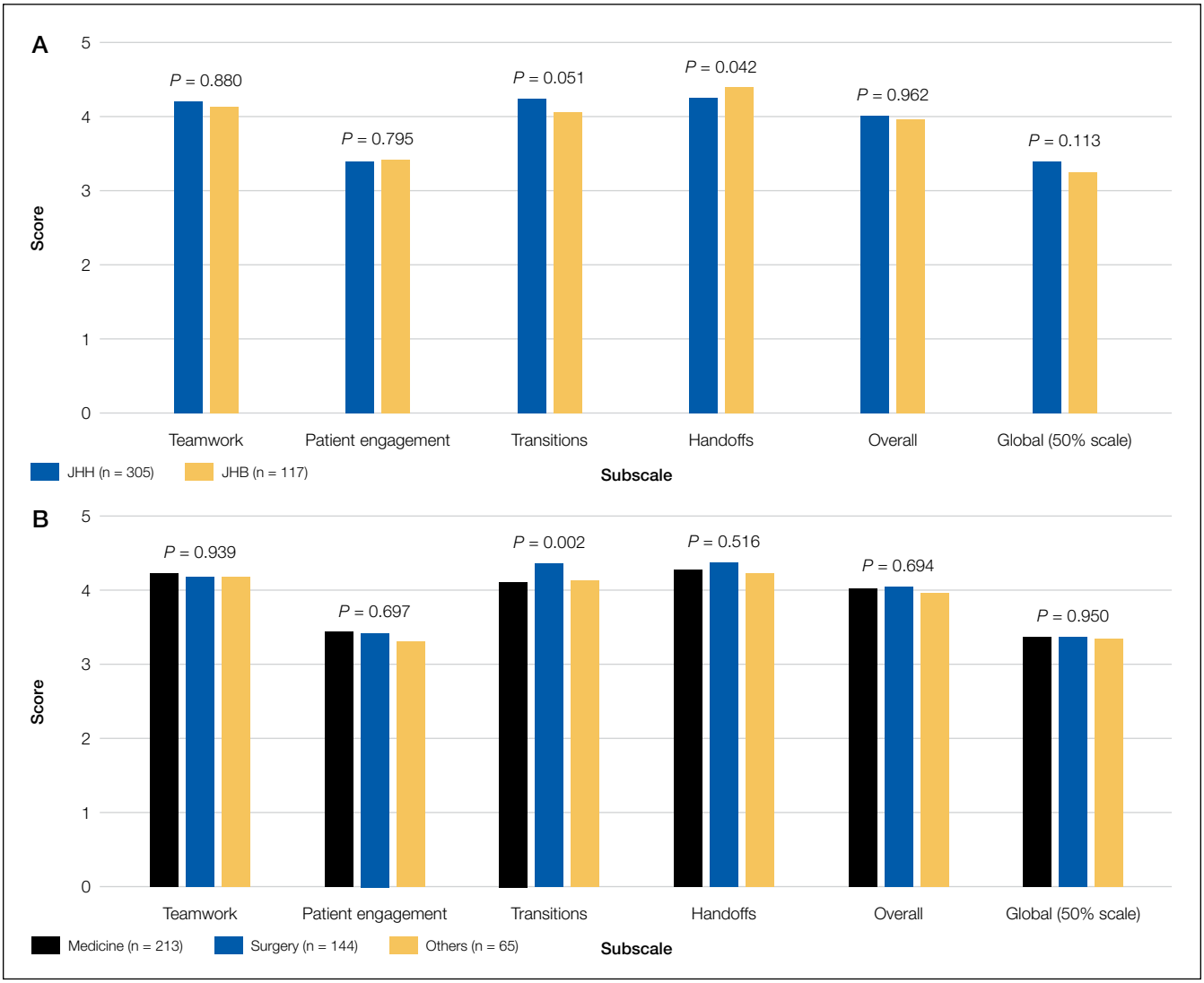

FIG. Mean subscale scores comparing nurses between hospitals (A) and departments (B). Subscale scores range from 1 to 5. Global scores range from 1 to 10 and are shown here in 50% scale for visual comparison. Higher scores indicate better care coordination. *P* values are generated from Wilcoxon rank sum test (A) and Kruskal-Wallis test (B).

en the limited number of respondents from individual units. It would be useful to collect more data at future time points, both to test the responsiveness of the scales and to evaluate the impact of future interventions at both the hospital and unit level.

The preliminary data from this study have generated insights about gaps in current practice, such as in engaging patients in the inpatient care process. It has also increased awareness by hospital leaders about the need to achieve high reliability in the adoption of new procedures and interdisciplinary practice. This tool might be used to find areas in need of improvement, to evaluate the effect of initiatives to improve care coordination, to monitor the change over time in the perception of care coordination among healthcare professionals, and to develop better intervention strategies for coordination activities in acute care settings. Additional research is needed to provide further evidence for the reliability and validity of this measure in diverse settings.

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Regional Variation in Standardized Costs of Care at Children's Hospitals

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BACKGROUND: Though regional variation in healthcare spending has received national attention, it has not been widely studied in pediatrics.

OBJECTIVES: (1) To evaluate regional variation in costs of care for 3 inpatient pediatric conditions, (2) assess potential drivers of variation, and (3) estimate cost savings from reducing variation.

DESIGN/SETTING/PATIENTS: Retrospective cohort study of hospitalizations for asthma, diabetic ketoacidosis (DKA), and acute gastroenteritis (AGE) at 46 children's hospitals from October 2014 to September 2015.

INTERVENTION/MEASUREMENTS: Variation in trimmed standardized costs were assessed within and across regions. Linear mixed effects models were adjusted for patient- and encounter-level variables to assess drivers of variation.

RESULTS: After adjusting for patient-level factors, variation remained. Using census division clusters, mean trimmed and adjusted total standardized costs were 120% higher for asthma ($1920 vs $4227), 46% higher for DKA ($7429 vs $10,881), and 150% higher for AGE ($3316 vs $8292) in the highest-cost compared with the lowest-cost region. Comparing hospitals in the same region, standardized costs were significantly different ($P < 0.001$) for each condition in each region. Drivers of variation were encounter-level variables including length of stay and intensive care unit utilization. For this cohort, annual savings from reducing variation would equal $69.1 million at the interregional level and $25.2 million at the intraregional level.

CONCLUSIONS: Pediatric hospital costs vary between and within regions. Future studies should examine how much of this variation is avoidable. To the extent that less spending does not compromise outcomes, care models may be adjusted to eliminate unwarranted variation and reduce costs. *Journal of Hospital Medicine* 2017;12:818-825. Published online first September 6, 2017. © 2017 Society of Hospital Medicine

With some areas of the country spending close to 3 times more on healthcare than others, regional variation in healthcare spending has been the focus of national attention.[1-7] Since 1973, the Dartmouth Institute has studied regional variation in healthcare utilization and spending and concluded that variation is "unwarranted" because it is driven by providers' practice patterns rather than differences in medical need, patient preferences, or evidence-based medicine.[8-11] However, critics of the Dartmouth Institute's findings argue that their approach does not adequately adjust for community-level income, and that higher costs in some areas reflect greater patient needs that are not reflected in illness acuity alone.[12-14]

While Medicare data have made it possible to study variations in spending for the senior population, fragmentation of insurance coverage and nonstandardized data structures make studying the pediatric population more difficult. However, the Children's Hospital Association's (CHA) Pediatric Health Information System (PHIS) has made large-scale comparisons more feasible. To overcome challenges associated with using charges and nonuniform cost data, PHIS-derived standardized costs provide new opportunities for comparisons.[15,16] Initial analyses using PHIS data showed significant interhospital variations in costs of care,[15] but they did not adjust for differences in populations and assess the drivers of variation. A more recent study that controlled for payer status, comorbidities, and illness severity found that intensive care unit (ICU) utilization varied significantly for children hospitalized for asthma, suggesting that hospital practice patterns drive differences in cost.[17]

This study uses PHIS data to analyze regional variations in standardized costs of care for 3 conditions for which children are hospitalized. To assess potential drivers of variation, the study investigates the effects of patient-level demographic and illness-severity variables as well as encounter-level variables on costs of care. It also estimates cost savings from reducing variation.

METHODS

Data Source

This retrospective cohort study uses the PHIS database (CHA, Overland Park, KS), which includes 48 freestanding children's hospitals located in noncompeting markets across

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the United States and accounts for approximately 20% of pediatric hospitalizations. PHIS includes patient demographics, *International Classification of Diseases, 9th Revision* (ICD-9) diagnosis and procedure codes, as well as hospital charges. In addition to total charges, PHIS reports imaging, laboratory, pharmacy, and "other" charges. The "other" category aggregates clinical, supply, room, and nursing charges (including facility fees and ancillary staff services).

Inclusion Criteria

Inpatient- and observation-status hospitalizations for asthma, diabetic ketoacidosis (DKA), and acute gastroenteritis (AGE) at 46 PHIS hospitals from October 2014 to September 2015 were included. Two hospitals were excluded because of missing data. Hospitalizations for patients >18 years were excluded.

Hospitalizations were categorized by using All Patient Refined-Diagnosis Related Groups (APR-DRGs) version 24 (3M Health Information Systems, St. Paul, MN)[18] based on the ICD-9 diagnosis and procedure codes assigned during the episode of care. Analyses included APR-DRG 141 (asthma), primary diagnosis ICD-9 codes 250.11 and 250.13 (DKA), and APR-DRG 249 (AGE). ICD-9 codes were used for DKA for increased specificity.[19] These conditions were chosen to represent 3 clinical scenarios: (1) a diagnosis for which hospitals differ on whether certain aspects of care are provided in the ICU (asthma), (2) a diagnosis that frequently includes care in an ICU (DKA), and (3) a diagnosis that typically does not include ICU care (AGE).[19]

Study Design

To focus the analysis on variation in resource utilization across hospitals rather than variations in hospital item charges, each billed resource was assigned a standardized cost.[15,16] For each clinical transaction code (CTC), the median unit cost was calculated for each hospital. The median of the hospital medians was defined as the standardized unit cost for that CTC.

The primary outcome variable was the total standardized cost for the hospitalization adjusted for patient-level demographic and illness-severity variables. Patient demographic and illness-severity covariates included age, race, gender, ZIP code-based median annual household income (HHI), rural-urban location, distance from home ZIP code to the hospital, chronic condition indicator (CCI), and severity-of-illness (SOI). When assessing drivers of variation, encounter-level covariates were added, including length of stay (LOS) in hours, ICU utilization, and 7-day readmission (an imprecise measure to account for quality of care during the index visit). The contribution of imaging, laboratory, pharmacy, and "other" costs was also considered.

Median annual HHI for patients' home ZIP code was obtained from 2010 US Census data. Community-level HHI, a proxy for socioeconomic status (SES),[20,21] was classified into categories based on the 2015 US federal poverty level (FPL) for a family of 4[22]: HHI-1 = ≤ 1.5 × FPL; HHI-2 = 1.5 to 2 × FPL; HHI-3 = 2 to 3 × FPL; HHI-4 = ≥ 3 × FPL. Rural-urban commuting area (RUCA) codes were used to determine the rural-urban classification of the patient's home.[23] The distance from home ZIP code to the hospital was included as an additional control for illness severity because patients traveling longer distances are often more sick and require more resources.[24]

The Agency for Healthcare Research and Quality CCI classification system was used to identify the presence of a chronic condition.[25] For asthma, CCI was flagged if the patient had a chronic condition other than asthma; for DKA, CCI was flagged if the patient had a chronic condition other than DKA; and for AGE, CCI was flagged if the patient had any chronic condition.

The APR-DRG system provides a 4-level SOI score with each APR-DRG category. Patient factors, such as comorbid diagnoses, are considered in severity scores generated through 3M's proprietary algorithms.[18]

For the first analysis, the 46 hospitals were categorized into 7 geographic regions based on 2010 US Census Divisions.[26] To overcome small hospital sample sizes, Mountain and Pacific were combined into West, and Middle Atlantic and New England were combined into North East. Because PHIS hospitals are located in noncompeting geographic regions, for the second analysis, we examined hospital-level variation (considering each hospital as its own region).

Data Analysis

To focus the analysis on "typical" patients and produce more robust estimates of central tendencies, the top and bottom 5% of hospitalizations with the most extreme standardized costs by condition were trimmed.[27] Standardized costs were log-transformed because of their nonnormal distribution and analyzed by using linear mixed models. Covariates were added stepwise to assess the proportion of the variance explained by each predictor. Post-hoc tests with conservative single-step stepwise mutation model corrections for multiple testing were used to compare adjusted costs. Statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC). P values < 0.05 were considered significant. The Children's Hospital of Philadelphia Institutional Review Board did not classify this study as human subjects research.

RESULTS

During the study period, there were 26,430 hospitalizations for asthma, 5056 for DKA, and 16,274 for AGE (Table 1).

Variation Across Census Regions

After adjusting for patient-level demographic and illness-severity variables, differences in adjusted total standardized costs remained between regions ($P < 0.001$). Although no region was an outlier compared to the overall mean for any of the conditions, regions were statistically different in pairwise comparison. The East North Central, South Atlantic, and West South Central regions had the highest adjusted total standardized costs for each of the conditions. The East

TABLE 1. Study Sample Characteristics by Hospitalization

Characteristics	Overall	West	West North Central	West South Central	East North Central	East South Central	North East	South Atlantic	*P*
Number of encounters	47,760	8467	3849	9235	7140	5664	7792	5613	
Number of hospitals	46	10	4	8	7	5	7	5	
Patient age									<.0001
<1 year	4659 (9.76)	664 (7.84)	425 (11.04)	961 (10.41)	623 (8.73)	713 (12.59)	729 (9.36)	544 (9.69)	
1 to 4 years	18,619 (38.98)	3580 (42.28)	1476 (38.35)	3108 (33.65)	2812 (39.38)	2169 (38.29)	3317 (42.57)	2157 (38.43)	
5 to 12 years	18,190 (38.09)	3208 (37.89)	1410 (36.63)	3935 (42.61)	2716 (38.04)	2058 (36.33)	2736 (35.11)	2127 (37.89)	
>12 years	6292 (13.17)	1015 (11.99)	538 (13.98)	1231 (13.33)	989 (13.85)	724 (12.78)	1010 (12.96)	785 (13.99)	
Gender: male	27,434 (57.44)	4899 (57.86)	2192 (56.95)	5337 (57.79)	4099 (57.41)	3185 (56.23)	4483 (57.53)	3239 (57.71)	.4693
Patient race									<.0001
White	18,179 (38.06)	2779 (32.82)	1769 (45.96)	3455 (37.41)	3361 (47.07)	2718 (47.99)	2653 (34.05)	1444 (25.73)	
Black	15,650 (32.77)	1049 (12.39)	1373 (35.67)	2782 (30.12)	2528 (35.41)	2396 (42.3)	2947 (37.82)	2575 (45.88)	
Hispanic or Latino	9596 (20.09)	3453 (40.78)	344 (8.94)	2521 (27.3)	810 (11.34)	206 (3.64)	1180 (15.14)	1082 (19.28)	
Asian	1006 (2.11)	390 (4.61)	73 (1.9)	102 (1.1)	123 (1.72)	35 (0.62)	173 (2.22)	110 (1.96)	
American Indian or Alaskan Native	128 (0.27)	63 (0.74)	22 (0.57)	15 (0.16)	5 (0.07)	5 (0.09)	10 (0.13)	8 (0.14)	
Native Hawaiian or other Pacific Islander	105 (0.22)	75 (0.89)	4 (0.1)	7 (0.08)	10 (0.14)	5 (0.09)	3 (0.04)	1 (0.02)	
Other	3096 (6.48)	658 (7.77)	264 (6.86)	353 (3.82)	303 (4.24)	299 (5.28)	826 (10.6)	393 (7)	
Payer									<.0001
Commercial/ private/ employer-based	15,817 (33.12)	3012 (35.57)	1644 (42.71)	2769 (29.98)	2406 (33.7)	1686 (29.77)	2491 (31.97)	1809 (32.23)	
Public	28,963 (60.64)	5165 (61)	2015 (52.35)	5375 (58.2)	4233 (59.29)	3809 (67.25)	4738 (60.81)	3628 (64.64)	
Uninsured	1008 (2.11)	157 (1.85)	68 (1.77)	244 (2.64)	168 (2.35)	95 (1.68)	139 (1.78)	137 (2.44)	
Other	1972 (4.13)	133 (1.57)	122 (3.17)	847 (9.17)	333 (4.66)	74 (1.31)	424 (5.44)	39 (0.69)	
Complex chronic condition(s) present	5923 (12.4)	1090 (12.87)	465 (12.08)	987 (10.69)	1001 (14.02)	608 (10.73)	1037 (13.31)	735 (13.09)	<.0001
Median household income									<.0001
HHI 1 ($36,375 or less)	20,106 (42.1)	2610 (30.83)	1348 (35.02)	4008 (43.4)	2873 (40.24)	3391 (59.87)	4180 (53.64)	1696 (30.22)	
HHI 2 ($36,376-$48,500)	14,257 (29.85)	2661 (31.43)	1094 (28.42)	2696 (29.19)	2601 (36.43)	1449 (25.58)	1898 (24.36)	1858 (33.1)	
HHI 3 ($48,501-$72,750)	10,818 (22.65)	2496 (29.48)	1208 (31.38)	1951 (21.13)	1476 (20.67)	693 (12.24)	1311 (16.82)	1683 (29.98)	
HHI 4 ($72,751 or more)	2579 (5.4)	700 (8.27)	199 (5.17)	580 (6.28)	190 (2.66)	131 (2.31)	403 (5.17)	376 (6.7)	
Severity of illness									<.0001
1	20962 (43.89)	2487 (29.37)	1878 (48.79)	4149 (44.93)	3046 (42.66)	2560 (45.2)	4381 (56.22)	2461 (43.84)	
2	21,649 (45.33)	4784 (56.5)	1575 (40.92)	4215 (45.64)	3332 (46.67)	2447 (43.2)	2738 (35.14)	2558 (45.57)	
3	4728 (9.9)	1100 (12.99)	367 (9.53)	792 (8.58)	696 (9.75)	614 (10.84)	611 (7.84)	548 (9.76)	
4	421 (0.88)	96 (1.13)	29 (0.75)	79 (0.86)	66 (0.92)	43 (0.76)	62 (0.8)	46 (0.82)	
ICU flag	4185 (8.76)	709 (8.37)	162 (4.21)	744 (8.06)	927 (12.98)	603 (10.65)	526 (6.75)	514 (9.16)	<.0001
RUCA code									<.0001
Urban core	40,553 (84.91)	7569 (89.39)	3207 (83.32)	7149 (77.41)	6120 (85.71)	4032 (71.19)	7354 (94.38)	5122 (91.25)	
Sub-urban	3638 (7.62)	425 (5.02)	364 (9.46)	1281 (13.87)	449 (6.29)	585 (10.33)	220 (2.82)	314 (5.59)	
Large rural town	1985 (4.16)	264 (3.12)	98 (2.55)	462 (5)	381 (5.34)	552 (9.75)	145 (1.86)	83 (1.48)	
Small town/isolated rural	1584 (3.32)	209 (2.47)	180 (4.68)	343 (3.71)	190 (2.66)	495 (8.74)	73 (0.94)	94 (1.67)	
Urban area	47,185 (98.8)	8397 (99.17)	3777 (98.13)	9113 (98.68)	7076 (99.1)	5484 (96.82)	7762 (99.61)	5576 (99.34)	<.0001

NOTE: The following are the states included in each region: West (**AK**, **AZ**, **CA**, **CO**, HI, ID, MT, NM, NV, OR, **UT**, **WA**, **WY**), West North Central (IA, KS, MN, **MO**, ND, **NE**, SD), West South Central (**AR**, **LA**, OK, **TX**), East North Central (**IL**, **IN**, **MI**, **OH**, **WI**), East South Central (**AL**, **KY**, **MS**, **TN**), North East (**CT**, **MA**, ME, NH, NJ, **NY**, **PA**, RI, VT), and South Atlantic (**DC**, DE, **FL**, **GA**, MD, NC, SC, **VA**, WV). States with hospitals represented in the analysis are italicized. Abbreviations: HHI, household income; ICU, intensive care unit; RUCA, rural-urban commuting area.

South Central and West North Central regions had the lowest costs for each of the conditions. Adjusted total standardized costs were 120% higher for asthma ($1920 vs $4227), 46% higher for DKA ($7429 vs $10,881), and 150% higher for AGE ($3316 vs $8292) in the highest-cost region compared with the lowest-cost region (Table 2A).

Variation Within Census Regions

After controlling for patient-level demographic and illness-severity variables, standardized costs were different across hospitals in the same region ($P < 0.001$; panel A in Figure). This was true for all conditions in each region. Differences between the lowest- and highest-cost hospitals within the same region

TABLE 2. Average Total Standardized Costs per Hospitalization Trimmed and Adjusted for Patient-Level Variables for Census Division Analysis and Hospital-Level Analysis

A: Census division regions	Asthma	DKA	AGE
West	$2621	$10,307[a]	$5360
West North Central	$1920[b]	$8023[a]	$4102
West South Central	$2869	$10,881[a]	$6830
East North Central	$4227[a]	$10,260[a]	$8292[a]
East South Central	$1932[b]	$7429[b]	$3316[b]
North East	$2710	$10,584[a]	$6451
South Atlantic	$3482	$10,681[a]	$7649
High-low difference	$2307	$3452	$4976
High-low difference (%)	120%	46%	150%
B: Each hospital as its own region	**Asthma**	**DKA**	**AGE**
High	$9087	$28,564	$23,387
Low	$721	$2738	$1317
High-low difference (%)	1160%	943%	1676%
High (excluding outliers)	$4678	$18,780	$10,281
Difference (excluding outliers)	549%	586%	681%
Interquartile range (after trimming)	$1748-$3218	$5683-$9481	$2708-$5991
Median	$2339	$6823	$4207
Average (all patients)	$2849	$4612	$2855

[a]Highest total adjusted standardized costs for the specific condition across the regions.

[b]Lowest total adjusted standardized costs for the specific condition across the regions.

NOTE: Where multiple cells are designated with an a or b for the same condition, regions were not statistically significantly different. A: Interregional variation using census division regions. Asthma: all regions were different except East South Central compared with West South Central and North East compared with West. DKA: West South Central, South Atlantic, North East and West were not different from each other, but they were all different from West North Central and East South Central. AGE: all regions were different except West South Central compared with North East. B: Interregional variation considering each of the 46 hospitals as its own region. Abbreviations: AGE, acute gastroenteritis; DKA, diabetic ketoacidosis.

TABLE 3. Measures of Intraregional Variation Using Census Division Geographic Clusters (Based on Average Total Standardized Costs Per Hospitalization, Trimmed and Adjusted for Patient-Level Variables)

	Asthma				DKA				AGE			
Region	High	Low	Difference	CV	High	Low	Difference	CV	High	Low	Difference	CV
West	$3218	$721	346%	35.5	$9731	$4147	135%	22.6	$9470	$2841	233%	47.6
West North Central	$3013	$1251	141%	39.2	$12,123	$2738	343%	56.1	$5567	$1859	199%	52.8
West South Central	$3950	$1399	182%	37.6	$18,780[a] $14,536	$3826	391% 280%	47.5	$10,281	$1689	509%	57.0
East North Central	$9087[a]	$1749	420%	63.1	$28,564[a]	$5741	398%	81.1	$23,387[a]	$2636	787%	97.9
	$5977[a] $3680	$1749 $1749	242% 110%	63.1 63.1	$13,539	$5741	136%	81.1	$8038	$2636	205%	97.9
East South Central	$2458	$1097	124%	31.2	$9178	$3741	145%	34.3	$4120	$1317	213%	29.1
North East	$3218	$1525	111%	26.9	$9674	$4806	101%	28.8	$6475	$2084	211%	32.1
South Atlantic	$4678	$1807	159%	34.7	$16,192	$5548	192%	43.0	$8710	$3265	167%	33.3

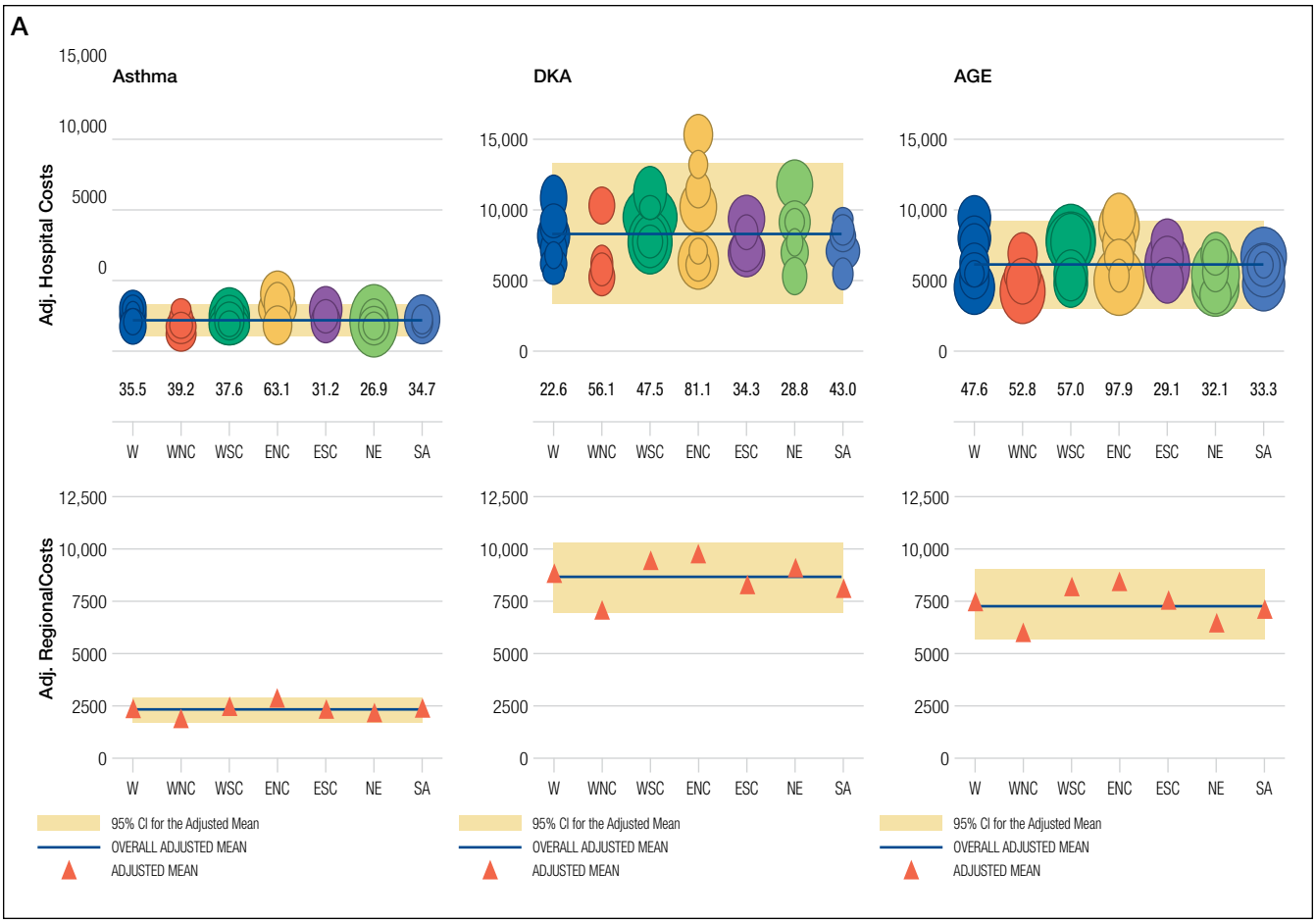
[a]This hospital was a statistical outlier (ie, it was outside of the 95% confidence interval compared to the mean across all hospitals). NOTE: Regions with outlier hospitals include multiple rows to show the effects of removing each outlier.

NOTE: Abbreviations: AGE, acute gastroenteritis; CV, coefficient of variation; DKA, diabetic ketoacidosis.

ranged from 111% to 420% for asthma, 101% to 398% for DKA, and 166% to 787% for AGE (Table 3).

Variation Across Hospitals (Each Hospital as Its Own Region)

One hospital had the highest adjusted standardized costs for all 3 conditions ($9087 for asthma, $28,564 for DKA, and $23,387 for AGE) and was outside of the 95% confidence interval compared with the overall means. The second highest-cost hospitals for asthma ($5977) and AGE ($18,780) were also outside of the 95% confidence interval. After removing these outliers, the difference between the highest- and lowest-cost hospitals was 549% for asthma ($721 vs



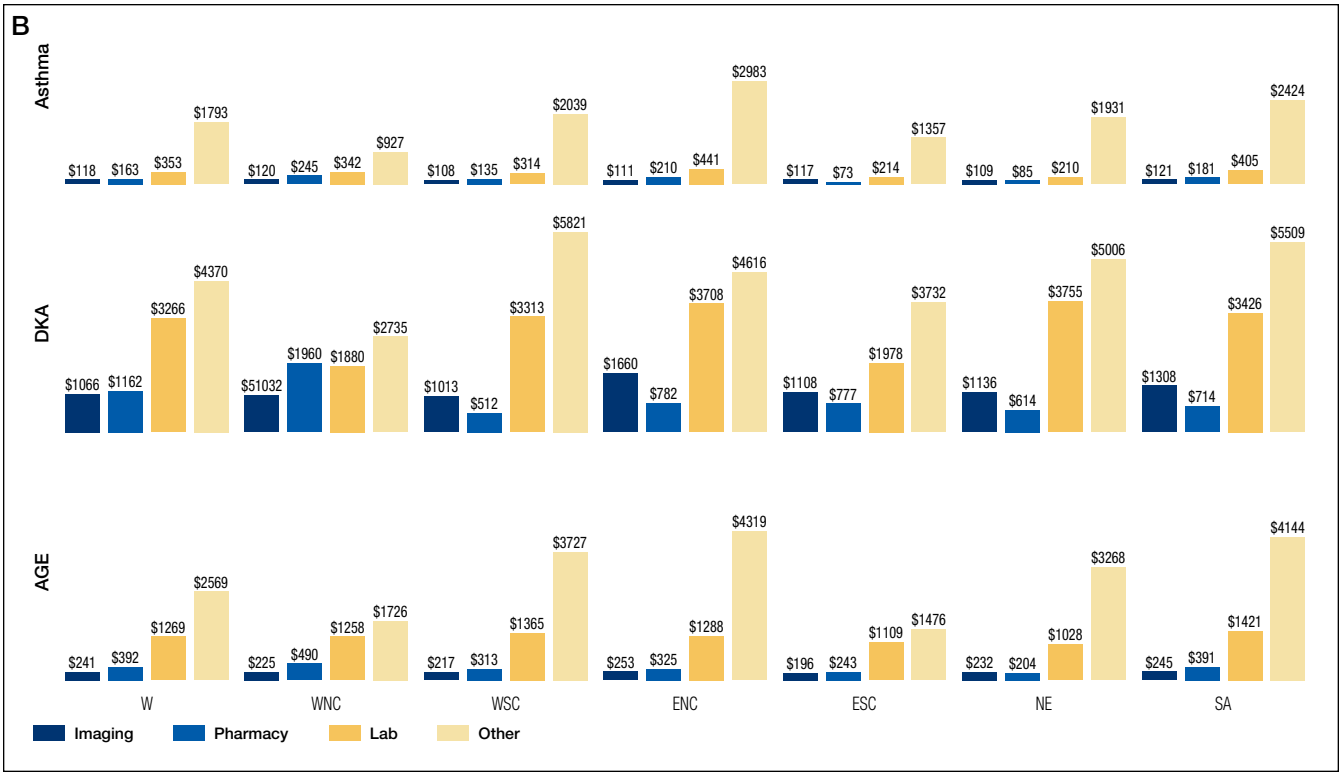


FIG. (A) Average hospital-level and regional-level total standardized costs per hospitalization (trimmed and adjusted). (B) Components of average total standard costs (trimmed and adjusted). NOTE: Abbreviations: AGE, acute gastroenteritis; DKA, diabetic ketoacidosis.

$4678), 491% for DKA ($2738 vs $16,192), and 681% for AGE ($1317 vs $10,281; Table 2B).

Drivers of Variation Across Census Regions

Patient-level demographic and illness-severity variables explained very little of the variation in standardized costs across regions. For each of the conditions, age, race, gender, community-level HHI, RUCA, and distance from home to the hospital each accounted for <1.5% of variation, while SOI and CCI each accounted for <5%. Overall, patient-level variables explained 5.5%, 3.7%, and 6.7% of variation for asthma, DKA, and AGE.

Encounter-level variables explained a much larger percentage of the variation in costs. LOS accounted for 17.8% of the variation for asthma, 9.8% for DKA, and 8.7% for AGE. ICU utilization explained 6.9% of the variation for asthma and 12.5% for DKA; ICU use was not a major driver for AGE. Seven-day readmissions accounted for <0.5% for each of the conditions. The combination of patient-level and encounter-level variables explained 27%, 24%, and 15% of the variation for asthma, DKA, and AGE.

Drivers of Variation Across Hospitals

For each of the conditions, patient-level demographic variables each accounted for <2% of variation in costs between hospitals. SOI accounted for 4.5% of the variation for asthma and CCI accounted for 5.2% for AGE. Overall, patient-level variables explained 6.9%, 5.3%, and 7.3% of variation for asthma, DKA, and AGE.

Encounter-level variables accounted for a much larger percentage of the variation in cost. LOS explained 25.4% for asthma, 13.3% for DKA, and 14.2% for AGE. ICU utilization accounted for 13.4% for asthma and 21.9% for DKA; ICU use was not a major driver for AGE. Seven-day readmissions accounted for <0.5% for each of the conditions. Together, patient-level and encounter-level variables explained 40%, 36%, and 22% of variation for asthma, DKA, and AGE.

Imaging, Laboratory, Pharmacy, and "Other" Costs

The largest contributor to total costs adjusted for patient-level factors for all conditions was "other," which aggregates room, nursing, clinical, and supply charges (panel B in Figure). When considering drivers of variation, this category explained >50% for each of the conditions. The next largest contributor to total costs was laboratory charges, which accounted for 15% of the variation across regions for asthma and 11% for DKA. Differences in imaging accounted for 18% of the variation for DKA and 15% for AGE. Differences in pharmacy charges accounted for <4% of the variation for each of the conditions. Adding the 4 cost components to the other patient- and encounter-level covariates, the model explained 81%, 78%, and 72% of the variation across census regions for asthma, DKA, and AGE.

For the hospital-level analysis, differences in "other" remained the largest driver of cost variation. For asthma, "other" explained 61% of variation, while pharmacy, laboratory, and imaging each accounted for <8%. For DKA, differences in imaging accounted for 18% of the variation and laboratory charges accounted for 12%. For AGE, imaging accounted for 15% of the variation. Adding the 4 cost components to the other patient- and encounter-level covariates, the model explained 81%, 72%, and 67% of the variation for asthma, DKA, and AGE.

Cost Savings

If all hospitals in this cohort with adjusted standardized costs above the national PHIS average achieved costs equal to the national PHIS average, estimated annual savings in adjusted standardized costs for these 3 conditions would be $69.1 million. If each hospital with adjusted costs above the average within its census region achieved costs equal to its regional average, estimated annual savings in adjusted standardized costs for these conditions would be $25.2 million.

DISCUSSION

This study reported on the regional variation in costs of care for 3 conditions treated at 46 children's hospitals across 7 geographic regions, and it demonstrated that variations in costs of care exist in pediatrics. This study used standardized costs to compare utilization patterns across hospitals and adjusted for several patient-level demographic and illness-severity factors, and it found that differences in costs of care for children hospitalized with asthma, DKA, and AGE remained both between and within regions.

These variations are noteworthy, as hospitals strive to improve the value of healthcare. If the higher-cost hospitals in this cohort could achieve costs equal to the national PHIS averages, estimated annual savings in adjusted standardized costs for these conditions alone would equal $69.1 million. If higher-cost hospitals relative to the average in their own region reduced costs to their regional averages, annual standardized cost savings could equal $25.2 million for these conditions.

The differences observed are also significant in that they provide a foundation for exploring whether lower-cost regions or lower-cost hospitals achieve comparable quality outcomes.[28] If so, studying what those hospitals do to achieve outcomes more efficiently can serve as the basis for the establishment of best practices.[29] Standardizing best practices through protocols, pathways, and care-model redesign can reduce potentially unnecessary spending.[30]

Our findings showed that patient-level demographic and illness-severity covariates, including community-level HHI and SOI, did not consistently explain cost differences. Instead, LOS and ICU utilization were associated with higher costs.[17,19] When considering the effect of the 4 cost components on the variation in total standardized costs between regions and between hospitals, the fact that the "other" category accounted for the largest percent of the variation is not surprising, because the cost of room occupancy and nursing services increases with longer LOS and more time in

the ICU. Other individual cost components that were major drivers of variation were laboratory utilization for asthma and imaging for DKA and AGE[31] (though they accounted for a much smaller proportion of total adjusted costs).[19]

To determine if these factors are modifiable, more information is needed to explain why practices differ. Many factors may contribute to varying utilization patterns, including differences in capabilities and resources (in the hospital and in the community) and patient volumes. For example, some hospitals provide continuous albuterol for status asthmaticus only in ICUs, while others provide it on regular units.[32] But if certain hospitals do not have adequate resources or volumes to effectively care for certain populations outside of the ICU, their higher-value approach (considering quality and cost) may be to utilize ICU beds, even if some other hospitals care for those patients on non-ICU floors. Another possibility is that family preferences about care delivery (such as how long children stay in the hospital) may vary across regions.[33]

Other evidence suggests that physician practice and spending patterns are strongly influenced by the practices of the region where they trained.[34] Because physicians often practice close to where they trained,[35,36] this may partially explain how regional patterns are reinforced.

Even considering all mentioned covariates, our model did not fully explain variation in standardized costs. After adding the cost components as covariates, between one-third and one-fifth of the variation remained unexplained. It is possible that this unexplained variation stemmed from unmeasured patient-level factors.

In addition, while proxies for SES, including community-level HHI, did not significantly predict differences in costs across regions, it is possible that SES affected LOS differently in different regions. Previous studies have suggested that lower SES is associated with longer LOS.[37] If this effect is more pronounced in certain regions (potentially because of differences in social service infrastructures), SES may be contributing to variations in cost through LOS.

Our findings were subject to limitations. First, this study only examined 3 diagnoses and did not include surgical or less common conditions. Second, while PHIS includes tertiary care, academic, and freestanding children's hospitals, it does not include general hospitals, which is where most pediatric patients receive care.[38] Third, we used ZIP code-based median annual HHI to account for SES, and we used ZIP codes to determine the distance to the hospital and rural-urban location of patients' homes. These approximations lack precision because SES and distances vary within ZIP codes.[39] Fourth, while adjusted standardized costs allow for comparisons between hospitals, they do not represent actual costs to patients or individual hospitals. Additionally, when determining whether variation remained after controlling for patient-level variables, we included SOI as a reflection of illness-severity at presentation. However, in practice, SOI scores may be assigned partially based on factors determined during the hospitalization.[18] Finally, the use of other regional boundaries or the selection of different hospitals may yield different results.

CONCLUSION

This study reveals regional variations in costs of care for 3 inpatient pediatric conditions. Future studies should explore whether lower-cost regions or lower-cost hospitals achieve comparable quality outcomes. To the extent that variation is driven by modifiable factors and lower spending does not compromise outcomes, these data may prompt reviews of care models to reduce unwarranted variation and improve the value of care delivery at local, regional, and national levels.

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Outpatient Treatment of Deep Vein Thrombosis in the United States: The Reasons for Geographic and Racial Differences in Stroke Study

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BACKGROUND: Outpatient versus inpatient treatment of deep vein thrombosis (DVT) is believed to result in equivalent outcomes with decreased costs. Little is known about the adoption of outpatient DVT treatment in the United States.

OBJECTIVE: To describe the uptake of outpatient DVT treatment in the United States and understand how comorbidities and socioeconomic conditions impact the decision to treat as an outpatient.

DESIGN AND SETTING: The Reasons for Geographic and Racial Differences in Stroke cohort study recruited 30,329 participants between 2003 and 2007. DVT events were ascertained through 2011.

MEASUREMENTS: Multivariable logistic regression was used to determine the correlates of outpatient treatment of DVT accounting for age, sex, race, education, income, urban or rural residence, and region of residence.

RESULTS: Of 379 venous thromboembolism events, 141 participants had a DVT without diagnosed pulmonary embolism and that did not occur during hospitalization. Overall, 28% (39 of 141) of participants with DVT were treated as outpatients. In a multivariable model, the odds ratio for outpatient versus inpatient DVT treatment was 4.16 (95% confidence interval [CI], 1.25-13.79) for urban versus rural dwellers, 3.29 (95% CI, 1.30-8.30) for white versus black patients, 2.41 (95% CI, 1.06-5.47) for women versus men, and 1.90 (95% CI, 1.19-3.02) for every 10 years younger in age. Living outside the southeastern United States and having higher education and income were not statistically significantly associated with outpatient treatment.

CONCLUSIONS: Despite known safety and efficacy, only 28% of participants with DVT received outpatient treatment. This study highlights populations in which efforts could be made to reduce hospital admissions. *Journal of Hospital Medicine* 2017;12:826-830. Published online first September 6, 2017. © 2017 Society of Hospital Medicine

Venous thromboembolism (VTE) is a common medical condition comprising deep vein thrombosis (DVT) and pulmonary embolism (PE). Estimates of the incidence of DVT in the United States vary between 0.5 and 1.5 cases per 1000 person-years.[1] Left untreated, roughly 50% of DVT patients progress to a PE, of whom 10% to 25% die within 3 months.[2]

Since the 1990s, multiple randomized controlled studies[3-5] demonstrated the safety and efficacy of outpatient treatment for selected DVT patients with low molecular weight heparin and warfarin. The United States Food and Drug Administration approved enoxaparin, a low molecular weight heparin for outpatient use in 1998,[6] and by the end of the decade, multiple treatment guidelines for VTE acknowledged the safety of outpatient treatment of DVT with low molecular weight heparin in selected patients.[7-9] Recently, the approval of direct oral anticoagulants (DOACs) by the Food and Drug Administration allows an all-oral treatment regimen for VTE, which could further facilitate outpatient treatment of DVT.

Costs associated with treatment of VTE are enormous. For outpatient treatment, researchers differ on individual estimates of cost savings associated with outpatient DVT management, but most report a cost savings of several thousand dollars per patient treated as an outpatient compared with as an inpatient.[6,10] Given the incidence of DVT, reducing costs while maintaining a high quality of care in even a small percentage of DVT patients would result in significant healthcare cost savings as well as increased convenience for patients.

Despite high-quality evidence supporting the efficacy and safety of outpatient DVT treatment, little is known about the adoption of outpatient DVT treatment in the United States. Several studies that have been published were limited to single hospitals and were small in size[11,12] or limited to a cohort of patients already diagnosed with DVT.[13]

The purpose of this study was to report the frequency of outpatient treatment of DVT in the United States and describe patient characteristics associated with outpatient treatment. Information was gathered from The Reasons for

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Geographic and Racial Differences in Stroke (REGARDS) study, a contemporary cohort study of more than 30,000 patients residing in the contiguous United States with racial and geographic diversity. We hypothesized that an individual's age, sex, race, region of residence, urban or rural residence, education level, and personal income would be associated with outpatient treatment. Results would allow the implementation of interventions to promote the appropriate use of outpatient treatment in order to reduce healthcare costs and increase patient convenience without compromising safety or efficacy of care.

METHODS

Cohort Characteristics

VTE events were ascertained in the REGARDS cohort, a prospective, longitudinal cohort study investigating the causes of racial and geographic disparities in stroke and cognitive decline.[14] Between 2003 and 2007, there were 30,239 participants in the contiguous United States ≥45 years old enrolled in REGARDS. By design, 55% were female, 41% were black, the mean age was 65 years, and 56% lived in the southeastern United States. Participants were recruited from a commercial list by mail and telephone contact followed by verbal consent. A telephone interview was followed by an in-home examination, including obtaining written informed consent. On study entry, many participants had comorbid conditions, including 8% with reported atrial fibrillation, 56% receiving treatment for hypertension, 22% receiving treatment for diabetes, 3.7% taking warfarin, and 14% who were actively smoking.[15,16] Participants were only excluded if they had active cancer, stated a self-reported race other than white or black, were unable to converse in English, had cognitive impairment as judged by the telephone interviewer, or were residing in or on the waiting list for a nursing home. Study methods were reviewed and approved by the institutional review boards at each study institution and have been published elsewhere.[14]

Event Ascertainment and Definitions

DVT event ascertainment is complete through 2011, with identification by telephone interview, review of reported hospitalizations, and review of deaths.[17] Questionnaires in similar epidemiological studies have 98% specificity and >70% sensitivity for ascertaining VTE events.[18] A research nurse reviewed the text and recorded each reported hospitalization through 2011. Any report of a blood clot in the legs, arms, or lungs was a potential case for physician review. Medical records were retrieved for up to 1 year before and 1 year after potential events. Retrieved records were used to help guide further record retrieval if they did not contain the primary VTE event. Primary inpatient and outpatient records including history and physical examinations, discharge summaries, imaging reports (to include limb ultrasounds, computed tomography scans, and magnetic resonance imaging), autopsies, and outpatient notes were retrieved using up to 3 attempts.[19] Using all available information, characteristics of the VTE event and treatment were systematically recorded. For each potential VTE case, two of three physician reviewers abstracted medical records to validate and classify the event. If the physician reviewers disagreed, the third physician would review the case, and if VTE status remained uncertain, cases were discussed and resolved. Race was determined by participant self-report as black or white. Location of residence was defined by geocoding the addresses, and urban or rural status was defined by United States census tract data using rural-urban commuting area codes (RUCA; with rural areas being RUCA codes 4–10).[20] Other risk factors were obtained through surveys, telephone interviews, or in-home visits.[14]

Outpatient treatment was defined as receiving a DVT diagnosis in an emergency department or ambulatory clinic but not receiving an overnight hospitalization. Inpatient treatment was defined as at least 1 overnight stay in a hospital (but not in an emergency department). Only participants admitted with a primary diagnosis of DVT were included in the analysis. If someone was noted to have DVT but was admitted to the hospital for another cause, he or she was not included in the analysis and classified as a hospital-associated DVT. A provoked DVT was defined as occurring within 90 days of a major trauma, surgery, or marked immobility or was associated with active cancer or treatment for cancer (ie, chemotherapy, radiotherapy, or surgical therapy), while an unprovoked DVT was defined as having none of the above provoking factors. A distal DVT was defined as a DVT occurring in the posterior tibial, anterior tibial, peroneal, or soleus sinuses. The primary outcome was DVT treated as an outpatient only without concurrent diagnosis of PE or VTE as a complication of hospitalization (as these individuals were not eligible for outpatient treatment at the time).

Statistical Analysis

Age, sex, race, region of residence (inside or outside the southeastern United States), education, income (determined as greater or less than $20,000 per year), and urban or rural status of residence were compared between DVT patients treated as outpatients and inpatients using $\chi 2$ analysis by inpatient or outpatient treatment. Univariable and multivariable logistic regression was then used to determine the odds ratio (OR) of receiving outpatient DVT treatment by the same variables with age per 10-year increment. ORs were adjusted for age, sex, race, year of DVT diagnosis, and region of residence as appropriate. Statistical significance was defined as $P < 0.05$. All statistical analyses were performed by N.A.Z. and conducted with SAS version 9.3 (SAS Institute, Cary, NC). All authors had access to the primary clinical data.

RESULTS

Over a mean of 4.7 years follow-up, 379 VTE events occurred (incident and recurrent); 185 were diagnosed with a PE, and 53 occurred as a complication of hospitalization (and were not eligible for outpatient treatment), leaving 141 DVT events potentially eligible for outpatient treatment out

TABLE 1. Characteristics of Participants with DVT by Treatment Location

Characteristics	Treated as Outpatient, Total = 39	Treated as Inpatient, Total = 102	*P*
Median age (interquartile range)	67 years (60-73)	70 years (63-76)	.02
DVT year (median)	2009	2008	.02
Female	23 (59%)	43 (42%)	.03
White	30 (77%)	62 (61%)	.04
Living outside the Southeast	21 (54%)	50 (49%)	.13
High school graduate	38 (97%)	90 (88%)	.07
Yearly income >$20,000	12 (82%)	58 (57%)	.02
Living in an urban area	35 (90%)	71 (70%)	.01
Provoked event	10 (26%)	42 (41%)	.09
Body mass index ≥30	20 (51%)	47 (47%)	.55
Current or former smoker	17 (44%)	53 (52%)	.45
Proximal DVT	28 (72%)	92 (90%)	<.01
Treated with full dose anticoagulation	34 (87%)	89 (87%)	.99
History of cancera	6 (25%)	14 (18%)	.43
Chronic kidney disease (eGFR <60)	5 (13%)	19 (19%)	.46
History of coronary artery diseasea	8 (21%)	23 (23%)	.77
History of hypertension	21 (54%)	70 (69%)	.10
History of diabetes*	4 (11%)	21 (22%)	.15
History of hyperlipidemia*	22 (56%)	53 (54%)	.80

[a]Data were missing for 38 participants with cancer, 1 participant with coronary artery disease, 7 participants with diabetes, and 4 participants with hyperlipidemia.
NOTE: Abbreviations: DVT, deep vein thrombosis; eGFR, estimated glomerular filtration rate.

of a population of 29,556 participants with available records and follow-up in the cohort (Figure).

Of 141 DVT events, 39 (28%) were treated as outpatients. Table 1 presents the characteristics of participants treated as inpatients and as outpatients. Factors significantly associated with outpatient DVT treatment were younger age, female sex, white race, residing in an urban area, having a distal DVT only, and having a higher income. In the study, DVT events were recorded between 2003 and 2011; the median year of a diagnosed DVT and treated as an outpatient was 2009, while the median year of inpatient treatment was 2008. Living in the Southeast versus the rest of the country ($P = 0.13$) and having a high school education or greater ($P = 0.07$) were marginally associated with receiving outpatient treatment. In absolute terms, 11% of people living in rural areas and 19% of black patients had outpatient DVT treatment while 33% of the urban dwellers and 32% of white patients received outpatient treatment (Table 1). At the time of cohort enrollment, 92% of participants claimed to have insurance; however, this did not differentiate between Medicare, Medicaid, and private insurance. Only 1 participant diagnosed with DVT had an estimated glomerular filtration rate <30, and this individual was admitted for treatment.

Table 2 reports the multivariable adjusted OR for outpa-

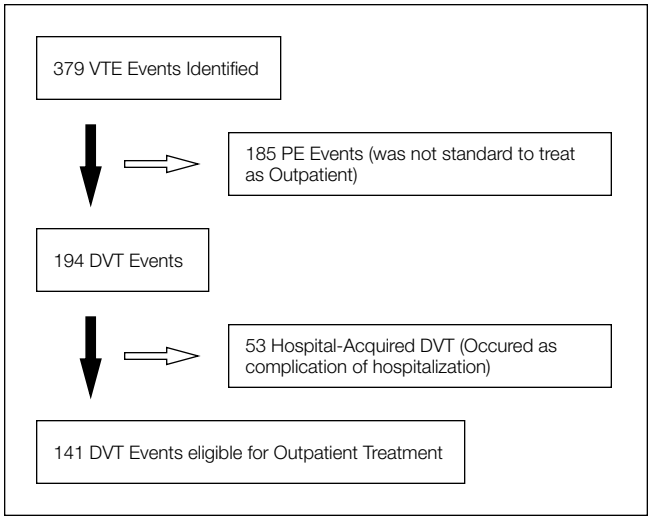

FIG. VTE Events in REGARDS

NOTE: Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism.

TABLE 2. Likelihood of Receiving Outpatient Treatment for DVT

Variable	Adjusted Odds Ratio (95% CI)[a]
Age (per 10 years younger)	1.90 (1.19-3.02)
Year of DVT diagnosis (per 1 year later)	1.35 (1.03-1.77)
Sex (female versus male)	2.41 (1.06-5.47)
Race (white versus black)	3.29 (1.30-8.30)
Region (outside Southeast versus in Southeast)	2.00 (0.87-4.63)
Education (high school graduate versus not)	4.51 (0.52-38.82)
Income >$20,000 (yes versus no)	2.63 (0.87-7.94)
Living in an urban area (yes versus no)	4.16 (1.25-13.79)

[a]Adjusted for age, sex, race, VTE event year, and region.

NOTE: Abbreviations: CI, confidence interval; DVT, deep vein thrombosis; VTE, venous thromboembolism.

tient treatment of DVT adjusted for age, sex, race, region, and year of DVT diagnosis. Outpatient treatment of VTE was associated with younger age (OR 1.90; 95% confidence interval [CI], 1.19-3.02 for every 10 years younger in age), female sex (OR 2.41; 95% CI, 1.06-5.47), and white race (OR 3.29; 95% CI, 1.30-8.30). For each progressive calendar year in which the diagnosis was made, individuals had a 1.35-fold increase in their odds (95% CI, 1.03-1.77) of receiving outpatient treatment. Individuals living in urban areas were 4.16 (95% CI, 1.25-13.79) times more likely to receive outpatient treatment than those in rural areas. Living outside of the southeastern United States and having an income of more than $20,000 per year had increased, but nonsignificant, odds of being treated as outpatient (Table 2).

DISCUSSION

In this national, prospective, observational cohort study, only 28% of participants diagnosed with DVT were treated as outpatients versus being hospitalized. Urban area of residence, white race, female sex, and younger age were significantly associated with an increased odds of outpatient treatment. Groups that had particularly low outpatient treatment rates were rural dwellers and black participants, who had outpatient treatment rates of 11% and 19%, respectively. The odds of receiving outpatient treatment did improve over the course of the study, but in the last year of VTE assessment, outpatient treatment remained at 40%, but this was quite variable over the study years (being 8% two years prior).

The feasibility of outpatient treatment of DVTs requires a coordinated healthcare system and patient support to ensure education and appropriate anticoagulation monitoring. While not all DVTs should be treated as outpatients, differences in treatment location by sex, race, and residence point to potential healthcare disparities that increase the burden on patients and increase healthcare costs. Other studies have documented low outpatient treatment rates of DVTs (20% in 1 United States multicenter DVT registry) but have not discussed the associations of outpatient versus inpatient treatment.[13] Outpatient treatment also appears to be underutilized in other developed countries; in the European Computerized Registry of Patients with Venous Thromboembolism, only 31% of DVT patients were treated on an outpatient basis between 2001 and 2011.[21] To our knowledge, this is the first study to document the uptake of outpatient DVT treatment in the United States across multiple states, regions, and health systems well after the safety and efficacy of outpatient treatment of DVT was established by randomized controlled trials.[3-5]

The strengths of this study are that these data are derived from a contemporary cohort with a large geographic and racial distribution in the United States and are well characterized with a mean of 4.6 years follow-up.[19] We are limited by a relatively small number of DVT events that were eligible for outpatient treatment (n = 141) and so may miss modest associations. Further, while the geographic scope of the cohort is a tremendous strength of our study, we may have missed some events and did not have complete record retrieval of reported events and could not assess access to healthcare in detail. These data were recorded before the use of DOACs became common. DOACs are an effective and safe alternative to conventional anticoagulation treatment for acute DVT.[22] Their use might result in increased outpatient treatment, as they are not parenteral; however, cost considerations (~$400.00 per month), especially with high-deductible insurance plans, may limit their impact on VTE treatment location.[23] This study cannot account for why the racial, sex, and urban–rural differences exist, and by extension if hospitalization rates differ due to associated comorbidities or if this represents a healthcare disparity. While it is reasonable from a healthcare perspective that younger individuals would more likely be treated as outpatients, there is no data to suggest that differences in DVT by sex, race, and residential location support decreased outpatient treatment. Due to the age of the cohort, most individuals had some form of insurance and a primary care provider. However, we were unable to assess the quality of insurance and the ease of access to their primary care providers. More research is needed to determine whether patients were hospitalized on medical grounds or because of a lack of coordinated healthcare systems to care for them as outpatients.

In conclusion, only a minority of patients who were potentially eligible for outpatient DVT treatment (28%) were treated as outpatients in this study, and there were significant racial and socioeconomic differences in who received inpatient and outpatient treatment. While outpatient treatment rates were below 40% in all groups, we identified groups with especially low likelihoods of receiving outpatient treatment. While all eligible individuals should be offered outpatient DVT treatment, these data highlight the need for specific efforts to overcome barriers to outpatient treatment in the elderly, rural areas, black patients, and men. Even modest increases in the rate of outpatient DVT treatment could result

in substantial cost savings and increased patient convenience without compromising the efficacy or safety of medical care.

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Post-Intensive Care Unit Psychiatric Comorbidity and Quality of Life

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The prevalence of psychiatric symptoms ranges from 17% to 44% in intensive care unit (ICU) survivors. The relationship between the comorbidity of psychiatric symptoms and quality of life (QoL) in ICU survivors has not been carefully examined. This study examined the relationship between psychiatric comorbidities and QoL in 58 survivors of ICU delirium. Patients completed 3 psychiatric screens at 3 months after discharge from the hospital, including the Patient Health Questionnaire-9 (PHQ-9) for depression, the Generalized Anxiety Disorder-7 (GAD-7) questionnaire for anxiety, and the Post-Traumatic Stress Syndrome (PTSS-10) questionnaire for posttraumatic stress disorder. Patients with 3 positive screens (PHQ-9 ≥ 10; GAD-7 ≥ 10; and PTSS-10 > 35) comprised the high psychiatric comorbidity group. Patients with 1 to 2 positive screens were labeled the low to moderate (low-moderate) psychiatric comorbidity group. Patients with 3 negative screens were labeled the no psychiatric morbidity group. Thirty-one percent of patients met the criteria for high psychiatric comorbidity. After adjusting for age, gender, Charlson Comorbidity Index, discharge status, and prior history of depression and anxiety, patients who had high psychiatric comorbidity were more likely to have a poorer QoL compared with the low-moderate comorbidity and no morbidity groups, as measured by a lower EuroQol 5 dimensions questionnaire 3-level Index (no, 0.69 ± 0.25; low-moderate, 0.70 ± 0.19; high, 0.48 ± 0.24; $P = 0.017$). Future studies should confirm these findings and examine whether survivors of ICU delirium with high psychiatric comorbidity have different treatment needs from survivors with lower psychiatric comorbidity. *Journal of Hospital Medicine* 2017;12:831-835. Published online first September 6, 2017. © 2017 Society of Hospital Medicine

The prevalence of depression, anxiety, and posttraumatic stress disorder (PTSD) symptoms in intensive care unit (ICU) survivors ranges from 17% to 44%.[1-4] Psychiatric comorbidity, the presence of 2 or more psychiatric disorders, is highly prevalent in survivors of acute respiratory distress syndrome and is associated with higher mortality in postsurgical ICU survivors.[5-7] While long-term cognitive impairment in patients with ICU delirium has been associated with poor quality of life (QoL),[1] the effects of psychiatric comorbidity on QoL among similar patients are not as well understood. In this study, we examined whether psychiatric comorbidity was associated with poorer QoL in survivors of ICU delirium.

METHODS

We examined subjects who participated in the Pharmacologic Management of Delirium (PMD) clinical trial. This trial examined the efficacy of a pharmacological intervention for patients who developed ICU delirium at a local tertiary-care academic hospital.[8] Out of 62 patients who participated in the follow-up of the PMD study, 58 completed QoL interviews and validated psychiatric screens (Patient Health Questionnaire-9 [PHQ-9] for depression, the Generalized Anxiety Disorder-7 [GAD-7] questionnaire for anxiety, and the Post-Traumatic Stress Syndrome [PTSS-10] questionnaire for PTSD) at 3 months after hospital discharge. High psychiatric comorbidity was defined as having significant symptoms for all 3 conditions (depression: PHQ-9 score ≥ 10; anxiety: GAD-7 ≥ 10; and PTSD: PTSS-10 > 35). No psychiatric morbidity was defined as having no significant symptoms for all 3 conditions. Low to moderate (low-moderate) psychiatric morbidity was defined as having symptoms for 1 to 2 conditions.

Participants also completed 2 complementary QoL measures: the EuroQol 5 dimensions questionnaire 3-level (EQ-5D-3L) Index and the EuroQol 5 dimensions Visual Analog Scale (EQ-5D-VAS).[9] The EQ-5D-3L Index asks participants to rate themselves as having (1) no problems, (2) some problems, or (3) extreme problems on the following 5 scales: mobility, self-care, usual activities, pain/discomfort, and

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TABLE. Demographics and Clinical Characteristics of 58 ICU Survivors Grouped by Comorbidity of Psychiatric Disorder Symptoms

Characteristics	No Psychiatric Morbidity (n = 26)	Low to Moderate Psychiatric Comorbidity (n = 14)	High Psychiatric Comorbidity (n = 18)	*P* Value
Demographics				
Age, years	59.0 (14.9)	52.7 (17.1)	52.9 (14.5)	.327
Female, % (n)	50.0 (13)	64.3 (9)	50.0 (9)	.699
African American, % (n)	50.0 (13)	35.7 (5)	38.9 (7)	.659
Education, years	12.3 (2.1)	11.0 (1.9)	11.8 (2.4)	.211
Prior depression % (n)	7.7 (2)	14.3 (2)	55.6 (10)	.001[a,b]
Prior anxiety, % (n)	3.8 (1)	0.0 (0)	22.2 (4)	.081
Prior, PTSD, % (n)	0.0 (0)	0.0 (0)	0.0 (0)	.000
IQCODE, mean (SD)	3.1 (0.2)	3.1 (0.2)	3.1 (0.1)	.929
Hospital Characteristics				
Service				.087
MICU, %	73.1 (19)	42.9 (6)	77.8 (14)	
SICU, %	26.9 (7)	57.1 (8)	22.2 (4)	
APACHE II score, mean (SD)	18.6 (9.1)	18.9 (9.0)	20.5 (8.1)	.768
ARF/Sepsis, % (n)	42.3 (11)	21.4 (3)	55.6 (10)	.182
Coma, % (n)	76.9 (20)	92.9 (13)	88.9 (16)	.460
Duration on ventilation, days (SD)	6.7 (7.4)	7.6 (4.8)	8.7 (9.9)	.701
Length of ICU stay, mean days (SD)	23.6 (19.5)	20.7 (17.9)	17.1 (11.2)	.350
Benzodiazapine drip, % (n)	38.5 (10)	42.9 (6)	55.6 (10)	.590
Dexmetatomidine drip, % (n)	15.4 (4)	35.7 (5)	33.3 (6)	.255
Propofol drip, % (n)	69.2 (18)	71.4 (10)	88.9 (16)	.328
Discharged Home, % (n)	38.5 (10)	50.0 (7)	72.2 (13)	.088

[a]No psychiatric comorbidity group significantly different from the high psychiatric comorbidity group.

[b]Low-moderate psychiatric comorbidity group significantly different from the high psychiatric comorbidity group.

NOTES: Continuous variables were expressed as average (SD). Dichotomous variables were expressed as % (N). Fischer's exact test was used to compare dichotomous outcomes for the 3 groups. One-way ANOVA was used to compare continuous outcomes for the 3 groups.

Patients who had significant depressive, anxiety, or posttraumatic stress disorder (PHQ-9 score ≥10, GAD-7 ≥10, and PTSS-10 >35) symptoms were in the high comorbidity psychiatry group.

Patients who had no significant symptoms were in the no morbidity psychiatry group. Patients who met criteria for 1-2 significant symptoms were in the low-moderate comorbidity psychiatry group. Abbreviations: ANOVA, analysis of variance; APACHE, Acute Physiologic and Chronic Health Evaluation; ARF, acute renal failure; GAD-7, Generalized Anxiety Disorder-7; ICU, intensive care unit; IQCODE, Informant Questionnaire on Cognitive Decline; MICU, medical intensive care unit; PHQ-9, Patient Health Questionnaire-9; PTSD, post-traumatic stress disorder; PTSS-10, Post-Traumatic Stress Syndrome; SD, standard deviation; SICU, surgical intensive care unit.

anxiety/depression. The scores are then indexed against the US population to create a continuous index scale ranging from −0.11 to 1.00. A score of 1 represents perfect health, 0 represents death, and negative values indicate a health state worse than death. The EQ-5D-VAS asks participants to draw a line on a visual scale from an anchor box to the point that represents their health state. The score ranges from 0 being the worst imaginable health state to 100 being the best imaginable health state. Demographic information, clinical characteristics, and prior history of depression, anxiety, and PTSD were obtained through PMD study records and clinical records. The Charlson Comorbidity Index, which measures chronic comorbidities, and Acute Physiology and Chronic Health Evaluation II, which estimates acute severity of illness within 24 hours of ICU admission, were calculated from patients' available clinical information.

Fisher's exact tests were used to compare dichotomous outcomes. Analysis of variance (ANOVA) was used to compare continuous outcomes across the 3 psychiatric groups. Analysis of covariance (ANCOVA) was used to determine whether psychiatric comorbidity in survivors of ICU delirium was associated with QoL measures. Models were adjusted

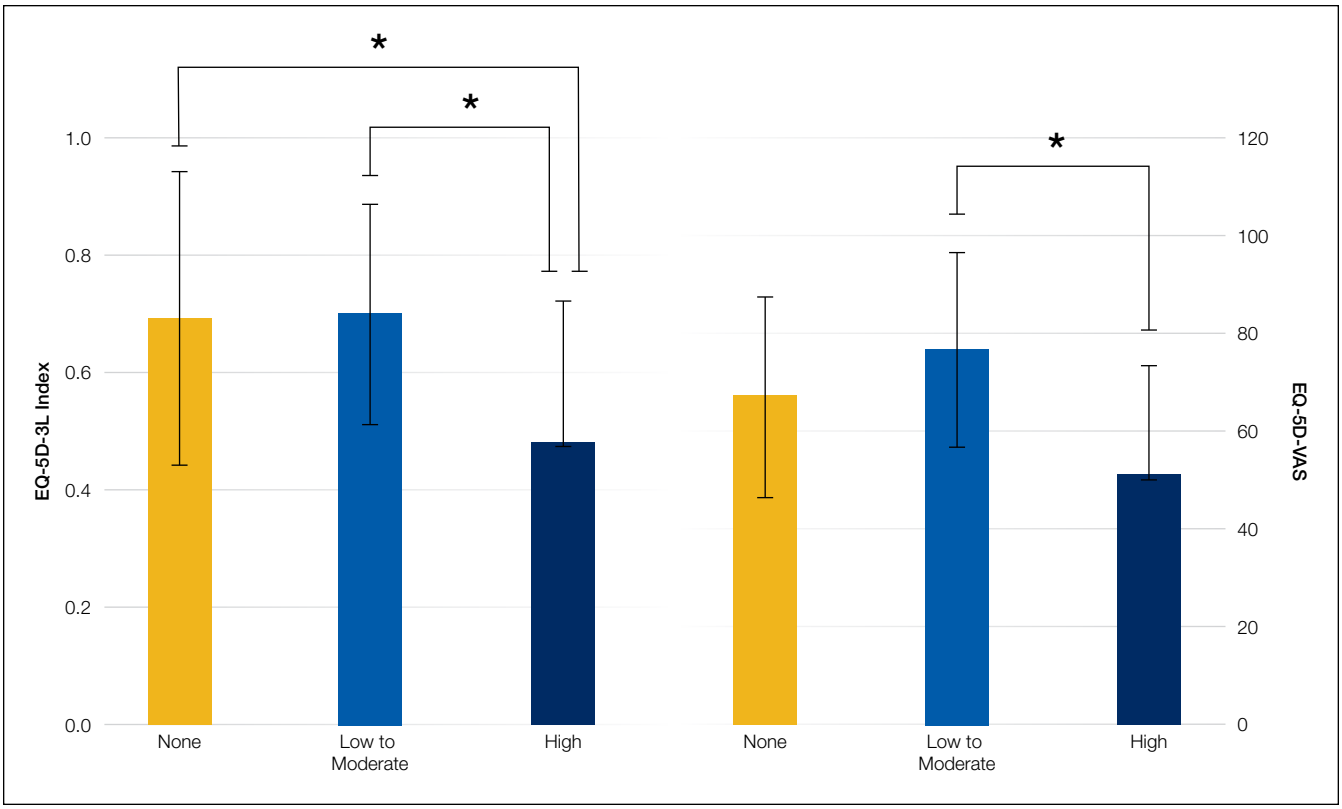

FIG. Mean EQ-5D-3L index or mean EQ-5D-VAS index grouped by psychiatric comorbidities. NOTE: ANCOVA models were adjusted for age, gender, Charlson Comorbidity Index, being discharged to home, prior history of depression, and prior history of anxiety. All *P* values are after covariate adjustment. *P* = .017 for overall trend for EQ-5D-3L Index, and *P* = .039 for overall trend for EQ-5D-VAS. **P* < .05 for pairwise comparison. Abbreviations: ANCOVA, analysis of covariance; EQ-5D-3L, EuroQol 5 dimensions questionnaire 3-level; EQ-5D-VAS, EuroQol 5 dimensions Visual Analog Scale.

for the following covariates: age, gender, Charlson Comorbidity Index, discharged to home, prior history of depression, and prior history of anxiety. To assess the relationship of psychiatric comorbidity with QoL, we chose the 2 continuous QoL measures as the outcome. Because we were interested in the effect of psychiatric burden on QoL, we used ANCOVA with QoL as the dependent variable and psychiatric burden as an independent variable. Pairwise comparisons were then performed when overall differences were significant ($P < 0.05$). We performed 2 separate sensitivity analyses. The first analysis looked solely at the subgroup of patients from the medical intensive care unit. We also recalculated the EQ-5D-3L index excluding the anxiety/depression item.

RESULTS

Nearly one-third of patients (18/58) had high psychiatric burden. The table looks at the demographic and clinical characteristics of patients with high psychiatric comorbidity versus those of low-moderate psychiatric comorbidity and those with no psychiatric morbidity. Patient groups did not differ significantly in terms of demographics. For clinical characteristics, patients with high psychiatric comorbidity were more likely than patients with low-moderate psychiatric comorbidity to have a prior history of depression ($P < 0.05$).

Patients with high psychiatric comorbidity were more likely to have a poorer QoL when compared with patients with low-moderate psychiatric comorbidity and to those with no morbidity as measured by a lower EQ-5D-3L Index (no, 0.69 ± 0.25; low-moderate, 0.70 ± 0.19; high, 0.48 ± 0.24; $P = 0.006$) and EQ-5D-VAS (no, 67.0 ± 20.7; low-moderate, 76.6 ± 20.0; high, 50.8 ± 22.4; $P = 0.004$). After adjusting for covariates, patients with high psychiatric comorbidity had a poorer QoL compared with those with no morbidity or low-moderate comorbidity on the EQ-5D-3L Index ($P = 0.017$ for overall differences), whereas patients who had high psychiatric comorbidity had a poorer QoL compared to those with low-moderate comorbidity on the EQ-5D-VAS ($P = 0.039$ for overall differences; Figure). Subgroup analysis of MICU patients yielded similar results. Patients with high psychiatric burden had significantly poorer QoL as measured by the EQ-5D-3L (unadjusted $P = 0.044$, adjusted $P = 0.003$) and the EQ-5D-VAS (unadjusted $P = 0.007$, adjusted $P = 0.021$). After excluding the anxiety/depression item from the EQ-5D-3L, we observed similar differences (no, 0.71 ± 0.24; low-moderate, 0.75 ± 0.15; high, 0.58 ± 0.22; unadjusted $P = 0.062$; adjusted $P = 0.040$).

DISCUSSION/CONCLUSION

Psychiatric comorbidities in ICU survivors are common and pose a significant clinical issue. Patients with multiple psy-

chiatric comorbidities can be more complicated to identify from a diagnostic standpoint and often require more prolonged, intensive mental health treatment when compared with patients with a single psychiatric disorder.[10,11] Our study showed that high psychiatric comorbidity in survivors of ICU delirium is associated with a decreased QoL compared with those with no psychiatric comorbidity or with low-moderate psychiatric comorbidity. This finding is consistent with previous studies in the general population that patients with multiple psychiatric comorbidities are associated with a poorer QoL compared with patients with a single psychiatric comorbidity.[10,11]

There is a pressing need to better characterize psychiatric comorbidities in ICU survivors because our current evidence suggests that the prevalence of psychiatric comorbidities of ICU survivors is substantially higher than that of the general population. We found that nearly one-third of survivors of ICU delirium had comorbid depression, anxiety, and PTSD symptoms at 3 months. This is consistent with the few other studies of ICU survivors, which showed a prevalence of psychiatric comorbidity of 25% to 33%.[5,12] These rates are substantially higher than the prevalence in the general population of 6%.[13]

The high rate of psychiatric comorbidities may render it difficult to effectively treat the mental health symptoms in ICU survivors.[14] Treating multiple psychiatric comorbidities may also be especially challenging in survivors of ICU delirium because they have a high prevalence of cognitive impairment. Mental health treatments for patients with psychiatric disorders and comorbid cognitive impairment are limited. Better characterization of psychiatric comorbidity in ICU survivors, particularly those with ICU delirium, is vital to the development of more effective, bundled treatments for this population with multiple comorbidities.

Standardized screenings of ICU survivors at a high risk for psychiatric disorders, such as survivors of ICU delirium, may help to identify patients with comorbid psychiatric disorder symptoms and have them referred to appropriate treatment earlier with the hope of improving their QoL sooner. Although opportunities to deliver integrated outpatient collaborative mental health and medical care for a subspecialty population are limited, one potential model of care would be to utilize a collaborative-care model in an ICU survivor clinic.[15]

Strengths of our study include the examination of psychiatric comorbidities in survivors of ICU delirium, who often have a poor QoL. A deeper understanding of psychiatric comorbidity and its relationship with QoL is needed to better understand how to deliver more effective treatments for these survivors. Limitations include the small sample size, a one-time measurement of psychiatric comorbidities at the 3-month follow-up based on screenings tools, and a lack of objective measures of physical functioning to determine the effects of psychiatric comorbidities on physical functioning. There may also have been differences in how patients with no psychiatric comorbidity responded to the EQ-5D-VAS as a result of premorbid differences (eg, they were healthier prior to their ICU stay and perceived their survivor status more negatively). This may explain why we did not see a statistically significant difference between no psychiatric comorbidity and high psychiatric comorbidity groups on the EQ-5D-VAS. Nevertheless, we did see a difference between the low-moderate psychiatric comorbidity group on EQ-5D-VAS and differences between the no comorbidity and low-moderate comorbidity groups versus the high comorbidity group on the EQ-5D-3L. Finally, data about psychiatric history and QoL prior to ICU hospitalization were limited. Therefore, truly determining incidence versus prevalence of post-ICU comorbidities and whether psychiatric symptoms and its effects on QoL were due to ICU hospitalization or to premorbid psychiatric symptoms is difficult.

Our study demonstrated that in survivors of ICU delirium, higher comorbidity of psychiatric symptoms was associated with poorer QoL. Future studies will need to confirm these findings. We will also need to identify potentially reversible risk factors for psychiatric comorbidity and poorer QoL and develop treatments to effectively target the mental health symptoms of survivors of ICU delirium.

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Hospital Privileging Practices for Bedside Procedures: A Survey of Hospitalist Experts

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Many hospitalists are routinely granted hospital privileges to perform invasive bedside procedures, but criteria for privileging are not well described. We conducted a survey of 21 hospitalist procedure experts from the Society of Hospital Medicine Point-of-Care Ultrasound Task Force to better understand current privileging practices for bedside procedures and how those practices are perceived. Only half of all experts reported their hospitals require a minimum number of procedures performed to grant initial (48%) and ongoing (52%) privileges for bedside procedures. Regardless, most experts thought minimums should be higher than those in current practice and should exist alongside direct observation of manual skills. Experts reported that the use of ultrasound guidance was nearly universal for paracentesis, thoracentesis, and central venous catheter placement, but only 10% of hospitals required the use of ultrasound for initial privileging of these procedures. *Journal of Hospital Medicine* 2017;12:836-839. Published online first September 6, 2017 © 2017 Society of Hospital Medicine

Performance of 6 bedside procedures (paracentesis, thoracentesis, lumbar puncture, arthrocentesis, central venous catheter [CVC] placement, and arterial line placement) are considered core competencies for hospitalists.[1] Yet, the American Board of Internal Medicine (ABIM) no longer requires demonstration of manual competency for bedside procedures, and graduates may enter the workforce with minimal or no experience performing such procedures.[2] As such, the burden falls on hospital privileging committees to ensure providers have the necessary training and experience to competently perform invasive procedures before granting institutional privileges to perform them.[3] Although recommendations for privileging to perform certain surgical procedures have been proposed,[4,5] there are no widely accepted guidelines for initial or ongoing privileging of common invasive bedside procedures performed by hospitalists, and current privileging practices vary significantly.

In 2015, the Society of Hospital Medicine (SHM) set up a Point-of-Care Ultrasound (POCUS) Task Force to draft evidence-based guidelines on the use of ultrasound to perform bedside procedures. The recommendations for certification of competency in ultrasound-guided procedures may guide institutional privileging. The purpose of this study was to better understand current hospital privileging practices for invasive bedside procedures both with and without ultrasound guidance and how current practices are perceived by experts.

METHODS

Study Design, Setting, and Participants

After approval by the University of Texas Health Science Center at San Antonio Institutional Review Board, we conducted a survey of hospital privileging processes for bedside procedures from a convenience sample of hospitalist procedure experts on the SHM POCUS Task Force. All 21 hospitalists on the task force were invited to participate, including the authors of this article. These hospitalists represent 21 unique institutions, and all have clinical, educational, and/or research expertise in ultrasound-guided bedside procedures.

Survey Design

A 26-question, electronic survey on privileging for bedside procedures was conducted (Appendix A). Twenty questions addressed procedures in general, such as minimum numbers of procedures required and use of simulation. Six questions focused on the use of ultrasound guidance. To provide context, many questions were framed to assess a privileging process being drafted by the task force. Answers were either multiple choice or free text.

Data Collection and Analysis

All members of the task force were invited to complete the survey by e-mail during November 2016. A reminder e-mail was sent on the day after initial distribution. No compensation was offered, and participation was not required. Survey

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results were compiled electronically through Research Electronic Data Capture, or "REDCap"™ (Nashville, Tennessee), and data analysis was performed with Stata version 14 (College Station, Texas). Means of current and recommended minimum thresholds were calculated by excluding responses of "I don't know," and responses of "no minimum number threshold" were coded as 0.

RESULTS

The survey response rate was 100% (21 of 21). All experts were hospitalists, but 2 also identified themselves as intensivists. Experts practiced in a variety of hospital settings, including private university hospitals (43%), public university hospitals (19%), Veterans Affairs teaching hospitals (14%), community teaching hospitals (14%), and community nonteaching hospitals (10%). Most hospitals (90%) were teaching hospitals for internal medicine trainees. All experts have personally performed bedside procedures on a regular basis, and most (86%) had leadership roles in teaching procedures to students, residents, fellows, physician assistants, nurse practitioners, and/or physicians. Approximately half (57%) were involved in granting privileges for bedside procedures at their institutions.

Most hospitals do not require the use of ultrasound guidance for the privileging of any procedure, but ultrasound guidance was reported to be routinely used for paracentesis (100%), thoracentesis (95%), and CVC placement (95%). Ultrasound guidance was less common for arterial line placement (57%), lumbar puncture (33%), and arthrocentesis (29%). There was strong agreement that ultrasound guidance ought to be required for initial and ongoing privileging of CVC placement, thoracentesis, and paracentesis. But there was less agreement for arterial line placement, arthrocentesis, and lumbar puncture (Figure 1).

Only half of the experts reported that their hospitals required a minimum number of procedures to earn initial (48%) or ongoing (52%) privileges to perform bedside procedures. Nevertheless, most experts thought there ought to be minimum numbers of procedures for initial (81%) and ongoing (81%) privileging, recommending higher minimums for both initial and ongoing privileging than are currently required at their hospitals (Figure 2).

The average difference between suggested and current minimum numbers of procedures required for initial privileging was 4.7 for paracentesis, 5.8 for thoracentesis, 5.8 for CVC catheter insertion, 5.4 for lumbar puncture, 4.8 for arterial line insertion, and 3.6 for arthrocentesis. The average difference between suggested and current minimum numbers of yearly procedures required for ongoing privileging was 2.0 for paracentesis, 2.8 for thoracentesis, 2.9 for CVC catheter insertion, 1.9 for lumbar puncture, 2.1 for arterial line insertion, and 2.5 for arthrocentesis (Appendix B).

Most hospitalist procedure experts thought that simulation training (67%) and direct observation of procedural skills (71%) should be core components of an initial privileging process. Many of the experts who did not agree with direct observation or simulation training as core components of initial privileging had concerns about feasibility with respect to manpower, availability of simulation equipment, and costs. In contrast, the majority (67%) did not think it was necessary to directly observe providers for ongoing privileging when routine monitoring was in place for periprocedural complications, which all experts (100%) agreed should be in place.

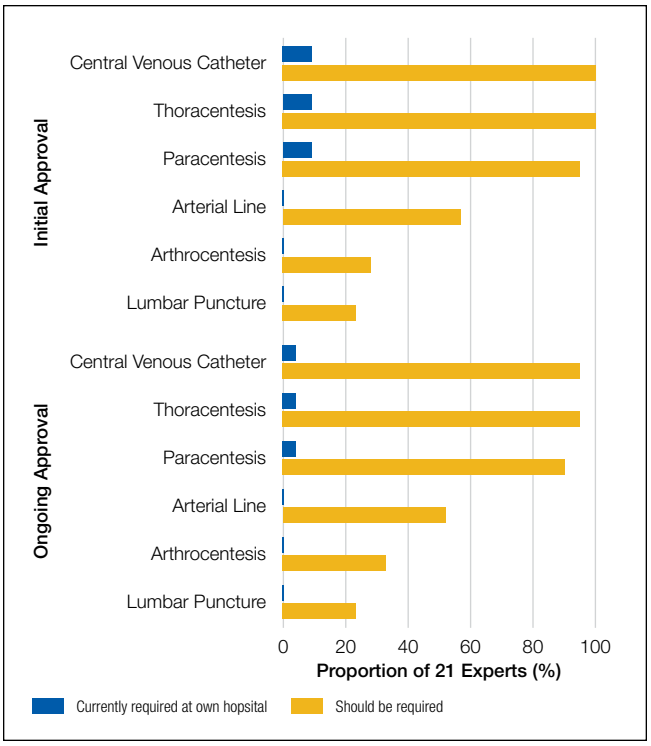

FIG 1. Hospitals that currently require use of ultrasound guidance versus should be required for approval to perform bedside procedures per hospitalist procedure experts.

DISCUSSION

Our survey identified 3 distinct differences between hospitalist procedure experts' recommendations and their own hospitals' current privileging practices. First, whereas experts recommended ultrasound guidance for thoracentesis, paracentesis, and CVC placement, it is rarely a current requirement. Second, experts recommend requiring minimum numbers of procedures for both initial and ongoing privileging even though such minimums are not currently required at half of their hospitals. Third, recommended minimum numbers were generally higher than those currently in place.

The routine use of ultrasound guidance for thoracentesis, paracentesis, and CVC placement is likely a result of increased adoption based on the literature showing clinical benefits.[6-9] Thus, the expert recommendations for required use of ultrasound guidance for these procedures seems both appropriate and feasible. The procedure minimums identified in our study are similar to prior ABIM guidelines when manual competency was required for board certification in internal medicine and are comparable to recent minimums

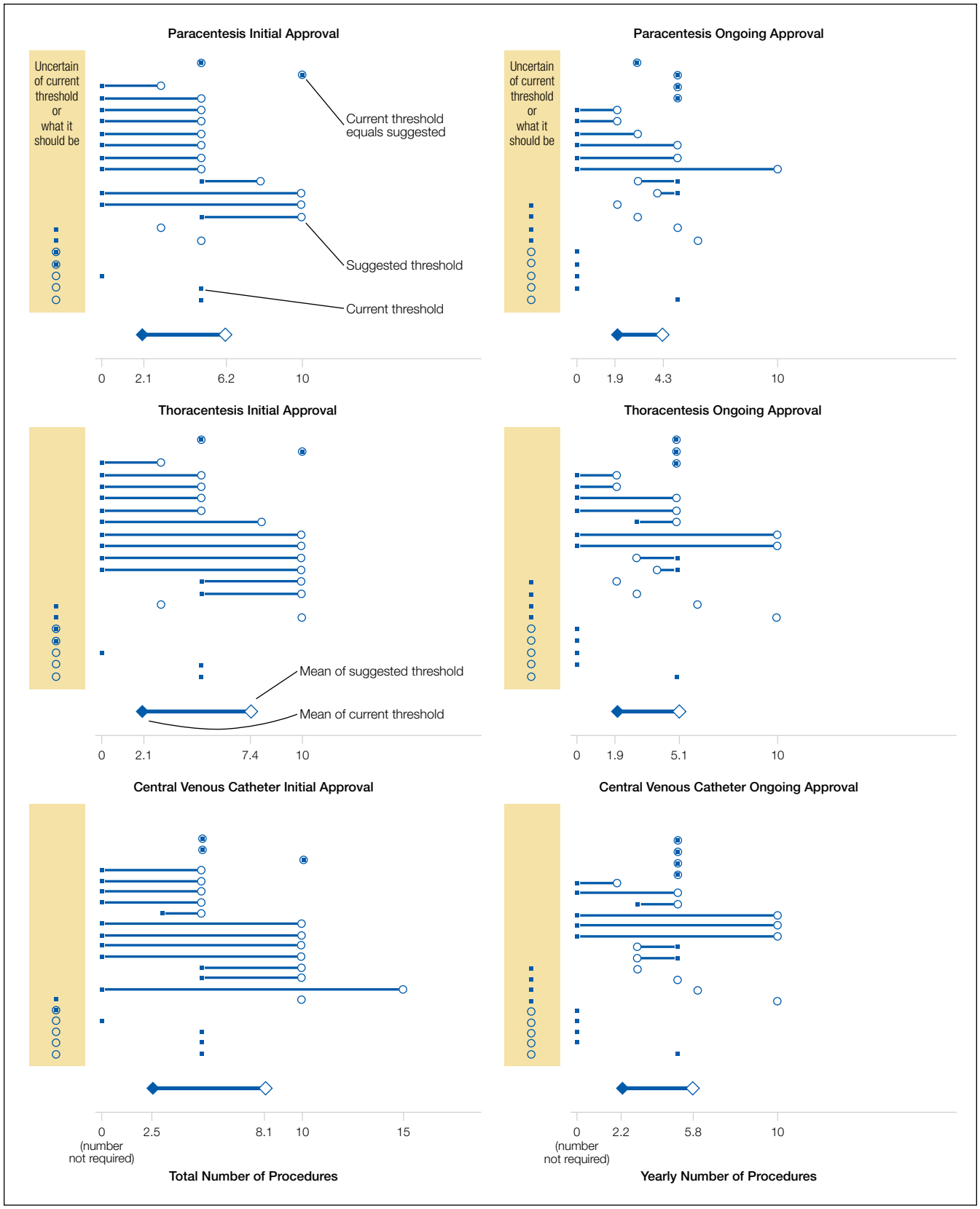

FIG 2. Approval to perform bedside procedures: current minimum thresholds versus what experts suggest. Each row represents an expert's paired responses (N = 21). Solid squares represent current minimum thresholds, and hollow circles represent what experts suggest they should be. The tan column indicates when experts answered, "I don't know." Hollow circles encircle solid squares when the 2 types of thresholds were equal, whereas lines connect them when they were not equal but known. Solid and hollow diamonds at the bottom of each panel represent the means of current and suggested minimum thresholds, respectively.

proposed by the Society of Critical Care Medicine, both of which recommended a minimum of 5 to 10 per procedure.[10,11] Nevertheless, no commonly agreed-upon minimum number of procedures currently exists for certification of competency, and the variability seen in the experts' responses further supports the idea that no specific number will guarantee competence. Thus, while requiring minimum numbers of procedures was generally considered necessary by our experts, minimums alone were also considered insufficient for initial privileging because most recommended that direct observation and simulation should be part of an initial privileging process.

These findings encourage more rigorous requirements for both initial and ongoing privileging of procedures. Nevertheless, our findings were rarely unanimous. The most frequently cited reason for disagreement on our findings was feasibility and capacity for direct observation, and the absence of ultrasound equipment or simulators, particularly in resource-limited clinical environments.

Our study has several strengths and limitations. One strength is the recruitment of study experts specifically composed of hospitalist procedure experts from diverse geographic and hospital settings. Yet, we acknowledge that our findings may not be generalizable to other specialties. Another strength is we obtained 100% participation from the experts surveyed. Weaknesses of this study include the relatively small number of experts who are likely to be biased in favor of both the use of ultrasound guidance and higher standards for privileging. We also relied on self-reported data about privileging processes rather than direct observation of those practices. Finally, questions were framed in the context of only 1 possible privileging pathway, and experts may respond differently to a different framing.

CONCLUSION

Our findings may guide the development of more standardized frameworks for initial and ongoing privileging of hospitalists for invasive bedside procedures. In particular, additional privileging requirements may include the routine use of ultrasound guidance for paracentesis, thoracentesis, and CVC insertion; simulation preceding direct observation of manual skills if possible; and higher required minimums of procedures for both initial and ongoing privileging. The goal of a standardized framework for privileging should be directed at improving the quality and safety of bedside procedures but must consider feasibility in diverse clinical settings where hospitalists work.

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An Opportunity to Improve Medicare's Planned Readmissions Measure

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In the Hospital Readmission Reduction Program (HRRP), the Centers for Medicare & Medicaid Services (CMS) utilizes a planned/unplanned algorithm to prevent hospitals from being penalized for scheduled rehospitalizations. We evaluated version 3.0 of the CMS planned readmission algorithm and hypothesized that some readmissions categorized as planned by the HRRP algorithm may actually be unplanned. We identified 143,054 index admissions and 16,116 thirty-day readmissions for 131 hospitals. Only 1252 readmissions were considered planned according to Medicare's readmission algorithm. The majority of these planned readmissions (723 [57.8%]) had an "emergent" or "urgent" admission type listed on the readmission claim, and many (513 [41.0%]) had emergency department charges, suggesting unanticipated returns to the hospital. HRRP should consider using the admission type variable and/or the presence of emergency department charges as a source of information when determining whether a readmission is planned or unplanned. *Journal of Hospital Medicine* 2017;12:840-842. © 2017 Society of Hospital Medicine

Readmissions result in $41.3 billion in annual healthcare expenses.[1] As a result of the Affordable Care Act, Centers for Medicare & Medicaid Services (CMS) implemented the Hospital Readmission Reduction Program (HRRP) to reduce expenditures and improve quality associated with hospital care.[2-5] The HRRP monitors readmission rates for pneumonia, congestive heart failure (CHF), acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), coronary artery bypass graft (CABG), and joint replacement. Hospitals are penalized for excess readmissions that occur following any of these index admissions. However, some readmissions within 30 days of an index admission are planned. For example, patients may have scheduled admissions for chemotherapy visits or may have prescheduled elective surgeries that happen to fall within a 30-day postdischarge window. Furthermore, even unplanned readmissions may not be a marker of suboptimal care.[6] To prevent penalization for planned readmissions, CMS developed an algorithm to exclude planned readmissions from the HRRP.[7]

Few studies have investigated the planned readmissions in the HRRP since Horwitz and colleagues[7] developed the algorithm with the assistance of a technical expert panel and validated it by reviewing charts in 2 healthcare systems comprising 7 hospitals. Most studies focus on unplanned readmissions.[8,9] We build on this work by studying readmissions for 131 hospitals and using administrative claims to determine whether the algorithm could be improved. Specifically, we examined planned readmissions after the conditions included in the HRRP and determine whether they occurred under elective, urgent, or emergent circumstances. The goal is to assess whether the algorithm may misclassify some readmissions as planned even though the readmission is unanticipated. We hypothesize that some readmissions considered planned by the HRRP will occur under emergent circumstances. Our findings will provide more nuanced insights regarding planned readmissions and potentially provide a mechanism to identify potentially misclassified readmissions without administrative burden.

METHODS

We analyzed Medicare claims from 2011 to 2015 for beneficiaries in Michigan who had index admissions for pneumonia, CHF, AMI, COPD, CABG, and joint replacement. Exclusion criteria were as follows: patients who were not continuously enrolled in Medicare Part A and B, had health maintenance organization coverage, were transferred to another hospital during the index admission, or received Medicare because of end-stage renal disease or disability. Patients with hip fractures were excluded because the HRRP readmission algorithm only includes elective, unilateral, total hip arthroplasties. Transfer patients were excluded because these patients are excluded from the HRRP readmission algorithm. We also excluded patients who died within 90 days of their index admission because these patients are often outliers in regards to healthcare utilization. The institutional review board at our health system deemed this study exempt from review.

For each hospital and each condition, we calculated 30-day readmission rates by identifying inpatient claims that occurred following discharge from the index admission. For patients who had multiple readmissions, we only considered

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TABLE 1. Total and Planned Readmissions in Michigan Hospitals, by Condition

Condition	Total Index Admissions	Total Readmissions	Planned Readmissions
Pneumonia	26,419	3137 (11.9%)	181 (5.8%)
AMI	19,981	3023 (15.1%)	474 (15.7%)
CHF	27,720	4514 (16.3%)	391 (8.7%)
COPD	24,059	3174 (13.2%)	152 (4.8%)
Joint	44,875	2268 (5.1%)	54 (2.4%)
Total	143,054	16,116 (11.3%)	1252 (7.8%)

NOTE: Abbreviations: AMI, acute myocardial infarction; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; Joint, joint replacement.

the first readmission, as this follows the HRRP method. All readmissions were credited to the hospital where the index admission occurred.

To calculate 30-day planned readmission rates, we examined all readmissions and identified those deemed planned by version 3.0 of the CMS readmissions algorithm.[10] We characterized these planned readmissions by examining the admission type variable and the presence or absence of emergency department (ED) charges. Planned readmissions that had an admission type of "emergent" or "urgent" and/or ED charges may have been unplanned. Because we cannot unequivocally determine whether or not the readmissions were misclassified, we refer to these readmissions as "potentially misclassified" in this manuscript. We also calculated the potential misclassification rate by hospital type.

RESULTS

For 131 Michigan hospitals, we identified 143,054 index admissions, 16,116 (11.3%) 30-day readmissions, and 1252 (7.8%) planned readmissions (Table 1).

Of the unplanned readmissions, 97.0% had either an admission type that was "urgent" or "emergent" and/or ED charges, 96.2% were associated with an "emergent" or "urgent" admission type, and 84.3% had emergency room charges on the claim line.

The majority of planned readmissions (723 [57.8%]) were associated with an "emergent" or "urgent" admission type (range: 55.8% for pneumonia to 66.5% for COPD; Table 2). In addition, many planned readmissions (513 [41.0%]) had ED charges reported on the claim (range: 37.3% for CHF to 52.6% for COPD). Of the potentially misclassified planned readmissions, the most frequent combination of primary diagnosis, secondary diagnosis, and procedure was by far "coronary atherosclerosis of native coronary artery," "intermediate coronary syndrome," and "percutaneous transluminal coronary angioplasty."

There were some differences in potential misclassification rate by hospital type. Specifically, teaching hospitals had lower potential misclassification rates than nonteaching hospitals (57.9% vs 59.7%). Larger (≥300 beds) hospitals had similar potential misclassification rates to smaller (<300 beds) hospitals (58.1% vs 58.6%). Urban hospitals had lower potential misclassification rates than rural hospitals (58.0% vs 63.3%).

TABLE 2. Potentially Misclassified Planned Readmissions, by Condition

Condition	% of Planned Readmissions Categorized as "Emergent" or "Urgent"	% of Planned Readmissions with >$0 of ED Charges
Pneumonia	55.8%	43.7%
AMI	57.2%	38.2%
CHF	56.0%	37.3%
COPD	66.5%	52.6%
Joint	57.4%	50.0%
Total	57.8%	41.0%

NOTE: Abbreviations: AMI, acute myocardial infarction; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; ED, emergency department; Joint, joint replacement.

DISCUSSION

In this study, we found that planned readmissions are generally infrequent. However, the majority are coded with an emergent or urgent admission type and many have ED charges reported on the claim. These findings suggest that the CMS readmission algorithm examined in this study may potentially misclassify many planned readmissions and that CMS should explore the use of admission type and presence of ED charges in the unplanned/planned readmission algorithm.

Our primary finding that planned readmissions are infrequent is supported by several observations.[7-9,11] In the initial article describing the CMS algorithm,[7] 7.8% of readmissions were considered planned; upon review of the discharge medical records from the index admissions, 41.3% of these planned readmissions were found to be unplanned. These findings closely correlate with our own findings that 7.8% of readmissions were considered planned by the CMS criteria, and 57.8% of planned readmissions were urgent or emergent. From a clinical perspective, there are few circum-

stances where a patient undergoing an elective procedure will transit electively through the ED.

The CMS algorithm was intentionally designed to have a high specificity for unplanned readmissions to ensure that truly planned readmissions would not be characterized as unplanned.[7] There is a potential tradeoff to increasing the sensitivity for unplanned readmissions, in that more planned readmissions might be inadvertently characterized as unplanned. Additional validation work (ie, medical chart review) will be required to explore potentially misclassified planned readmissions in greater detail.

Our study has several limitations. First, we rely solely on information in administrative claims to determine whether an admission is planned. The full clinical story is obviously limited by this method. However, the CMS readmission algorithm is only based on information from administrative claims,[7] and our goal was to explore a method of improving the algorithm that could be applied by CMS in a pragmatic manner. Second, the validity of the admission type variable for the purpose of identifying "emergent" and "urgent" admissions is not entirely clear. However, based on personal communication with the Research Data Assistance Center, the variable is known to be reliable, although no specific validity testing has been performed. Third, it is possible that some truly planned readmissions began in the ED. This situation may arise at small hospitals. However, we found that most of the planned readmissions that started in the ED had secondary diagnosis codes associated with acute conditions. In addition, we did not find a disproportionate number of potentially misclassified planned readmissions at small hospitals. Fourth, the association between high readmission rates and poor quality of care has been called into question recently. However, the purpose of this study is not to assess the quality of healthcare provided by these hospitals; our intent is to explore opportunities to improve the HRRP planned readmission algorithm. Fifth, our analysis only included the state of Michigan. However, Michigan is 1 of the 10 largest states by population, and we do not expect significant differences between our data and the rest of the country. Sixth, we conducted this analysis with version 3.0 of the CMS readmission algorithm. The latest version (4.0) has made several substantial changes to reduce the number of potentially misclassified planned readmissions. However, neither admission type nor presence of ED charges are considered in the updated version. Therefore, our study provides another potential target for further improvement.

These limitations notwithstanding, these findings have important implications for key stakeholders. Relevant to policymakers, the finding that a large percentage of the planned readmissions had ED charges and/or emergent/urgent admission claim type suggests that CMS should explore the use of these variables in their readmission algorithm. Relevant to hospitals and physicians, the potential misclassification of some planned readmissions suggests that close evaluation of the sources and causes of readmission is imperative during the local development of readmission reduction initiatives.

Collectively, these findings suggest that although planned readmissions are infrequent, many of these planned readmissions may actually be nonelective or unplanned in nature. Furthermore, our findings suggest that the CMS readmission algorithm might improve its accuracy by considering the admission type and the presence of ED charges. Future research in this area should focus on validating the use of ED charges and admission type to identify unplanned readmissions through medical chart review. The aim of the HRRP is to identify signals of poor quality in a fair and equitable manner. Misclassification of readmissions will limit CMS' ability to achieve this important goal.

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Against Medical Advice Discharges

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The "Things We Do for No Reason" (TWDFNR) series reviews practices which 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.

Against medical advice (AMA) discharges, which account for up to 2% of all inpatient discharges, are associated with worse health and health services outcomes and disproportionately affect vulnerable patient populations. This paper will review the background data on AMA discharges as well as the reasons physicians may choose to discharge patients AMA. From a healthcare quality perspective, the designation of a discharge as AMA is low-value care in that it is a routine hospital practice without demonstrated benefit and is not supported by a strong evidence base. We argue that designating discharges as AMA has never been shown to advance patient care and that it has the potential to harm patients by reducing access to care and promoting stigma. We believe that greater attention to both shared decision-making as well as harm reduction principles in discharge planning can serve as effective, patient-centered alternatives when patients choose not to follow a healthcare professional's recommended advice.

CASE PRESENTATION

A 54-year-old man with active intravenous (IV) drug use and hepatitis C was admitted with lower extremity cellulitis. On hospital day 2, the patient insisted that he wanted to go home. The treatment team informed the patient that an additional 2-3 days of IV antibiotics would produce a more reliable cure and reduce the risk of readmission. Should the team inform the patient that he will be discharged against medical advice (AMA) if he chooses to leave the hospital prematurely?

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BACKGROUND

In the United States, patients are discharged AMA approximately 500,000 times per year (1%-2% of all discharges).[1] These discharges represent a wide array of clinical scenarios that all culminate in the formal recognition and documentation of a competent patient's choice to decline further inpatient medical care and leave the hospital prior to a recommended clinical endpoint. Compared with standard discharges, AMA discharges are associated with an increased adjusted relative risk of 30-day mortality as high as 10% and 30-day readmission rates that are 20%-40% higher than readmission rates following standard discharges.[2] AMA discharges are more likely among patients with substance use disorders, psychiatric illness, and HIV.[3]

WHY YOU MIGHT THINK AMA DISCHARGES ARE HELPFUL

Although there are little empirical data to inform how and why physicians choose to designate a discharge as AMA when patients decline recommended care, the existing evidence suggests that fears of legal liability are strongly driving the practice.[4] Physicians may believe that they must discharge patients AMA in order to fulfill their legal and ethical responsibilities, or to demonstrate in writing the physician's concern and the significant risk of leaving.[5,6] Clinicians may have been acculturated during training to believe that an AMA discharge may also be seen as a way of formally distancing themselves from the patient's request for a nonstandard or unsafe discharge plan, thus deflecting any potential blame for worse patient outcomes.

Finally, clinicians and administrators may also believe that an AMA discharge is the appropriate designation for a hospital stay that ended because the patient chose to prematurely discontinue the treatment relationship or to decline the postdischarge placement recommendations. This reasoning may explain why the hospital penalties authorized by Medicare's Hospital Readmission Reduction Program generally exclude initial admissions ending in an AMA discharge[7] and may provide the rationale (and perhaps a financial incentive) to discharge patients AMA in order to limit CMS readmission penalties.

WHY AMA DISCHARGES ADD NO VALUE TO A PATIENT'S FULLY INFORMED DECLINATION OF CARE

The AMA discharge is a routine hospital practice without demonstrated patient benefit and which disproportionately affects vulnerable populations. There is also a growing liter-

ature that demonstrates that AMA discharges stigmatize patients, reduce their access to care, and can reduce the quality of informed consent discussions in discharge planning.[8-10] Although there are no conclusive data that AMA discharges are more likely among underrepresented racial minorities, the disproportionate burden of AMA discharges and their worse health outcomes are borne by the homeless, those with substance use disorders, and the uninsured.[3,11]

Compared to patients discharged conventionally from an emergency department, 25% of patients discharged AMA reported not wanting to return for follow-up care.[8] This reluctance to return for care is in part mediated by provider-generated stigma and blame[9,12] and may be exacerbated when patients believe that their decision to leave AMA was based upon extenuating circumstance or competing necessity (eg, limited care options for their dependents, poor quality hospital care, etc.).

To persuade patients to remain hospitalized, 85% of trainees and 67% of attending physicians in one study incorrectly informed their patients that insurance will not reimburse a hospitalization if they leave AMA.[13] Because this study demonstrated that there is no empirical evidence that payment after AMA discharges is denied by private or government payers, physicians sharing this misinformation can breed distrust and coercively undermine patients' ability to make a voluntary choice.

When clinicians assert they are bound by duty to discharge a patient AMA, they may be conflating a presumed legal obligation to formally designate the discharge as AMA in the medical record with their actual obligation to obtain the patient's informed consent for the discharge. In other words, there is no identifiable medico-legal requirement to specifically designate a discharge as AMA.

Although clinicians may presume that the AMA designation provides protection from liability, the claim is not supported by the available literature.[14,15] In these studies, which reviewed relevant case law, defendants prevailed not because of the physician's AMA designation, but because the plaintiff was not able to prove negligence. The proper execution of the discharge process, not the specific designation of AMA, is what conferred liability protection.[5] Indeed, malpractice claims, which are associated with patient perceptions of feeling deserted or devalued,[16] might be more likely with AMA discharges when they result from flawed and stigmatizing communication processes.[17]

Finally, there are no clinical, regulatory, or professional standards that specify the designation of an AMA discharge. Neither the Joint Commission nor any other professional organization specify under what conditions a clinician should discharge a patient AMA, thus promoting wide variability in its use and further limiting it as a valid and reliable healthcare metric.

WHAT SHOULD PHYSICIANS DO INSTEAD: AVOID THE AMA DESIGNATION AND PROMOTE SHARED DECISION-MAKING AND HARM REDUCTION

Because all competent patients have the right to decline recommended inpatient treatment, the ethical and legal standard is that the physician obtain the patient's informed consent to leave by communicating the risks, benefits, and alternatives to leaving and fully documenting the conversation in the medical record.[2] The additional steps of formalizing the discharge as AMA and providing AMA forms for the patient to sign have never been demonstrated to improve quality (and add needless clerical work). When declining any treatment, even life-sustaining treatment, the request for a patient signature to decline such treatment has not been demonstrated to improve risk communication and is not considered a best practice for informed consent.[18] When the physician's motives for this behavior are punitive or directed primarily at reducing liability, it may distract the physician from their fiduciary duty to put patients first.

The solution to improve quality is straightforward—avoid designating discharges as AMA. Instead, clinicians should maintain a single discharge process with clear, objective documentation including providing appropriate prescriptions and follow-up appointments regardless of whether the patient's choice is consistent with a physician's recommendation. In its place, the physician should use shared decision-making (SDM) and harm reduction principles to enhance the patient's well-being within the identified constraints. SDM involves physicians and patients making healthcare decisions together by combining the patients' values and preferences for care with the physicians' expertise and knowledge of medical evidence. Harm reduction practices seek to reduce the adverse health consequences that may come from unhealthy behaviors while assuming that patients will likely continue such behaviors. Evidence-based and widely accepted examples of harm reduction strategies include nicotine replacement therapy and needle exchange programs.[19]

SDM in discharge planning provides a range of discharge and transitional care options that are within prevailing medical standards, not simply a single recommendation that prioritizes health promotion to the exclusion of other identified patient goals. Quality discharge planning should provide the "right care for the right patient at the right time"[20] that moves beyond the false choice of either remaining in the hospital under the conditions specified by the physician or leaving AMA. Although physicians are understandably concerned about patients making choices that do not prioritize their health, physicians can consider the evidence for harm reduction programs' effectiveness in improving health outcomes[21] and accommodate patients by providing harm-reducing discharge options that, while suboptimal, may not be substandard.[22]

Physicians who wish to promote stronger patient-centered discharge practices may find that avoiding or limiting AMA discharges may conflict with their institution's policy. In those cases, physicians should work closely with their leadership and legal counsel to ensure that any proposed practice changes are legally compliant but also improve SDM and reduce stigma for this population.

Although ending the clinical practice of designating discharges as AMA is unlikely to completely ameliorate the

morbidity and costs associated with patients declining episodes of inpatient care, there is reasonable face validity to conclude that replacing the AMA practice with greater attention to harm reduction and SDM can reduce some of the preventable harms like stigmatization and reduced access to care. Together, these practices demonstrate the profession's continued commitment to the public to practice patient-centered care.

RECOMMENDATIONS

- Treat all discharges similarly. Avoid designating an inpatient discharge as AMA.
- Ensure there is objective documentation of the patient's informed choice to leave the hospital.
- When patients wish to leave the hospital prior to a physician-recommended clinical endpoint, engage in SDM with a focus on providing all medically reasonable treatment options that promote harm reduction.
- If you choose to designate a discharge as AMA, approach the discharge planning process consistently and with patient-centered principles by optimizing SDM and harm reduction.

CONCLUSION

The physician informed the patient of the risks, benefits, and alternatives to leaving the hospital prior to the completion of IV antibiotics and confirmed the patient's decision-making capacity. Next, the physician elicited the patient's preferences for care and identified competing priorities. The patient wanted treatment for his cellulitis, but he was experiencing pain and opioid withdrawal. The physician then expanded the range of potential treatment options, including evaluation for medication-assisted treatment for the patient's opioid use disorder (OUD) and harm reduction measures such as safer injection practices, needle exchange, housing assistance, and overdose prevention and treatment education.[23] An alternative harm-reducing option included discharge with oral antibiotics and follow-up with his primary physician in 48-72 hours. After the patient indicated that he wanted to leave because he was not yet ready for OUD treatment, he was discharged with the standard discharge paperwork and antibiotics, and the physician documented the informed consent discussion.

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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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Dust in the Wind

The approach to clinical conundrums by an expert clinician is revealed through the presentation of an actual patient's case in an approach typical of a morning report. Similarly to patient care, sequential pieces of information are provided to the clinician, who is unfamiliar with the case. The focus is on the thought processes of both the clinical team caring for the patient and the discussant.

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

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A 52-year-old woman presented with a 4-day history of progressive dyspnea, nonproductive cough, pleuritic chest pain, and subjective fevers. She described dyspnea at rest, which worsened with exertion. She reported no chills, night sweats, weight change, wheezing, hemoptysis, orthopnea, lower extremity edema, or nasal congestion. She also denied myalgia, arthralgia, or joint swelling. She reported no rash, itching, or peripheral lymphadenopathy. She had no seasonal allergies. She was treated for presumed bronchitis with azithromycin by her primary care provider 4 days prior to presentation but experienced progressive dyspnea.

The constellation of dry cough, fever, and dyspnea is often infectious in origin, with the nonproductive, dry cough more suggestive of a viral than bacterial syndrome. Atypical organisms such as *Mycoplasma pneumoniae*, *Legionella pneumophila*, and *Chlamydia pneumoniae* may also present with these symptoms. Noninfectious etiologies should also be considered, including pulmonary embolism, systemic lupus erythematosus, asbestosis, hypersensitivity pneumonitis, sarcoidosis, and lung cancer. The dyspnea at rest stands out as a worrisome feature, as it implies hypoxia; therefore, an oxygen saturation is necessary to quickly determine her peripheral oxygen saturation.

Her past medical history was notable for lung adenocarcinoma, for which she had undergone right upper lobectomy, without chemotherapy or radiation, 13 years ago without recurrence. She had no history of chronic obstructive pulmonary disease, asthma, or pneumonia, nor a family history of chronic obstructive pulmonary disease, asthma, pneumonia, or lung cancer. Her only medication was azithromycin. She drank alcohol on occasion and denied illicit drug use. Three weeks prior to admission, she began smoking 4 to 5 cigarettes per day after 13 years of abstinence. Her smoking history prior to abstinence was 1 pack per day for 20 years. She worked as a department store remodeler; she had no exposure to asbestos, mold, or water-damaged wood. She reported no recent travel, sick contacts, or exposure to animals.

A primary lung neoplasm with a pleural effusion could cause her shortness of breath and pleuritic chest pain. Her history of lung cancer at age 39 raises the possibility of recurrence. For cigarette smokers, a second lung cancer may occur many years after the first diagnosis and treatment, even if they have quit smoking. A review of her original cancer records is essential to confirm the diagnosis of pulmonary adenocarcinoma. What is now being described as pulmonary adenocarcinoma may have been a metastatic lesion arising from outside the lung. Although unlikely, a primary adenocarcinoma may remain active.

Infectious etiologies continue to merit consideration. A parapneumonic effusion from a pneumonia or an empyema are consistent with her symptoms. Systemic lupus erythematosus can cause lung disease with pleural effusions. She does exhibit dyspnea and pleurisy, which are consistent with autoimmune disease, but does not exhibit some of the more typical autoimmune symptoms such as arthralgias, joint swelling, and rash. Pneumothorax could also produce her symptoms; however, pneumothorax usually occurs spontaneously in younger patients or after trauma or a procedure. Remote right upper lobectomy would not be a cause of pneumothorax now. Her reported history makes lung disease or pneumoconiosis due to occupational exposure to mold or aspergillosis a possibility. Legionellosis, histoplasmosis, or coccidioidomycosis should be considered if she lives in or has visited a high-risk area. Pulmonary embolism remains a concern for all patients with new-onset shortness of breath. Decision support tools, such as the Wells criteria, are valuable, but the gestalt of the physician does not lag far behind in accuracy.

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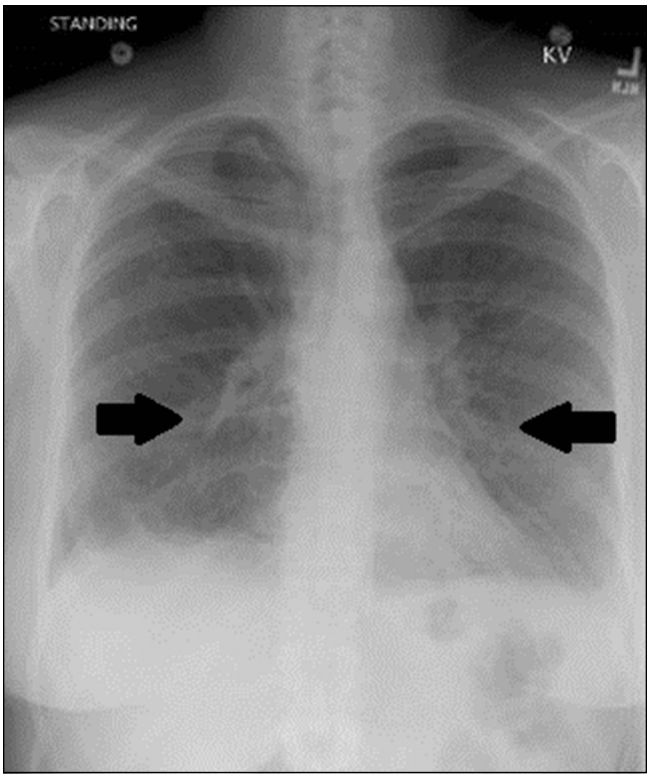

FIG 1. Chest radiograph demonstrating diffusely increased interstitial markings, bilateral hilar adenopathy, and a small left pleural effusion.

Cardiac disease is also in the differential. Bibasilar crackles, third heart sound gallop, and jugular vein distension would suggest heart failure. A pericardial friction rub would be highly suggestive of pericarditis. A paradoxical pulse would raise concern for pericardial tamponade. Pleurisy may be associated with a pericardial effusion, making viral pericarditis and myocarditis possibilities.

She was in moderate distress with tachypnea and increased work of breathing. Her temperature was 36.7°C, heart rate 104 beats per minute, respiratory rate 24 breaths per minute, oxygen saturation was 88% on room air, 94% on 3 liters of oxygen, and blood pressure was 147/61 mmHg. Auscultation of the lungs revealed bibasilar crackles and decreased breath sounds at the bases. She was tachycardic, with a regular rhythm and no appreciable murmurs, rubs, or gallops. There was no jugular venous distention or lower extremity edema. Her thyroid was palpable, without appreciation of nodules. Skin and musculoskeletal examinations were normal.

Unless she is immunocompromised, infection has become lower in the differential, as she is afebrile. Decreased breath sounds at the bases and bibasilar crackles may be due to pleural effusions. Congestive heart failure is a possibility, especially given her dyspnea and bibasilar crackles. Volume overload from renal failure is possible, but she does not have other signs of volume overload such as lower extremity edema or jugular venous distension. It is important to note that crackles may be due to other etiologies, including atelectasis, fibrosis, or pneumonia. Pulmonary embolism may cause hypoxia, tachycardia, and pleural effusions. Additional diseases may present similarly, including human immunodeficiency virus with *Pneumocystis jirovecii*, causing dyspnea, tachypnea, and tachycardia; hematologic malignancy with anemia, causing dyspnea and tachycardia; and thyrotoxic states with thyromegaly, causing dyspnea and tachycardia. Thyroid storm patients appear in distress, are tachycardic, and may have thyromegaly.

Moderate distress, increased work of breathing, tachycardia, tachypnea, and hypoxia are all worrisome signs. Her temperature is subnormal, although this may not be accurate, as oral temperatures may register lower in patients with increased respiratory rates because of increased air flow across the thermometer. Bibasilar crackles with decreased bibasilar sounds require further investigation. A complete blood count, complete metabolic profile, troponin, arterial blood gas (ABG), electrocardiogram (ECG), and chest radiograph are warranted.

Laboratory studies revealed a white blood cell count of 8600 per mm^3 with 11% bands and 7.3% eosinophils, and a hemoglobin count of 15 gm/dL. Basic metabolic panel, liver function tests, coagulation panel, and urinalysis were within normal limits, including serum creatinine 0.7 mg/dL, sodium 143 mmoL/L, chloride 104 mmoL/L, bicarbonate 30 mEq/L, anion gap 9 mmoL/L, and blood urea nitrogen 12 mg/dL. Chest radiograph disclosed diffusely increased interstitial markings and a small left pleural effusion (Figure 1).

Her bandemia suggests infection. Stress can cause a leukocytosis by demargination of mature white blood cells; however, stress does not often cause immature cells such as bands to appear. Her chest radiograph with diffuse interstitial markings is consistent with a community-acquired pneumonia. Empiric antibiotic therapy should be initiated because of the possibility of community-acquired pneumonia. Recent studies demonstrate that steroids decrease mortality, the need for mechanical ventilation, and the length of stay for patients hospitalized with community-acquired pneumonia; therefore, this patient should also be treated with steroids.

Eosinophilia may be seen in drug reactions, allergies, pulmonary emboli, pleural effusions, and occasionally in malignancy. Eosinophilic pneumonia typically has the "reverse pulmonary edema" picture, with infiltrates in the periphery and not centrally, as in congestive heart failure.

A serum bicarbonate of 30 mEq/L suggests a metabolic compensation for a chronic respiratory acidosis as renal compensation, and rise in bicarbonate generally takes 3 days. She may have been hypoxic longer than her symptoms suggest.

An ABG should be ordered to determine the degree of hypoxia and whether a higher level of care is indicated. The

abnormal chest radiograph, along with her hypoxia, merits a closer look at her lung parenchyma with chest computed tomography (CT). A D-dimer would be beneficial to rule out pulmonary embolism. If the D-dimer is positive, chest CT with contrast is indicated to determine if a pulmonary embolism is present. A brain natriuretic peptide would assist in the diagnosis of congestive heart failure. A sputum culture and Gram stain and respiratory viral panel may establish a pathogen for pneumonia. An ECG and troponin to rule out myocardial infarction should be performed as well.

She was admitted to the medical floor and treated for community-acquired pneumonia with azithromycin and ceftriaxone. By hospital day 3, she had no improvement in her dyspnea and required supplemental oxygen at 3.5 L/min via nasal cannula. An ABG revealed a pH of 7.38, PCO2 47 mmHg, PaO2 64 mmHg, bicarbonate 32 mEq/L, and an oxygen saturation level of 94% on 1.5 L/min of oxygen, the least amount of oxygen she could tolerate. Human immunodeficiency virus antibody and heterophile screens were negative. The erythrocyte sedimentation rate was elevated, at 49 mm/hr (reference range 0-30 mm/hr), as was the D-dimer at 0.82 fibrinogen equivalent units (reference range <0.43). Sputum cultures and respiratory viral panel were not obtained. Chest CT with intravenous contrast in a pulmonary embolism protocol demonstrated no evidence of pulmonary embolism but did reveal bilateral pleural effusions and symmetrical, bilateral hilar and subcarinal lymphadenopathy (Figure 2). The lungs showed mild to moderate emphysematous changes and slight volume-loss of the right middle lobe, with minimal ground-glass opacities. Patchy ground-glass opacities were noted in the right lower lobe lateral basal segment. Interstitial markings of both lungs were diffusely increased. An ECG was not obtained.

The presence of hilar and subcarinal lymph nodes expands the differential. Stage IV pulmonary sarcoid may present with diffuse infiltrates and nodes, although the acuity in this case makes it less likely. A very aggressive malignancy such as Burkitt lymphoma may have these findings. Acute viral and atypical pneumonias remain possible. Right middle lobe syndrome may cause partial collapse of the right middle lobe. Tuberculosis can be associated with right middle lobe syndrome; however, in this day and age an obstructing mass is more likely the cause. Pulmonary disease, such as cryptogenic organizing pneumonia, idiopathic pulmonary fibrosis, and interstitial lung disease, should be considered in patients with pneumonia unresponsive to antibiotics. Lung biopsy and bronchoalveolar lavage (BAL) would help make the diagnosis and should be the next step, unless her degree of hypoxia is prohibitive. Similarly, thoracentesis with analysis of the pleural fluid for cell count, Gram stain, and culture may help make the diagnosis. Thoracentesis should be done with fluoroscopic guidance, given the risk of pneumothorax, which would further compromise her tenuous respiratory status.

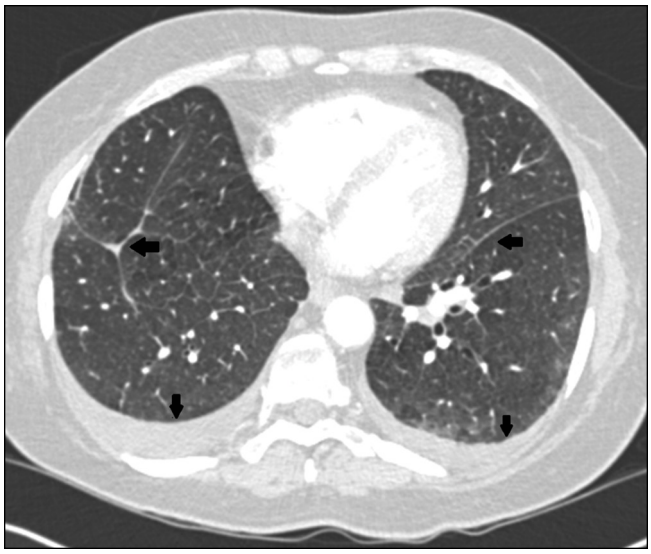

FIG 2. Chest computed tomography with intravenous contrast demonstrating symmetrical, bilateral, diffusely increased interstitial markings, and small bilateral pleural effusions.

Thoracentesis was attempted, but the pleural effusion was too small to provide a sample. Subsequent serum blood counts with differential showed an increased eosinophilia to 20% and resolved bandemia. Upon further questioning, she recalled several months of extensive, daily, fine-dust exposure from demolition during the remodeling of a new building.

Hypereosinophilia and pulmonary infiltrates narrow the differential considerably to include asthma; parasitic infection, such as the pulmonary phase of ascariasis; exposure, such as to dust, cigarettes, or asbestosis; or hypereosinophilic syndromes characterized by peripheral eosinophilia, along with a tissue eosinophilia, causing organ dysfunction. Idiopathic hypereosinophilic syndrome, a hypereosinophilic syndrome of unknown etiology despite extensive diagnostic testing, is rare, and eosinophilic leukemia even rarer. Her history strongly suggests exposure. Many eosinophilic diseases respond rapidly to steroids, and response to treatment would help narrow the diagnosis. If she does not respond to steroids, a lung and/or bone marrow biopsy would be the next step.

A BAL of the right middle lobe revealed 51% eosinophils, 3% neutrophils, 15% macrophages, and 28% lymphocytes. Gram stain, as well as cultures for bacteria, acid fast bacilli, fungus, herpes simplex virus, and cytomegalovirus cultures, were negative. Transbronchial lung biopsy revealed focal interstitial fibrosis and inflammation, without evidence of infection.

Eosinophils are primarily located in tissues; therefore, peripheral blood eosinophil counts often underestimate the

degree of infiltration into end organs such as the lung. With 50% eosinophils, her BAL reflects this. Mold, fungus, chemical, and particle exposure could produce an eosinophilic BAL. She does not appear to be at risk for parasitic exposure. Eosinophilic granulomatosis (previously known as Churg-Strauss) is a consideration, but the lack of signs of vasculitis and wheezing make this less likely. A negative antineutrophil cytoplasmic antibody may provide reassurance. "Fine dust exposure" is consistent with environmental exposure but not a specific antigen. Steroids provide a brisk eosinophil reduction and are appropriate for this patient. There is the possibility of missing infectious or parasitic etiologies; therefore, a culture of BAL fluid should be sent.

Eosinophilic infiltration may lead to fibrosis, as was found on the lung biopsy. She should be counseled to avoid "fine dust exposure" in the future. Follow-up lung imaging and pulmonary function tests (PFTs) should be performed once her acute illness resolves. She should be strongly urged not to smoke tobacco. Interestingly, there are reports that ex-smokers who restart smoking have an increased risk of eosinophilic pneumonia, but in this case dust exposure is the more likely etiology.

She was diagnosed with acute eosinophilic pneumonia (AEP). Antibiotics were discontinued, and oral prednisone was initiated at 40 mg daily, with a brisk response and resolution of her dyspnea. She was discharged with a 6-week prednisone taper. She had no cough, dyspnea, chest pain, or fevers at her follow-up 14 days after discharge. On a 6-week, postdischarge phone call, she continued to report no symptoms, and she maintained abstinence from cigarette smoking.

This case highlights that the very best test in any medical situation is a thorough, detailed history and physical examination. A comprehensive history with physical examination is noninvasive, safe, and cheap. Had the history of fine-dust exposure been known, it is likely that a great deal of testing and money would have been saved. The patient would have been diagnosed and treated earlier, and suffered less.

COMMENTARY

First described in 1989,[1,2] AEP is an uncommon cause of acute respiratory failure. Cases have been reported throughout the world, including in the United States, Belgium, Japan, and Iraq.[2,3] AEP is an acute febrile illness with cough, chest pain, and dyspnea for fewer than 7 days, diffuse pulmonary infiltrates on chest radiograph, hypoxemia, no history of asthma or atopic disease, no infection, and greater than 25% eosinophils on a BAL.[1,3] Physical examination typically reveals fever, tachypnea, and crackles on auscultation.[1] Peripheral blood eosinophilia is inconsistently seen at presentation but generally observed as the disease progresses.[1] Peripheral eosinophilia at presentation is positively correlated with a milder course of AEP, including higher oxygen saturation and fewer intensive care admissions.[4] Acute respiratory failure in AEP progresses rapidly, often within hours.[1] Delayed recognition of AEP may lead to respiratory failure, requiring intubation, and even to death.[1]

Reticular markings with Kerley-B lines, mixed reticular and alveolar infiltrates, and pleural effusions are usually found on chest radiography.[1] Bilateral areas of ground-glass attenuation, interlobular septal thickening, bronchovascular bundle thickening, and pleural effusions are seen on chest CT.[5] Marked eosinophilic infiltration of the interstitium and alveolar spaces, as well as diffuse alveolar damage with hyaline membrane fibroblast proliferation and inflammatory cells, are present on lung biopsy.[1] Restriction with impaired diffusion capacity is found on PFTs. However, PFTs return to normal after recovery.[1]

AEP is distinguished from other pulmonary diseases by BAL, lung biopsy, symptoms, symptom course, and/or radiographically. AEP is often misdiagnosed as severe community-acquired pneumonia and/or acute respiratory distress syndrome, as AEP tends to occur in previously healthy individuals who have diffuse infiltrates on chest radiograph, fevers, and acute, often severe, respiratory symptoms.[1-3] Other eosinophilic lung diseases to rule out include simple pulmonary eosinophilia, chronic eosinophilic pneumonia, eosinophilic granulomatosis with polyangitis (Churg-Strauss), idiopathic hypereosinophilic syndrome, infection, and drug reactions.[1,3,5] Simple eosinophilic pneumonia is characterized by no symptoms or very mild pulmonary symptoms and transient patchy infiltrates on radiography.[3,5] Patients with simple pulmonary eosinophilia do not have interlobular septal thickening, thickening of the bronchovascular bundles, or pleural effusions radiographically, as seen with AEP.[5] Chronic eosinophilic pneumonia is subacute, with respiratory symptoms of more than 3 months in duration, in contrast with the 7 days of respiratory symptoms for AEP, and is also not associated with interlobular septal thickening, thickening of the bronchovascular bundles, or pleural effusions on radiography.[3,5] Unlike AEP, chronic eosinophilic pneumonia often recurs after the course of steroids has ended.[3] In contrast with AEP, eosinophilic granulomatosis with polyangitis is associated with concomitant asthma and the involvement of nonpulmonary organs.[3] Idiopathic hypereosinophilic syndrome is characterized by extremely high peripheral eosinophilia and by eosinophilic involvement of multiple organs, and it requires chronic steroid use.[3] Patients with allergic bronchopulmonary aspergillosis (ABPA), in contrast with AEP, typically have steroid-dependent asthma and chronic respiratory symptoms.[3] ABPA also differs from AEP in that radiographic infiltrates are localized and transient, and the syndrome may relapse after steroid treatment.[3] Other infectious etiologies that may present similarly to AEP include invasive pulmonary aspergillosis, pulmonary coccidiodomycosis, *Pneumocystis jioveri* pneumonia, pulmonary toxocariasis, pulmonary filariasis, paragonimiasis, and Loeffler syndrome (pneumonia due to *Strongyloides*, *Ascaris*, or hookworms), highlighting the importance of a thorough travel and exposure history.[1,3] Several drugs may cause eosin-

ophilic lung disease, including nitrofurantoin, tetracyclines, phenytoin, L-tryptophan, acetaminophen, ampicillin, heroin, and cocaine, which necessitates a thorough review of medication and illegal drug use.[3]

Steroids and supportive care are the treatment of choice for AEP, although spontaneous resolution has been seen.[1,3] Significant clinical improvement occurs within 24 to 48 hours of steroid initiation.[1,3] Optimal dose and duration of therapy have not been determined; however, methylprednisolone 125 mg intravenously every 6 hours until improvement is an often-used option.[1] Tapers vary from 2 to 12 weeks with no difference in outcome.[1-3] AEP does not recur after appropriate treatment with steroids.[1,3]

Little is known about the etiology of AEP. It usually occurs in young, healthy individuals and is presumed to be an unusual, acute hypersensitivity reaction to an inhaled allergen.[1] A report of 18 US soldiers deployed in or near Iraq proposed dust exposure and cigarette or cigar smoking as a cause of AEP.[2] Similar to our patient's fine-dust exposure and recent onset of cigarette smoking, the soldiers were exposed to the dusty, arid environment for at least 1 day and had been smoking for at least 1 month.[2] The authors proposed that small dust particles irritate alveoli, stimulating eosinophils, which are exacerbated by the onset of smoking. Alternatively, cigarette smoke may prime the lung such that dust triggers an inflammatory cascade, resulting in AEP.[2] Because of the potential for the rapid progression of respiratory failure, it is critical that clinicians recognize that AEP may be caused by relatively new cigarette smoking and dust in the wind.

TEACHING POINTS

- With the potential for the rapid progression of respiratory failure, it is imperative that the diagnosis of AEP be considered for a patient with diffuse infiltrates on a chest radiograph and acute respiratory failure of unknown cause.
- A thorough history of exposure is key to including AEP in the differential of acute pulmonary disease, with recent-onset cigarette smoking and dust exposure.
- The rapid initiation of steroids leads to a full recovery without recurrence and may be life-saving in AEP.

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Tools, Clinical Prediction Rules, and Algorithms for the Insertion of Peripheral Intravenous Catheters in Adult Hospitalized Patients: A Systematic Scoping Review of Literature

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BACKGROUND: First-time peripheral intravenous catheter (PIVC) insertion success is dependent on patient, clinician, and product factors. Failed PIVC insertion are an under-recognized clinical phenomenon.

OBJECTIVE: To provide a scoping review of decision aids for PIVC insertion including tools, clinical prediction rules, and algorithms (TRAs) and their findings on factors associated with insertion success.

METHODS: In June 2016, a systematic literature search was performed using the medical subject heading of peripheral catheterization and tool* or rule* or algorithm*. Data extraction included clinician, patient, and/or product variables associated with PIVC insertion success. Information about TRA reliability, validity, responsiveness, and utility was also extracted.

RESULTS: We screened 36 studies, and included 13 for review. Seven papers reported insertion success ranging from 61%-90% (4030 insertion attempts), 6 on validity, and 5 on reliability, with none reporting on responsiveness and utility. Failed insertions were associated with obesity (odds ratio [OR], 0.71-1.7; 2 studies) and smaller gauge PIVCs (OR, 6.4; 95% Confidence Interval [CI}, 3.4-11.9). Successful inser tions were associated with visible veins (OR, 0.87-3.63; 3 studies) or palpable veins (OR, 0.79-5.05; 3 studies) and inserters with greater procedural volume (OR, 4.4; 95% CI, 1.6-12.1) or who predicted that insertion would be successful (OR, 1.06; 95% CI, 1.04-1.07). Definitions of insertion difficulty are heterogeneous such as time to insert to a number of failed attempts.

CONCLUSION: Few well-validated reliable TRAs exist for PIVC insertion. Patients would benefit from a validated, clinically pragmatic TRA that matches insertion difficulty with clinician competency. *Journal of Hospital Medicine* 2017;12:851-858. Published online first September 6, 2017.

Up to a billion peripheral intravenous catheters (PIVCs) are inserted annually; therefore, the importance of this invasive device in modern medicine cannot be argued.[1] The insertion of a PIVC is a clinical procedure undertaken by a range of clinical staff and in a variety of patient populations and settings. In many clinical environments (for example, the emergency department [ED]), PIVCs are the predominant first-choice vascular access device (VAD).[2,3] Researchers in one study estimated over 25 million PIVCs are used in French EDs each year,[3] and intravenous therapy is the leading ED treatment in the United States.[4]

First-time insertion success (FTIS) for PIVCs has been reported at 18% to 98% in adult populations.[5,6] The variability of FTIS likely reflects not just a variety of clinician groups and patient populations but also the absence of uniform approaches to PIVC insertion. Terms frequently used to describe or formalize a pattern of care or a clinical procedure include the following: diagnostic and prognostic tools and/or plans, frameworks, predictive assessment tools, prediction models, rules, decision-making rules, scores, scales, risk factors, risk algorithms, and algorithms.[7-12] In this paper, we use the terms tools, clinical prediction rules, and algorithms (TRAs) to review such frameworks that have been reported in the context of promoting FTIS for PIVCs.

The purpose of this systematic scoping review was to investigate what PIVC decision-making approaches exist to facilitate FTIS of PIVCs in adult hospitalized patients. Our intention was to systematically synthesize the research on TRAs, to review significant associations identified with these TRAs, and to critique TRA validity and reliability.

METHODS

Scoping Review

We selected a scoping review method that, by definition, maps the evidence to identify gaps,[13,14] set research agendas, and identify implications for decision making. This allowed a targeted approach to answering our 3 research questions:

- What published clinical TRAs exist to facilitate PIVC insertion in adults?

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TABLE 1. Characteristics of Included Studies

Authors	Year	Country	Study Aim	Study Design and Setting	Study Population and Sample Size	Variables Identified	Analytics and Measurement Property Reported	FTIS	Category of TRA
Carr et al.[23]	2016	Australia	To identify factors affecting FTIS.	Prospective cohort (self-report) single center ED	Adult patients in ED (N = 460)	Visible and palpable veins; weight status, skin shade; number of sites; location; vein size; Clinician variables: Role; numerical experience; likelihood of success; PIVC gauge.	Face validity; multivariate logistic regression model; ROC curve	86%	Clinical prediction rule
de la Toree et al.[28]	2013	Spain	To develop a PIVC insertion scale that classifies easy to difficult PIVC insertion.	Prospective observational single center oncology	Initial sample to assess patient characteristics, (N = 16); Evaluation phase (N = 108) Oncology and nononcologic background (as control).	Number of veins ACF--Hand; PIVC gauge; extravasation risk determined by the clinician.	Descriptive statistics; reliability	N/A	Scale
Fields et al.[26]	2014	USA	To identify risk factor for difficult venous access in the ED.	Prospective observational single center ED	Adult patients (N = 767)	Diabetes; intravenous drug abuse; sickle cell disease.	Multivariate logistic regression model	77%	Risk factors
Jacobson and Winslow[25]	2005	USA	To identify clinical variables associated with PIVC insertion difficulty and those associated with success and failure.	Descriptive study both in-patient and outpatient settings.	PIVC insertions (N = 339)	A combination of patient, clinician, and product variables.	Content validity described; Likert scale; descriptive statistics chi-square, t test, Pearson correlation	65%	Clinical prediction rule
Kelly and Egerton-Warburton[29]	2014	Australia	Define criteria for PIVC insertion.	Cross-sectional survey	Medical and nursing emergency clinicians	39 potential presenting complaints.	Modified Delphi technique	N/A	Score
Pagnutti et al.[19]	2016	Italy	Development of a tool for measuring difficulty in patients receiving chemotherapy.	A pilot validated study; two phases: Phase 1: Expert opinion and literature review. Phase 2: Cohort study	Adult patients (N = 260)	A number of vein assessment criteria; chemotherapy treatment; duration and multiple venepuncture.	Validity; face and content and construct; Reliability; IRR Cohen's Kappa	N/A	Tool
Piredda et al.[27]	2017	Italy	To identify risk factors for difficult intravenous cannulation.	Prospective observational (self-report) single center radiology	Adult patients undergoing a radiologic scan (N = 763)	Vein characteristics (visibility; palpability; vein fragility; veins with many valves).	Univariate and multivariate logistic regression model	90%	Clinical prediction rule
Sebbane, et al.[3]	2013	France	To investigate the relationship between BMI and PIVC insertion difficulty.	Prospective observational single center ED	Adult patients (N = 563)	Extremes of BMI vein assessment.	Reliability; interrater; multivariable logistic regression model; ROC curve	79%	Clinical prediction rule
Ung et al.[20]	2002	Australia	Results from the use of a standardized assessment tool to investigate the impact nursing education and experience has on PIVC performance.	Correlational design oncology units and wards	Registered nurses (N = 38)	Patient education; PIVC gauge/ type; site selection; insertion technique.	Validity; face and content; 2 x 2 factorial analysis of variance; Hierarchical multiple regression analysis	N/A	Tool

Continued on page 853

TABLE 1. Characteristics of Included Studies (continued)

Authors	Year	Country	Study Aim	Study Design and Setting	Study Population and Sample Size	Variables Identified	Analytics and Measurement Property Reported	FTIS	Category of TRA
van Loon et al.[24]	2016	Netherlands	To develop a predictive scale to identify adult patients with PIVC difficulty	Prospective observational cross-sectional cohort single center anesthesiology department	Adult patients (N = 1063)	Predominately patient assessment factors, such as vein diameter, visibility, and palpability; DIVA history; PIVC gauge.	Univariate and multivariate logistic regression model; ROC curve	83%	Clinical prediction rule
Webster, Morris, Robinson, Sanderson[21]	2007	Australia	To assess the validity and reliability of a VAT.	Cohort survey medical imaging	10 nurses (5 oncology nurses and 8 medical imaging nurses; 2 radiographers) Adult patients (N = 10)	Vein visibility, vein size, vein palpation.	Reliability; interrater; ICC; validity; face	N/A	Tool
Wells[22]	2008	UK	To develop 2 tools: the validity of the VAT and the reliability of a tool to select a VAD.	Cohort survey	VAT study: patients (N = 14) and nurses (N = 8) Second study: patients (N = 30) and nurses (N = 2)	Vein assessment; patient vascular access history.	Reliability; interrater K stat; validity; face (expert opinion)	N/A	Tool
Witting[30]	2012	USA	To estimate the incidence of PIVC insertion difficulty and its impact on time.	Prospective cohort single center ED	Adult patients (N = 125)	Specific patient variables; patient self-report of insertion difficulty from none-severe.	Descriptive statistics; relative risk	61%	Incidence report

NOTE: Abbreviations: ACF, ; BMI, body mass index; DIVA, difficult intravenous access; ED, emergency department; FTIS, first-time insertion success; ICC, interclass correlation; IRR, ; N/A, not applicable; PIVC, peripheral intravenous catheter; ROC, receiver operating characteristic curve; TRA, tools, clinical prediction rules, and algorithms; VAD, vascular access device; VAT, vein assessment tool.

- What clinical, patient and/or product variables have been identified using TRAs as having significant associations with FTIS for PIVCs in adult patients?
- What is the reported reliability, validity, responsiveness, clinical feasibility, and utility of existing TRAs for PIVC insertion in adults?

Our aim was to identify the amount, variety and essential qualities of TRA literature rather than to critically appraise and evaluate the effectiveness of TRAs, a process reserved for systematic review and meta-analysis of interventional studies.[13,14] We followed scoping review guidelines published by members and collaborators of the Joanna Briggs Institute, an internationally recognized leader in research synthesis, evidence use, and implementation. The guidance is based on 5 steps: (i) scoping review objective and question, (ii) background of the topic to support scoping review, (iii) study selection, (iv) charting the results, and (v) collating and summarizing results.[15] Clinicometric assessment of a TRA or any clinical prediction rule requires 4 specific phases: (i) development (identification of predictors from data), (ii) validation (testing the rule in a separate population for reliability), (iii) impact analysis or responsiveness (How clinically useful is the rule in the clinical setting? Is it resource heavy or light? Is it cost effective?), and (iv) implementation and adoption (uptake into clinical practice).[16]

Search Strategy

We included studies that described the use or development of any TRA regarding PIVC insertion in the adult hospitalized population.

Inclusion Criteria

Studies were included if they were published in the English Language, included TRAs for PIVC insertion in adult hospital patients, and prospectively assessed a clinical category of patient for PIVC insertion using a traditional approach. We defined a traditional PIVC insertion approach as an assessment and/or insertion with touch and feel, therefore, without vessel-locating technology such as ultrasound and/or near infrared technology.

Exclusion Criteria

Exclusion criteria included pediatric studies, authors' personal (nonresearch) experience of tools, TRAs focused on postinsertion assessment of the cannula (such as phlebitis, infiltration, and/or dressing failure), and papers with a focus on VADs other than PIVCs. We excluded studies using PIVC ultrasound and/or near infrared technology because these are not standard in all insertions and greatly change the information available for pre-insertion assessment as well as the likelihood of insertion success.

In June 2016, a systematic search of the Cochrane li-

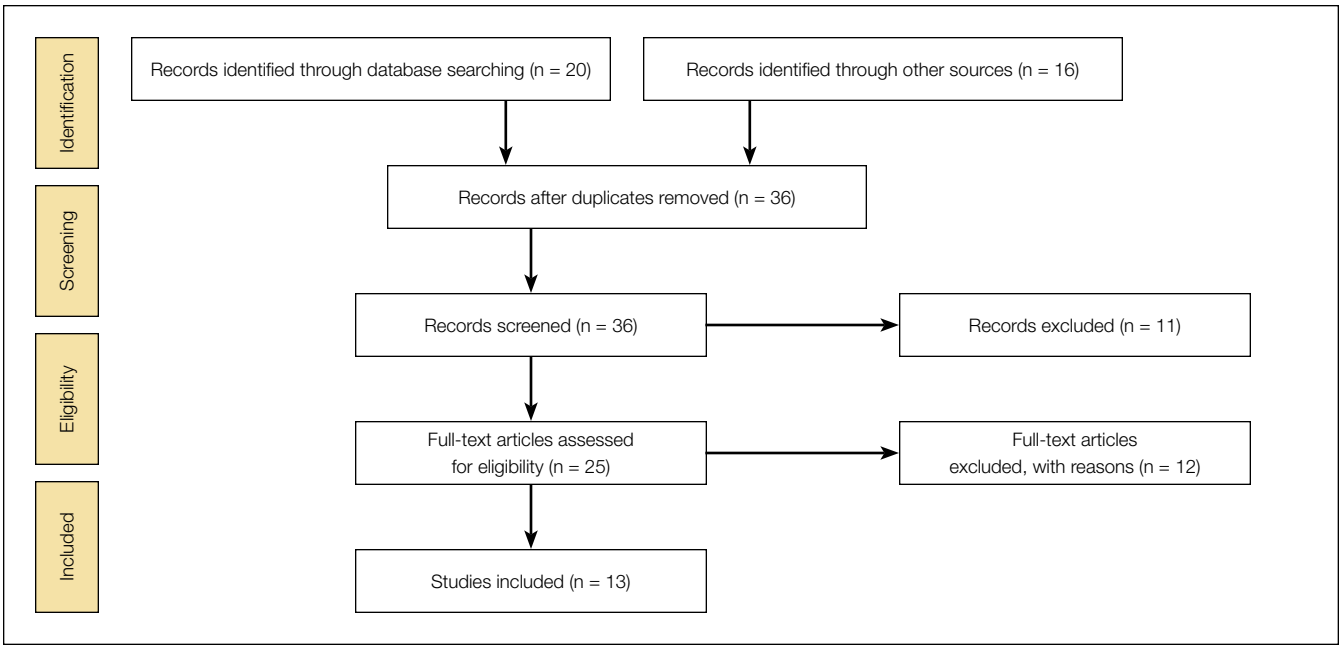

FIG. Prisma flowchart.

brary, Ovid Medline® In-process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>, EBSCO CINAHL databases, and Google Scholar with specific keywords to identify publications that identified or defined TRAs was undertaken. Medical subject headings were created with assistance from a research librarian using tailored functions within individual databases. With key search terms, we limited studies to those related to our inclusion criteria. See Appendix 1 for our search strategy for Medline and CINAHL.

We used Covidence, a web-based application specifically designed for systematic reviews to screen and evaluate eligible publications.[17] Two authors (PJC and NSH) screened the initial retrieved searches based upon the predetermined inclusion and exclusion criteria.

Data Extraction

A paper template was developed and used by 2 reviewers (P.J.C. and N.S.H.). Data included the following: study sample, aim(s), design, setting and country in which the study took place, clinical and patient variables, and how the TRAs were developed and tested. Studies were categorized by TRA type. We also sought to identify if clinical trial registration (where appropriate) was evidenced, in addition to evidence of protocol publication and what standardized reporting guidelines were used (such as those outlined by the EQUATOR Network).[18]

Data Synthesis

Formal meta-analysis was beyond the scope and intention of this review. However, we provide the FTIS rate and the ranges of odds ratios (ORs) with 95% confidence intervals (CIs) for certain independent predictors.

RESULTS

Thirty-six references were imported for screening against title and abstract content, with 11 studies excluded and 25 studies assessed for full-text eligibility (see Figure, PRISMA Flowchart). We then excluded a further 12 studies (6 did not meet inclusion criteria, 2 were focused on the prehospital setting, 2 were personal correspondence and focused on another type of VAD, 1 was a protocol to establish a TRA, and 1 was a framework for all device types), leaving 13 studies included in the final review (see Figure). These studies presented data on 4 tools,[19-22] 4 predictive models[3,23-25] (of which 3 present receiver operating characteristic/area under the curve scores),[3,23,24] 2 framed as risk factor studies,[26,27] and 1 of each of the following: a scale,[28] a score,[29] and an estimation of the incidence report rate (Table 1).[30] Seven studies had "difficult" or "difficulty" in their title as a term to use to describe insertion failure.[3,19,24-27,30] One study was titled exclusively for the nursing profession,[20] 5 studies were reported in medical journals,[3,24,26,29,30] and 6 were reported in nursing journals,[19-22,25,27] with the remainder published in a vascular access journal.[23,28]

General Characteristics of Included Studies

One TRA which was registered as a clinical trial[24] involved a standardized reporting tool as is recommended by the EQUATOR Network.[18]

Nine of the 13 papers reported that TRA components were chosen based on identified predictors of successful insertion from observational data[3,19,23-28,30], with 5 papers using multivariate logistic regression to identify independent predictors.[3,23,24,26,2] At least 4330 insertion attempts on patients were reported. Seven papers reported FTIS, which ranged from 61%-90%.[3,23-27,30]

Two clinical settings accounted for 10 of the 13 included

studies. We identified 5 papers from the ED setting[3,23,26,29,30] and 5 studies specific to cancer settings.[19-22,28] Two ED papers identified clinical predictors of insertion difficulty, with 1 identifying an existing medical diagnosis (such as sickle cell disease, diabetes, or intravenous drug abuse) and the other reporting a pragmatic patient self-report of difficulty.[26,30] Three studies focused on patient-exclusive variables (such as vein characteristics)[19,21,28] and some with a combined clinician and patient focus.[3,23-25,27,30]

Relatively few studies reported interobserver measurements to describe the reliability of clinical assessments made.[3,19,21,28] Webster et al. in Australia assessed interrater reliability of a vein assessment tool (VAT) and found high agreement (kappa 0.83 for medical imaging nurses and 0.93 for oncology nurses).[21] Wells compared reliability with Altman's K scores obtained from a different VAT when compared with the Deciding on Intravenous Access tool and found good agreement.[22] Vein deterioration was proposed as a variable for inclusion when developing an assessment tool within an oncological context.[31] In Spain, de la Toree and colleagues[28] demonstrated good interrater agreement (with kappa, 0.77) for the Venous International Assessment (VIA) tool. The VIA offers a grading system scale to predict the patient's declining vessel size while undergoing chemotherapy via peripheral veins with PIVCs. Grade I suggests little or no insertion failure, whereas a Grade V should predict insertion failure.

We could not find any reported evidence that the included studies we reviewed were clinically adopted and with what degree of success and impact. Therefore, it is unknown how clinically responsive or, indeed, what the clinical utility of these TRAs is. From the retrieved papers, a triad of variables influence PIVC insertion success and include patient characteristics, clinician characteristics, and product characteristics.

Patient Variables

Vein characteristics were significant independent factors associated with insertion success in a number of studies.[3,19,23,24,27,28] These included the number of veins, descriptive quality (eg, small, medium, large), size, location, visible veins, and palpable veins. Other factors appear to be patient specific (such as chronic conditions), including diabetes (OR, 2.1 [adjusted to identify demographic risk factors]; 95% CI, 1.3-3.4), sickle cell disease (OR, 3.5; 95% CI, 1.4-4.8), and intravenous drug abuse (OR, 2.4; 95% CI, 1.1-5.3).[26] It is unclear if a consistent relationship between weight classification and insertion outcomes exists. Despite a finding that BMI was not independently associated with insertion difficulty,[26] one study reports that BMI was independently associated with insertion failure (BMI <18.5 [OR, 2.24; 95% CI, 1.07-4.67], BMI >30 [OR, 1.98; 95% CI, 1.9-3.60])[3] and another reports emaciated patients were associated with greater failure when compared to normal weight patients (OR, 0.07; 95% CI, 0.02-0.34).[23] Consequently, extremes of BMI appear to be associated with insertion outcomes despite 1 study reporting no significant association with BMI as an independent factor of insertion failure.[26] A history of difficult intravenous access (DIVA) was reported in 1 study and independently associated with insertion failure (OR, 3.86; 95% CI, 2.39-6.25; see Table 2). DIVA appears to be the motivating factor in the title of 7 studies. When defined, the definitions of DIVA are heterogeneous and varied and include the following: >1 minute to insert a PIVC and requiring >1 attempt[27]; 2 failed attempts[30]; 3 or more PIVC attempts.[26] In the remaining 4 studies, variables associated with difficulty are identified and, therefore, TRAs to target those in future with predicted difficulty prior to any attempts are proposed.[3,19,24,25]

Clinician Variables

Specialist nurse certification, years of experience, and self-report skill level ($P < 0.001$) appear to be significantly associated with successful insertions.[25] This is in part validated in another study reporting greater procedural inserting PIVCs as an independent predictor of success (OR, 4.404; 95% CI, 1.61-12-06; see Table 2).[23] Two studies involved simple pragmatic percentage cut offs for PIVCs: likelihood of use[29] and likelihood of insertion success.[23] One paper using a cross-sectional design that surveyed ED clinicians suggested if the clinician's predicted likelihood of the patient needing a PIVC was >80%, this was a reasonable trigger for PIVC insertion.[29] The other, in a self-report cohort study, reported that a clinician's likelihood estimation of PIVC FTIS prior to insertion is independently associated with FTIS (OR, 1.06; 95% CI, 1.04-1.07).[23]

Product Variables

In this review, higher failure rates were identified in smaller sizes (22-24 g).[26] One study revealed gauge size was significantly associated with a failed first attempt in a univariate analysis (OR, 0.44; 95% CI, 0.34-0.58), but this was not retained in a multivariate model.[24] Matching the PIVC size with vein assessment is considered in the VIA tool.[28] It suggests a large PIVC (18 g) can be considered in patients with at least 6 vein options; smaller PIVCs of 22 to 24 g are recommended when 3 or fewer veins are found.[28] One paper describes a greater proportion of success between PIVC brands.[25]

DISCUSSION

The published evidence for TRAs for PIVCs is limited, with few studies using 2 or more reliability, validity, responsiveness, clinical feasibility, or utility measurements in their development. There is a clear need to assess the clinical utility and clinical feasibility of these approaches so they can be externally validated prior to clinical adoption.[16] For this reason, a validated TRA is likely required but must be appropriate for the capability of the healthcare services to use it. We suggest the consistent absence of all of these phases is owing to the variety of healthcare practitioners who are responsible for the insertion, the care and surveillance of peripheral cannulae, and the fragmentation of clinical approaches that exist.[32]

Previously, a comprehensive systematic review on the subject of PIVCs found that the presence of a visible and/or

TABLE 2. Patient, Clinician and Product Characteristics of PIVC Insertion Outcomes

Patient Predictor	Study	Total Cases	Standard error	Effect Size (OR)	95% CI	Comparison
Weight	Carr et al[23]	460		0.07	0.02-0.34	Emaciated (n=10) vs Normal (n=250)
				0.4	0.16-1.02	Underweight (n=73) vs Normal
				1.07	0.43-2.64	Overweight (n=91) vs Normal
				0.71	0.23-2.20	Obese n=(36) vs Normal
						Obese 36 v Nonobese= 424
	Piredda et al[27]	667		1.7	1.37-2.10	Obese n=94 (12.4%) vs Nonobese n=667 (87.6%)
						Obese n=94 (12.4%) vs Nonobese n=667 (87.6%)
	Sebanne et al[3]	563		2.24	1.07-4.67	Underweight (BMI <18.5) n= 45 (8%) 18 +/- 0.7 vs Normal (BMI 18.5-<25) n=266 (47%) 22 +/-1.8
						Overweight (BMI 25-<30) n=138 (24%) 27+/- 1.3 vs Normal
						Obese (BMI >30) n=114 (20%) 37 +/- 8.6 vs Normal
						Obese=114 vs Nonobese= 449
Visible Vein	Carr et al[23]	460		2.7	.17-9.86	Visible Vein Yes 379 (82.39%) vs No 81(17.61%)
Visible Vein	Piredda et al[27]	763		0.87	0.83-0.91	Visible Vein Yes vs No
Visible Vein	van Loon et al[24]	1063	0.282	3.63	2.09-6.32	Visible Vein
Palpable Vein	Carr et al[23]	460		5.05	1.37-18.64	Palpable Vein Yes 445 (96.74%) vs No 15 (3.26%)
Palpable Vein	Piredda et al[27]	763		0.79	0.74-0.83	Palpable Vein Yes vs No
Palpable Vein	van Loon et al[24]	1063	0.28	4.94	2.85-8.56	Palpable Vein
Vein Diameter	van Loon et al[24]	1063		3.37	2.12-5.36	
H/O DIVA	van Loon et al[24]	1063		3.86	2.39-6.25	
Diabetes	Fields[26]	743		2.1	1.3-3.4	
IVD	Fields[26]	743		2.4	1.1-5.3	
Sickle Cell Disease	Fields[26]	743		3.5	1.4-4.8	
Clinician Predictor	**Study**			**Effect Size**	**95% CI**	
Likelihood of FTIS	Carr et al[23]	460		1.07	1.05-1.08	N/A
Procedural Volume >800	Carr et al[23]	460		4.404	1.61-12.06	N/A
Product and Technology Predictor	**Study**			**Effect Size**	**95% CI**	
Smaller Size PIVC assoc with DIVA	Fields et al[26]	743		6.4	3.4-11.9	N/A

[a]Results are exclusive and not grouped in the main abstract because of heterogeneity.

NOTE: Abbreviations: BMI, body mass index; DIVA, difficult intravenous access; FTIS, first-time insertion success; IVD, ; N/A, not applicable; PIVC, peripheral intravenous catheter.

palpable vein is usually associated with FTIS.[33] This current review found evidence of simple scores or cutoff percentage estimates in 2 TRA reports to predict either appropriate PIVC insertion or FTIS.[23,29] If such methods are supported by future experimental trials, then such simple approaches could initiate huge clinical return, particularly given that idle or unused PIVCs are of substantial clinical concern.[34-36] PIVCs transcend a variety of clinical environments with excessive use identified in the ED, where it may be performed for blood sampling alone and, hence, are labeled as "just in case" PIVCs and contribute to the term "idle PIVC."[23,34] Therefore, a clinical indication to perform PIVC insertion in the first instance must be embedded into any TRA; for example, clinical deterioration is likely and the risks are outweighed by benefit, intravenous fluids and/or medicines are required, and/or diagnostic or clinical procedures are requested (such as contrast scans or procedural sedation).

In the majority of papers reviewed, researchers described how to categorize patients into levels of anticipated and predicted difficulty, but none offered corresponding detailed recommendations for strategies to increase insertion success, such as insertion with ultrasound or vascular access expert. Hypothetically, adopting a TRA may assist with the early identification of difficult to cannulate patients who may require a more expert vascular access clinician. However, in this review, we identify that a uniform definition for DIVA

is lacking. Both Webster et al.[21] and Wells[22] suggest that an expert inserter is required if difficult access is identified by their tools, but there is no clear description of the qualities of an expert inserter in the literature.[37] Recently, consensus recommendations for the definition of vascular access specialist add to discussions about defining vascular access as an interdisciplinary specialist role.[38] This is supported by other publications that highlight the association between PIVC procedural experience and increased insertion success.[6,23,39-41]

With regards to products, PIVC gauge size may or may not be significantly associated with insertion success. For identifying a relationship of PIVC gauge with vein quality, both the vein diameter and description will help with the clinical interpretation of results. For example, it may be the case that bigger veins are easier to insert a PIVC and, thus, larger PIVCs are inserted. The opposite can occur when the veins are small and poorly visualized; hence, one may select a small gauge catheter. This argument is supported by Prottengeier et al.[42] in a prehospital study that excluded PIVC size in a multivariate analysis because of confounding. However, gauge size is very likely to influence postinsertion complications. Prospective studies are contradictory and suggest 16 to 18 g PIVCs are more likely to contribute to superficial thrombus,[43] phlebitis, and, thus, device failure, in contrast to others reporting more frequent dislodgement with smaller 22 g PIVCs.[6,44]

Finally, the studies included did not assess survival times of the inserted PIVCs, given postinsertion failure in the hospitalized patient is prevalent[45] and, importantly, modifiable.[46] A TRA may yield initial insertion success, but if postinsertion the PIVC fails because of a modifiable reason that the TRA has not acknowledged, then it may be of negligible overall benefit. Therefore, TRAs for PIVC insertion need calibration, further development, and ongoing refinement prior to external validation testing.[24] Future research should also examine the role of TRAs in settings where ultrasound or other insertion technology is routinely used.

CONCLUSION

This review identifies a clinically significant gap in vascular access science. The findings of this review support recent work on vessel health and preservation[47-49] and appropriate device insertion.[50] It also points to the need for further research on the development and testing of an appropriate clinical TRA to improve vascular access outcomes in clinical practice.

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A Search for Tools to Support Decision-Making for PIVC Use

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Peripheral intravenous catheters (PIVCs) are the most frequently used vascular access devices (VADs) in all patient populations and practice settings. Because of its invasive nature and the fact that PIVCs are placed and medications are administered directly into the bloodstream, vascular access is risky. There are multiple factors to consider when placing a PIVC, the least of which is determining the most appropriate device for the patient based on the prescribed therapy.

VAD planning and assessment needs to occur at the first patient encounter so that the most appropriate device is selected and it aligns with the duration of the treatment, minimizes the number of unnecessary VADs placed, and preserves veins for any future needs. The level of the clinician's expertise, coupled with challenging environments of care, add to the complexity of what most perceive to be a "simple" procedure—placing a PIVC. For these reasons, it's imperative that clinicians are competent in the use and placement of VADs to ensure safe patient care.

Carr and colleagues[1] performed a notable scoping review to determine the existence of tools, clinical prediction rules, and algorithms (TRAs) that would support decision-making for the use of PIVCs and promote first-time insertion success (FTIS). They refined their search strategy to studies that described the use or development of any TRA regarding PIVC insertion in hospitalized adult patients.

The team identified 36 references for screening and based on their inclusion and exclusion criteria, were left with 13 studies in the final review. Inclusion criteria included TRAs for PIVC insertion in hospitalized adult patients using a traditional insertion approach, which was defined as "an assessment and/or insertion with touch and feel, therefore, without vessel locating technology such as ultrasound and/or near infrared technology."[1] Of note is that some of the exclusion criteria included pediatric studies, TRAs focused on postinsertion assessment, studies that examined VADs other than PIVCs, and studies in which vascular visualization techniques were used.

In general, the authors were unable to find reported evidence that the study recommendations were adopted in clinical practice or to what degree any TRA had on the success of a PIVC insertion. As a result, they were unable to determine what, if any, clinical value the TRAs had.

The review of the studies, however, identified 3 variables that had an impact on PIVC insertion success: patient, clinician, and product characteristics. Vein characteristics, such as the number, size, and location of veins, and patients' clinical conditions, such as diabetes, sickle cell anemia, and intravenous drug abuse, were noted as predictors of PIVC insertion success. In 7 papers, the primary focus was on patients with a history of difficult intravenous access (DIVA). The definition of DIVA varied from time to insertion of the PIVC to the number of failed attempts, ranging from 1 to 3 or more attempts.

Clinician variables, such as specialty nurse certification, years of experience, and self-reporting skill level, were associated with successful insertions, and clinicians who predicted FTIS were likely to have FTIS. Product variables included PIVC gauge size and the number of vein options and the relationship with successful first attempts.

Limitations noted by the researchers were a lack of sufficient published evidence for TRAs for PIVC insertion and standardized definitions for DIVA and expert inserters. The number of variables and the dearth of standardized terms may also influence the ability to adopt any TRAs.

While the purpose of the research was to identify TRAs that could guide clinical practice for the use of PIVCs and successful insertions, the authors make an important point that dwell time was not considered. While a TRA may lead to a successful insertion, it may not transcend the intended life of the PIVC or the duration of the therapy. Therefore, TRAs should embed steps that ensure the appropriate device is selected at the start of the patient's treatment.

The authors identified a need for undertaking and providing research in a critical area of patient care and safety. This article increases awareness of issues related to PIVCs and the impact they have on patient care. FTIS rates vary and the implications of their use are many. Patient satisfaction, no delay in treatment, vein preservation, a decreased risk of complications, and the cost of labor and products are factors to consider. Tools to improve patient outcomes related to device insertion, care, and management need to be developed and validated. The authors also note that future TRAs should integrate the use of ultrasound and vascular visualization technologies.

In a complex, challenging healthcare environment, tools and guidance that enhance practice do not only help clinicians; they have a positive impact on patient care. The need for research, so that gaps in knowledge and science can be bridged, is

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clear. Gaps must be identified, research conducted, and TRAs developed and adopted to enhance patient outcomes.

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Noise and Light Pollution in the Hospital: A Call for Action

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"Unnecessary noise is the most cruel abuse of care which can be inflicted on either the sick or the well."

–Florence Nightingale[1]

Motivated by the "unsustainable" rise in noise pollution and its "direct, as well as cumulative, adverse health effects," an expert World Health Organization (WHO) task force composed the *Guidelines for Community Noise*, outlining specific noise recommendations for public settings, including hospitals.[2] In ward settings, these guidelines mandate that background noise (which is defined as unwanted sound) levels average <35 decibels (dB; ie, a typical library) during the day, average <30 dB at night, and peak no higher than 40 dB (ie, a normal conversation), a level sufficient to awaken someone from sleep.

Since the publication of these guidelines in 1999, substantial new research has added to our understanding of hospital noise levels. Recent research has demonstrated that few, if any, hospitals comply with WHO noise recommendations.[3] Moreover, since 1960, hospital sound levels have risen ~4 dB per decade; based on the logarithmic decibel scale, if this trend continues, this translates to a 528% increase in loudness by 2020.[3]

The overwhelming majority of research on hospital noise has focused on the intensive care unit (ICU), where beeping machines and busy staff often push peak nighttime noise levels over 80 dB (ie, a kitchen blender).[4] When evaluated during sleep, noise in the ICU causes frequent arousals and awakenings. When noise is combined with other factors, such as bright light and patient care interactions, poor sleep quality invariably results.[4]

While it has been known for years that critically ill patients experience markedly fragmented and nonrestorative sleep,[5] poor sleep has recently gained attention due to its potential role as a modifiable risk factor for delirium and its associated consequences, including prolonged length of stay and long-lasting neuropsychological and physical impairments.[6] Due to this interest, numerous interventions have been attempted,[7] including multicomponent bundles to promote sleep,[8] which have been shown to reduce delirium in the ICU.[9-12] Therefore, efforts to promote sleep in the ICU, including interventions to minimize nighttime noise, are recommended in Society of Critical Care Medicine clinical practice guidelines[13] and are listed as a top 5 research priority by an expert panel of ICU delirium researchers.[14]

In contrast to the ICU, there has been little attention paid to noise in other patient care areas. Existing studies in non-ICU ward settings suggest that excessive noise is common,[3] similar to the ICU, and that patients experience poor sleep, with noise being a significant disruptor of sleep.[5,15,16] Such poor sleep is thought to contribute to uncontrolled pain, labile blood pressure, and dissatisfaction with care.[16,17]

In this issue of the *Journal of Hospital Medicine*, Jaiswal and colleagues[18] report on an important study evaluating sound and light levels in both non-ICU and ICU settings within a busy tertiary-care hospital. In 8 general ward, 8 telemetry, and 8 ICU patient rooms, the investigators used meters to record sound and light levels for 24 to 72 hours. In each of these locations, they detected average hourly sound levels ranging from 45 to 54 dB, 47 to 55 dB, and 56 to 60 dB, respectively, with ICUs consistently registering the highest hourly sound levels. Notably, all locations exceeded WHO noise limits at all hours of the day. As a novel measure, the investigators evaluated sound level changes (SLCs), or the difference between peak and background sound levels, based on research suggesting that dramatic SLCs (≥17.5 dB) are more disruptive than constant loud noise.[19] The authors observed that SLCs ≥17.5 dB occur predominantly during daytime hours and, interestingly, at a similar rate in the wards versus the ICU.

Importantly, the authors do not link their findings with patient sleep or other patient outcomes but instead focus on employing rigorous methods to gather continuous recordings. By measuring light levels, the authors bring attention to an issue often considered less disruptive to sleep than noise.[6,10,20] Similar to prior research,[21] Jaiswal and colleagues demonstrate low levels of light at night, with no substantial difference between non-ICU and ICU settings. As a key finding, the authors bring attention to low levels of light during daytime hours, particularly in the morning, when levels range from 22 to 101 lux in the wards and 16 to 39

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lux in the ICU. While the optimal timing and brightness of light exposure remains unknown, it is well established that ambient light is the most potent cue for circadian rhythms, with levels >100 lux necessary to suppress melatonin, the key hormone involved in circadian entrainment. Hence, the levels of morning light observed in this study were likely insufficient to maintain healthy circadian rhythms. When exposed to abnormal light levels and factors such as noise, stress, and medications, hospitalized patients are at risk for circadian rhythm misalignment, which can disrupt sleep and trigger a complex molecular cascade, leading to end-organ dysfunction including depressed immunity, glucose dysregulation, arrhythmias, and delirium.[22-24]

What are the major takeaway messages from this study? First, it confirms that sound levels are not only high in the ICU but also in non-ICU wards. As hospital ratings and reimbursements now rely on favorable patient ratings, future noise-reduction efforts will surely expand more vigorously across patient care areas.[25] Second, SLCs and daytime recordings must be included in efforts to understand and improve sleep and circadian rhythms in hospitalized patients. Finally, this study provides a sobering reminder of the challenge of meeting WHO guidelines and facilitating an optimal healing environment for patients. Sadly, hospital sound levels continue to rise, and quiet-time interventions consistently fail to lower noise to levels anywhere near WHO limits.[26] Hence, to make any progress, hospitals of the future must entertain novel design modifications (eg, sound-absorbing walls and alternative room layouts), fix common sources of noise pollution (eg, ventilation systems and alarms), and critically evaluate and update interventions aimed at improving sleep and aligning circadian rhythms for hospitalized patients.[27]

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Planned, Related or Preventable: Defining Readmissions to Capture Quality of Care

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In this issue of the *Journal of Hospital Medicine*, Ellimoottil and colleagues examine characteristics of readmissions identified as planned by the planned readmission algorithm developed for the Center for Medicare & Medicaid Services (CMS) by using Medicare claims data from 131 hospitals in Michigan.[1] They found that a substantial portion of readmissions currently classified as planned by the algorithm appear to be nonelective, as defined by the presence of a charge by an emergency medicine physician or an admission type of emergent or urgent, making those hospitalizations unlikely to be planned. They suggest that the algorithm could be modified to exclude such cases from the planned designation.

To determine whether modifying the algorithm as recommended is a good idea, it is helpful to examine the origins of the existing planned readmission algorithm. The algorithm originated as a consequence of hospital accountability measures for readmissions and was developed by this author in collaboration with colleagues at Yale University and elsewhere.[2] Readmission measures have been controversial in part because clearly some (undetermined) fraction of readmissions is unavoidable. Many commentators have asked that readmission measures therefore capture only avoidable or related readmissions. Avoidable readmissions are those that could have been prevented by members of the healthcare system through actions taken during or after hospitalization, such as patient counseling, communication among team members, and guideline-concordant medical care. Related readmissions are those directly stemming from the index admission. However, reliably and accurately defining such events has proven elusive. One study, for instance, found the rate of physician-assessed preventability in published studies ranged from 9% to 48%.[3] The challenge is even greater in trying to determine preventability using just claims data, without physician review of charts. Imagine, for instance, a patient with heart failure who is readmitted with heart failure exacerbation. The readmission preceded by a large fast-food meal is likely preventable; although even in this case, some would argue the healthcare system should not be held accountable for a readmission if the patient had been properly counseled about avoiding salty food. The one preceded by progressively worsening systolic function in a patient who reliably takes medications, weighs herself daily, and watches her diet is likely not. But both appear identical in claims. Related is also a difficult concept to operationalize. A recently hospitalized patient readmitted with pneumonia might have acquired it in the hospital (related) or from her grandchild 2 weeks later (unrelated). Again, both appear identical in claims.

In the ideal world, clinicians would be held accountable only for preventable readmissions. In practice, that has not proven to be possible.

Instead, the CMS readmission measures omit readmissions that are thought to be planned in advance: necessary and intentional readmissions. Defining a planned readmission is conceptually easier than defining a preventable readmission, yet even this is not always straightforward. The clearest case might be a person with a longstanding plan to have an elective surgery (say, a hip replacement) who is briefly admitted with something minor enough not to delay a subsequent admission for the scheduled surgery. Other patients are admitted with acute problems that require follow-up hospitalization (for instance, an acute myocardial infarction that requires a coronary artery bypass graft 2 weeks later).[4] More ambiguous are patients who are sent home on a course of treatment with a plan for rehospitalization if it fails; for instance, a patient with gangrene is sent home on intravenous antibiotics but fails to improve and is rehospitalized for an amputation. Is that readmission planned or unplanned? Reasonable people might disagree.

Nonetheless, assuming it is desirable to at least try to identify and remove planned readmissions from measures, there are a number of ways in which one might do so. Perhaps the simplest would be to classify each hospitalization as planned or not on the UB-04 claim form. Such a process would be very feasible but also subject to gaming or coding variability. Given that there is some ambiguity and no standard about what types of readmissions are planned and that current policy provides incentives to reduce unplanned readmission rates, hospitals might vary in the cases to which they would apply such a code. This approach, therefore, has not been favored by payers to date. An alternative is to prospectively

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flag admissions that are expected to result in planned readmissions. In fiscal year 2014, the CMS implemented this option for newborns and patients with acute myocardial infarction by creating new discharge status codes of "discharged to [location] with a planned acute care hospital inpatient readmission." Institutions can flag discharges that they know at the time of discharge will be followed by a readmission, such as a newborn who requires a repeat hospitalization for repair of a congenital anomaly.[5] There is no time span required for the planned readmission to qualify. However, the difficulty in broadening the applicability of this option to all discharges lies in identification and matching; there also remains a possibility for gaming. The code does not specify when the readmission is expected nor for what diagnosis or procedure. How, then, do we know if the subsequent readmission is the one anticipated? Unexpected readmissions may still occur in the interim. Conversely, what if the discharging clinicians don't know about an anticipated planned procedure? What would stop hospitals from labeling every discharge as expected to be followed by a planned readmission? These considerations have largely prevented the CMS from asking hospitals to apply the new code widely or from applying the code to identify planned readmissions.

Instead, the existing algorithm attempts to identify procedures that might be done on an elective basis and assumes readmissions with these procedures are planned if paired with a nonurgent diagnosis. Ellimoottil and colleagues attempt to verify whether this is accurate using a creative approach of seeking emergency department (ED) charges and admission type of emergent or urgent, and they found that roughly half of planned readmissions are, in fact, likely unplanned. This figure agrees closely with the original chart review validation of the algorithm. In particular, they found that some procedures, such as percutaneous cardiac interventions, appear to be paired regularly with a nonurgent principal diagnosis, such as coronary artery disease, even when done on an urgent basis.

This validation was performed prior to the availability of version 4.0 of the planned readmission algorithm, which removes several high-frequency procedures from the potentially planned readmission list (including cardiac devices and diagnostic cardiac catheterizations) that were very frequently mischaracterized as planned in the original chart validation.[6] At least 8 such cases were also identified in this validation according to the table. Therefore, the misclassification rate of the current algorithm version is probably less than that reported in this article. Nonetheless, percutaneous transluminal coronary angioplasty remains on the planned procedure list in version 4.0 and appears to account for a substantial error rate, and it is likely that the authors' approach would improve the accuracy even of the newer version of the algorithm.

The advantages of the suggested modifications are that they do not require chart review and could be readily adopted by the CMS. Although seeking ED charges for Medicare is somewhat cumbersome in that they are recorded in a different data set than the inpatient hospitalizations, there is no absolute barrier to adding this step to the algorithm, and doing so has substantial face validity. That said, identifying ED visits is not straightforward because nonemergency services can be provided in the ED (ie, critical care or observation care) and because facilities and providers have different billing requirements, producing different estimates depending on the data set used.[7] Including admission type would be easier, but it would be less conservative and likely less accurate, as this field has not been validated and is not typically audited. Nonetheless, adding the presence of ED charges seems likely to improve the accuracy of the algorithm. As the CMS continues to refine the planned readmission algorithm, these proposed changes would be very reasonable to study with chart validation and, if valid, to consider adopting.

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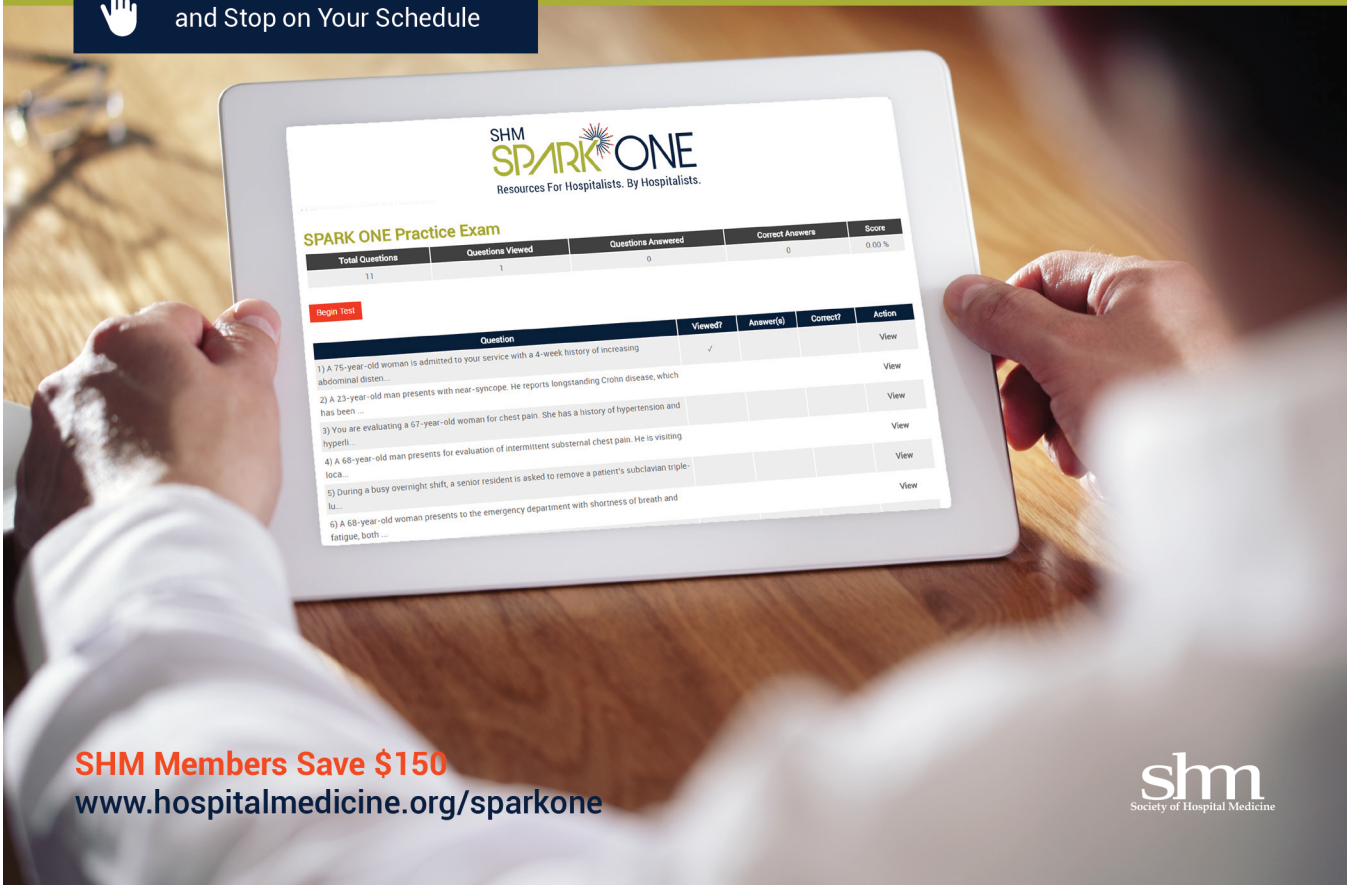

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