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Trends in Troponin-Only Testing for AMI in Academic Teaching Hospitals and the Impact of Choosing Wisely®

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BACKGROUND: Identifying hospitals that are both early and consistent adopters of high-value care can help shed light on the culture and practices at those institutions that are necessary to promote high-value care nationwide. The use of troponin to diagnose acute myocardial infarction (AMI), and not to test for myoglobin or creatine kinase-MB (CK-MB), is a high-value recommendation of the Choosing Wisely® campaign.

OBJECTIVE: To examine the variation in cardiac biomarker testing and the effect of the Choosing Wisely® troponin-only recommendation for the diagnosis of AMI.

DESIGN: A retrospective observational study using administrative ordering data from Vizient's Clinical Database/Resource Manager.

SETTING: Ninety-one academic medical centers from the fourth quarter of 2013 through the third quarter of 2016.

PATIENTS: Hospitalized patients with a principal discharge diagnosis of AMI.

INTERVENTION: The Choosing Wisely® recommendation to order troponin-only testing to diagnose AMI was released during the first quarter of 2015.

RESULTS: In 19 hospitals, troponin-only testing was consistently ordered to diagnose AMI before the Choosing Wisely® recommendation and throughout the study period. In 34 hospitals, both troponin and myoglobin/CK-MB were ordered to diagnose AMI even after the Choosing Wisely® recommendation. In 26 hospitals with low rates of troponin-only testing before the Choosing Wisely® recommendation, the release of the recommendation was associated with a statistically significant increase in the rate of troponin-only testing to diagnose AMI.

CONCLUSION: In institutions with low rates of troponin-only testing prior to the Choosing Wisely® recommendation, the recommendation was associated with a significant increase in the rate of troponin-only testing. *Journal of Hospital Medicine* 2017;12:957-962. Published online first September 20, 2017. © 2017 Society of Hospital Medicine

Evidence suggests that troponin-only testing is the superior strategy to diagnose acute myocardial infarction (AMI).[1] Because of this, in February 2015, the Choosing Wisely® campaign issued a recommendation to use troponin I or T to diagnose AMI, and not to test for myoglobin or creatine kinase-MB (CK-MB).[2] This recommendation was in line with guidelines from the American Heart Association and the American College of Cardiology, which recommended that myoglobin and CK-MB are not useful and offer no benefit for the diagnosis of acute coronary syndrome.[3] Some institutions have developed interventions to promote troponin-only testing, reporting substantial cost savings and no negative consequences.[4,5]

Despite these successes, it is likely that institutions vary with respect to the adoption of the Choosing Wisely® troponin-only testing recommendation.[6] Implementing this recommendation requires both promoting clinician behavior change and a strong institutional culture of high-value care.[7] Understanding the variation across institutions of troponin-only testing could inform how to promote high-value care recommendations nationwide. We aimed to describe patterns of troponin, myoglobin, and CK-MB testing in a sample of academic teaching hospitals before and after the Choosing Wisely® recommendation.

METHODS

Troponin, myoglobin, and CK-MB ordering data were extracted from Vizient's (formerly University HealthSystem Consortium, Chicago, IL) Clinical Database/Resource Manager (CDB/RM®) for all patients with a principal discharge diagnosis of AMI at all hospitals reporting all 36 months from the fourth quarter of 2013 through the third quarter of 2016. This period includes time both before and after the Choosing Wisely® recommendation, which was released in the first quarter of 2015. Vizient's CDB/RM contains ordering data for 300 academic medical centers and their affiliated hospitals and includes the discharge diagnoses for patients cared for by these institutions. Only patients with a principal discharge diagnosis of AMI were included because the Choosing Wisely® recommendation is specific with regard to troponin-only testing for the diagnosis of AMI. Patients with a principal diagnosis code for subcategories of myocardial ischemia (eg, stable angina, unstable angina) were

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not included because of the large number of diagnosis codes for these subcategories (more than 100 in the *International Classification of Diseases, Ninth Revision* and the *International Classification of Diseases, Tenth Revision*) and because the variation in their use across institutions within the dataset limited the utility of using these codes to consistently and accurately identify patients with myocardial ischemia. Moreover, the diagnosis of AMI encompasses the subcategories of myocardial ischemia.[8]

Hospital rates of ordering cardiac biomarkers (troponin-only or troponin and myoglobin/CK-MB) were determined overall for the entire study period and for each quarter of the study period based on the total patients with a discharge diagnosis of AMI. For each quarter of the 12 study quarters, all the hospitals were divided into tertiles based on their rate of troponin-only testing per discharge diagnosis of AMI. Hospitals were then classified into 3 groups based on their tertile ranking over the full 12 study quarters. The first group included hospitals whose rate of troponin-only testing placed them in the top tertile for each and all quarters throughout the study period. The second group included hospitals whose troponin-only testing rate placed them in the bottom tertile for each and all quarters throughout the study period. The third group included hospitals whose troponin-only testing rate each quarter led to either an increase or decrease in their tertile ranking throughout the study period. χ^2 tests were used to test for bivariate associations among hospitals based on their rate of troponin-only testing and hospital size (number of beds), their regional geographic location, the volume of AMI patients seen at the hospital, whether the primary physician during the hospitalization was a cardiologist or other provider, and the hospitals' quality ratings. Quality rating was based on an internal Vizient rating and the "Best Hospitals for Cardiology and Heart Surgery Rankings" as published in the *US News & World Report*.[9] The Vizient quality rating is based on a composite score that combines scores from the domains of quality (hospital quality incentive scores), safety (patient safety indicators), patient-centeredness (Hospital Consumer Assessment of Healthcare Providers and Systems Hospital Survey), and equity (distribution of care by race/ethnicity, gender, and age). Simple slopes were calculated to determine the rate of change in troponin-only testing for each study quarter, and Student t tests were used to compare the rates of change of these simple slopes across study quarters.

RESULTS

Of the 300 hospitals in Vizient's CDB/RM, 91 (30%, 91/300) had full reporting of data throughout the study period. These hospitals had a total of 106,954 inpatient discharges with a principal diagnosis of AMI during the study period. The overall rates of troponin-only testing for AMI discharges by hospital varied from 0% to 87.4% (Figure 1). The mean rate of troponin-only testing across all patients with a discharge diagnosis of AMI was 29.2% at the start of the study (fourth quarter of 2013) and 53.5% at the end of the study (third quarter 2016; Supplemental Figure). Nineteen hospitals (21%, 19/91; 27,973 discharges) had high rates of troponin-only testing for AMI and were in the top tertile of all hospitals throughout the study period. Thirty-four hospitals (37%, 34/91; 35,080 discharges) ordered both troponin and myoglobin/CK-MB tests to diagnose AMI, and they were in the bottom tertile of all hospitals throughout the study period. In the 38 hospitals (42%, 38/91; 43,090 discharges) that were not in the top or bottom tertile for all study quarters, the rate of troponin-only testing for AMI increased at each hospital during each quarter of the study period (Table).

Pattern of Troponin-Only Testing by Hospital Size

Of the hospitals in the top tertile of troponin-only testing throughout the study period, the majority had ≥500 beds (13/19), but the highest rate of troponin-only testing was in hospitals that had <250 beds (n = 4, troponin-only testing rate of 82/100 patients). Additionally, in hospitals that improved their troponin-only testing during the study period, hospitals that had <500 beds had higher rates of troponin-only testing than did hospitals with ≥500 beds. The differences in the rates of troponin-only testing across the 3 groups of hospitals and hospital size were statistically significant ($P < 0.0001$; Table).

Pattern of Troponin-Only Testing by Geographic Region

The rate of troponin-only testing also varied and was statistically significantly different when comparing the 3 groups of hospitals across geographic regions of the country ($P < 0.0001$). Of the hospitals in the top tertile of troponin-only testing throughout the study period, the majority were in the Midwest (n = 6) and Mid-Atlantic (n = 5) regions. However, the rate of troponin-only testing for AMI in this group was highest in hospitals in the West (86/100 patients) and/or Southeast (75/100 patients) regions, although this rate was based on a small number of hospitals in these geographic areas (n = 1 in the West, n = 2 in the Southeast). Of hospitals in the bottom tertile of troponin-only testing throughout the study period, the majority were in the Mid-Atlantic region (n = 10). Hospitals that increased their troponin-only testing during the study period were predominantly in the Midwest (n = 12) and Mid-Atlantic regions (n = 11; Table), with the hospitals in the Midwest having the highest rate of troponin-only testing in this group.

Pattern of Troponin-Only Testing by Volume of AMI Patients

Of the hospitals in the top tertile of troponin-only testing during the study period, the majority cared for ≥1500 AMI patients (n = 9), but interestingly, among these hospitals, those caring for a smaller volume of AMI patients all had higher rates of troponin-only testing per 100 patients ($P < 0.0001$; Table). There was no other obvious pattern of troponin-only testing based on the volume of AMI patients cared for in hospitals in either the bottom tertile of troponin-only testing or hospitals that improved troponin-only testing during the study period.

TABLE. Hospital Characteristics and Bivariate Associations by Rate of Troponin-Only Testing

	Study Cohort (91 Hospitals with 106,954 AMI Cases)			Top Tertile Throughout Study Period (19 Hospitals with 27,973 AMI Cases)			Bottom Tertile Throughout Study Period (34 Hospitals with 35,080 AMI cases)			Tertile Change During Study Period (38 Hospitals with 43,901 AMI Cases)			
	Number of Hospitals	Cases	%	Number of Hospitals	Cases	Troponin-only Order Rate/100 Cases	Number of Hospitals	Cases	Troponin-only Order Rate/100 Cases	Number of Hospitals	Cases	Troponin-only Order Rate/100 Cases	*P* Value[a]
Size of Hospital (No. of Beds)													<.0001
<250	19	6403	5.99%	4	1339	82.00	6	1698	1.00	9	3366	62.09	
250-499	21	15,910	14.87%	2	2343	42.04	9	4523	24.47	10	9044	60.31	
500-749	29	39,431	36.87%	7	11,759	67.69	12	14,662	34.36	10	13,010	37.33	
≥750	22	45,210	42.27%	6	12,532	69.76	7	14,197	17.71	9	18,481	32.07	
Geographic Region													<.0001
Mid-Atlantic	26	31,361	29.32%	5	6029	60.84	10	10,660	28.52	11	14,672	40.47	
Midcontinent	13	11,902	11.13%	3	3737	61.47	5	5027	18.80	5	3138	18.93	
Midwest	24	28,088	26.26%	6	11,110	66.70	6	7731	14.27	12	9247	62.94	
Northeast	7	10,327	9.66%	2	3361	60.64	4	4380	15.78	1	2586	51.93	
Southeast	11	18,391	17.19%	2	1914	75.86	3	4541	48.44	6	11,936	27.20	
West	10	6885	6.44%	1	1822	86.00	6	2741	27.07	3	2322	59.73	
Volume of AMI Patients													<.0001
<500	22	5480	5.12%	4	1152	76.65	10	2554	18.17	8	1774	49.32	
500-899	23	16,115	15.07%	3	1945	88.79	11	8166	29.71	9	6004	38.49	
900-1,499	23	27,752	25.95%	3	2870	80.73	7	8602	37.92	13	15,280	51.47	
≥1500	23	58,607	54.79%	9	22,006	61.37	6	15,758	16.30	8	20,843	34.92	
Primary Physician During Admission													<.0001
Cardiologist		57,681	53.93%		15,120	70.50		21,956	23.85		20,605	34.28	
Other		49,273	46.07%		12,853	60.47		13,124	20.55		23,296	48.36	
Quality Rating													
Vizient Q&A 2015													<.0001
Yes	11	14,261	13.33%	4	6994	88.82	2	1840	21.85	5	5427	56.57	
No	80	92,693	86.66%	15	20,979	58.25	32	33,240	25.05	33	38,474	39.66	
US News 2015[b]													<.0001
Yes	8	17,466	16.33%	3	6546	74.98	3	7974	18.59	2	2946	18.05	
No	83	89,488	83.67%	16	21,427	63.12	31	27,106	27.50	36	40,955	46.46	

[a]*P* value is for $\chi 2$ test of hospital rates of troponin-only testing.

[b]*US News & World Report* Best Hospitals for Cardiology and Heart Surgery.

NOTE: Abbreviations: AMI, acute myocardial infarction; Q&A, question and answer.

Pattern of Troponin-Only Testing by Physician Type

Of the hospitals in the top tertile of troponin-only testing throughout the study period, those where a cardiologist cared for patients with AMI had higher rates of troponin-only testing (71/100 patients) than did hospitals where patients were cared for by a noncardiologist (60/100 patients). However, of the hospitals that improved their troponin-only testing during the study period, higher rates of troponin-only testing were seen in hospitals where patients were cared for by a noncardiologist (48/100 patients) compared with patients cared for by a cardiologist (34/100 patients; Table). These differences in hospital rates of troponin-only testing during the study period based on physician type were statistically significant ($P < 0.0001$; Table).

Pattern of Troponin-Only Testing by Quality Rating

Hospitals that were in the top tertile of troponin-only testing and were rated highly by Vizient's quality rating or recognized as a top hospital by the *US News & World Report* had higher rates of troponin-only testing per 100 patients than did hospitals in the top tertile that were not ranked highly by Vizient's quality rating or recognized as a top hospital by the *US News & World Report*. However, the majority of hospitals in the top tertile of troponin-only testing were not rated highly by Vizient (n = 15) or recognized as a top hospital by the *US News & World Report* (n = 16). The large majority of hospitals in the bottom tertile of troponin-only testing were not recognized as high-quality hospitals by Vizient (n = 32) or the *US News & World Report* (n = 31).

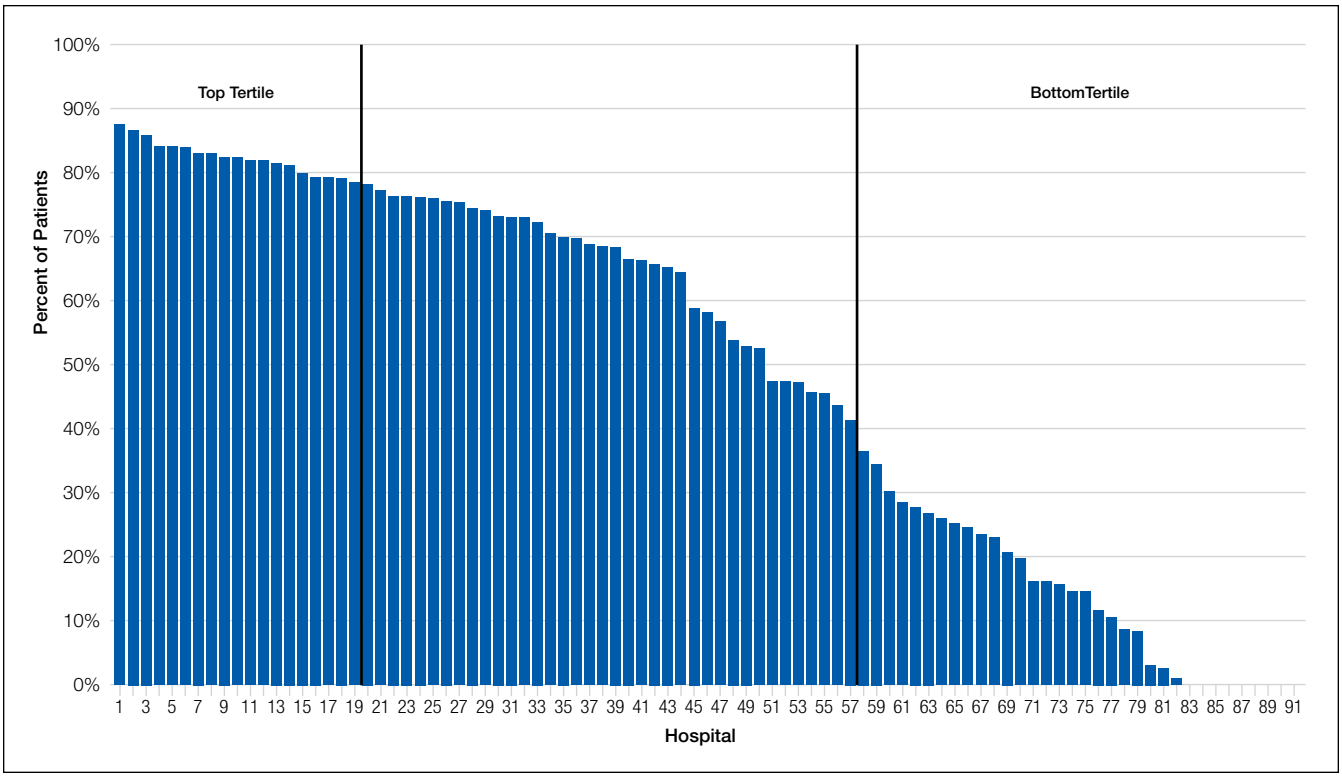

FIG 1. The proportion of troponin-only testing for the diagnosis of AMI by hospitals across the study period. NOTE: Abbreviation: AMI, acute myocardial infarction.

Of the hospitals that improved their troponin-only testing during the study period, the majority were not recognized as high-quality hospitals by Vizient (n = 33) or the *US News & World Report* (n = 36), but among this group, those hospitals recognized by Vizient as high quality (n = 5) had the highest rate of troponin-only testing (57/100 patients). The differences in the rate of troponin-only testing across the different groups of hospitals and quality ratings were statistically significant ($P < 0.0001$; Table).

The Effect of Choosing Wisely® on Troponin-Only Testing

While in many institutions the rates of troponin-only testing were increasing before the Choosing Wisely® recommendation was released in 2015, the release of the recommendation was associated with a significant increase in the rate of troponin-only testing in the institutions that were in the bottom tertile of troponin-only testing prior to the release of the recommendation but moved to the top tertile after the release of the recommendation (n = 5). The slope percentage of the rate of change of the 5 hospitals that went from the bottom tertile to the top tertile after the release of the Choosing Wisely® recommendation was 5.7%. Additionally, the Choosing Wisely® recommendation was associated with an accelerated rate of troponin-only testing in hospitals moving from the bottom tertile before the release of the recommendation to the middle tertile after the recommendation (n = 15; slope = 3.2%) and in hospitals moving from the middle tertile before the release of the recommendation to the top tertile after (n = 6; slope = 2.4%) (Figure 2). For all of these hospitals (n = 26), the increased rate of troponin-only testing in the study quarter after the Choosing Wisely® recommendation was statistically significantly higher and different from the rate of troponin-only testing in all other study quarters, except for the period between 2014 quarter 3 and quarter 4 ($P = 0.08$), the period between 2015 quarter 2 and quarter 3 ($P = 0.18$), and 2015 quarter 3 and quarter 4 ($P = 0.06$), where the effect did not quite reach statistical significance (Figure 3).

DISCUSSION

In a broad sample of academic teaching hospitals, there was an overall increase in the rate of troponin-only testing starting from the fourth quarter of 2013 through the third quarter of 2016. However, there was wide variation in the adoption of troponin-only testing for AMI across institutions. Our study identified several high-performing hospitals where the rate of troponin-only testing was high prior to and after the Choosing Wisely® troponin-only recommendation. Additionally, we identified several poor-performing hospitals, which even after the release of the Choosing Wisely® recommendation continue to order both troponin and myoglobin/CK-MB tests for the diagnosis of AMI. Lastly, we identified several hospitals in which the release of the Choosing Wisely® recommendation was associated with a significant increase in the rate of troponin-only testing for the diagnosis of AMI. The high-performing hospitals in our sample that were in the top tertile of troponin-only testing throughout the study period are "early adopters," having already institut-

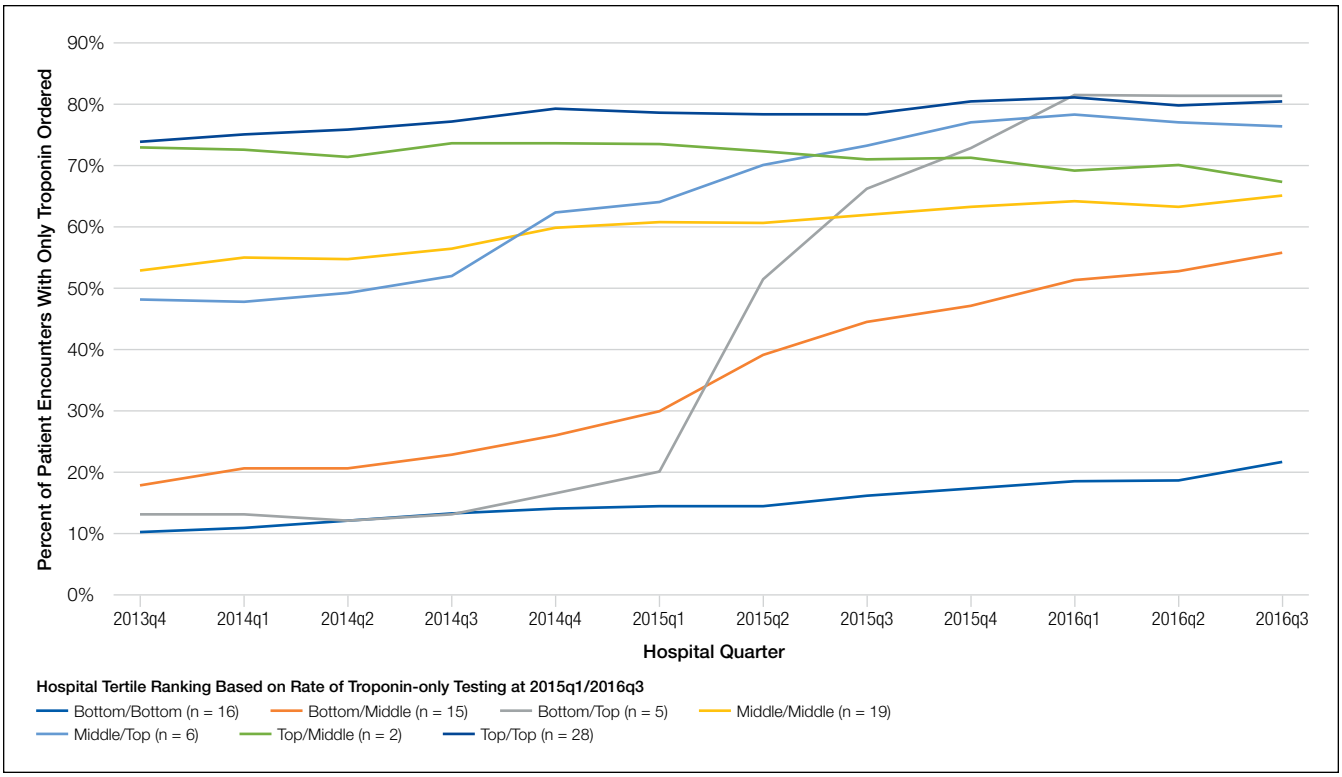

FIG 2. Hospital percentage of patient encounters and tertile ranking of troponin-only testing to diagnose AMI by study quarter. NOTE: Abbreviation: AMI, acute myocardial infarction.

ed troponin-only testing before the release of the Choosing Wisely® troponin-only recommendation. These hospitals vary in size, geographic region of the country, volume of AMI patients cared for, whether AMI patients are cared for by a cardiologist or other provider, and quality rating. Interestingly, in these hospitals, AMI patients admitted under the care of a cardiologist had higher rates of troponin-only testing than when admitted under another physician type. This is perhaps not surprising given that cardiologists would be the most likely to be aware of the data supporting troponin-only testing prior to the Choosing Wisely® recommendation and the most likely to institute interventions to promote troponin-only testing and disseminate this knowledge across their institution. These institutions and their practice of troponin-only testing before the Choosing Wisely® recommendation represent the idea of positive deviance,[10] whereby they had identified troponin-only testing as a superior strategy and instituted successful initiatives to reduce the use of unnecessary myoglobin and CK-MB testing before their peer hospitals and the release of the Choosing Wisely® recommendation. Further efforts to explore and understand the additional factors that define the hospitals that had high rates of troponin-only testing prior to the Choosing Wisely® recommendation may be helpful to understanding the necessary culture and institutional factors that can promote high-value care.

In the hospitals that demonstrated increasing adoption of troponin-only testing, there are several interesting patterns. First, among these hospitals, smaller hospitals tended to have higher overall rates of troponin-only testing per 100 patients than larger hospitals. Additionally, the hospitals with the highest rates were located in the Midwest region. These hospitals may be learning from and following the high-performing institutions observed in our data that are also located in the Midwest. Additionally, among the hospitals that significantly increased their rate of troponin-only testing, we see that the Choosing Wisely® recommendation appeared to facilitate accelerated adoption of troponin-only testing. In these institutions, it is likely that the impact of Choosing Wisely® was significant because there was attention to high-value care and already an existing movement underway to institute such high-value practices. For example, natural champions, leadership, infrastructure, and a supportive culture may all be prerequisites for Choosing Wisely® recommendations to become institutionally adopted.

Lastly, in the hospitals that have continued to order myoglobin and CK-MB, future work is needed to understand and overcome barriers to adopting high-value care practices.

There are several limitations to this study. First, because this was an observational study, we cannot prove a causal relationship between the Choosing Wisely® recommendation and the increased rates of troponin-only testing. Additionally, the Vizient CDB/RM contains reporting data for a limited number of academic medical centers only, and therefore, these results may not represent practices at nonacademic or even other academic medical centers. Our study

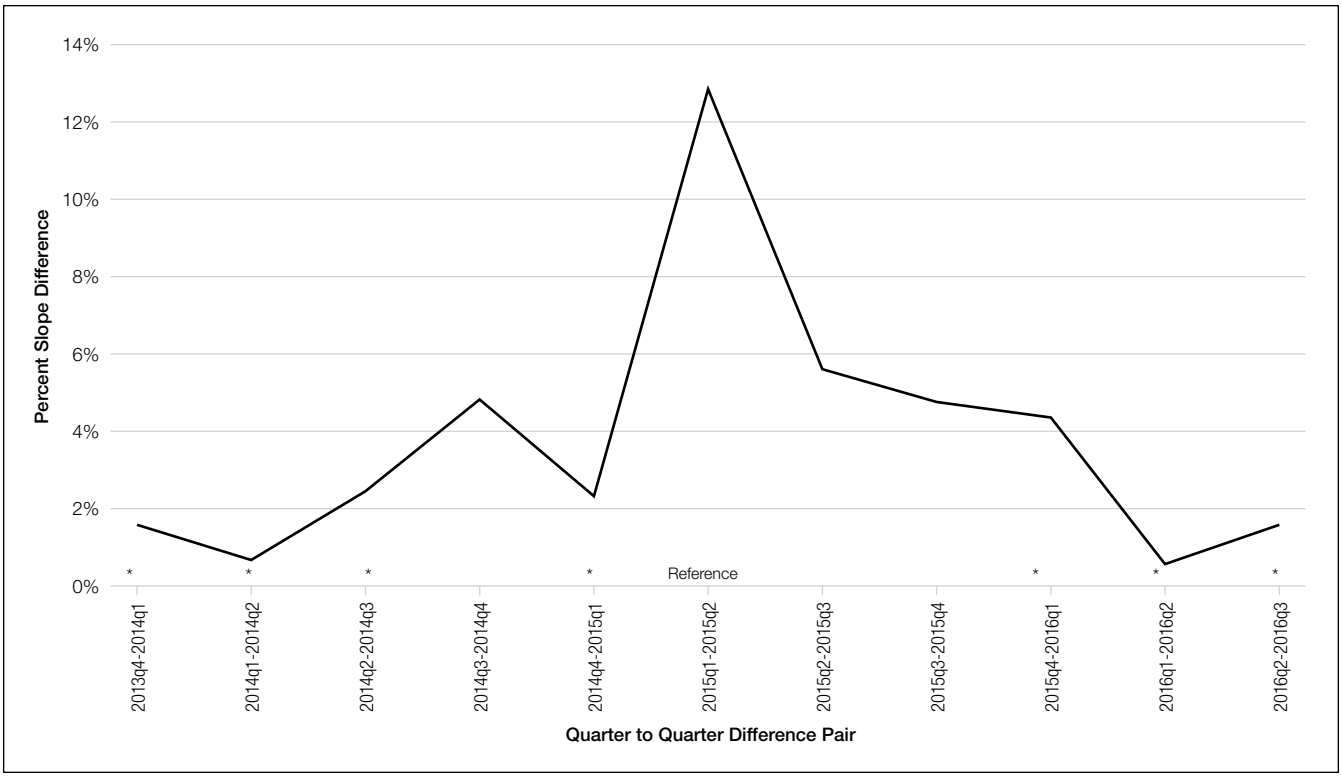

FIG 3. Average quarterly rate of change in troponin-only testing among hospitals that improved their troponin-only testing tertile.

NOTE: *$P < .05$

only included patients with a principal discharge diagnosis of AMI because the Choosing Wisely® recommendation to order troponin-only is specific for diagnosing patients with AMI. However, it is possible that the Choosing Wisely® recommendation also has affected provider ordering in patients with diagnoses such as chest pain or angina, and these affects would not be captured in our study. Lastly, because instituting high-value care practices take time, our follow-up time may not have been long enough to capture improvement in troponin-only testing at institutions responding to and attempting to adhere to the Choosing Wisely® recommendation to order troponin-only testing for patients with AMI.

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Hospital Perceptions of Medicare's Sepsis Quality Reporting Initiative

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BACKGROUND: In October 2015, the Centers for Medicare and Medicaid Services (CMS) implemented the Sepsis CMS Core Measure (SEP-1) program, requiring hospitals to report data on the quality of care for their patients with sepsis.

OBJECTIVE: We sought to understand hospital perceptions of and responses to the SEP-1 program.

DESIGN: A thematic content analysis of semistructured interviews with hospital quality officials.

SETTING: A stratified random sample of short-stay, nonfederal, general acute care hospitals in the United States.

SUBJECTS: Hospital quality officers, including nurses and physicians.

INTERVENTION: None.

MEASUREMENTS: We completed 29 interviews before reaching content saturation.

RESULTS: Hospitals reported a variety of actions in response to SEP-1, including new efforts to collect data, improve sepsis diagnosis and treatment, and manage clinicians' attitudes toward SEP-1. These efforts frequently required dedicated resources to meet the program's requirements for treatment and documentation, which were thought to be complex and not consistently linked to patient-centered outcomes. Most respondents felt that SEP-1 was likely to improve sepsis outcomes. At the same time, they described specific changes that could improve its effectiveness, including allowing hospitals to focus on the treatment processes most directly associated with improved patient outcomes and better aligning the measure's sepsis definitions with current clinical definitions.

CONCLUSIONS: Hospitals are responding to the SEP-1 program across a number of domains and in ways that consistently require dedicated resources. Hospitals are interested in further revisions to the program to alleviate the burden of the reporting requirements and help them optimize the effectiveness of their investments in quality-improvement efforts.
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Sepsis affects over 1 million Americans annually, resulting in significant morbidity, mortality, and costs for hospitalized patients.[1-4] There is an increasing interest in policy-oriented approaches to improving sepsis care at both the state and national levels.[5,6] The most prominent policy is the Centers for Medicare and Medicaid Services (CMS) Sepsis CMS Core (SEP-1) program, which was formally implemented in October 2015; the program mandates that hospitals report their compliance with a variety of sepsis treatment processes (Table 1). Academic quality experts generally applaud the increased attention to sepsis but are concerned that the measure's design and specifications advance beyond the existing evidence base.[7,8] However, remarkably little is known about how front-line hospital quality officials perceive the program and how they are responding or not responding, to the new requirements. This knowledge gap is a critical barrier to evaluating the program's practical impact on sepsis treatment and outcomes.

We therefore sought to understand hospital stakeholders' perceptions of the SEP-1 program in general as well as their characterization of their local hospitals' responses to the program. We were specifically interested in obtaining a focused perspective on the policy and hospitals' responses to the policy rather than individual physicians' attitudes regarding sepsis care protocols, which are complex and may be independent from the policy itself.[9] We used a qualitative research approach designed to generate both a deep and broad understanding of how hospitals are responding to SEP-1 requirements, including the resources required to implement their responses.

METHODS

Study Design, Setting, and Subjects

We conducted a qualitative study by using semistructured telephone interviews with hospital quality officers in the United States. We targeted hospital quality officers because they are in a position to provide overarching insights into hospitals' perceptions of and responses to the SEP-1 program. We enrolled quality officers at general, short-stay, nonfederal acute care hospitals because those are the hospitals to which the SEP-1 program applies. We generated a stratified random sample of hospitals by using 2013 data

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TABLE 1. Summary of Components of SEP-1 Bundle

Patients	Time Frame	Process
Severe sepsis	Within 3 hours	Measure lactate Obtain blood cultures prior to antibiotics Administer antibiotics
	Within 6 hours	Remeasure lactate if initial value is elevated
Septic shock	Within 3 hours	All elements of severe sepsis bundle, plus administer 30 cc/kg of crystalloid
	Within 6 hours	Administer vasopressors for fluid-refractory hypotension Document responsiveness to resuscitation via: • A 5-component physical exam OR • 2 out of 4 elements from a quantitative physiological assessment: ○ CVP ○ ScVO2 ○ Bedside cardiac echocardiogram ○ Straight leg raise/fluid challenge

NOTE: Adapted from Barbash IJ, Kahn JM, Thompson BT. Medicare's Sepsis Reporting Program: Two Steps Forward, One Step Back. *Am J Respir Crit Care Med.*[7] 2016;194(2):139-141 Abbreviations: CVP, central venous pressure; ScvO2, central venous oxygen saturation; SEP-1, Sepsis Centers for Medicare and Medicaid Services Core Measure program.

TABLE 2. Hospital Characteristics

Characteristic	N = 29 Hospitals
Total beds, median (IQR)	210 (111-301)
ICU beds, median (IQR)	19 (10-32)
Teaching hospital (N%)	14 (48%)
Nonprofit, N (%)	14 (48%)
Interview length, median (IQR)	25 minutes (20-32)

NOTE: Abbreviations: ICU, intensive care unit; IQR, interquartile range.

from Medicare's Healthcare Cost and Reporting Information System (HCRIS) database.[10] We stratified by size (greater than or less than 200 total beds), teaching status (presence or absence of any resident physician trainees), and ownership (for-profit vs nonprofit), creating 8 mutually exclusive strata. This sampling frame was designed to ensure representativeness from a broad range of hospital types, not to enable comparisons across hospital types, which is outside the scope of qualitative research.

Within strata, we contacted hospitals in a random order by phone using the primary number listed in the HCRIS database. We asked the hospital operator to connect us to the chief quality officer or an appropriate alternative hospital administrator with knowledge of hospital quality-improvement activities. We limited participation to 1 respondent per hospital. We did not offer any specific incentives for participation.

The study was approved by the University of Pittsburgh Institutional Review Board with a waiver of signed informed consent.

Data Collection

Interviews were conducted by a trained research coordinator between February 2016 and October 2016. Interviews were conducted concurrently with data analysis by using a constant comparison approach.[11] The constant comparison approach involves the iterative refinement of themes by comparing the existing themes to new data as they emerge during successive interviews. We chose a constant comparison approach because we wanted to systematically describe hospital responses to SEP-1 rather than specifically test individual hypotheses.[11] As is typical in qualitative research, we did not set the sample size a priori but instead continued the interviews until we achieved thematic saturation.[12,13]

The interview script included a mix of directed and open-ended questions about respondents' perspectives of and hospital responses to the SEP-1 program. The questions covered the following 4 domains: hospitals' sepsis quality-improvement initiatives before and after the Medicare reporting program, reception of the hospital responses, the approach to data abstraction and reporting, and the overall impressions of the program and its impact.[6-8,14] We allowed for updates and revisions of the interview guide as necessary to explore any new content and emergent themes. We piloted the interview guide on 2 hospital quality officers at our institution and then revised its structure again after interviews with the initial 6 hospitals. The complete final interview guide is available in the supplemental digital content.

Analysis

Interviews were audio recorded, transcribed, and loaded onto a secure server. We used NVivo 11 (QSR International, Cambridge, Massachusetts) for coding and analysis. We iteratively reviewed and thematically analyzed the transcripts for structural content and emergent themes, consistent with established

TABLE 3. Respondents' Perspectives on SEP-1

Domain	Representative Quotations
The measure is complex	"There is absolutely no reason for them to have made it so confusing. If you have to read the darn thing 10 times just to start to understand..."
Heavy reliance on clinical documentation	"And for them to miss it because they didn't document the capillary refill time or something is kind of hard to justify with the physicians. 'So yea, this falls out because you didn't chart this.' You know?...Did that make a difference to the patient?"
All-or-none approach is frustrating	"If one person doesn't do what's supposed to be done, then the core measure fails."
Not the only quality program but requires significant resources	"I just think there are so many quality initiatives and not enough people to go around."
It's driving increased attention to sepsis	"As complicated and flawed as the measure is, I think it's drawing so much more attention to sepsis."

NOTE: Abbreviation: SEP-1, Centers for Medicare and Medicaid Services Sepsis Core Measure program.

TABLE 4. Hospital Responses to SEP-1

Domain of Response	Range of Responses	Barriers and Challenges	Representative Quotations
Efforts to collect data	• use of third-party vendors • employing in-house abstractors	• time and money • coding variation • heavy reliance on clinical documentation	"It's such a horrendous and time-consuming abstraction process."
Efforts to coordinate hospital responses	• development of multistakeholder committees • employing dedicated staff and sepsis coordinators	• requires multiple moving parts • human resources • iterative revision/refinement	"We had a little bit of stumbling issues when we first started that group, as far as assuring that we had the right people at the table. And we have representatives now from critical care, emergency room, administrative support, and our quality folks as well as bedside nurses."
Efforts to improve sepsis diagnosis	• electronic sepsis alerts • manual screening for sepsis	• resource requirements • alert fatigue	"We're building [an alert] into the electronic system that we've had for some time (and we're continuing this), is certain vital sign changes go directly to our MET teams that will come and look at people that may have those issues: sepsis or something similar."
Efforts to improve sepsis treatment	• sepsis treatment protocols • structured order sets	• resistance to protocolized care: "cookbook medicine" • different needs in different places	"Well some of them said it was 'cookbook medicine.' That they're trying to tell us how to practice when they don't know the patient."
Efforts to manage clinicians' attitudes	• local clinician champions • show clinicians the data • infusion of new individuals/culture • top-down support from administration	• lack of buy-in; particularly around documentation • hierarchy (within clinical medicine and QI infrastructure)	"We're quality nurses. We don't have any authority or say over the nurses on the floor or in the ER, or the physicians as far as educating them and holding them accountable...and so it's been real frustrating." "I'm very fortunate in the physician champion in the emergency department is very engaged. And then has engaged some of the nursing leadership there."

NOTE: Abbreviations: ER, emergency room; MET, medical emergency team; QI, quality improvement; SEP-1, Centers for Medicare and Medicaid Services Sepsis Core Measure program.

qualitative methods.[15] Three investigators reviewed the initial 20 transcripts and developed the codebook through iterative discussion and consensus. The codes were then organized into themes and subthemes. Subsequently, 1 investigator coded the remaining transcripts. The results are presented as a series of key themes supported by direct quotes from the interviews.

RESULTS

Sample Description

We performed 29 interviews prior to achieving thematic saturation. Each of the 8 strata from the sampling frame was represented by at least 3 hospitals. Hospitals in the final sample were diverse in total bed size, intensive care unit bed capacity, teaching status, and ownership (Table 2). The median interview length was 25 minutes (interquartile range, 20-32 minutes). Respondents included 6 quality coordinators, 6 quality managers, and 11 quality directors, with the remainder holding a variety of other quality-related titles. Most respondents worked in hospital quality departments, although 4 were affiliated with individual clinical departments (eg, emergency medicine and/or critical care services). Of the 9 respondents who reported their professional training, 8 were registered nurses. Eleven respondents reported participating in measure abstraction.

Perspectives on SEP-1

Respondents' general perspectives on the SEP-1 program are outlined in Table 3, with several key themes emerging. Foremost was the sheer complexity of the measure compounded by its reliance on time-stamped clinical documentation, and in particular, the physical reassessment in individual medical notes. Respondents expressed frustration with the "all-or-none" approach to declaring sepsis treatment a "suc-

cess," which they noted was unfair and difficult to justify to their local clinicians. In part because of the time and effort required to comply with the measure and report results to CMS, several respondents noted that the measure is a uniquely burdensome addition to an already-crowded landscape of hospital quality programs. Despite the resources required to adhere to the measures' standards and report results to CMS, respondents expressed a belief that the increased attention to sepsis is driving positive changes in hospital care and leading to improved patient outcomes.

Responses to SEP-1

Respondents identified several specific ways in which their hospitals responded to the SEP-1 mandate (Table 4), including investments in measurement, planning and coordinating sepsis-specific quality-improvement activities, improving the early identification of patients with sepsis, improving sepsis treatment and measure compliance, and addressing negative attitudes towards the implementation of the SEP-1 program.

Efforts to Collect Data for SEP-1 Reporting

Respondents reported challenges in reliably and validly measuring and reporting data for the SEP-1 program. First, patient identification and the measurement of treatment processes depends largely on manual medical record review, which is subject to variation across coders. This presents a particular challenge because the clinical definition of sepsis itself is in evolution,[1] creating the possibility that treating physicians could identify a given patient as having sepsis or septic shock based on the most up-to-date definitions but not based on the measure's specifications or vice versa. Second, each case requires up to an hour of manual medical record review and patients who develop sepsis during prolonged hospitalizations can require several hours or more, which is an unprecedented length of time to spend abstracting data for a single measure.

In addressing these measurement challenges, investment in human resources is the rule. No respondent reported automating abstraction of all the SEP-1 data elements, underscoring concerns regarding the measurement burden of the SEP-1 program.[7,8,14] Rather, hospitals with sufficient financial resources frequently employ full-time data abstractors and individuals responsible for ongoing performance feedback, which facilitates the iterative revision of sepsis quality-improvement initiatives. In contrast, hospitals with fewer resources often rely on contracts with third-party vendors, which delays reporting and complicates efforts to use the data for individualized performance improvement.

Efforts to Coordinate Hospital Responses Across Care Teams

Complying with the measure involves the longitudinal coordination of multiple care teams across different units, so planning and executing local hospital responses required interdepartmental and multidisciplinary stakeholder involvement. Respondents were uncertain about the ideal strategy to coordinate these quality-improvement efforts, yielding iterative changes to electronic health records (EHRs), education programs, and data collection methods. This "learning by doing" is necessary because no prior CMS quality measure is as complex as SEP-1 or as varied in the sources of data required to measure and report the results. By requiring hospitals to improve coordination of care throughout the hospital, SEP-1 presents a quality-improvement and measurement challenge that may ultimately drive innovation and better patient care.

Efforts to Improve Sepsis Diagnosis

Several hospitals are implementing sepsis screening and alerts to speed sepsis recognition and meet the measure's time-sensitive treatment requirements. An example of a less-intensive alert is one hospital's lowering of the threshold for lactate values that are viewed as "critical" (and thus requiring notification of the bedside clinician). Examples of more resource-intensive alerts included electronic screening for vital sign abnormalities that trigger bedside assessment for infection as well as nurse-driven manual sepsis screening tools.

Frequently, these more intensive efforts faced barriers to successful implementation related to the broader issues of performance measurement rather than the specifics of SEP-1. EHRs generally lacked built-in electronic screening capacity, and few hospitals had the resources required for customized EHR modification. Manual screening required nurses to spend time away from direct patient care. For both electronic and manual screening, respondents expressed concern about how these new alerts would fit into a care landscape already inundated with alerts, alarms, and care notifications.[16,17]

Efforts to Improve Sepsis Treatment

Many hospitals are implementing sepsis-specific treatment protocols and order sets designed to help meet SEP-1 treatment specifications. In hospitals and health systems with preexisting sepsis quality-improvement efforts, SEP-1 stimulated adaptation and acceleration of their efforts; in hospitals without preexisting sepsis-specific quality improvement, SEP-1 inspired de novo program development and implementation. These programs were wide ranging. Several hospitals implemented a process by which an initially elevated lactate value automates an order for a repeat lactate level, facilitating an assessment of the clinical response to treatment. Other examples include triggers for sepsis-specific treatment protocols and checklists that bedside nurses can begin without initial physician oversight. In 1 hospital, sepsis alerts triggered by emergency medical first responders initiate responses prior to hospital arrival in a manner analogous to prehospital alerts for myocardial infarction and stroke.[18,19]

Efforts to implement these protocols encountered several common challenges. Physicians were often resistant to adopting inflexible treatment rules that did not allow them to tailor therapies to individual patients. Furthermore, even protocols and order sets that worked in 1 setting did not necessarily generalize throughout the hospital or health system, reflecting the difficulty in implementing a

highly specified measure across diverse treatment environments.

Efforts to Manage Clinician Attitudes Toward SEP-1 Implementation

In addition to addressing clinicians' behaviors, hospitals sought to address stakeholders' attitudes when those attitudes created barriers to SEP-1 implementation. First, hospitals frequently faced a lack of buy-in from clinicians who were resistant to the idea of protocolized care in general and who were specifically skeptical that initiatives designed to increase clinical documentation would drive improvements in patient-centered outcomes. Second, respondents had to confront a hierarchical hospital culture, which manifests not only in clinical care, but also in the quality-improvement infrastructure. Many respondents reported that physicians were more receptive to performance feedback from fellow physicians rather than nonphysician quality administrators.

Respondents described a range of approaches to counteract these attitudes. First, hospitals deployed department- and profession-specific "champions" to provide peer-to-peer performance feedback supported by data demonstrating a link between process improvements and patient outcomes. Second, many respondents noted that the addition of new clinical staff, who were often younger and more receptive to new initiatives, could alter a hospital's quality culture; in smaller hospitals, just a few individuals could significantly alter the dynamic. Finally, when other efforts failed, some respondents indicated that top-down administrative support could persuade resistant individuals to change their approach. However, this solution worked best with employed physicians and was less effective with independent physician groups without direct financial ties to hospital performance. These efforts to overcome negative attitudes toward SEP-1 implementation required individuals' time and energy, leading to frustration at times and adding to the resources required to comply with the program.

Planning for the Future of SEP-1

Respondents anticipate that performance of the SEP-1 measure will eventually become publicly reported and incorporated into value-based purchasing calculations. Hospitals are therefore seeking greater interaction with CMS as it makes iterative revisions to the measure because respondents expect that their hospitals' level of performance, rather than just the act of participating, will affect hospital finances. Respondents expressed a desire for more live, interactive educational sessions with CMS moving forward, rather than limiting the opportunities for clarification to online comment forums or statements elsewhere in the public record. In addition, respondents hope that public reporting and pay-for-performance could be delayed to allow more time to work out the "kinks" in measurement and reporting.

DISCUSSION

We conducted semistructured telephone interviews with quality officers in U.S. hospitals in order to understand hospitals' perceptions of and responses to Medicare's SEP-1 sepsis quality-reporting program. Hospitals are struggling with the program's complexity and investing considerable resources in order to iteratively revise their responses to the program. However, they generally believe that the program is bringing much-needed attention to sepsis diagnosis and treatment. These findings have several implications for the SEP-1 measure in particular and for hospital-based quality measurement and pay-for-performance policies in general.

First, we demonstrate that SEP-1 consistently requires a substantial investment of resources from hospitals already struggling under the weight of numerous local, state, and national quality-reporting and improvement programs.[14,20,21] In aggregate, these programs can stretch hospitals' resources to their limit. Respondents universally reported that the SEP-1 program is requiring dedicated staff to meet the data abstraction and reporting requirements as well as multicomponent quality-improvement initiatives. In the absence of well-established roadmaps for improving sepsis care, these sepsis quality-improvement efforts require experimentation and iterative revision, which can contribute to fatigue and frustration among quality officers and clinical staff. This process of innovation inherently involves successes, failures, and the risk of harm and opportunity costs that strain hospital resources.

Second, our study indicates how SEP-1 could exacerbate existing inequalities in our health system. Sepsis incidence and mortality are already higher in medically underserved regions.[22] Given the resources required to respond to the SEP-1 program, optimal performance may be beyond the reach of smaller hospitals, or even larger hospitals, whose resources are already stretched to their limits. Public reporting and pay-for-performance can be adisadvantage to hospitals caring for underserved populations.[23,24] To the extent that responding to sepsis-oriented public policy requires resources that certain hospitals cannot access, these policies could exacerbate existing health disparities.

Third, our findings highlight some specific ways that CMS could revise the SEP-1 program to better meet the needs of hospitals and improve outcomes for patients with sepsis. Primarily, although the program's current specifications take an "all-or-none" approach to treatment success, a more flexible approach, such as a weighted score or composite measure that combines processes and outcomes,[25,26] could allow hospitals to focus their efforts on those components of the bundle with the strongest evidence for improved patient outcomes.[27] Second, policy makers need to reconcile the 2 existing clinical definitions for sepsis.[1,28] CMS has already stated its plans to retain the preexisting sepsis definition,[29] but this does not change the reality that frontline providers and quality officials face different, and at times conflicting, clinical definitions while caring for patients. Finally, current implementation challenges may support a delay in moving the measure toward public reporting and pay-for-performance. Hospitals are already responding to the measure in a substantial way, providing an opportunity for early quantitative evaluations of the program's impact that could inform evidence-based revisions to the measure.

Our study has several limitations. First, by interviewing only individual quality officers within each hospital, it is possible that our findings were not representative of the perspectives of other individuals within their hospitals or the hospital as a whole; indeed, to the extent that quality officers "buy in" to quality measurement and reporting, their perspectives on SEP-1 may skew more positive than other hospital staff. Our respondents represented individuals from a range of positions within the quality infrastructure, whereas "hospital quality leaders" are often chief executive officers, chief medical officers, or vice presidents for quality.[30] However, by virtue of our purposive sampling approach, we included respondents from a broad range of hospitals and found similar themes across these respondents, supporting the internal validity of our findings. Second, as is inherent in interview-based research, we cannot verify that respondents' reports of hospital responses to SEP-1 match the actual changes implemented "on the ground." We are reassured, however, by the fact that many of the perspectives and quality-improvement changes that respondents described align with the opinions and suggestions of academic quality experts, which are informed by clinical experience.[6-8] Third, while respondents believe that hospital responses to SEP-1 are contributing to improvements in treatment and outcomes, we do not yet have robust objective data to support this opinion or to evaluate the association between quality officers' perspectives and hospital performance. A quantitative evaluation of the clinical impact of SEP-1, as well as the relationship between hospital performance and quality officers' perspectives on the measure, are important areas for future research.

CONCLUSIONS

In a qualitative study of hospital responses to Medicare's SEP-1 program, we found that hospitals are implementing changes across a variety of domains and in ways that consistently require dedicated resources. Giving hospitals the flexibility to focus on treatment processes with the most direct impact on patient-centered outcomes might enhance the program's effectiveness. Future work should quantify the program's impact and develop novel approaches to data abstraction and quality improvement.

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Health Literacy and Hospital Length of Stay: An Inpatient Cohort Study

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BACKGROUND: Associations between low health literacy (HL) and adverse health outcomes have been well documented in the outpatient setting; however, few studies have examined associations between low HL and in-hospital outcomes.

OBJECTIVE: To compare hospital length of stay (LOS) among patients with low HL and those with adequate HL.

DESIGN: Hospital-based cohort study.

SETTING: Academic urban tertiary-care hospital.

PATIENTS: Hospitalized general medicine patients.

MEASUREMENTS: We measured HL using the Brief Health Literacy Screen. Severity of illness and LOS were obtained from administrative data. Multivariable linear regression controlling for illness severity and sociodemographic variables was employed to measure the association between HL and LOS.

RESULTS: Among 5540 participants, 20% (1104/5540) had low HL. Participants with low HL had a longer average LOS (6.0 vs 5.4 days, $P < 0.001$). Low HL was associated with an 11.1% longer LOS (95% confidence interval [CI], 6.1%-16.1%; $P < 0.001$) in multivariate analysis. This effect was significantly modified by gender ($P = 0.02$). Low HL was associated with a 17.8% longer LOS among men (95% CI, 10.0%-25.7%; $P < 0.001$), but only a 7.7% longer LOS among women (95% CI, 1.9%-13.5%; $P = 0.009$).

CONCLUSIONS: In this single-center cohort study, low HL was associated with a longer hospital LOS. The findings suggest that the adverse effects of low HL may extend into the inpatient setting, indicating that targeted interventions may be needed for patients with low HL. Further work is needed to explore these negative consequences and potential mitigating factors. *Journal of Hospital Medicine* 2017;12:969-973. Published online first September 20, 2017. © 2017 Society of Hospital Medicine

Health literacy (HL), defined as patients' ability to understand health information and make health decisions,[1] is a prevalent problem in the outpatient and inpatient settings.[2,3] In both settings, low HL has adverse implications for self-care including interpreting health labels[4] and taking medications correctly.[5] Among outpatient cohorts, HL has been associated with worse outcomes and acute care utilization.[6] Associations with low HL include increased hospitalizations,[7] rehospitalizations,[8,9] emergency department visits,[10] and decreased preventative care use.[11] Among the elderly, low HL is associated with increased mortality[12] and decreased self-perception of health.[13]

A systematic review revealed that most high-quality HL outcome studies were conducted in the outpatient setting.[6] There have been very few studies assessing effects of low HL in an acute-care setting.[7,14] These studies have evaluated postdischarge outcomes, including admissions or readmissions,[7-9] and medication knowledge.[14] To the best of our knowledge, there are no studies evaluating associations between HL and hospital length of stay (LOS).

LOS has received much attention as providers and payers focus more on resource utilization and eliminating adverse effects of prolonged hospitalization.[15] LOS is multifactorial, depending on clinical characteristics like disease severity, as well as on sociocultural, demographic, and geographic factors.[16] Despite evidence that LOS reductions translate into improved resource allocation and potentially fewer complications, there remains a tension between the appropriate LOS and one that is too short for a given condition.[17]

Because low HL is associated with inefficient resource utilization, we hypothesized that low HL would be associated with increased LOS after controlling for illness severity. Our objectives were to evaluate the association between low HL and LOS and whether such an association was modified by illness severity and sociodemographics.

METHODS

Study Design, Setting, Participants

An in-hospital, cohort study design of patients who were admitted or transferred to the general medicine service at the University of Chicago between October 2012 and November 2015 and screened for inclusion as part of a large, ongoing study of inpatient care quality was conducted.[18] Exclusion criteria included observation status, age under 18 years, non-English speaking, and repeat participants. Those who died during hospitalization or whose discharge status

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was missing were excluded because the primary goal was to examine the association of HL and time to discharge, which could not be evaluated among those who died. We excluded participants with LOS >30 days to limit overly influential effects of extreme outliers (1% of the population).

Variables

HL was screened using the Brief Health Literacy Screen (BHLS), a validated, 3-question verbal survey not requiring adequate visual acuity to assess HL.[19,20] The 3 questions are as follows: (1) "How confident are you filling out medical forms by yourself?", (2) "How often do you have someone help you read hospital materials?", and (3) "How often do you have problems learning about your medical condition because of difficulty understanding written information?" Responses to the questions were scored on a 5-point Likert scale in which higher scores corresponded to higher HL.[21,22] The scores for each of the 3 questions were summed to yield a range between 3 and 15. On the individual questions, prior work has demonstrated improved test performance with a cutoff of ≤3, which corresponds to a response of "some of the time" or "somewhat"; therefore, when the 3 questions were summed together, scores of ≤9 were considered indicative of low HL.[21,23]

For severity of illness adjustment, we used relative weights derived from the 3M (3M, Maplewood, MN) All Patient Refined Diagnosis Related Groups (APR-DRG) classification system, which uses administrative data to classify the severity. The APR-DRG system assigns each admission to a DRG based on principal diagnosis; for each DRG, patients are then subdivided into 4 severity classes based on age, comorbidity, and interactions between these variables and the admitting diagnosis.[24] Using the base DRG and severity score, the system assigns relative weights that reflect differences in expected hospital resource utilization.

LOS was derived from hospital administrative data and counted from the date of admission to the hospital. Participants who were discharged on the day of admission were counted as having an LOS of 1. Insurance status (Medicare, Medicaid, no payer, private) also was obtained from administrative data. Age, sex (male or female), education (junior high or less, some high school, high school graduate, some college, college graduate, postgraduate), and race (black/African American, white, Asian or Pacific Islander [including Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, other Asian, Native Hawaiian, Guam/Chamorro, Samoan, other Pacific], American Indian or Alaskan Native, multiple race) were obtained from administrative data based on information provided by the patient. Participants with missing data on any of the sociodemographic variables or on the APR-DRG score were excluded from the analysis.

Statistical Analysis

χ^2 and 2-tailed t tests were used to compare categorical and continuous variables, respectively. Multivariate linear regressions were employed to measure associations between the independent variables (HL, illness severity, race, gender, education, and insurance status) and the dependent variable, LOS. Independent variables were chosen for clinical significance and retained in the model regardless of statistical significance. The adjusted R^2 values of models with and without the HL variable included were reported to provide information on the contribution of HL to the overall model.

Because LOS was observed to be right skewed and residuals of the untransformed regression were observed to be non-normally distributed, the decision was made to natural log transform LOS, which is consistent with previous hospital LOS studies.[16] Regression coefficients and confidence intervals were then transformed into percentage estimates using the following equation: $100(e^{\beta}–1)$. Adjusted R^2 was reported for the transformed regression.

The APR-DRG relative weight was treated as a continuous variable. Sociodemographic variables were dichotomized as follows: female vs male; high school graduates vs not; African American vs not; Medicaid/no payer vs Medicare/private payer. Age was not included in the multivariate model because it has been incorporated into the weighted APR-DRG illness severity scores.

Each of the sociodemographic variables and the APR-DRG score were examined for effect modification via the same multivariate linear equation described above, with the addition of an interaction term. A separate regression was performed with an interaction term between age (dichotomized at ≥65) and HL to investigate whether age modified the association between HL and LOS. Finally, we explored whether effects were isolated to long vs short LOS by dividing the sample based on the mean LOS (≥6 days) and performing separate multivariate comparisons.

Sensitivity analyses were performed to exclude those with LOS greater than the 90th percentile and those with APR-DRG score greater than the 90th percentile; age was added to the model as a continuous variable to evaluate whether the illness severity score fully adjusted for the effects of age on LOS. Furthermore, we compared the participants with missing data to those with complete data across both dependent and independent variables. Alpha was set at 0.05; analyses were performed using Stata Version 14 (Stata, College Station, TX).

RESULTS

A total of 5983 participants met inclusion criteria and completed the HL assessment; of these participants, 75 (1%) died during hospitalization, 9 (0.2%) had missing discharge status, and 79 (1%) had LOS >30 days. Two hundred eighty (5%) were missing data on sociodemographic variables or APR-DRG score. Of the remaining (n = 5540), the mean age was 57 years (standard deviation [SD] = 19 years), over half of participants were female (57%), and the majority were African American (73%) and had graduated from high school (81%). The sample was divided into those with private insurance (25%), those with Medicare (46%), and those with Medicaid (26%); 2% had no payer. The mean APR-DRG score was 1.3 (SD = 1.2), and the scores ranged from 0.3 to 15.8.

On the BHLS screen for HL, 20% (1104/5540) had inad-

TABLE 1. Associations with Length of Stay

	Unadjusted		Adjusted	
Characteristic	% Change (95% CI)	*P* Value	% Change (95% CI)	*P* Value
HL				
Adequate HL	Reference		Reference	
Low HL	14.3 (8.5 to 20.1)	<.001	11.1 (6.1 to 16.1)	<.001
Severity of Illness				
APR-DRG, 1 point increase	36.0 (34.1 to 38.0)	<.001	35.3 (33.3 to 37.2)	<.001
Sociodemographics				
Female	–5.9 (–9.7 to –2.0)	.003	0.0 (–3.6 to 3.5)	1
Non-HS grad	–4.1 (–9.0 to 0.9)	.1	–3.3 (–7.8 to 1.2)	.1
African American	–16.1 (–20.0 to –12.3)	<.001	–7.2 (–11.0 to –3.4)	<.001
Medicaid/Uninsured	–13.0 (–16.9 to –9.1)	<.001	–7.4 (–11.1 to –3.7)	<.001
N, Adj R^2			5540, 25.0%	

NOTE: Multivariate models adjusted for the following covariates: HL, APR-DRG score, gender, education, race, and insurance status. Abbreviations: Adj, adjusted; APR-DRG, all payer refined diagnosis related group; CI, confidence interval; HL, health literacy; HS, high school.

equate HL. Participants with low HL had higher weighted illness severity scores (average 1.4 vs 1.3; $P = 0.003$). Participants with low HL were also more likely to be 65 or older (55% vs 33%; $P < 0.001$), non-high school graduates (35% vs 15%; $P < 0.001$), and African American (78% vs 72%; $P < 0.001$), and to have Medicare or private insurance (75% vs 71%; $P = 0.02$). There was no significant difference with respect to gender (54% male vs 57% female; $P = 0.1$)

The mean and median LOS were 6 ± 5 days and 4 days (interquartile range 2-7 days), respectively. Those with low HL had a longer average LOS (6.0 vs 5.4 days; $P < 0.001$). In multivariate analysis controlling for APR-DRG score, gender, education, race, and insurance status, low HL was associated with an 11.1% longer LOS (95% CI, 6.1-16.1; $P < 0.001$; Table 1). The adjusted R^2 value for the regression was 25.0% including HL and 24.7% with HL excluded. Additionally, being African American ($P < 0.001$) and having Medicaid or no insurance ($P < 0.001$) were associated with a shorter LOS in multivariate analysis (Table 1). The association of HL and LOS in multivariate modeling remained significant among participants with LOS <6 days (10.2%; 95% CI, 5.6%-14.9%; $P < 0.001$), but not among participants with LOS ≥6 days (0.4%; 95% CI, −3.6% to 4.4%; $P = 0.8$).

Neither age ≥65 ($P = 0.4$) nor illness severity score ($P = 0.5$) significantly modified the effect of HL on LOS. However, the effect of HL on hospital LOS was significantly modified by gender ($P = 0.02$). Among men, low HL was associated with a 17.8% longer LOS (95% CI, 10.0%-25.7%; $P < 0.001$), but among women, low HL was associated with only a 7.7% longer LOS (95% CI, 1.9%-13.5%; $P = 0.009$). Among the remaining demographics, high school graduation status ($P = 0.4$), being African American ($P = 0.6$), and insurance status ($P = 0.2$) did not significantly modify the effect of HL on LOS. In sensitivity analysis, excluding participants with LOS above the 90th percentile of 12 days and excluding participants with illness severity scores above the 90th percentile, low HL was still associated with longer LOS ($P < 0.001$ and $P = 0.001$, respectively; Table 2). In the final sensitivity analysis, although age remained a significant predictor of longer LOS after controlling for illness severity (0.2% increase per year, 95% CI, 0.1%-0.3%; $P < 0.001$), low HL nevertheless remained significantly associated with longer LOS ($P < 0.001$; Table 2).

Finally, we compared the group with missing data (n = 280) to the group with complete data (n = 5540). The participants with missing data were more likely to have low HL (31% [86/280] vs 20%; $P < 0.001$) and to have Medicare or private insurance (82% [177/217] vs 72%; $P = 0.002$); however, they were not more likely to be 65 or older (40% [112/280] vs 37%; $P = 0.3$), high school graduates (88% [113/129] vs 81%; $P = 0.06$), African American (69% [177/256] vs 73%; $P = 0.1$), or female (57% [158/279] vs 57%; $P = 1$), nor were they more likely to have longer LOS (5.7 [n = 280] vs 5.5 days; $P = 0.6$) or higher illness severity scores (1.3 [n = 231] vs 1.3; $P = 0.7$).

DISCUSSION

To our knowledge, this study is the first to evaluate the association between low HL and an important in-hospital outcome measure, hospital LOS. We found that low HL was associated with a longer hospital LOS, a result which remained significant when controlling for severity of illness and sociodemographic variables and when testing the model for sensitivity to the highest values of LOS and illness severity. Additionally, the association of HL with LOS appeared concentrated among participants with shorter LOS. Relative to other predictors, the contribution of HL to the overall LOS model was small, as evidenced by the change in adjusted R^2 values with HL excluded.

Among the covariates, only gender modified the association between HL and LOS; the findings suggested that men were more susceptible to the effect of low HL on increased

TABLE 2. Associations with Length of Stay: Sensitivity Analysis

	Excluding >90th % LOS		Exclude >90th % APR-DRG		Including Age	
Characteristic	% Change (95% CI)	*P* Value	% Change (95% CI)	*P* Value	% Change (95% CI)	*P* Value
HL						
Adequate HL	Reference		Reference		Reference	
Low HL	8.8 (4.1 to 13.5)	<.001	8.6 (3.6 to 13.7)	.001	9.1 (4.1 to 14.1)	<.001
Severity of Illness						
APR-DRG, 1 point increase	33.1 (30.5 to 35.6)	<.001	87.7 (80.7 to 94.6)	<.001	35.1 (33.2 to 37.1)	<.001
Sociodemographics						
Female	2.3 (–1.2 to 5.8)	.2	1.7 (–2.0 to 5.3)	.4	–0.4 (–4.0 to 3.1)	.8
Non-HS grad	–2.0 (–6.3 to 2.2)	.4	–3.3 (–7.8 to 1.3)	.2	–4.5 (–8.9 to –0.05)	.048
African American	–4.2 (–8.0 to –0.4)	.03	–5.3 (–9.4 to –1.3)	.009	–7.8 (–11.6 to –4.0)	<.001
Medicaid/Uninsured	–7.3 (–10.8 to –3.8)	<.001	–6.7 (–10.5 to –2.9)	.001	–3.7 (–7.9 to 0.6)	.09
Age (1 year increase)	—	—	—	—	0.2 (0.1 to 0.3)	<.001
N, Adj R^2	5079, 15.5%		4988, 19.6%		5540, 25.2%	

NOTE: Multivariate models adjusted for the following covariates: HL, APR-DRG score, gender, education, race, insurance status, and age (in the third model). Abbreviations: —, no data; %, percentile; Adj, adjusted; APR-DRG, all patient refined diagnosis related group; CI, confidence interval; HL, health literacy; HS, high school; LOS, length of stay.

LOS. Illness severity and other sociodemographics, including age ≥65, did not appear to modify the association. We also found that being African American and having Medicaid or no insurance were associated with a significantly shorter LOS in multivariate analysis.

Previous work suggested that the adverse health effects of low HL may be mediated through several pathways, including health knowledge, self-efficacy, health skills, and illness stigma.[25-27] The finding of a small but significant relationship between HL and LOS was not surprising given these known associations; nevertheless, there may be an additional patient-dependent effect of low HL on LOS not discovered here. For instance, patients with poor health knowledge and self-efficacy might stay in the hospital longer if they or their providers do not feel comfortable with their self-care ability.

This finding may be useful in developing hospital-based interventions. HL-specific interventions, several of which have been tested in the inpatient setting,[14,28,29] have shown promise toward improving health knowledge,[30] disease severity,[31] and health resource utilization.[32]

Those with low HL may lack the self-efficacy to participate in discharge planning; in fact, previous work has related low HL to posthospital readmissions.[8,9] Conversely, patients with low HL might struggle to engage in the inpatient milieu, advocating for shorter LOS if they feel alienated by the inpatient experience.

These possibilities show that LOS is a complex measure shown to depend on patient-level characteristics and on provider-based, geographical, and sociocultural factors.[16,33] With these forces at play, additional effects of lower levels of HL may be lost without phenotyping patients by both level of HL and related characteristics, such as self-efficacy, health skills, and stigma. By gathering these additional data, future work should explore whether subpopulations of patients with low HL may be at risk for too-short vs too-long hospital admissions.

For instance, in this study, both race and Medicaid insurance were associated with shorter LOS. Being African American was associated with shorter LOS in our study but has been found to be associated with longer LOS in another study specifically focused on diabetes.[34] Prior findings found uninsured patients have shorter LOS.[35] Therefore, these findings in our study are difficult to explain without further work to understand whether there are health disparities in the way patients are cared for during hospitalization that may shorten or lengthen their LOS because of factors outside of their clinical need.

The finding that gender modified the effect of low HL on LOS was unexpected. There were similar proportions of men and women with low HL. There is evidence to support that women make the majority of health decisions for themselves and their familes[36]; therefore, there may be unmeasured aspects of HL that provide an advantage for female vs male inpatients. Furthermore, omitted confounders, such as social support, may not fully capture potential gender-related differences. Future work is needed to understand the role of gender in relationship to HL and LOS.

Limitations of this study include its observational, single-centered design with information derived from administrative data; positive and negative confounding cannot be ruled out. For instance, we did not control for complex aspects affecting LOS, such as discharge disposition and goals of care (eg, aggressive care after discharge vs hospice). To address this limitation, multivariate analyses were performed, which were adjusted for illness severity scores and took into account both comorbidity and severity of the current illness. Additionally, although it is important to study such populations, our largely urban, minority sample is not representative of the U.S. population, and within our large sample,

there were participants with missing data who had lower HL on average, although this group represented only 5% of the sample. Finally, different HL tools have noncomplete concordance, which has been seen when comparing the BHLS with more objective tools.[20,37] Furthermore, certain in-hospital clinical scenarios (eg, recent stroke or prolonged intensive care unit stay) may present unique challenges in establishing a baseline HL level. However, the BHLS was used in this study because of its greater feasibility.

In conclusion, this study is the first to evaluate the relationship between low HL and LOS. The findings suggest that HL may play a role in shaping outcomes in the inpatient setting and that targeting interventions toward screened patients may be a pathway toward mitigating adverse effects. Our findings need to be replicated in larger, more representative samples, and further work understanding subpopulations within the low HL population is needed. Future work should measure this association in diverse inpatient settings (eg, psychiatric, surgical, and specialty), in addition to assessing associations between HL and other important in-hospital outcome measures, including mortality and discharge disposition.

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How Exemplary Teaching Physicians Interact with Hospitalized Patients

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BACKGROUND: Effectively interacting with patients defines the consummate clinician.

OBJECTIVE: As part of a broader study, we examined how 12 carefully selected attending physicians interacted with patients during inpatient teaching rounds.

DESIGN: A multisite study using an exploratory, qualitative approach.

PARTICIPANTS: Exemplary teaching physicians were identified using modified snowball sampling. Of 59 potential participants, 16 were contacted, and 12 agreed to participate. Current and former learners of the participants were also interviewed. Participants were from hospitals located throughout the United States.

INTERVENTION: Two researchers—a physician and a medical anthropologist—conducted 1-day site visits, during which they observed teaching rounds and patient-physician interactions and interviewed learners and attendings.

MEASUREMENTS: Field notes were taken during teaching rounds. Interviews were recorded and transcribed, and code reports were generated.

RESULTS: The attendings generally exhibited the following 3 thematic behaviors when interacting with patients: (1) care for the patient's well-being by being a patient advocate and forming a bond with the patient; (2) consideration of the "big picture" of the patient's medical and social situation by anticipating what the patient may need upon discharge and inquiring about the patient's social situation; and (3) respect for the patient through behaviors such as shaking hands with the patient and speaking with the patient at eye level by sitting or kneeling.

CONCLUSIONS: The key findings of our study (care for the patient's well-being, consideration of the "big picture," and respect for the patient) can be adopted and honed by physicians to improve their own interactions with hospitalized patients. *Journal of Hospital Medicine* 2017;12:974-978. Published online first September 20, 2017. © 2017 Society of Hospital Medicine

Approximately a century ago, Francis Peabody taught that "the secret of the care of the patient is in caring for the patient."[1] His advice remains true today. Despite the advent of novel diagnostic tests, technologically sophisticated interventional procedures, and life-saving medications, perhaps the most important skill a bedside clinician can use is the ability to connect with patients.

The literature on patient-physician interaction is vast[2-11] and generally indicates that exemplary bedside clinicians are able to interact well with patients by being competent, trustworthy, personable, empathetic, and effective communicators. "Etiquette-based medicine," first proposed by Kahn,[12] emphasizes the importance of certain behaviors from physicians, such as introducing yourself and explaining your role, shaking hands, sitting down when speaking to patients, and asking open-ended questions.

Yet, improving patient-physician interactions remains necessary. A recent systematic review reported that almost half of the reviewed studies on the patient-physician relationship published between 2000 and 2014 conveyed the idea that the patient-physician relationship is deteriorating.[13]

As part of a broader study to understand the behaviors and approaches of exemplary inpatient attending physicians,[14-16] we examined how 12 carefully selected physicians interacted with their patients during inpatient teaching rounds.

METHODS

Overview

We conducted a multisite study using an exploratory, qualitative approach to inquiry, which has been described previously.[14-16] Our primary purpose was to study the attributes and behaviors of outstanding general medicine attendings in the setting of inpatient rounds. The focus of this article is on the attendings' interactions with patients.

We used a modified snowball sampling approach[17] to identify 12 exemplary physicians. First, we contacted individuals throughout the United States who were known to the principal investigator (S.S.) and asked for suggestions of excellent clinician educators (also referred to as attendings) for potential inclusion in the study. In addition to these personal contacts, other individuals unknown to the investigative team were contacted and asked to provide suggestions for attendings to include in the study. Specifically, the *US News & World Report* 2015 Top Medical Schools: Research Rankings,[18] which are widely used to represent the best U.S. hospitals, were reviewed in an effort to identify attendings from

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a broad range of medical schools. Using this list, we identified other medical schools that were in the top 25 and were not already represented. We contacted the division chiefs of general internal (or hospital) medicine, chairs and chiefs of departments of internal medicine, and internal medicine residency program directors from these medical schools and asked for recommendations of attendings from both within and outside their institutions whom they considered to be great inpatient teachers.

This sampling method resulted in 59 potential participants. An internet search was conducted on each potential participant to obtain further information about the individuals and their institutions. Both personal characteristics (medical education, training, and educational awards) and organizational characteristics (geographic location, hospital size and affiliation, and patient population) were considered so that a variety of organizations and backgrounds were represented. Through this process, the list was narrowed to 16 attendings who were contacted to participate in the study, of which 12 agreed. The number of attendings examined was appropriate because saturation of metathemes can occur in as little as 6 interviews, and data saturation occurs at 12 interviews.[19] The participants were asked to provide a list of their current learners (ie, residents and medical students) and 6 to 10 former learners to contact for interviews and focus groups.

TABLE 1. Characteristics of Selected Attendings

Characteristic	N
Gender	
Male	9
Female	3
Region	
Northeast	1
South	2
Midwest	6
West	3
Top 25 on the 2015 *US News & World Report* Top Medical Schools: Research Rankings	9
Institutions represented	
Baylor College of Medicine	1
Cleveland Clinic	1
Massachusetts General Hospital	1
Northwestern University; Jesse Brown Veterans Affairs Medical Center	1
Rush University; Cook County Hospital Chicago	1
Tulane University	1
University of California, San Francisco; San Francisco Veterans Affairs Medical Center	2
University of Chicago, Pritzker School of Medicine	1
University of Michigan	1
University of Washington; Seattle Veterans Affairs Medical Center	1
University of Wisconsin-Madison	1
Academic position	
Staff physician	1
Assistant professor	1
Associate professor	7
Professor	3
Mean years in practice (range)	26 (11-44)

Data Collection

Observations

Two researchers conducted the one-day site visits. One was a physician (S.S.) and the other a medical anthropologist (M.H.), and both have extensive experience in qualitative methods. The only exception was the site visit at the principal investigator's own institution, which was conducted by the medical anthropologist and a nonpracticing physician who was unknown to the participants. The team structure varied slightly among different institutions but in general was composed of 1 attending, 1 senior medical resident, 1 to 2 interns, and approximately 2 medical students. Each site visit began with observing the attendings (n = 12) and current learners (n = 57) on morning rounds, which included their interactions with patients. These observations lasted approximately 2 to 3 hours. The observers took handwritten field notes, paying particular attention to group interactions, teaching approaches, and patient interactions. The observers stood outside the medical team circle and remained silent during rounds so as to be unobtrusive to the teams' discussions. The observers discussed and compared their notes after each site visit.

Interviews and Focus Groups

The research team also conducted individual, semistructured interviews with the attendings (n = 12), focus groups with their current teams (n = 46), and interviews or focus groups with their former learners (n = 26). Current learners were asked open-ended questions about their roles on the teams, their opinions of the attendings, and the care the attendings provide to their patients. Because they were observed during rounds, the researchers asked for clarification about specific interactions observed during the teaching rounds. Depending on availability and location, former learners either participated in in-person focus groups or interviews on the day of the site visit, or in a later telephone interview. All interviews and focus groups were audio recorded and transcribed.

This study was deemed to be exempt from regulation by the University of Michigan Institutional Review Board. All participants were informed that their participation was completely voluntary and that they could refuse to answer any question.

Data Analysis

Data were analyzed using a thematic analysis approach,[20] which involves reading through the data to identify patterns (and create codes) that relate to behaviors, experiences, meanings, and activities. The patterns are then grouped into themes to help further explain the findings.[21] The research team members (S.S. and M.H.) met after the first site visit and developed initial ideas about meanings and possible patterns. One team member (M.H.) read all the transcripts from the site visit and, based on the data, developed a code-

TABLE 2. Key Approaches for Effective Patient-Physician Interactions

Care for the Patient's Well-Being
- Be a patient advocate and attend to each patient's comfort.
- Talk with the patient about topics other than medicine to form a bond.
- Use touch to comfort the patient.

Consideration of the "Big Picture"
- Explain so the patient and family can understand.
- Use teach-back techniques to ensure the patient and family understand the plan.
- Consider what the patient needs in the outpatient setting upon discharge.
- Inquire about the patient's social situation and support system to anticipate problems the patient may face in the outpatient setting.

Respect for the Patient
- Shake hands with the patient when entering and exiting the room.
- Introduce the team members who are present or have them introduce themselves to the patient.
- Leave the room and the patient the way they were found.
- Consider using appropriate humor to make the patient or family members feel more comfortable.
- Speak with the patient at eye level by either sitting or kneeling when the patient is lying in bed.

book to be used for this study. This process was repeated after every site visit, and the coding definitions were refined as necessary. All transcripts were reviewed to apply any new codes when they developed. NVivo® 10 software (QSR International, Melbourne, Australia) was used to assist with the qualitative data analysis.

To ensure consistency and identify relationships between codes, code reports listing all the data linked to a specific code were generated after all the field notes and transcripts were coded. Once verified, codes were grouped based on similarities and relationships into prominent themes related to physician-patient interactions by 2 team members (S.S. and M.H.), though all members reviewed them and concurred.

RESULTS

A total of 12 attending physicians participated (Table 1). The participants were from hospitals located throughout the U.S. and included both university-affiliated hospitals and Veterans Affairs medical centers. We observed the attending physicians interact with more than 100 patients, with 3 major patient interaction themes emerging. Table 2 lists key approaches for effective patient-physician interactions based on the study findings.

Care for the Patient's Well-Being

The attendings we observed appeared to openly care for their patients' well-being and were focused on the patients' wants and needs. We noted that attendings were generally very attentive to the patients' comfort. For example, we observed one attending sending the senior resident to find the patient's nurse in order to obtain additional pain medications. The attending said to the patient several times, "I'm sorry you're in so much pain." When the team was leaving, she asked the intern to stay with the patient until the medications had been administered.

Learners noticed when an attending physician was especially skilled at demonstrating empathy and patient-centered care. While education on rounds was emphasized, patient connection was the priority. One learner described the following: "… he really is just so passionate about patient care and has so much empathy, really. And I will tell you, of all my favorite things about him, that is one of them..."

The attendings we observed could also be considered patient advocates, ensuring that patients received superb care. As one learner said about an attending who was attempting to have his patient listed for a liver transplant, "He is the biggest advocate for the patient that I have ever seen." Regarding the balance between learning biomedical concepts and advocacy, another learner noted the following: "… there is always a teaching aspect, but he always makes sure that everything is taken care of for the patient…"

Building rapport creates and sustains bonds between people. Even though most of the attendings we observed primarily cared for hospitalized patients and had little long-term continuity with them, the attendings tended to take special care to talk with their patients about topics other than medicine to form a bond. This bonding between attending and patient was appreciated by learners. "Probably the most important thing I learned about patient care would be taking the time and really developing that relationship with patients," said one of the former learners we interviewed. "There's a question that he asks to a lot of our patients," one learner told us, "especially our elderly patients, that [is], 'What's the most memorable moment in your life?' So, he asks that question, and patient[s] open up and will share."

The attendings often used touch to further solidify their relationships with their patients. We observed one attending who would touch her patients' arms or knees when she was talking with them. Another attending would always shake the patient's hand when leaving. Another attending would often lay his hand on the patient's shoulder and help the patient sit up during the physical examination. Such humanistic behavior was noticed by learners. "She does a lot of comforting touch, particularly at the end of an exam," said a current learner.

Consideration of the "Big Picture"

Our exemplary attendings kept the "big picture" (that is, the patient's overall medical and social needs) in clear focus. They behaved in a way to ensure that the patients understood the key points of their care and explained so the patients and families could understand. A current learner said, "[The attending] really makes sure that the patient understands what's going on. And she always asks them, 'What do you understand, what do you know, how can we fill in any blanks?' And that makes the patient really involved in their own care, which I think is important." This reflection was supported by direct observations. Attendings posed the fol-

lowing questions at the conclusion of patient interactions: "Tell me what you know." "Tell me what our plan is." "What did the lung doctors tell you yesterday?" These questions, which have been termed "teach-back" and are crucial for health literacy, were not meant to quiz the patient but rather to ensure the patient and family understood the plan.

We noticed that the attendings effectively explained clinical details and the plan of care to the patient while avoiding medical jargon. The following is an example of one interaction with a patient: "You threw up and created a tear in the food tube. Air got from that into the middle of the chest, not into the lungs. Air isn't normally there. If it is just air, the body will reabsorb [it]... But we worry about bacteria getting in with the air. We need to figure out if it is an infection. We're still trying to figure it out. Hang in there with us." One learner commented, "… since we do bedside presentations, he has a great way of translating our gibberish, basically, to real language the patient understands."

Finally, the attendings anticipated what patients would need in the outpatient setting. We observed that attendings stressed what the next steps would be during transitions of care. As one learner put it, "But he also thinks ahead; what do they need as an outpatient?" Another current learner commented on how another attending always asked about the social situations of his patients stating, "And then there is the social part of it. So, he is very much interested [in] where do they live? What is their support system? So, I think it has been a very holistic approach to patient care."

Respect for the Patient

The attendings we observed were steadfastly respectful toward patients. As one attending told us, "The patient's room is sacred space, and it's a privilege for us to be there. And if we don't earn that privilege, then we don't get to go there." We observed that the attendings generally referred to the patient as Mr. or Ms. (last name) rather than the patient's first name unless the patient insisted. We also noticed that many of the attendings would introduce the team members to the patients or ask each member to introduce himself or herself. They also tended to leave the room and patient the way they were found, for example, by pushing the patient's bedside table so that it was back within his or her reach or placing socks back onto the patient's feet.

We noted that many of our attendings used appropriate humor with patients and families. As one learner explained, "I think Dr. [attending] makes most of our patients laugh during rounds. I don't know if you noticed, but he really puts a smile on their face[s] whenever he walks in. … Maybe it would catch them off guard the first day, but after that, they are so happy to see him."

Finally, we noticed that several of our attendings made sure to meet the patient at eye level during discussions by either kneeling or sitting on a chair. One of the attendings put it this way: "That's a horrible power dynamic when you're an inpatient and you're sick and someone's standing over you telling you things, and I like to be able to make eye contact with people, and often times that requires me to kneel down or to sit on a stool or to sit on the bed. … I feel like you're able to connect with the people in a much better way…" Learners viewed this behavior favorably. As one told us, "[The attending] gets down to their level and makes sure that all of their questions are answered. So that is one thing that other attendings don't necessarily do."

DISCUSSION

In our national, qualitative study of 12 exemplary attending physicians, we found that these clinicians generally exhibited the following behaviors with patients. First, they were personable and caring and made significant attempts to connect with their patients. This occasionally took the form of using touch to comfort patients. Second, they tended to seek the "big picture" and tried to understand what patients would need upon hospital discharge. They communicated plans clearly to patients and families and inquired if those plans were understood. Finally, they showed respect toward their patients without fail. Such respect took many forms but included leaving the patient and room exactly as they were found and speaking with patients at eye level.

Our findings are largely consistent with other key studies in this field. Not surprisingly, the attendings we observed adhered to the major suggestions that Branch and colleagues[2] put forth more than 15 years ago to improve the teaching of the humanistic dimension of the patient-physician relationship. Examples include greeting the patient, introducing team members and explaining each person's role, asking open-ended questions, providing patient education, placing oneself at the same level as the patient, using appropriate touch, and being respectful. Weissmann et al.[22] also found similar themes in their study of teaching physicians at 4 universities from 2003 to 2004. In that study, role-modeling was the primary method used by physician educators to teach the humanistic aspects of medical care, including nonverbal communication (eg, touch and eye contact), demonstration of respect, and building a personal connection with the patients.[22]

In a focus group-based study performed at a teaching hospital in Boston, Ramani and Orlander[23] concluded that both participating teachers and learners considered the patient's bedside as a valuable venue to learn humanistic skills. Unfortunately, they also noted that there has been a decline in bedside teaching related to various factors, including documentation requirements and electronic medical records.[23] Our attendings all demonstrated the value of teaching at a patient's bedside. Not only could physical examination skills be demonstrated but role-modeling of interpersonal skills could be observed by learners.

Block and colleagues[24] observed 29 interns in 732 patient encounters in 2 Baltimore training programs using Kahn's "etiquette-based medicine" behaviors as a guide.[12] They found that interns introduced themselves 40% of the time, explained their role 37% of the time, touched patients on 65% of visits (including as part of the physical examination), asked open-ended questions 75% of the time, and sat down with

patients during only 9% of visits.[24] Tackett et al.[7] observed 24 hospitalists who collectively cared for 226 unique patients in 3 Baltimore-area hospitals. They found that each of the following behaviors was performed less than 30% of the time: explains role in care, shakes hand, and sits down.[7] However, our attendings appeared to adhere to these behaviors to a much higher extent, though we did not quantify the interactions. This lends support to the notion that effective patient-physician interactions are the foundation of great teaching.

The attendings we observed (most of whom are inpatient based) tended to the contextual issues of the patients, such as their home environments and social support. Our exemplary physicians did what they could to ensure that patients received the appropriate follow-up care upon discharge.

Our study has important limitations. First, it was conducted in a limited number of US hospitals. The institutions represented were generally large, research-intensive, academic medical centers. Therefore, our findings may not apply to settings that are different from the hospitals studied. Second, our study included only 12 attendings and their learners, which may also limit the study's generalizability. Third, we focused exclusively on teaching within general medicine rounds. Thus, our findings may not be generalizable to other subspecialties. Fourth, attendings were selected through a nonexhaustive method, increasing the potential for selection bias. However, the multisite design, the modified snowball sampling, and the inclusion of several types of institutions in the final participant pool introduced diversity to the final list. Former-learner responses were subject to recall bias. Finally, the study design is susceptible to observer bias. Attempts to reduce this included the diversity of the observers (ie, both a clinician and a nonclinician, the latter of whom was unfamiliar with medical education) and review of the data and coding by multiple research team members to ensure validity. Although we cannot discount the potential role of a Hawthorne effect on our data collection, the research team attempted to mitigate this by standing apart from the care teams and remaining unobtrusive during observations.

Limitations notwithstanding, we believe that our multisite study is important given the longstanding imperative to improve patient-physician interactions. We found empirical support for behaviors proposed by Branch and colleagues[2] and Kahn[12] in order to enhance these relationships. While others have studied attendings and their current learners,[22] we add to the literature by also examining former learners' perspectives on how the attendings' teaching and role-modeling have created and sustained a lasting impact. The key findings of our national, qualitative study (care for the patient's well-being, consideration of the "big picture," and respect for the patient) can be readily adopted and honed by physicians to improve their interactions with hospitalized patients.

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A Randomized Cohort Controlled Trial to Compare Intern Sign-Out Training Interventions

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BACKGROUND: Although previous studies have investigated the efficacy of specific sign-out protocols (such as the illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by reviewer [I-PASS] bundle), the implementation of a bundle can be time consuming and costly. We compared 4 sign-out training pedagogies on sign-out quality.

OBJECTIVE: To evaluate training interventions that best enhance multidimensional sign-out quality measured by information exchange, task accountability, and personal responsibility.

INTERVENTION: Four general internal medicine firms were randomly assigned into 1 of the following 4 training interventions: didactics (control), I-PASS, policy mandate on task accountability, and Plan-Do-Study-Act (PDSA).

SETTING: First-year interns at a large, Mid-Atlantic internal medicine residency program.

MEASUREMENTS: Eight trained observers examined 10 days each in the pre- and postintervention periods for each firm using a standardized sign-out checklist.

RESULTS: Pre- and postintervention differences showed significant improvements in the transfer of patient information, task accountability, and personal responsibility for the I-PASS, policy mandate, and PDSA groups, respectively, in line with their respective training foci. Compared to the control, I-PASS reported the best improvements in sign-out quality, although there was room to improve in task accountability and responsibility.

CONCLUSIONS: Different training emphases improved different dimensions of sign-out quality. A combination of training pedagogies is likely to yield optimal results. *Journal of Hospital Medicine* 2017;12:979-983. © 2017 Society of Hospital Medicine

Patient sign-outs are defined as the transition of patient care that includes the transfer of information, task accountability, and personal responsibility between providers.[1-3] The adoption of mnemonics as a memory aid has been used to improve the transfer of patient information between providers.[4] In the transfer of task accountability, providers transfer follow-up tasks to on-call or coverage providers and ensure that directives are understood. Joint task accountability is enhanced through collaborative giving and cross-checking of information received through assertive questioning to detect errors, and it also enables the receiver to codevelop an understanding of a patient's condition.[5-8] In the transfer of personal responsibility for the primary team's patients, the provision of anticipatory guidance enables the coverage provider to have prospective information about potential, upcoming issues to facilitate care plans.[6] Enabling coverage providers to anticipate overnight events helps them exercise responsibility for patients who are under their temporary care.[2]

The Accreditation Council for Graduate Medical Education requires residency programs to provide formal instruction on sign-outs.[9] Yet, variability across training programs exists,[8,10] with training emphasis on the transfer of information over accountability or responsibility.[11] Previous studies have demonstrated the efficacy of sign-out training, such as the illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by reviewer (I-PASS) bundle.[3] Yet, participation is far from 100% because the I-PASS bundle requires in-person workshops, e-learning platforms, organizational change campaigns, and faculty participation,[12] involving resource and time commitments that few programs can afford. To address this issue, we seek to compare resource-efficient, knowledge-based, skill-based, compliance-based, and learner-initiated sign-out training pedagogies. We focused on the evening sign-out because it is a high-risk period when care for inpatients is transferred to smaller coverage intern teams.

METHODS

Setting and Study Design

A prospective, randomized cohort trial of 4 training interventions was conducted at an internal medicine residency program at a Mid-Atlantic, academic, tertiary-care hospital with 1192 inpatient beds. The 52 interns admitted to the

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TABLE. Description of the 4 Training Interventions

	Firm 1: Didactics (Control)	Firm 2: I-PASS Mnemonic	Firm 3: Policy Mandate	Firm 4: PDSA
Educational strategy	Acquisition of sign-out knowledge to understand sign-out process	Acquisition of sign-out skills to perform sign-outs	Compliance to sign-out policy to enhance accountability	Learner-initiated sign-out protocol to enhance responsibility
Resources in training	1. Business school faculty trained attending physician on content of sign-out lecture 2. Attending physician delivered 1-hour lecture with 3-minute video on sign-outs	1. Senior resident developed 3 sign-out role-play scenarios 2. Business school faculty delivered 15-minute lecture with 3-minute video on sign-outs 3. Interns role-played 3 scenarios as sender, receiver, and observer of sign-outs for about 45 minutes (12-15 minutes per role-play). 4. Additional feedback given to interns from attending physician, 3 senior residents, and business faculty for each role-play	1. Business school faculty trained attending physician on content of sign-out lecture 2. Attending physician delivered 15-minute lecture with 3-minute video on sign-outs 3. Attending discussed video content and shared sign-out experiences for 45 minutes 4. Attending close training by motivating and directing interns to provide the night cover with sign-out tasks to perform.	1. Business school faculty met with attending physician to obtain support for PDSA intervention on sign-out protocol 2. Business school faculty delivered 15-minute lecture with 3-minute video on sign-outs 3. Forty-five minutes for interns to discuss sign-out problems experienced and reach consensus on sign-out problems to solve using PSDA technique with attending physician input 4. Two half-hour meetings posttraining with business faculty to answer questions and discuss implementation of new sign-out
Content	1. Why have sign-out training 2. Video contrasting poor and good sign-outs 3. Discussion on video content a. Sign-out challenges b. Why a good sign-out will help you 4. Strategies for quality sign-outs a. Update written records b. Use face-to-face sign-out c. Limit interruptions d. Sign-out everyone e. Share the basics of patient information	1. Why have sign-out training 2. Video contrasting poor and good sign-outs 3. Discussion on video content a. Sign-out challenges b. Why a standardized approach will help you 4. Lecture on I-PASS mnemonic to standardize verbal sign-out 5. 3 role plays to sign-out new patients, very sick patients, and stable patients a. Teams of 3 interns rotate role-play as sender, receiver, and observer of sign-out to give feedback b. Attending physician, 3 senior residents, and business faculty gave additional feedback to each person for each role-play c. Senior resident debriefed with learning points	1. Why have sign-out training 2. Video contrasting poor and good sign-outs 3. Discussion on video content a. Sign-out challenges b. How could sender and receiver do better 4. Attending motivated interns with a policy mandate to pay attention to tasks at sign-out: a. Give rationale for tasks b. Ask and invite questions c. Read back tasks	1. Why have sign-out training 2. Video contrasting poor and good sign-outs 3. Interns given a goal to develop their own sign-out protocol 4. Lecture on PDSA technique to design own protocol 5. Discussed and reached consensus on contingency plan as key problem to solve at sign-outs 6. Organized interns for PDSA cycle on sign-out solution 7. Developed logistics to implement sign-out protocol

Checklist items covered in training	Firm 1: Didactics (Control Group)	Firm 2: I-PASS Mnemonic	Firm 3: Policy Mandate	Firm 4: PDSA
Age	x	x		
Gender	x	x		
Admission reason	x	x		
Medical history	x	x		
Diagnoses	x	x		
To-do task	x	x	x	
Rationale for to-do tasks			x	
Sender invite questions of to-do tasks			x	
Receiver asks questions of to-do tasks		x	x	
Read back to-do tasks	x	x	x	
Current status	x	x		
Overnight changes to anticipate		x		x
If-then plans	x	x		x
Rationale for if-then plans				x
Sender invites questions about if-then plans				x
Receiver asks questions of if-then plans		x		x
Read back if-then plans	x	x		x
Number of elements taught	10	14	5	6

NOTE: Abbreviations: I-PASS, illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by reviewer; PDSA, Plan-Do-Study-Act

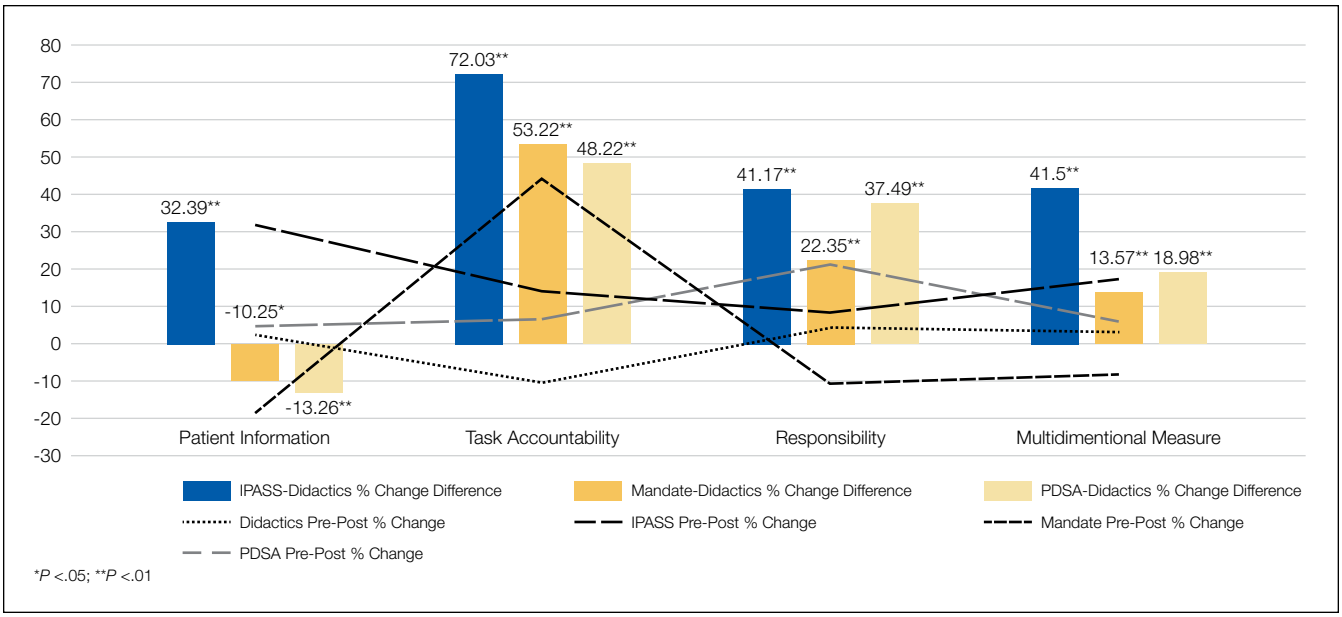

FIG. Improvements in Sign-out Elements Compared to Didactics Training.

program were randomly assigned to 4 firms caring for up to 25 inpatients on each floor of the hospital. The case mix faced by each firm was similar because patients were randomly assigned to firms based on bed availability. Teams of 5 interns in each firm worked in 5-day duty cycles, during which each intern rotated as a night cover for his or her firm. Interns remain in their firm throughout their residency. Sign-outs were conducted face to face with a computer. Receivers printed sign-out sheets populated with patient information and took notes when senders communicated information from the computer. The hospital's institutional review board approved this study.

Interventions

The firms were randomly assigned to 1 of 4 one-hour quality-improvement training interventions delivered at the same time and day in November 2014 at each firm's office, located on different floors of the hospital. There was virtually no cross-talk among the firms in the first year, which ensured the integrity of the cohort randomization and interventions. Faculty from an affiliated business school of the academic center worked with attending physicians to train the firms.

All interventions took 1 hour at noontime. Firm 1 (the control) received a didactic lecture on sign-out, which participants heard during orientation. Repeating that lecture reinforced their knowledge of sign-outs. Firm 2 was trained on the I-PASS mnemonic with a predictable progression of information elements to transfer.[3,12] Interns role-played 3 scenarios to practice sign-out.[3] They received skills feedback and a debriefing to link I-PASS with information elements to transfer. Firm 3 was dealt a policy mandate by the interns' attending physician to perform specific tasks at sign-out. Senders were to provide the night cover with to-do tasks, and receivers were to actively discuss and verify these tasks to ensure task accountability.[13] Firm 4 was trained on a Plan-Do-Study-Act (PDSA) protocol to identify and solve perceived barriers to sign-outs. Firm 4 agreed to solve the problem of the lack of care plans by the day team to the night cover. An ad hoc team in Firm 4 refined, pilot tested, and rolled out the solution within a month. Its protocol emphasized information on anticipated changes in patient status, providing contingency plans and their rationale as well as discussions to clarify care plans. Details of the 4 interventions are shown in the Table.

Data Collection Process

Eight trained senior residents, recruited by the last author (S.V.D.), volunteered to observe 10 evening sign-outs in each firm 1 month prior to the intervention and another 10 nights 4 months after training. Observations were standardized with a sign-out checklist developed from the literature review and the Joint Commission's 2006 National Patient Safety Goal 2E that followed the Situation, Background, Assessment, and Recommendation communication structure with opportunities for questioning and information verification.[14,15] Observers indicated "1" for each of the 17 sign-out elements in the checklist they observed, as shown in the supporting Table. Observers did not have supervisory relationships with the interns. Occasionally, the pairs of observers were different depending on their availability.

Outcomes

We measured improvements in sign-out quality by the mean percentage differences for each of the 3 dimensions of sign-out, as well as a multidimensional measure of sign-out comprising the 3 dimensions for each firm in 2 ways: (1) pre- and postintervention, and (2) vis-à-vis the control group postintervention.

Statistical Analysis

We factor analyzed the 17 sign-out elements using principal components analysis with varimax rotation to confirm their groupings within the 3 dimensions of sign-out using Statistical Package for the Social Sciences (SPSS) version 24 (IBM, North Castle, NY). We calculated the mean percentage differences and used Student t tests to evaluate statistical differences at $P < 0.05$.

RESULTS

Five hundred and sixty-three patient sign-outs were observed prior to the training interventions ($\kappa = 0.646$), and 620 patient sign-outs were observed after the interventions ($\kappa = 0.648$). Kappa values derived from SPSS were within acceptable interrater agreement ranges. Factor analysis of the 17 sign-out elements yielded 3 factors that we named patient information, task accountability, and responsibility, as shown in the supporting Table.

The supporting Figure reports 2 sets of results. The line graphs show the pre- and postintervention differences for each firm while the bar charts show the postintervention differences between each firm vis-à-vis the control group on sign-out dimensions. The line graphs indicate the greatest improvements in patient information, task accountability, and responsibility for the I-PASS, policy mandate, and PDSA groups, respectively. Mandate and PDSA groups reported low relative scores on sign-out dimensions that were not the foci of their training while the didactics group scored around 0 pre- and postintervention. I-PASS had the highest improvement on the multidimensional measure of sign-out quality but was not significantly different from the PDSA group at $P < 0.05$ (see supporting Figure for the calculations). The bar charts indicate that all groups vis-à-vis the control had higher improvements in task accountability, responsibility, and the multidimensional measure of sign-out quality. I-PASS vis-à-vis the control had the highest improvement but was not statistically different from the PDSA at $P < 0.05$. No sentinel events were reported during the entire study period.

DISCUSSION

The results indicated that after only 1 hour of training, skill-based, compliance-based, and learner-initiated sign-out training improved sign-out quality beyond knowledge-based didactics even though the number of sign-out elements taught in the latter 2 was lower than in the didactics group. Different training emphases influenced different dimensions of sign-out quality so that training interns to focus on task accountability or responsibility led to improvements in those dimensions only. The lower scores in other dimensions suggest potential risks in sign-out quality from focusing attention on 1 dimension at the expense of other dimensions. I-PASS, which covered the most sign-out elements and utilized 5 facilitators, led to the best overall improvement in sign-out quality, which is consistent with previous studies.[3,12] We demonstrated that only 1 hour of training on the I-PASS mnemonics using video, role-playing, and feedback led to significant improvements. This approach is portable and easily applied to any program. Potential improvements in I-PASS training could be obtained by emphasizing task accountability and responsibility because the mandate and PDSA groups obtained higher scores than the I-PASS group in these dimensions.

Limitations

We measured sign-out quality in the evening at this site because it was at greatest risk for errors. Future studies should consider daytime sign-outs, interunit handoffs, and other hospital settings, such as community or rural hospitals and nonacute patient settings, to ascertain generalizability. Data were collected from observations, so Hawthorne effects may introduce bias. However, we believe that using a standardized checklist, a control group, and assessing relative changes minimized this risk. Although we observed almost 1200 patient sign-outs over 80 shift changes, we were not able to observe every intern in every firm. Finally, no sentinel events were reported during the study period, and we did not include other measures of clinical outcomes, which represent an opportunity for future researchers to test which specific sign-out elements or dimensions are related to clinical outcomes or are relevant to specific patient types.

CONCLUSION

The results of this study indicate that 1 hour of formal training can improve sign-out quality. Program directors should consider including I-PASS with additional focus on task accountability and personal responsibility in their sign-out training plans.

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Things We Do For No Reason: Echocardiogram in Unselected Patients with Syncope

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

Syncope is a common cause of emergency department (ED) visits and hospitalizations. Echocardiogram is frequently used as a diagnostic tool in the evaluation of syncope, performed in 39%-91% of patients. The diagnostic yield of echocardiogram for detecting clinically important abnormalities in patients with a normal history, physical examination, and electrocardiogram (ECG), however, is extremely low. In contrast, echocardiograms performed on patients with syncope with a positive cardiac history, abnormal examination, and/or ECG identify an abnormality in up to 29% of cases, though these abnormalities are not always definitively the cause of symptoms. Recently updated clinical guidelines for syncope management from the American College of Cardiology now recommend echocardiogram only if initial history or examination suggests a cardiac etiology, or the ECG is abnormal. Universal echocardiography in patients with syncope exposes a significant number of patients to unnecessary testing and cost and does not represent evidence-based or high-value patient care.

CLINICAL SCENARIO

A 57-year-old woman presented to the ED after a syncopal episode. She had just eaten dinner when she slumped over and became unresponsive. Her husband estimated that she regained consciousness 30 seconds later and quickly returned to baseline mental status. She denied chest pain, shortness of breath, or palpitations. Her medical history included hypertension and hypothyroidism. Her medication regimen was unchanged.

Vital signs, including orthostatic blood pressures, were within normal ranges. A physical examination revealed regular heart sounds without murmur, rub, or gallop. ECG showed normal sinus rhythm, normal axis, and normal intervals. Chest radiograph, complete blood count, chemistry, pro-brain natriuretic peptide (pro-BNP), and troponin were within normal ranges.

BACKGROUND

Syncope, defined as "abrupt, transient, complete loss of consciousness, associated with inability to maintain postural tone, with rapid and spontaneous recovery,"[1] is a common clinical problem, accounting for 1% of ED visits in the United States.[2] As syncope has been shown to be associated with increased mortality,[3] the primary goal of syncope evaluation is to identify modifiable underlying causes, particularly cardiac causes. Current guidelines recommend a complete history and physical, orthostatic blood pressure measurement, and ECG as the initial evaluation for syncope.[1] Echocardiogram is a frequent additional test, performed in 39%-91% of patients.[4-8]

WHY YOU MAY THINK ECHOCARDIOGRAM IS HELPFUL

Echocardiogram may identify depressed ejection fraction, a risk factor for ventricular arrhythmias, along with structural causes of syncope, including aortic stenosis, pulmonary hypertension, and hypertrophic cardiomyopathy.[9] Structural heart disease is the underlying etiology in about 3% of patients with syncope.[10]

Prior guidelines stated that "an echocardiogram is a helpful screening test if the history, physical examination, and ECG do not provide a diagnosis or if underlying heart disease is suspected."[11] A separate guideline for the appropriate use of echocardiogram assigned a score of appropriateness on a 1-9 scale based on increasing indication.[12] Echocardiogram for syncope was scored a 7 in patients with "no other symptoms or signs of cardiovascular disease."[12] Only 25%-40% of patients with syncope will have a cause identified after the history, physical examination, and ECG,[13,14] creating diagnostic uncertainty that often leads to further testing.

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TABLE. Studies Reporting Transthoracic Echo Results in Patients with Syncope and Normal ECG, History, and Physical Examination[a]

Lead Author	Year	Study Design	Population (n)	Setting	Methods	Definition of Abnormal ECG	Outcome Measures	Results
Recchia[4]	1995	Retrospective Cohort	Adult patients admitted to the hospital for syncope over 6-month period (128 patients; 38 with normal history, exam, and ECG had TTE)	Single tertiary care center in Midwest	Charts reviewed for all patients admitted with syncope. Excluded patients with: Near-syncope Known cause of syncope Seizure Prior syncope referred for electrophysiological testing	Q waves Bundle branch block PVC Arrhythmia Mobitz II or higher	TTE with findings that explained syncope	0/38 TTE results explained syncope
Sarasin[15]	2002	Prospective Cohort	Adult patients presenting to the ED with unexplained syncope after initial history, physical, and ECG who underwent echocardiogram over 18-month period (155 patients, 67 with normal history and ECG)	Single university ED in Switzerland	All patients underwent TTE, carotid massage, 24-hour Holter monitor, tilt-table testing, and electrophysiology testing if indicated. Those with vs without abnormal initial ECG and/or cardiac history were compared.	Arrhythmia Any nondiagnostic finding except nonspecific ST and T wave changes	TTE with diagnostic findings for syncope Severe AS HOCM Severe PAH Myxoma or thrombus with outflow obstruction	0/67 patients with normal history and ECG had a relevant abnormality on TTE; 24/88 patients with abnormal history and/or ECG had abnormal TTE
Mendu[5]	2009	Retrospective Cohort	Consecutive adults older than 65 admitted for syncope over 5-year period (2106 admissions)	Single tertiary care center in Northeast	Charts reviewed for all diagnostic tests performed on consecutive elderly patients hospitalized with syncope. Patients were stratified as positive (n = 807) or negative (n = 1299) for the SFSR; positive if patient had congestive heart failure, hematocrit <30%, abnormal ECG, shortness of breath, or systolic blood pressure <90 mmHg.	Not defined	Diagnostic test results that affected management or determined etiology of syncope	821/2109 patients (39%) had echo. 10/488 (2%) of those negative for SFSR had echo that affected management, 4 (1%) had result that determined etiology. 26/333 (8%) of those positive for SFSR had echo that affected management and 9 (3%) had result that determined etiology
Anderson[6]	2012	Retrospective Cohort	Adults admitted to ED observation unit over 18-month period (323 patients; 267 with normal ECG, 235 of whom had TTE)	Single urban, university-affiliated ED in North Carolina	Charts reviewed for consecutive patients admitted to a syncope observation unit. Patients could not enter unit with any of the following: Unstable VS New ECG ischemic changes + Cardiac markers Abnormal neurologic exam Trauma Seizures Abnormal CT head Acute GI bleed	Arrhythmias PACs or PVCs Pacing Second- or third-degree AV block Left bundle branch block	Structural abnormalities on TTE Moderate to severe valvular regurgitation, stenosis, or diastolic dysfunction Severe LVH EF <45% Septal wall motion abnormalities	0/235 of those with normal ECG and TTE done had an abnormality; 7/35 of those with abnormal ECG and TTE done had an abnormality

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WHY ECHOCARDIOGRAM IS NOT NECESSARY IN ALL PATIENTS

Several studies have found that transthoracic echocardiogram has an extremely low diagnostic yield in patients with no cardiac history and a normal physical examination and ECG[4-8,15] (Table). A prospective study by Sarasin et al.[15] identified 155 patients with unexplained syncope after an initial ED evaluation. All patients underwent echocardiogram, carotid massage, 24-hour Holter monitor, tilt-table testing, and electrophysiology testing if indicated. Patients were stratified by the presence of ECG abnormalities, defined as any arrhythmia or finding other than nonspecific ST and T wave abnormalities, or abnormal cardiac history, defined as documented coronary artery disease, valvular disease, or cardiomyopathy. None of the 67 patients with normal ECG and a negative cardiac history had findings on echocardiogram to explain syncope.

Recchia et al.[4] performed a retrospective review of 128 patients admitted to a single center with syncope. Charts were reviewed for abnormal cardiac history, including coronary artery disease and congestive heart failure, and ECG abnormalities, defined as Q waves, any bundle branch block,

TABLE. Studies Reporting Transthoracic Echo Results in Patients with Syncope and Normal ECG, History, and Physical Examination[a] (continued)

Lead Author	Year	Study Design	Population (n)	Setting	Methods	Definition of Abnormal ECG	Outcome Measures	Results
Chang[7]	2016	Retrospective Cohort	Adult patients admitted to hospital for syncope over 1-year period (468 patients; 321 with normal ECG, 192 of whom had TTE)	Single tertiary care hospital in Northeast	Charts reviewed for all patients admitted with syncope. Those with normal vs abnormal ECG were compared.	Arrhythmias Q waves Ischemic changes Second- or third-degree AV block Paced rhythm QTc >500 Left bundle branch block Bifascicular block Abnormal axis	TTE with abnormal findings EF <45% Severe PAH Moderate to severe regurgitation or stenosis Severe LVH Wall motion abnormalities HOCM with outflow obstruction Tamponade	8/192 patients with normal ECG and TTE done had a new abnormality (all were EF<45% and did not clearly explain syncope); 27/93 patients with abnormal ECG and TTE done had abnormality
Han[8]	2017	Retrospective Cohort	Adults presenting to ED for syncope over 1-year period (241 patients; 126 with none of predefined risk factors, 47 of whom had TTE)	Tertiary care ED in South Korea	Consecutive patients with syncope were evaluated for following risk factors: Prodromal chest pain or palpitations Prior cardiac history Abnormal CK-MB and/or BNP Abnormal ECG Outcomes were compared for those with vs without risk factors.	Sinus bradycardia Arrhythmias PAC or PVCs Second- or third-degree AV block LVH Q waves Ischemia related ST and T wave abnormalities QTc prolongation	TTE with abnormal findings: Moderate to severe regurgitation, stenosis, or diastolic dysfunction HOCM with outflow obstruction PAH Wall motion abnormalities	1/47 patients without risk factors had abnormal TTE; 27/97 patients with risk factors had abnormal TTE

[a]The studies by Anderson et al. and Chang et al. evaluated only for normal versus abnormal ECG.

NOTE: Abbreviations: AS, aortic stenosis; AV, atrioventricular; BNP, brain natriuretic peptide; CK-MB, creatine kinase-MB; CT, computed tomography; ECG, electrocardiogram; ED, emergency department; EF, ejection fraction; GI, gastrointestinal; HOCM, hypertrophic obstructive cardiomyopathy; LVH, left ventricular hypertrophy; PAC, premature atrial contraction; PAH, pulmonary arterial hypertension; PVC, premature ventricular contraction; ;QTc, corrected QT interval; SFSR, San Francisco Syncope Rule; TTE, transthoracic echocardiogram; VS, vital signs.

ventricular ectopy/arrhythmia, supraventricular arrhythmia, or Mobitz II or higher atrioventricular block. Of the 38 patients with a normal cardiac history, examination, and ECG who underwent echocardiogram, none had findings that explained syncope.

Mendu et al.[5] performed a single-center, retrospective study of the diagnostic yield of testing for syncope in 2106 consecutive patients older than 65 admitted over the course of 5 years. They retrospectively applied the San Francisco Syncope Rule (SFSR), which patients met if they had congestive heart failure, hematocrit <30%, abnormal ECG, shortness of breath, or systolic blood pressure <90 mm Hg. There were 821 patients (39%) who underwent echocardiogram. Among the 488 with no SFSR criteria, 10 patients (2%) had echocardiogram results that affected management, and 4 patients (1%) had results that helped determine the etiology of syncope.

Anderson et al. studied 323 syncope patients in a single ED observation unit over 18 months.[6] Patients with high-risk features, including unstable vital signs, abnormal cardiac biomarkers, or ischemic ECG changes, were excluded from the unit. The initial ECG was considered abnormal if it contained arrhythmia, premature atrial or ventricular contractions, pacing, second- or third-degree heart block, or left bundle branch block. Of the 235 patients with a normal ECG who underwent echocardiogram, none had an abnormal study.

Chang et al.[7] performed a retrospective review of 468 patients admitted with syncope at a single hospital. Charts were reviewed for ECG and echocardiogram results. Abnormal ECGs were defined as those containing arrhythmias, Q waves, ischemic changes, second- and third-degree heart block, paced rhythm, corrected QT interval (QTc) >500 ms, left bundle branch or bifasicular block, Brugada pattern, or abnormal axis. Among 321 patients with normal ECGs, echocardiograms were performed in 192. Eleven of those echocardiograms were abnormal: 3 demonstrated aortic stenosis in patients who already carried the diagnosis, and the other 8 abnormal echocardiograms revealed unexpected left ventricular ejection fractions <45% or other nonaortic valvular pathology. None of the findings were felt to be the cause of syncope.

Han et al.[8] performed a retrospective cohort study of all syncope patients presenting to a single ED over the course of 1 year. Patients were stratified as high risk if they had chest pain, palpitations, a history of cardiac disease (defined as prior arrhythmia, heart failure, coronary artery disease, or structural heart disease), abnormal cardiac biomarkers, or an abnormal ECG (defined as sinus bradycardia, arrhythmia, premature beats, second- or third-degree heart block, ventricular hypertrophy, ischemic Q or ST changes, or abnormal QT interval). Patients with none of those symptoms or findings were considered low risk. Of those categorized as

low risk (n = 115), 47 underwent echocardiogram, only 1 of which was abnormal.

Across studies, the percentage of patients with a normal cardiac history, examination, and ECG with new, significant abnormalities on echocardiogram was 0% in 3 studies (n = 340),[4,6,15] 2% in 1 study (10/488 patients),[5] 2.1% in 1 study (1/47 patients),[8] and 4.2% in 1 study (8/192 patients).[7] The 11 echocardiograms with significant findings in the studies by Mendu et al.[5] and Han et al.[8] were not further described. The 8 patients with abnormal echocardiograms reported by Chang et al.[7] had depressed left ventricular ejection fraction or nonaortic valvular disease that did not represent a definitive etiology of their syncope. Given the cost of $1,000 to $2,220 per study,[16] routine echocardiograms in patients with a normal history, examination, and ECG would thus require $60,000 to $132,000 in spending to find 1 new significant abnormality, which may be unrelated to the actual cause of syncope.

SITUATIONS IN WHICH ECHOCARDIOGRAM MAY BE HELPFUL

The diagnostic yield of echocardiogram is higher in patients with a positive cardiac history or abnormal ECG. In the prospective study by Sarasin et al.[15] a total of 27% of patients with a positive cardiac history or abnormal ECG were found to have an ejection fraction less than or equal to 40%. Other studies reporting percentages of abnormal echocardiograms in patients with abnormal history, ECG, or examination found rates of 8% (26/333),[5] 20% (7/35),[6] 28% (27/97),[8] and 29% (27/93).[7] It should be noted that not all of these abnormalities were felt to be the cause of syncope. For example, Sarasin et al.[15] reported that only half of the patients with newly identified depressed ejection fraction were diagnosed with arrhythmia-related syncope. Chang et al[7] reported that 6 of the 27 patients (22%) with abnormal ECG and echocardiogram had the cause of syncope established by echocardiogram.

Finally, some syncope patients will have cardiac biomarkers sent in the ED. Han et al.[8] found that among patients with syncope, those with abnormal versus normal echocardiogram were more likely to have elevated BNP (70% vs 23%) and troponin (36% vs 12.4%). Thus, obtaining an echocardiogram in patients with syncope and abnormal cardiac biomarkers may be reasonable. It should be noted, however, that while some studies have suggested a role for biomarkers in differentiating cardiac from noncardiac syncope,[17-20] current guidelines state that the usefulness of these tests is uncertain.[1]

WHAT YOU SHOULD DO INSTEAD OF ECHOCARDIOGRAM FOR ALL PATIENTS

Clinicians should carefully screen patients with syncope for abnormal findings suggesting cardiac disease on history, physical examination, and ECG. Relevant cardiac history includes known coronary artery disease, valvular heart disease, arrhythmia, congestive heart failure, and risk factors for cardiac syncope (supplemental Appendix). The definition of abnormal ECG varies among studies, but abnormalities that should prompt an echocardiogram include arrhythmia, premature atrial or ventricular contractions, second- or third-degree heart block, sinus bradycardia, bundle branch or fascicular blocks, left ventricular hypertrophy, ischemic ST or T wave changes, Q waves, or a prolonged QTc interval. New guidelines from the American College of Cardiology state, "Routine cardiac imaging is not useful in the evaluation of patients with syncope unless cardiac etiology is suspected on the basis of an initial evaluation, including history, physical examination, or ECG."[1]

RECOMMENDATIONS

- All patients with syncope should receive a complete history, physical examination, orthostatic vital signs, and ECG.
- Perform echocardiogram on patients with syncope and a history of cardiac disease, examination suggestive of structural heart disease or congestive heart failure, or abnormal ECG.
- Echocardiogram may be reasonable in patients with syncope and abnormal cardiac biomarkers.

CONCLUSIONS

While commonly performed as part of syncope evaluations, echocardiogram has a very low diagnostic yield in patients with a normal history, physical, and ECG. The patient described in the initial case scenario would have an extremely low likelihood of having important diagnostic information found on echocardiogram.

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

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A Strong Diagnosis of Weakness

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. Similar 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 man presented with bilateral weakness in all extremities. He noted the gradual onset of progressive muscle weakness 6 months prior to presentation. He reported generalized fatigue and difficulty with climbing stairs and carrying heavy objects.

Initial considerations of chronic weakness and fatigue are myopathy, polyneuropathy, medications, malignancy, endocrinopathies, human immunodeficiency virus (HIV), neuromuscular junction dysfunction, and central nervous system (CNS) disorders, such as amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS). Symmetrical muscle involvement and proximal weakness make myopathy most likely. Polyneuropathy, such as chronic inflammatory demyelinating polyneuropathy (CIDP), is less likely but still possible given the slowly progressive course. The use of medications that can cause myopathy should be explored, including colchicine, steroids, and statins. Gathering further history should focus on risk factors for HIV, as well as alcohol and illicit drug use. Malignancy can cause paraneoplastic myopathy. The review of systems should include symptoms of endocrinopathies, such as thyrotoxicosis and hypothyroidism. Fluctuations in weakness and dysphagia or ocular symptoms would suggest myasthenia gravis (MG). The time course and symmetrical weakness make a central disorder, such as ALS or MS, unlikely.

His past medical history was notable for pulmonary tuberculosis diagnosed at the age of 6 years, which was treated with hospitalization and an unknown medication regimen. He was not taking medications prior to this admission. His family history was significant for diabetes mellitus in both parents. He denied sick contacts. He was sexually active with his wife. He denied the use of tobacco and illicit drugs but endorsed alcohol consumption on a daily basis over the last 32 years. He reported no fluctuation in his symptoms, muscle or joint pains, rash, fevers, chills, diaphoresis, chest pain, dyspnea, abdominal pain, diarrhea, paresthesias, weight loss, or night sweats. He had never had a colonoscopy.

Painless progressive weakness of the limbs without sensory deficit is typical of a myopathy. Though CIDP can present with only motor weakness, the majority of patients have sensory symptoms, making this less likely. Although chronic alcohol abuse can cause myopathy, it seems less likely because other neurologic complications, such as sensory polyneuropathy or ataxia, would be expected. A review of systems does not suggest a thyroid disorder or malignancy, although this does not preclude an evaluation for both. The absence of fluctuations in weakness argues against MG. Though ALS, MG, MS, and CIDP are less likely, a neurologic exam is crucial in excluding them. The hallmark of ALS is upper motor neuron (UMN) and lower motor neuron signs in the absence of sensory symptoms and signs, while global hyporeflexia would be expected in CIDP, and fatigability on repeated power testing would be expected in MG. Neurologic findings disseminated in space (neuro-anatomically) would be expected in MS.

On physical examination, the patient had a temperature of 36.9°C, heart rate of 70 beats per minute, and regular respiratory rate of 10 breaths per minute, blood pressure 130/80 mmHg, and oxygen saturation 98% while breathing ambient air. Auscultation of the heart and lungs revealed normal findings. The abdomen was soft, nontender, and without masses or organomegaly. Neurologic examination disclosed bilateral symmetric upper and lower extremity weakness with positive Gower sign. Muscle strength scores of the bilateral biceps brachii, iliopsoas,

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and digitis extensor were between 4 and 5 without fatigability. Grasping power was impaired. Deep tendon reflexes were preserved, and there were no UMN signs. There was no tenderness to palpation in any muscle groups. Sensory testing was normal. Skin and lymph examinations were without abnormality. The rest of the physical examination was unremarkable.

Gower sign, characteristic of but not specific to muscular dystrophy, indicates proximal muscle weakness of lower extremities, wherein hands and arms are used to walk up the body into an upright position. The exam also reveals distal weakness as shown by reduced hand grasp. Symmetrical proximal weakness of all extremities without sensory deficits suggests a myopathic process, albeit one with some distal involvement. The absence of UMN signs argues against ALS, lack of fatigability argues against MG, and the absence of CNS or sensory deficits argues against MS.

Because myopathy is most likely, the next step would be to determine if this is an idiopathic inflammatory myopathy, such as polymyositis (PM) or dermatomyositis (DM), secondary inflammatory myopathy, or noninflammatory myopathy due to endocrinopathies. The time course is consistent with an inflammatory myopathy, such as PM or DM. Inclusion body myositis (IBM), another inflammatory myopathy, presents much more insidiously over years and tends to be asymmetric compared to PM. The absence of myalgia, arthralgia, rash, and gastrointestinal symptoms makes myopathy as a component of a connective tissue disease, such as systemic lupus erythematosus, or a mixed connective tissue disease unlikely. The next steps would be laboratory testing of muscle enzymes, complete blood count, biochemical profile, and antinuclear antibody (ANA).

Laboratory studies revealed a white blood cell count of 4460/mm^3 with normal differential, hemoglobin 12.5 g/dL, and platelet count 345,000/mm^3. Creatinine was 0.87 mg/dL, aspartate aminotransferase 61 IU/mL, alanine aminotransferase 45 IU/mL, and creatine kinase (CK) 529 U/L (normal range, 38-174 U/L). Other liver function enzymes were normal. Biochemistry studies disclosed normal sodium, potassium, glucose, calcium, and magnesium levels. Dipstick urinalysis revealed blood and protein, and the microscopic examination of urinary sediment was unremarkable without the presence of erythrocytes. Twenty-four-hour creatinine clearance was 106 mL/min (normal range, 97-137 mL/min). Chest radiography was unrevealing.

The modest increase in CK, evidence of myoglobinuria, and proteinuria can all occur with an inflammatory or metabolic myopathy. The combination of proximal and distal weakness, coupled with only a modestly elevated CK, makes IBM more likely than PM, as PM usually presents with proximal weakness and much higher CK values. Normal skin examination makes DM less likely, as skin manifestations are generally found at time of presentation. The onset of symptoms after age 50 and the patient being male also favor IBM, though a longer time course would be expected. Definitively distinguishing IBM from PM is important because treatment and prognosis differ.

Thyroid function and HIV testing should be obtained. ANA, more common in PM than in IBM, should be checked because these myopathies can be associated with other autoimmune diseases. Imaging is generally not essential, although magnetic resonance imaging (MRI) of the thighs may help to differentiate IBM from PM. Electromyography (EMG) should be done to determine the pattern of myopathy and select muscle biopsy sites.

Additional testing revealed a normal thyroid stimulating hormone level. HIV and ANA were negative. Serum aldolase level was 19 IU/L (normal range, 2.7-5.9 IU/L), myoglobin 277 ng/mL (normal range, 28-72 ng/mL), lactate dehydrogenase 416 IU/mL (normal range, 119-229 IU/mL), and C-reactive protein 0.32 mg/dL. An EMG revealed mild myogenic changes in all extremities. An MRI of the left brachial muscle revealed multiple scattered high-signal lesions.

The EMG and MRI findings are consistent with an inflammatory myopathy. The modest elevation in muscle enzymes and negative ANA are more consistent with IBM since most patients with PM or DM are ANA positive. Muscle biopsy can be very helpful in establishing the etiology of myopathy.

Given the concern for possible PM or DM, further imaging was obtained to assess for malignancy. Fluorodeoxyglucose (FDG) positron emission tomography (PET) and computerized axial tomography (CT) revealed multiple areas of linear uptake of FDG diffusely distributed along the bundles of systemic skeletal striated muscles (Figure 1). Gallium scintigraphy demonstrated intense up-

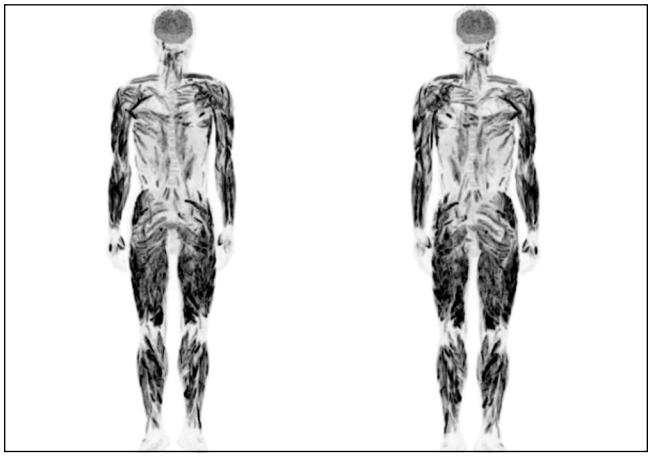

FIG 1. F-18 fluorodeoxyglucose positron emission tomography (FDG PET)/computed tomography (CT) findings of the presented case. FDG PET/CT revealed multiple areas of linear uptake of FDG diffusely distributed along the bundles of systemic skeletal striated muscles.

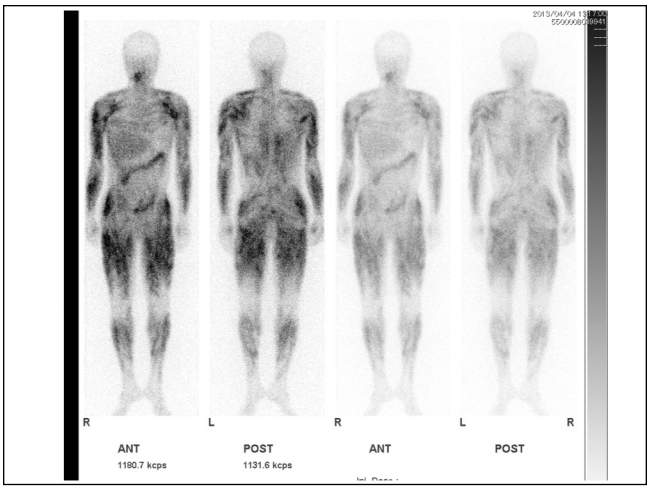

FIG 2. 67 Gallium (Ga)-scintigraphy of the presented case. Ga-scintigraphy demonstrated intense uptake within the systemic skeletal striated muscles of all 4 extremities.

take within the systemic skeletal striated muscles of all 4 extremities (Figure 2). There was no imaging evidence of malignancy.

Malignancy is associated with DM and PM in about 9% and 4% of patients, respectively. The common cancers associated with these conditions are adenocarcinomas of the ovary, cervix, lung, pancreas, and stomach. Most cancers are diagnosed around the time of myositis diagnosis, although they can precede or follow by years. Idiopathic IBM is not associated with cancer.

In idiopathic inflammatory myopathy, screening for cancer should consist of appropriate laboratory studies, chest radiography, and age-, sex-, and symptom-driven testing. FDG PET/CT is the most sensitive test for detecting occult cancer. The gallium scan positivity, though not specific, suggests possible sarcoid myopathy. Asymptomatic muscle involvement can be found histologically in up to 70% of patients with sarcoidosis, but symptomatic myopathy is uncommon. This patient has neither muscle pain nor evidence of thoracic sarcoidosis. Myopathy as an initial presentation of sarcoidosis is rare. Gallium scanning should be reserved for patients in whom muscle biopsy or other signs and symptoms suggest sarcoidosis.

Open surgical muscle biopsy of the left biceps brachii was performed. Light microscopic examination disclosed interstitial edema and noncaseating granulomas. Immunostaining revealed an increase in the number of cluster of differentiation (CD) 4+ T cells. Caseating granulomas and Langhans giant cells were not present (Figure 3).

The biopsy shows granulomatous myopathy (GM), suggestive of but not pathognomonic for sarcoid myopathy. GM can be found in other causes of inflammatory myopathies, including vasculitides, PM, DM, tuberculosis, inflammatory bowel disease, lymphoma, and MG. This patient has no symptoms, signs, laboratory, or radiologic evidence of any of the above conditions. Remaining possibilities include sarcoid chronic myopathy and idiopathic granulomatous myositis, but it is crucial to exclude all other etiologies. Serum antineutrophil cytoplasmic antibody (ANCA) should be checked, and biopsy specimens should be stained for acid-fast bacilli (AFB) and fungal elements. The gallium scan should be reviewed for salivary and lacrimal gland uptake (panda sign), which would be suggestive of sarcoidosis.

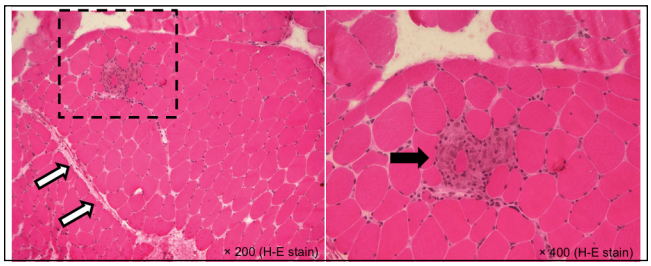

FIG 3. Findings from an open surgical muscle biopsy of the left biceps brachii. Light microscopic examination disclosed interstitial edema (white arrows) and noncaseating granulomas (black arrow). Caseating granulomas and Langhans giant cells were not present.

Tuberculin reaction and interferon-γ-release assay were negative. Staining for AFB and fungi was negative. ANCA, rheumatoid factor (RF), anti-Ro/SSA, anti-La/SSB, anti-Sm, anti-RNP, and anti-Jo-1 were all negative or unremarkable. Serum angiotensin converting enzyme (ACE) level was 155.6 U/L (normal range, 7-25 U/L). Twenty-four-hour urine analysis revealed calcium excretion of 517.7 mg/day (normal range, 58-450 mg/day), β2-microglobulin 69,627 ug/day (normal range, <254 ug/day), and N-acetyl-D-glucosamine 95.3 U/day (normal range, <5.1 U/day) with a normal creatinine clearance. Serum intact parathyroid hormone level (PTH) was 5 pg/mL (normal range, 10-65 pg/mL), and 25-hydroxyvitamin D level was 51.1 ng/mL (normal range, 30-80 ng/mL). A CT of the thorax revealed a small ground-glass density lesion in the left lower lobe but no hilar or mediastinal lymphadenopathy.

Negative ANCA, RF, and autoantibodies exclude systemic vasculitis and connective tissue disease as causes of GM. Hypercalciuria is suggestive of granulomatous production of calcitriol, which, in turn, suppresses PTH. Hypercalcemia is not common in patients with sarcoidosis, but hypercalciuria occurs frequently. Serum ACE is a marker associated with sarcoidosis, but its diagnostic and prognostic utility is unclear.

Though there is a concern for sarcoidosis, this diagnosis can only be confidently made by finding noncaseating granulomas on a background of compatible clinical and radiologic findings after alternate possible etiologies are excluded. The chest CT reveals a small ground-glass density lesion without hilar adenopathy. These findings, though not incompatible,

are not typical for pulmonary sarcoidosis. Therefore, finding noncaeseating granulomas in a second organ system would point toward systemic sarcoidosis as a unifying diagnosis. Bronchoscopy with bronchoalveolar lavage (BAL) and transbronchial biopsy has a reasonable yield even in the absence of hilar adenopathy or typical parenchymal findings. A CD4/CD8 T-cell ratio of 2 or more on BAL provides supportive evidence for sarcoidosis.

It is reasonable to start empiric glucocorticoids for GM given that the AFB and fungal stains on histopathology are negative and that there is no evidence of lymphoma.

The patient underwent a bronchoscopy with BAL fluid, demonstrating 76% macrophages, 23.5% lymphocytes, and a CD4/CD8 T-cell ratio of 3.7. Culture of this fluid was negative for infection. The patient was diagnosed with sarcoidosis with the extrapulmonary manifestation of sarcoid myopathy. He underwent treatment with 1 mg/kg of prednisolone daily, which resulted in rapid decreases in serum CK and ACE levels as well as urine calcium excretion. He noted gradual improvement in his weakness over the ensuing 3 months. Also noted was the complete resolution of the uptake in systemic skeletal muscles on gallium scintigraphy (Figure 4). Eighteen months later, the patient is taking 7 mg of prednisolone daily and continues to be free of weakness.

The CD4/CD8 T-cell ratio greater than 2, combined with the absence of neutrophils and eosinophils on BAL, is helpful in distinguishing sarcoidosis from other pulmonary diseases. This patient's inflammatory myopathy was revealed to be a rare initial manifestation of systemic sarcoidosis.

DISCUSSION

Weakness is a common symptom of muscle disorders such as myopathies and muscular dystrophy. Idiopathic inflammatory myopathies include PM, DM, and others.[1,2] These usually present with proximal-dominant muscle weakness, decreased endurance, and muscle inflammation. A diagnosis is made according to symptoms in combination with diagnostic examinations, including elevated serum CK levels, abnormal EMG findings, and histopathology of skeletal muscle biopsy specimens.

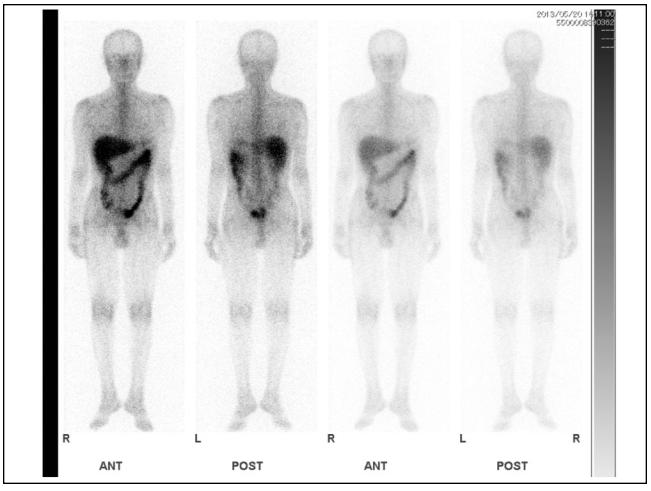

FIG 4. Ga-scintigraphy after the initiation of glucocorticoid therapy in the presented case. Complete resolution of the uptake in systemic skeletal muscles on Ga-scintigraphy was observed after the initiation of glucocorticoid.

Sarcoidosis, a multisystem disorder of unknown etiology, is characterized histopathologically by noncaseating granulomas in affected organs.[3] It typically affects young adults, with incidence peaking at 20 to 39 years of age. Although any organ may be involved, the disorder usually presents with 1 or more common abnormalities, including bilateral hilar lymphadenopathy, lung lesions, and skin and eye involvement. Musculoskeletal involvement is less common. It is estimated that skeletal muscle is involved in 50% to 80% of patients with sarcoidosis but is rarely symptomatic (0.5% to 2.5%).[4-6]

In this patient, weakness was distributed in both proximal and distal muscles, yet proximal weakness is the most characteristic feature in PM and DM. Therefore, sarcoidosis should be considered in the differential diagnosis of idiopathic inflammatory myopathies, especially when weakness accompanies abnormalities in other organs typically affected by sarcoidosis.

Myoglobinuria often is observed in rhabdomyolysis and inflammatory myopathies, conditions that produce high levels of serum CK and myoglobin. Myoglobinuria, often accompanied by the elevation of urinary β2-microglobulin and N-acetyl-D-glucosamine levels, can induce tubulointerstitial damage, which leads to acute kidney injury. In this case, however, these abnormal kidney findings were observed without high levels of serum CK or myoglobin. This suggests the potential for other causes of tubulointerstitial damage, such as granulomatous interstitial nephritis in renal sarcoidosis.[3]

Another characteristic abnormality was the elevation of urinary calcium excretion, which indicated an underlying granulomatous disorder, such as mycobacterial infection, granulomatosis with polyangiitis, or sarcoidosis. In sarcoidosis, hypercalciuria occurs in 40% of patients, hypercalcemia in 11%, and renal calculi in 10%.[3,7] Hypercalciuria, for this patient, was important in arriving at the correct diagnosis after the gallium scan was obtained given the dearth of other typical features of sarcoidosis.

Although muscle biopsy is essential, imaging studies for idiopathic inflammatory myopathy are considered useful tools to narrow the differential diagnosis. The use of MRI of the skeletal muscle is helpful to both identify an adequate muscle for biopsy and demonstrate the pattern of affected muscles beyond clinical appearance, which aids in excluding, for example, muscular dystrophies.[8,9]

FDG PET/CT is a very sensitive imaging modality used to detect neoplastic lesions and has been widely used to screen for occult neoplasms and detect metastases.[10-12] It is also useful for detecting inflammation in patients with osteomyelitis, metastatic infectious diseases, rheumatoid arthritis, vasculitis, inflammatory bowel diseases, fever of unknown origin,

and sarcoidosis.[11,12] In PM and DM, however, the sensitivity of FDG PET/CT for detection of myositis is reportedly lower than that of EMG and MRI.[13] Similarly, gallium scintigraphy is usually performed to examine the disease activity of interstitial pneumonia or to detect malignancy. Previous literature and this case show that the striking images of gallium scintigraphy and FDG PET/CT have utility, not only for detection of sarcoid myopathy but also for the evaluation of treatment efficacy.[14-17] Characteristic imaging findings on FDG PET/CT have been described as a "tiger man" appearance.[17]

For the treatment of sarcoid myopathy, systemic glucocorticoids are used for patients with symptomatic acute or chronic forms. The standard doses of prednisolone used for other forms of idiopathic inflammatory myopathies are usually administered.[3-6] In general, the response of acute sarcoid myopathy to glucocorticoid therapy is favorable, and the clinical course is usually benign. However, the course in chronic sarcoid myopathy can be unpredictable with exacerbations. Given the lack of randomized trials of this therapy and because glucocorticoids themselves can cause steroid-induced myopathy, they are not used for asymptomatic patients.

In the end, astute clinical thinking, deductive reasoning, and pattern recognition were all instrumental in making this strong diagnosis of weakness.

KEY TEACHING POINTS

- Proximal muscle–dominant weakness is the characteristic feature in inflammatory myopathies like PM and DM. Myopathy causing proximal and distal weakness is more characteristic of sarcoidosis, IBM, alcohol, and statins.
- Elevations of urinary β2-microglobulin and N-acetyl-D-glucosamine are often observed in inflammatory muscle diseases because of myoglobin-induced tubulointerstitial damage. These findings may also be caused by other conditions that affect the tubules, such as lupus nephritis, Sjogren's syndrome, or renal sarcoidosis.
- Hypercalciuria in a patient with myopathy could suggest an underlying granulomatous disorder, such as mycobacterial infection, granulomatosis with polyangiitis, or sarcoidosis.
- The striking uptake within systemic skeletal striated muscles on gallium scintigraphy and "tiger man" appearance on FDG PET/CT are characteristic features of acute sarcoid myopathy; these are not common in other inflammatory myopathies.

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Inpatient Management of Diabetic Foot Infections: A Review of the Guidelines for Hospitalists

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Diabetic foot infections (DFIs) are common and represent the leading cause for hospitalization among diabetic complications. Without proper management, DFIs may lead to amputation, which is associated with a decreased quality of life and increased mortality. However, there is currently significant variation in the management of DFIs, and many providers fail to perform critical prevention and assessment measures. In this review, we will provide an overview of the diagnosis, management, and discharge planning of hospitalized patients with DFIs to guide hospitalists in the optimal inpatient care of patients with this condition. *Journal of Hospital Medicine* 2017;12:994-1000. Published online first September 20, 2017.

Diabetic foot infection (DFI) is a common result of diabetes and represents the most frequent complication requiring hospitalization and lower extremity amputation.[1,2] Hospital discharges related to diabetic lower extremity ulcers increased from 72,000 in 1988 to 113,000 in 2007,[3] and admissions related to infection rose 30% between 2005 and 2010.[2] Ulceration and amputation are associated with a 40% to 50% 5-year mortality rate.[4,5]

Aggressive risk-factor management and interprofessional care can significantly reduce major amputations and mortality.[6-13] Consistent and high-quality care for patients admitted with DFI is essential for optimizing outcomes; however, management varies widely, and critical assessment and prevention measures are often not employed by providers.[14] This review synthesizes recommendations from existing guidelines to provide an overview of the best practices for the diagnosis, management, and discharge of DFI in the hospital setting (Supplementary Table 1, Supplementary Figure).

DETECTION AND STAGING OF INFECTION

The first step in the management of a DFI is a careful assessment of the presence and depth of infection.[15] The Infectious Diseases Society of America (IDSA) guidelines recommend using at least 2 signs of classic inflammation (erythema, warmth, swelling, tenderness, or pain) or purulent drainage to diagnose soft tissue infection.[1,15,16] Patients with ischemia may present atypically, with nonpurulent secretions, friable or discolored granulation tissue, undermining of wound edges, and foul odor.[1,15,16] Additional risk factors for DFI include ulceration for more than 30 days, recurrent foot ulcers, a traumatic foot wound, severe peripheral arterial disease (PAD) in the affected limb (ankle brachial index [ABI] <0.4), prior lower extremity amputation, loss of protective sensation, end-stage renal disease, and a history of walking barefoot.[15,17,18]

Appropriate classification of wound severity is critical in determining the need for hospitalization, antibiotic selection, surgical intervention, and prognosis. Multiple staging systems that incorporate physical examination findings, markers of systemic inflammation, and ischemia[15,19,20] have been proposed. The Perfusion, Extent, Depth, Infection, and Sensation (PEDIS) grade was developed as a research tool and incorporates infection, ischemia, neuropathy, wound size, and systemic inflammation.[15] The International Working Group on the Diabetic Foot (IWGDF) and the IDSA recommend use of the full or simplified PEDIS score in clinical practice (the IWGDF/IDSA Classification, Table 1) because these classifications predicted hospitalization and lower extremity amputation in prospective studies, with amputation rates of 3% for uninfected ulcers and up to 70% for severe infection.[1,15] Patients with PEDIS grade 4 infections also have an increased mean length of stay compared with patients with grade 3 infections.[21,22]

CRITERIA FOR HOSPITALIZATION

In practice, the decision to admit is based on clinical and systems-based drivers (Supplementary Table 2). The IDSA and IWGDF guidelines recommend hospitalization for patients with severe (PEDIS grade 4) infection, moderate (PEDIS grade 3) infection with certain complications (eg, severe PAD or lack of home support), an inability to comply with required outpatient treatment, lack of improvement with outpatient therapy, or presence of metabolic or hemodynamic instability.[1,15] Clinicians must also consider the

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TABLE 1. Infectious Disease Society of America and International Working Group on the Diabetic Foot Classifications of Diabetic Foot Infection, Reproduced with Permission[a]

Clinical Manifestation of Infection	PEDIS Grade	IDSA Infection Severity
No symptoms or signs of infection	1	Uninfected
Infection present, as defined by the presence of at least 2 of the following items: Local swelling or induration Erythema Local tenderness or pain Local warmth Purulent discharge (thick, opaque to white or sanguineous secretion). Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). If erythema, must be >0.5 cm to ≤2 cm around the ulcer. Excludes other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis).	2	Mild
Local infection (as described above) with erythema >2 cm or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), and no systemic inflammatory response signs (as described below).	3	Moderate
Local infection (as described above) with the signs of SIRS, as manifested by ≥2 of the following: Temperature >38°C or <36°C Heart rate >90 beats per min Respiratory rate >20 breaths per min or PaCO2 < 32 mm Hg White blood cell count >12,000 or <4000 cells per μL or ≥10% immature (band) forms	4	Severe

[a]The presence of ischemia may increase the severity of infection, and additional vascular assessment and staging is needed for a full assessment of infection severity.

NOTE: Abbreviations: IDSA, Infectious Disease Society of America; PEDIS, Perfusion, Extent, Depth, Infection, and Sensation; SIRS, systemic inflammatory response syndrome.

need for surgical debridement or complex antibiotic choices due to allergies and comorbidities. Hospitalists may also consider admission in cases in which outpatient follow-up cannot be easily arranged (eg, uninsured patients).

Outpatient management may be appropriate for patients with mild infections who are willing to be reassessed within 72 hours, or sooner if the infection worsens.[23] For patients with moderate infections (eg, osteomyelitis without systemic signs of infection), access to an outpatient interprofessional DFI care team can potentially decrease the need for admission.

DIAGNOSIS OF OSTEOMYELITIS

Clinical features that raise suspicion for osteomyelitis include ulceration for at least 6 weeks with appropriate wound care and offloading, wound extension to the bone or joint, exposed bone, ulcers larger than 2 cm^2, previous history of a wound, multiple wounds, and appearance of a sausage digit.[15]

The gold standard for diagnosis of osteomyelitis is a bone biopsy with histology. In the absence of histology, physicians rely on physical examination, inflammatory markers, and imaging to make the diagnosis. The presence of visible, chronically exposed bone within a forefoot ulcer is diagnostic. The accuracy of a probe to bone test depends on the pretest probability of osteomyelitis. Sensitivity and specificity range from 60% to 87% and from 85% to 91%, respectively.[24] For patients with a single forefoot ulcer and PEDIS grade 2 or 3 infection, considering both ulcer depth and serum inflammatory markers (ulcer depth greater than 3 mm, or C-reactive protein greater than 3.2 mg/dL; ulcer depth greater than 3 mm, or erythrocyte sedimentation rate greater than 60 mm/h) increases sensitivity to 100%, although the specificity is relatively low (55% and 60%, respectively).[25] When the diagnosis remains uncertain by physical examination, imaging is necessary for further evaluation.

ROLE OF IMAGING

All patients with DFI should have plain radiographs to look for foot deformities, soft tissue gas, foreign bodies, and osteomyelitis. If plain radiographs show classic evidence of osteomyelitis, (ie, cortical erosion, periosteal reaction, mixed lucency, and sclerosis in the absence of neuro-osteoarthropathy), advanced imaging is not necessary. However, these changes may not appear on plain films for up to 1 month after infection onset.[15,26]

The purpose of advanced imaging in the inpatient management of DFI is to detect conditions not obvious by physical examination or by plain radiographs that would alter surgical management (ie, deep abscess or necrotic bone) or antibiotic duration (ie, osteomyelitis or tenosynovitis).[15] Magnetic resonance imaging (MRI) is the diagnostic modality of choice when the wound does not probe to bone and the diagnosis remains uncertain[27] due to its accuracy and availability.[1,15] However, MRI cannot always distinguish between infection and neuro-osteoarthropathy, especially in patients who have infection superimposed on a Charcot foot, have had recent surgical intervention, or have osteosynthesis material at the infection site.[24] If MRI is contraindicated, guidelines vary on the next recommended test. The IDSA and the Society for Vascular Surgery recommend a labeled white blood cell scan combined with a bone scan, whereas the IWGDF recommends a labeled leukocyte scan, a single photon emission computed tomography (SPECT/CT), or a fluorodeoxyglucose positron emission tomogra-

phy (FDG PET) scan.[1,15,19] A recent comparison of a labeled white blood cell SPECT/CT versus MRI (using histology as the gold standard) reported that SPECT/CT had a similar sensitivity (89% versus 87%, respectively) and specificity (35% versus 37%, respectively) to MRI.[28] In practice, physicians should consider which studies are readily available and confidently interpreted by radiologists at their institution.

ASSESSMENT OF ULCER ETIOLOGY

After infection is diagnosed and staged, clinicians should determine the underlying derangement in order to prevent recurrence after discharge. Common derangements leading to ulceration in diabetics include PAD, neuropathy, muscular tension, altered foot mechanics, trauma, or a combination of the above.[1,15,29-31] All patients with DFI should undergo pedal perfusion assessment by an ABI, ankle and pedal Doppler arterial waveforms, and either toe brachial index (TBI) or transcutaneous oxygen pressure.[1,15,19] In cases of suspected calcification, TBI is a more reliable measure of ischemia compared with the ABI.[16,19] For patients with signs and symptoms of ischemia and an abnormal ABI or TBI measurement (ABI <0.9 and TBI <0.7), a nonurgent consultation with a vascular surgeon is recommended, while patients with severe ischemia (ABI <0.4) usually require urgent revascularization.[15,32]

A sensory examination with a Semmes-Weinstein monofilament should be conducted to identify patients with loss of protective sensation who may benefit from offloading devices and custom orthotics.[15] Foot anatomy and mechanics as well as potential Achilles tendon contractures should be evaluated by a foot specialist such as a podiatrist, orthotist, orthopedist, or vascular surgeon, especially if debridement or amputation is being contemplated.

OBTAINING CULTURES

After diagnosing the infection clinically, appropriately obtained cultures are essential to guide therapy in all except mild cases with no prior antibiotic exposure or MRSA risk.[1,15] Guidelines strongly recommend that specimens be obtained by biopsy or curettage from deep tissue at the base of the ulcer after the wound has been cleansed and debrided and prior to initiating antibiotics.[1,15,33] Aspiration of purulent secretions using a sterile needle and syringe is another acceptable culturing method.[15] While convenient, swab cultures are prone to both false-positive and false-negative results.[34] Repeat cultures are only needed for patients who are not responding to treatment or for surveillance of resistant organisms.[1]

In cases of osteomyelitis, bone specimens should be sent for culture and histology either during surgical debridement or a bone biopsy. At the time of debridement, cultures and pathology should be sent from the proximal (clean) bone margin in order to document whether there is residual osteomyelitis postdebridement.[35] For patients not planned for debridement, a bone biopsy is recommended if the diagnosis of osteomyelitis is unclear, response to empiric therapy is poor, broad-spectrum antibiotics are being considered, or the infection is in the midfoot or hindfoot.[1,15,19] Results from soft tissue or sinus tract specimens should not be used to guide antibiotic selection in osteomyelitis, as several studies suggest that they do not correlate with bone culture results; one retrospective review found a mere 22.5% correlation between wound swabs and bone biopsy.[1,36] A 2-week antibiotic-free period prior to biopsy is recommended in order to minimize the risk of false-negative results but must be balanced with the risk of worsening infection.[1,15] If possible, the biopsy should be performed through uninfected tissue under fluoroscopy or CT guidance, with 2 to 3 cores obtained for culture and histology.[1,15]

INTERPROFESSIONAL INPATIENT CARE

A growing number of health systems have created inpatient and/or outpatient interprofessional diabetic foot care teams, and several studies demonstrated an association between these teams and a reduction in major amputations.[7-11,13] The goal of the inpatient team is to rapidly triage patients with moderate to severe infections, expedite surgical interventions and culture collection, establish an effective treatment plan, and ensure adherence postdischarge to optimize outcomes. The common core of most teams includes podiatry, endocrinology, wound care, and vascular surgery, but team composition may vary based on the availability of local specialists with interest and expertise in DFI.[9,10,33]

The division of consultation between podiatry and orthopedic surgery is highly dependent upon individual practice patterns and hospital structure. In general, forefoot ulcers may be managed by podiatry or orthopedic surgery, while severe Charcot deformities are most often treated by orthopedic surgeons. Wound care nurses are often integral to successful wound healing, collaborating across specialties and serving as a weekly or biweekly point of contact for patients.

Early involvement of Infectious Disease (ID) specialists can be useful for guiding antibiotic choices and facilitating follow-up. ID should be involved with patients who require long-term antibiotic therapy (ie, cases of deep-tissue infection that are not completely amputated or debrided), have failed outpatient or empiric therapy, have antibiotic allergies or drug-resistant pathogens, or are being considered for outpatient parenteral antibiotic therapy.

ANTIBIOTIC THERAPY

Empiric antibiotic therapy should be based on infection severity and the likely causative agent (Figure). Mild cases are managed with oral agents that target *Staphylococcus aureus* and *Streptococcus* species such as cephalexin or clindamycin.[1,15] Antibiotics for moderate (PEDIS grade 3) infections can be oral or parenteral (eg, ampicillin-sulbactam or ertapenem) and should include coverage for the above pathogens in addition to *Enterobacteriaciae* and anaerobes.[1,15] Empiric anti-MRSA coverage is optional in mild to moderate infections and should be reserved for patients with known risk factors, such as prior colonization, recent hospitalization,

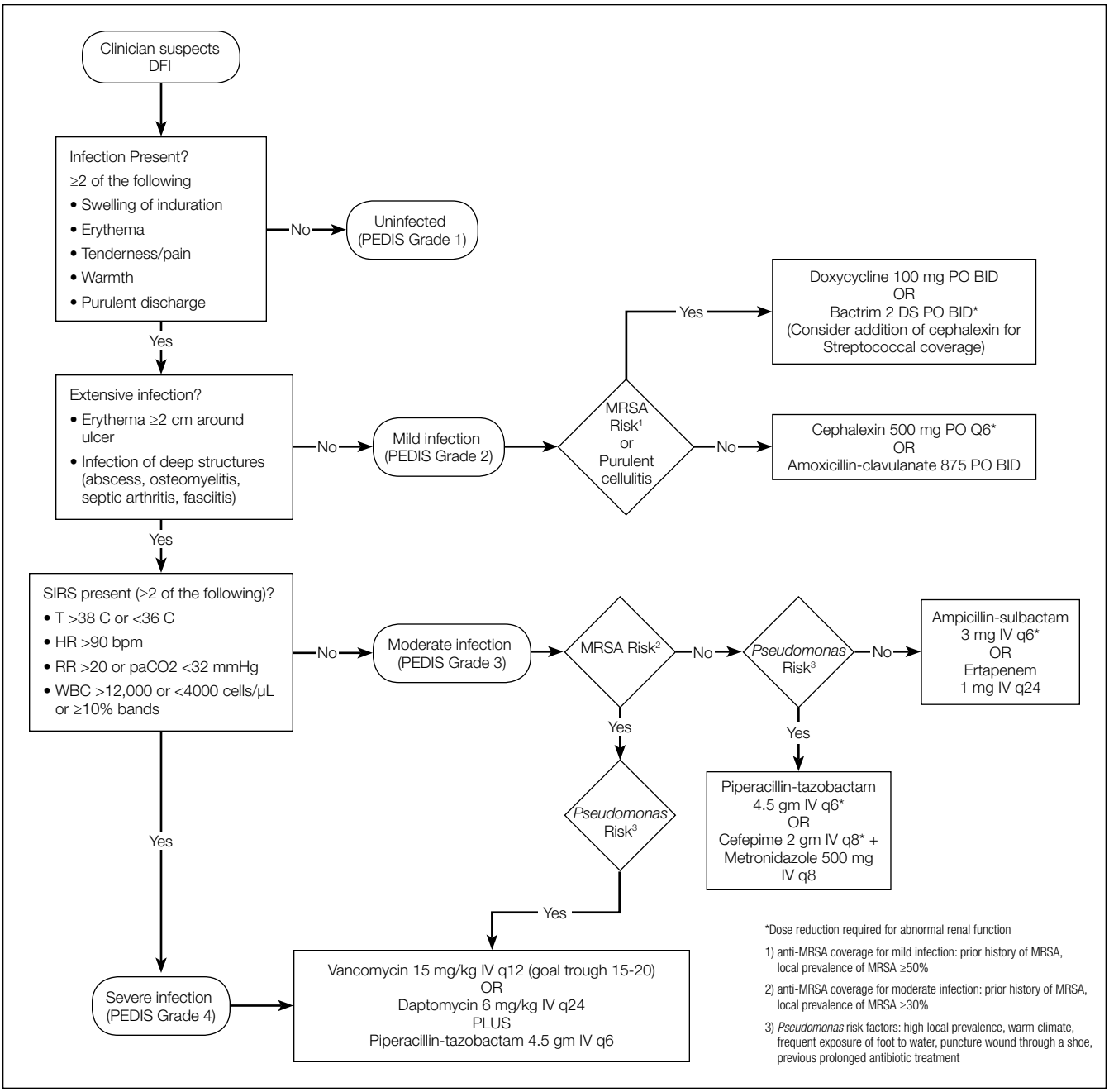

FIG. Algorithm overview of classification and initial treatment of diabetic foot infections.

residence in a chronic care facility, previous amputation, or a high local prevalence of MRSA (50% MRSA prevalence for mild infections or 30% prevalence for moderate infections). [1,15] Fluoroquinolones are no longer effective against *S. aureus* in most of the United States and should not be used as monotherapy if MRSA is suspected.[37,38] A recent retrospective observational study found that ceftaroline fosamil treatment of DFI was associated with an 81% success rate, including for patients with comorbidities, MRSA, mixed infections, or surgical intervention, but it has not yet been studied in a comparative trial.[39] Antipseudomonal therapy is not necessary in most moderate cases and should be reserved for patients who have severe infections (PEDIS grade 4) or specific risk-factors for *Pseudomonas*.[1,15] Severe infections, gangrenous wounds, or necrotizing infections require parenteral agents to cover MRSA (ie, vancomycin or daptomycin), *Pseudomonas* (ie, cefepime or piperacillin-tazobactam), and anaerobes. [1,15] Anaerobic coverage must be added to cefepime but is not necessary with piperacillin-tazobactam or meropenem.[40] Definitive therapy should be based on culture results, sensitivity testing, and the patient's clinical response to the empiric regimen.[15]

The duration of antibiotic treatment for DFI is based on the severity of infection and response to treatment (Supplemen-

TABLE 2. Medical Versus Surgical Considerations for Diabetic Foot Infections

Factors Favoring Medical Therapy	Factors Favoring Surgical Intervention
Patient Factors	
Medically unstable for surgery	High risk for antibiotic-adverse event
No contraindications to prolonged antibiotics (ie, recurrent *Clostridium difficile*)	Intolerance to antibiotics
Strong preference to avoid surgery	Preference to avoid long-term antibiotics
Good foot perfusion	Poor foot perfusion and penetration of antibiotics
Ambulatory patient	Already nonambulatory patient
	Indwelling prosthesis vulnerable to metastatic infection (ie, heart valve)
Severity of Infection	
Sepsis and soft tissue infection controlled with antibiotics	Persistent sepsis or spreading infection despite antibiotics
	Soft tissue abscess
	Compartment syndrome
	Necrotizing infection
	Pathogen resistant to available antibiotics
Tissue Quality	
Minimal tissue destruction, good chance of functional foot with antibiotics alone	Extensive bone or soft tissue necrosis
	Exposed or infected joint
	Nonsalvageable foot
	Visible, chronically exposed trabecular bone in forefoot ulcer

tary Table 3). Treatment should continue until the signs and symptoms of infection resolve, but there is no strong evidence to support treatment through complete healing. Healing will usually occur in 1 to 2 weeks for mild infections and in 2 to 3 weeks for moderate or severe infections. However, prescribing antibiotics for a fixed duration is not recommended and can result in an inadequate or unnecessarily prolonged course, with the potential for increased costs, adverse events, and antibiotic resistance.[1,15,16] Therapy may be shortened by debridement, resection, or amputation, or lengthened in patients who are immunocompromised; have deep, large, necrotic, or poorly perfused wounds; do not undergo resection; or have an implanted foreign body at the infection site.[1] If the patient does not improve despite targeted antibiotic treatment, providers should assess the need to revascularize, repeat debridement for new cultures, resect any progression of infection, or modify the antibiotic regimen to maximize tissue penetration and minimize drug interactions.[1]

Traditional management of diabetic foot osteomyelitis has relied almost exclusively on resection of all infected bone. However, data have emerged over the last 10 years to support initial medical management of select patients. Further research regarding the optimal treatment regimen and duration is ongoing, with 1 recent, randomized control trial comparing 6 versus 12 weeks of antibiotics for patients treated medically for osteomyelitis finding no difference in remission rates.[1,41] Patients managed surgically for osteomyelitis are often treated parenterally for at least 4 weeks, but this practice is not based on strong evidence, and guidelines suggest most patients could be switched to highly bioavailable oral agents after a shorter course of intravenous therapy.[1,15] Guidelines recommend 2 to 5 days of antibiotics after complete resection of infected bone and soft tissue (Supplementary Table 3). If the infected soft tissue remains, 1 to 3 weeks of therapy is usually sufficient, while 4 to 6 weeks is often needed if there is residually infected but viable bone.[15]

SURGICAL MANAGEMENT

Inpatient providers should be familiar with the indications for surgery in DFI patients in order to effectively utilize surgical consultants and ensure critical procedures are completed prior to discharge. Surgical consultation, preferably with a surgeon skilled in foot preservation, is recommended for patients with moderate or severe infections.[1,15,33] Surgical indications include abscess, necrosis, compartment syndrome, refractory sepsis despite antibiotics, and extensive bone or joint destruction underlying the open wound, as well as other conditions listed in Table 2. While debridement often aids wound healing, it should be avoided in cases with dry eschar, especially when ischemia is present, as the infection will usually resolve with autoamputation.[1,42,43]

In patients with osteomyelitis, the decision between medical and surgical management is complex. Absolute indications for surgical resection include systemic toxicity with associated tissue infection, an open or infected joint space, and patients with prosthetic heart valves.[27] However, the need for surgery is unclear beyond these absolute indications, and approximately two-thirds of osteomyelitis cases may be arrested or cured with antibiotic therapy alone.[1] A prospective randomized comparative trial of patients with diabetic foot osteomyelitis found that patients treated with 90 days of antibiotics had similar healing rates, times to healing, and short-term complications as compared with those who underwent conservative bone resection.[44] While further research is needed to determine which types of patients with osteomyelitis may be successfully treated without surgery, the IWGDF, the IDSA, and osteomyelitis experts have offered guidance on this decision (Table 2).[1,15,27] If resection is necessary, hospitalists should request at least 4 specimens to help guide postoperative antibiotic therapy (1 sample for histology and 1 for microbiology, at both the grossly abnormal bone and the bone margin), as negative margin cultures predict a lower relapse risk for infection.[1,35]

Every effort should be made to preserve the limb, and urgent amputation is rarely needed except in cases with extensive necrosis or life-threatening infection. Elective amputation may be considered for patients who have recurrent ulceration or irreversible loss of foot function or who would require an excessively prolonged or intensive hospital stay.[15] All patients with plantar ulcers that are unresponsive to conservative management and limited ankle dorsiflexion should be evaluated for pressure-relieving surgeries, such as Achilles lengthening and gastrocnemius recession.[45,46] Studies suggest that pressure-relieving surgeries can increase rates of ulcer healing from 88% to 100% when added to total contact casting.[47]

CRITERIA FOR DISCHARGE

Guidelines suggest that patients be clinically stable before discharge, complete any urgent surgery, achieve acceptable glycemic control, and be presented with a comprehensive outpatient plan, including antibiotic therapy, offloading, wound care instructions, and outpatient follow-up (Supplementary Table 4). Physicians must consider patient and family preferences, expected adherence to therapy, availability of home support, and payer and cost issues when creating the discharge plan.[15]

INTERPROFESSIONAL OUTPATIENT CARE

An effective outpatient care team is critical to ensure wound healing and infection resolution. Efforts should be made to discharge patients to a comprehensive outpatient interprofessional foot care team, with a plan that includes professional foot care, patient education, and adequate footwear.[48] Team composition varies but often includes representatives from vascular surgery, podiatry, orthotics, wound care, endocrinology, orthopedics, physical therapy and rehabilitation, infectious disease, and dermatology.[11-13] Interprofessional outpatient clinics can ease the burden of transportation and shorten the time to needed interventions in the case of treatment failure. Follow-up appointments within 1 to 2 weeks postdischarge have been found to reduce the risk of readmission in other high-risk conditions, and this is a reasonable time frame for DFI as well.[49]

CONCLUSION

DFIs are a common cause of morbidity in patients with diabetes and result in significant costs to the US healthcare system. Hospitalized patients with a DFI require appropriate classification of wound severity and assessment of vascular status, protective sensation, and potential osteomyelitis. Inpatient management of these patients includes obtaining necessary cultures, choosing an antibiotic regimen based on infection severity and the likely causative agent, and evaluating the need for surgical intervention. Prior to discharge, providers should determine a comprehensive follow-up plan and ensure patient engagement. Finally, interprofessional management has been shown to improve outcomes in DFI and should be adopted in both the inpatient and outpatient settings.

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The SDM 3 Circle Model: A Literature Synthesis and Adaptation for Shared Decision Making in the Hospital

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Patient engagement through shared decision-making (SDM) is increasingly seen as a key component for patient safety, patient satisfaction, and quality of care. Current SDM models do not adequately account for medical and environmental contexts, which may influence medical decisions in the hospital. We identified leading SDM models and reviews to inductively construct a novel SDM model appropriate for the inpatient setting. A team of medicine and pediatric hospitalists reviewed the literature to integrate core SDM concepts and processes and iteratively constructed a synthesized draft model. We then solicited broad SDM expert feedback on the draft model for validation and further refinement. The SDM 3 Circle Model identifies 3 core categories of variables that dynamically interact within an "environmental frame." The resulting Venn diagram includes overlapping circles for (1) patient/family, (2) provider/team, and (3) medical context. The environmental frame includes all external, contextual factors that may influence any of the 3 circles. Existing multistep SDM process models were then rearticulated and contextualized to illustrate how a shared decision might be made. The SDM 3 Circle Model accounts for important environmental and contextual characteristics that vary across settings. The visual emphasis generated by each "circle" and by the environmental frame direct attention to often overlooked interactive forces and has the potential to more precisely define, promote, and improve SDM. This model provides a framework to develop interventions to improve quality and patient safety through SDM and patient engagement for hospitalists. *Journal of Hospital Medicine* 2017;12:1001-1008. Published online first October 18, 2017. © 2017 Society of Hospital Medicine

Evolving models of medical care emphasize the importance of shared decision-making (SDM) on practical and ethical grounds.[1-3] SDM is a cognitive, emotional, and relational process in which provider and patient collaborate in a decision after discussing the options, evidence, and potential benefits and harms, while considering the patient's values, preferences, and circumstances.[4] Categories of decisions include information gathering, pharmacotherapy, therapeutic procedures, consultations and referrals, counseling and precautions (eg, behavior modification, goals of care, end-of-life care), and care transitions (eg, transfer or discharge to home).[5] Decisions span the continuum of urgency and may be anticipatory or reactive.[6] The patient's environment[7,8] and the provider-patient relationship[9] have been explicitly incorporated into the ideal SDM process.

SDM has been conceptually and empirically linked with evidence-based practice,[1] although the relationship between SDM and clinical outcomes is less clear.[10,11] SDM is desired by patients[12] and may bolster patient satisfaction, trust, and adherence.[13,14] Limited evidence suggests SDM could reduce inappropriate treatments and testing,[15] decrease adverse events,[16] and promote greater patient safety,[17-19] but more well-designed studies are needed.

Provider, patient, and contextual factors influence the extent to which SDM occurs. Providers commonly cite time constraints and perceived lack of applicability to certain clinical scenarios or settings.[19] Providers may also lack training and competency in SDM skills.[2] Patients may be reluctant to disagree with their provider or fear being mislabeled as "difficult."[20] When faced with high stakes or emotionally charged decisions, patients' surrogates may prefer to have the provider serve as the sole decision-maker.[21] Contextually, there may be limited evidence, high clinical stake, or a number of equally beneficial (or harmful) options.[22,23]

Current SDM models guide clinicians in determining when and how to engage in SDM, yet models vary widely. For example, Elwyn's model emphasizes the ethical imperative for SDM and outlines 3 SDM steps: introduce choice, describe options, and help patients explore preferences and make decisions.[3] Using a multimodal review and clinician-driven feedback, Legaré's "IP-SDM" (Interprofessional Shared Decision Making) model illustrates the roles of the interprofessional team and emphasizes the influence of environmental factors on decision-making.[24] Recent sys-

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TABLE 1. Examples of differences between inpatient and outpatient shared decision-making

Outpatient Setting	Inpatient Setting
Timing / Temporality of Decisions	
Single office visit/encounter or multiple discrete visits	Series of encounters over the course of hospitalization
Time limited to appointment slot with some decisions made over multiple visits	Time variability per daily encounter(s)
Healthcare staff interface within appointment window	Members of healthcare staff and team interface at variable times during the day
	Different healthcare staff interface at different periods
Decision-Making Environment	
Time to ponder decisions away from the clinical environment after the brief and discrete clinical encounter	Continued frequent conversations about clinical decision
Ability to access second opinions out of healthcare team's institution (including family, PCP, specialists)	Quick access to variable specialists and members of the same institution's healthcare team (including nurses, social workers)
Quick return to patient's natural environment	Patient in foreign environment for undefined time
Inpatient hospital resources not as readily available (imaging, tests, procedures, hospital consultants)	Closely monitored patient environment with hospital resources readily available (imaging, tests, procedures, consultants)
Generally, less time pressure to make decision	Constant reminders of medical decision(s) needed for patient
Relationships Between Decision Makers	
Decisions for elective or urgent matters	Decisions for elective, urgent, or emergent matters
Longer-term relationships with medical home providers	Variable time relationships with shift-work providers (days, nights, weekends)
Single encounter relationships for urgent care or overflow visits	Interprofessional provider engagement
Single trainee working with provider per patient	In academic institutions, tendency for larger teams, including multiple trainees per team and potentially multiple teams per patient
Common Issues	
Limited time per encounter	Limited time per patient during rounds
Difficulties with follow-up appointments	Confusion regarding provider roles
Difficulties with timeliness (eg, of tests, consults, procedures, etc.)	Unpredictability of provider/personnel visits throughout the day
Difficulties with care coordination (PCP, specialists)	Confusion stemming from conflicting opinions of different teams
Decision stakeholders may not be present at the discrete visit	Multiple teams involved in patient care activities
Recall bias when there are lengthy intervals between encounters	Care discontinuity – resulting from shift-work and changes in medical team
Care discontinuity - different providers as part of practice group or team	

tematic reviews of SDM models have attempted to identify common elements, language, and processes.[2,25,26]

Although published SDM models demonstrate varying emphases–eg, evidence-based medicine,[2] provider-patient relationships,[9] interprofessional practices and environmental influences,[24] or patient contextual factors [7,8]–none specifically address hospitalization and the issues that impact decisions as a patients' clinical condition and care needs change. Studies of SDM in hospitalized patients have relied on either general theoretical frameworks for patient engagement or conceptual models developed specifically for outpatient care.[16,27,28] Although the key tenets of SDM are relevant across clinical settings, hospitalization introduces a number of unique and highly relevant factors that may influence all aspects of the SDM process. Table 1 provides several examples from the authors of how inpatient and outpatient SDM may differ.

This study reviews leading SDM models to construct a more environmentally and contextually sensitive model that is appropriate for the hospital setting. Although developed with hospital medicine in mind, a synthesized model that attends to environmental and systems context, provider/team factors, patient factors, and disease/medical variables is highly relevant in any setting where SDM occurs.

METHODS

We constructed a model that is appropriate for SDM across the care continuum through the following 3-part, iterative group process: (1) a comprehensive literature review of existing SDM models, (2) synthesis and inductive development of a new draft model, and (3) modification of the new model using feedback from SDM experts.

Narrative Literature Review

We performed a structured, comprehensive literature review [29] to compare and contrast existing SDM models and frameworks. Leading models and key concepts were first identified using 2 systematic reviews [25,26] and a comprehensive review.[2] In order to extend the search to 2016 and include any overlooked articles, a PubMed search was performed using the terms "shared decision-making" or "medical decision-making" AND "model" or "theory" or "framework" for

TABLE 2. Annotated list of selected SDM studies and models/frameworks

Author(s) and Citation	Description
Braddock CH, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. 1999[57]	Using a cross-sectional descriptive evaluation of audiotaped office visits of primary care and surgeon office visits. Informed (shared) decision-making was found to be incomplete. Conclusion: More needs to be done to encourage SDM.
Braddock III CH, Fihn SD, Levinson W. et al. 1997[56]	Cross-sectional descriptive evaluation of informed decision-making based on audiotaped primary care office encounters. Authors used 6 criteria to score informed decision-making and found that a discussion of risks and benefits and patient understanding was infrequent.
Charles C, Gafni A, Whelan T. 1997[51] Charles C, Gafni A, Whelan T. 1999[4]	Landmark studies that described a framework for shared decision-making based on a physician-patient partnership in the decision-making process. The process included sharing of information including treatment preferences and agreement on a decision.
Elwyn G, Frosch D, Thomson R, et al. 2012[3]	Authors describe an SDM model for treatment decision in primary care. The model focuses on patient's active involvement in the process, exploration of expectations and options, teach back and follow up. Three key steps include choice talk, option talk and decision talk.
Elwyn G, Lloyd A, May C, et al. 2014[37]	Authors describe the collaborative deliberation model of decision-making based on 5 communicative efforts of constructive interpersonal engagement, recognition of alternative actions, comparative learning, preference construction and elicitation and preference integration. The model could apply to different types of communication in healthcare including motivational interviewing, SDM, goal setting and action planning.
Epstein RM, Gramling RE. 2013[53]	Review of the SDM in the context of complex and uncertain situations and the role of preference, relationship and the concept of shared attentional focus. Authors also include the role of information technology, healthcare teams and health systems in decision-making.
Hoffmann TC, Montori VM, Del Mar C. 2014[1]	Authors highlight the interconnection between evidence-based medicine (EBM) and SDM - each is necessary in combination to improve patient care. Calls for SDM and EBM to be included in practice guidelines and future research.
Holzmueller CG, Wu AW, Pronovost PJ. 2012[36]	Framework for physicians to determine patient involvement in decision-making and includes patient-related factors. The framework further delineates situations when patients should decide and when physicians should decide.
Kon, AA. 2010[54]	Commentary describes SDM as a continuum with one end being patient driven and the opposite physician driven with a middle being both as equal partners. Different decisions and situations call for varying degrees of patient and physician input in the process.
Légaré F, Stacey D, Pouliot S, et al. 2011[40] Légaré F., Stacey D, Gagnon S. 2011[60]	The model describes an interprofessional approach to SDM. Each professional works either in collaboration with other providers or sequentially with the patient. The model includes the role of environment in SDM and includes clarification of values and feasibility of options.
Makoul G, Clayman ML. 2006[25]	Literature review of SDM models and propose a model based on 9 essential elements. The elements include: define/explain problem, present options, discuss pros/cons, patient preferences/values, patient ability, physician recommendations, checking for understandings, make/defer decision and arrange follow up. Authors also include ideal elements and general qualities that promote SDM.
Moumjid N, Gafni A, Bremond A, et al. 2007[26]	Explores if there is a clear definition of SDM, whether authors provide a definition of SDM when they use the term, and whether they are consistent in doing so.
Muëller-Engelmann M, Keller H, Donner-Banzhoff N, Krones T. 2013[45]	This paper investigates current social norms regarding the appropriateness of SDM in different situations. The authors find that SDM is considered most important in severe illness and chronic condition. SDM was also indicated as necessary when there is more than 1 therapeutic option without one being clearly superior.
Rapley T. 2008[55]	Describes a framework for how to conceptualize decision-making as an evolving series of encounters over time interfacing with several different individuals, knowledge acquisitions and technologies.
Stacey D, Légaré F, Pouliot S, et al. 2010[52]	Comprehensive theory analysis of SDM conceptual models to determine how relevant they are to interprofessional collaboration in clinical practice. They concluded that most SDM models did not utilize an interprofessional approach. This highlights the need for a model that is more inclusive of other health professionals.
Torke AM,Petronio S, Sachs GA, et al. 2012[34]	This article uses literature from medicine, communication studies, and medical ethics to build a conceptual model of the role of communication in decision-making. Information processing and relationship building were found to be 2 major elements of interpersonal communication.
Towle A, Godolphin W. 2006[59]	Model is developed from proposed physician and patient competencies for learning and teaching SDM. The competencies include developing a physician-patient partnership, explicit discussion around patient preference and readiness, role of the patient in the decision-making process, developing an action plan and resolving conflict.
Weiner SJ, Schwartz A, Sharma G, et al. 2013[8]	Observational study using a protocol of medical chart audits and audiotaped provider encounters at internal medicine clinics at 2 VA hospitals to evaluate for contextualizing care (also called patient-centered decision-making); providers were scored on their ability to incorporate contextual factors such as barriers to treatment into care planning. The developed protocol could be used to assess physician performance around contextualized decision-making.
Whitney SN. 2003[23]	This article proposes a model of medical decisions based on importance and clarity. It also identifies 3 types of decisions that are less well suited to a collaborative decision: major decisions with low certainty, minor decisions that have high certainty, and major decisions that have high certainty when patients and physicians disagree.

English-language articles from inception to 2016. The search was repeated using Google Scholar to verify results and obtain the number of citations per article as a proxy for impact and saturation. In order to minimize possible search error or selection bias, reference lists in high-impact publications were hand searched to identify additional articles. All abstracts were manually reviewed by 2 independent authors for relevance and later inclusion in our group iterative process. A priori inclusion criteria were limited to provider-patient SDM (ie, not clinical reasoning or making decisions in general) and

complete descriptions of a conceptual model or framework. Additional publications suggested by experts (eg, perspective pieces or terminology summaries) were also reviewed.

Model Development and Expert Review

An electronic SDM reference library and annotated bibliography of the selected articles (Table 2) was created to guide the synthesis of SDM models and highlight needed revisions for hospital medicine. In a process similar to Legaré,[24] a group of 8 pediatric and adult medicine hospitalists, a palliative care physician, a cognitive psychologist, a biostatistician, and 3 medical trainees reviewed the selected SDM publications and models[30] and independently created their own adapted inpatient SDM models. Through an iterative, consensus-building group process, each model was discussed to select key elements or features to be integrated into a synthesized model. This model was guided by principles of social ecological theory, which emphasizes the role of the individual as influenced by and interactive with systems and the environment.[31]

The draft model and a standardized set of questions (supplementary Appendix A) were then emailed to all first and last authors of the reviewed studies (Table 2). Expert responses were compiled, coded, and analyzed independently by 3 coauthors. Inductive coding techniques and a constant comparative approach were used to code the qualitative data.[32] Preliminary findings were shared among the 3 reviewers and discussed until consensus was reached on emerging themes and implications for the new SDM model and multistep SDM pathway. A master list of suggested revisions was shared with the larger authorship team and the model was refined accordingly.

RESULTS

Two previously published systematic reviews[25,26] identified 494 articles, 161 conceptual definitions of SDM, and over 30 separate key concepts. The additional PubMed search garnered 1957 publications (with many overlapping from the systematic reviews). A manual search of the systematic reviews and PubMed abstracts identified 16 unique and complete decision-making models for further review. Hand searches of their citations yielded an additional 6 models for a total of 22 models.[3,4,13,23,33-51] The majority of excluded articles described specific decision aids and small clinical studies, focused on only one step of the decision-making process, or were not otherwise relevant. The first (SR) and senior authors (JS) reviewed the 22 models for SDM relevance, generalizability, and content saturation, yielding a final sample of 9 SDM models. A subsequent Google Scholar search did not identify any new SDM models but 2 SDM theory papers[1,52] and 2 commentaries[53,54] were selected based on influence (ie, number of citations), expert recommendation, or coverage of a novel aspect of SDM. A total of 15 studies (9 SDM models + 6 reviews; Table 2) were used by our development team to create a synthesized SDM model. A 10th SDM model[55] and 3 additional descriptive and normative studies[8,56,57] were later added based on expert feedback and incorporated into our final SDM 3 Circle Model.

Expert Feedback

Twenty-one of 27 (78%) SDM expert authors responded to our e-mail request for feedback. The majority (62%) agreed with the basic elements of the model, including the environmental frame and the 3 domains. Some respondents viewed SDM as strictly a process between patient and provider independent of the disease, leading to refinement of the medical context category. Several experts emphasized the importance of SDM "set-up," which includes the elicitation of patient preferences in how decisions are made and the extent of patient and/or surrogate involvement.

Several respondents identified time constraints (N = 2), acuity of disease (N = 3), and presence of multiple teams (N = 6) to be the significant factors distinguishing inpatient from outpatient SDM. For some experts, "team" referred to the interprofessional care team, whereas others referred to it as the collaboration among attending physicians and trainees. Experts noted that although the intensity and frequency of inpatient interactions could promote SDM, higher patient acuity and the urgency of decisions could negatively influence SDM and/or the patient's ability to participate. Similarly, the presence of other team members may either impede or promote SDM by either contributing to miscommunication or bringing well-trained SDM experts to the bedside. Financial impact on patients and resource constraints were also noted as relevant. All of these elements have been incorporated into the final SDM 3 Circle Model and multistep SDM Pathway (Supplemental Appendix A and B).

The SDM 3 Circle Model

The SDM 3 Circle Model comprises 3 categories of SDM barriers and facilitators that intersect within the environmental frame of an inpatient ward or other setting: (1) provider/team, (2) patient/family, and (3) medical context. A Venn diagram visually represents the conceptual overlaps and distinctions among these categories that are all affected by the environment in which they occur (Supplemental Appendix A).

The patient/family circle mirrors prior SDM models that address the role of patient preferences in making decisions,[3,4,12] with the explicit addition of the roles of families and surrogates as either decision-makers or influencers. This circle includes personal characteristics, such as cognitions (eg, beliefs, attitudes), emotions (eg, anxiety, hope), behaviors (eg, adherence, assertiveness), illness history (ie, subjective experience and understanding of one's own medical history), and related social features (eg, culture, education, literacy, social supports).

Patient factors are not static over time or context. They occur within an environmental setting and are likely to be influenced by concurrent provider and medical variables (the second and third circles). Disease exacerbation leading to hospitalization or transfer to a subacute facility could dramati-

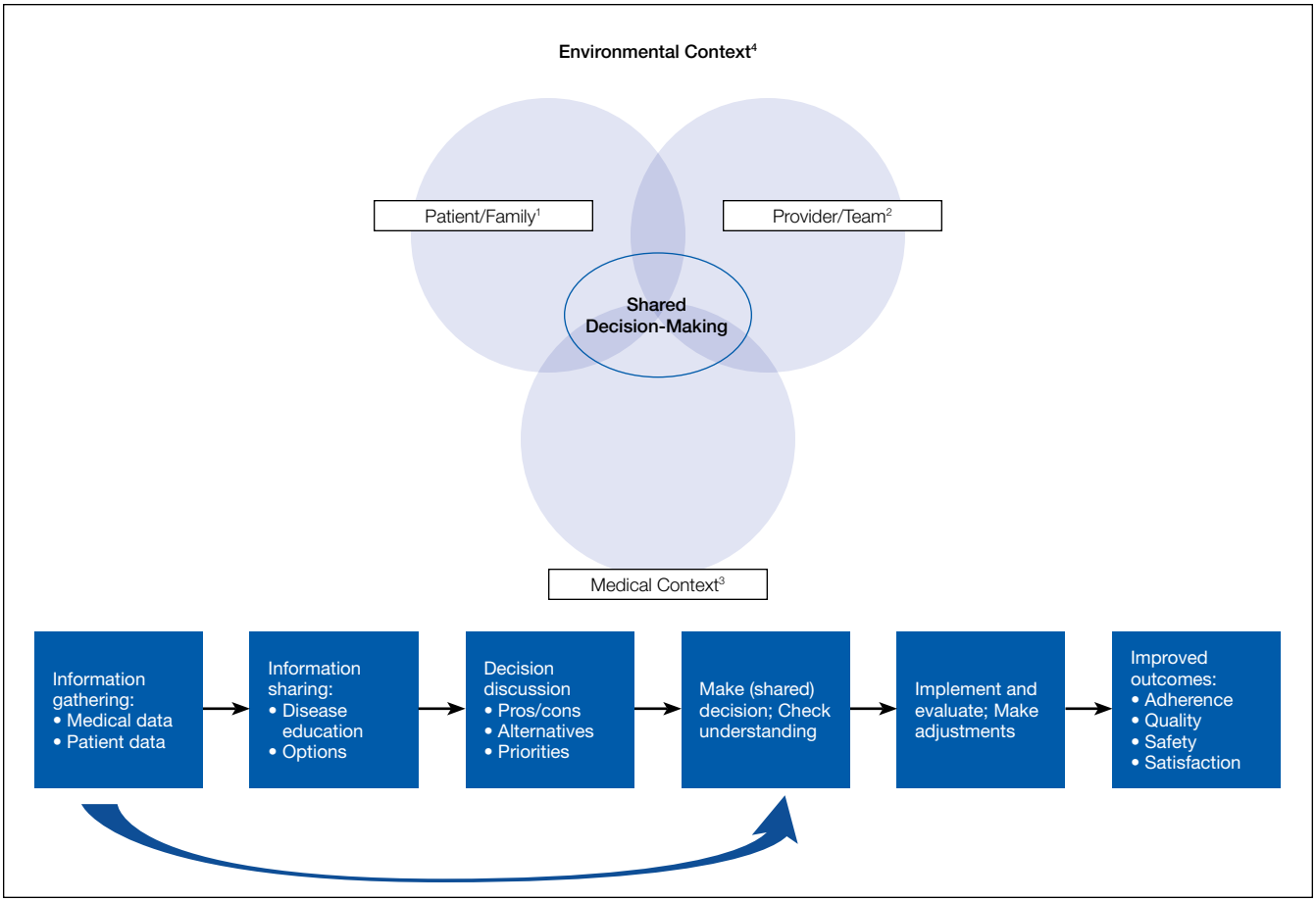

FIG. SDM 3-Circle Conceptual Model and Multistep Shared Decision-Making (SDM) Pathway

NOTE: [1]Patient/Family: A patient's ability to engage in SDM reflects one's health (eg, functional and cognitive status) and life circumstances (eg, socio-economic status; presence of a family member to serve as a surrogate). [2]Provider/Team: SDM engagement is influenced by characteristics of an inpatient team (eg, attending physician, trainees, nurse, social workers, case managers, dietitians, therapists) and characteristics of the healthcare providers it comprises (eg, fatigued vs. well-rested; variable familiarity with SDM guidelines). [3]Medical Context: Some decisions require a patient to provide informed consent (eg, invasive hospital tests and procedures; blood product transfusions); others require a patient to play a fundamental role (eg, adhere to prescription or course of rehabilitation). [4]Environment: A clinical service (eg, medicine or pediatrics, emergency department, hospital floor or intensive care unit) operates within a hospital (eg, university-based/community-based) located in a community (eg, transportation options) and health system (with varying incentives and priorities). Features of each level can influence the SDM encounter through their bearing on the three domains. *Certain situations may warrant bypassing or limiting the steps of information sharing and decision discussion such as time-sensitive emergencies (e.g. emergency surgery) or if the patient and/or surrogate are uninterested or unable to participate in SDM

cally shift the calculus a patient uses to determine preferences or activate dormant family dynamics. Strong provider-patient rapport (the overlap of patient and provider factors) may influence the development of trust and subsequent decisions.[9] The type of disease or symptom presentation (circle 3–medical context) may further influence patient factors due to stigma, perceived vulnerability, or assumed prognosis.

The provider/team circle includes both individual and team-based factors falling into similar categories as the patient/family domain, such as cognitions, behavior, and social features; however, these factors include both personal (eg, the provider's personal history, values, and beliefs) and professional (eg, past medical training, decision-making style, past experiences treating a disease) characteristics. Decisions may involve an interprofessional team representing a broad range of personalities and professional values. Decisions and decision-making processes may change over time as team composition changes, as level of provider expertise varies, or as environmental, patient, or disease/illness factors influence providers and teams.

Medical context includes factors related to the disease and the potential ways to evaluate or manage it. Examples of disease factors include acuity, symptoms, course, and prognosis. Most obviously, disease factors will influence the content of risk-benefit discussions but may also affect the SDM process through disease stigma or cultural assumptions about etiology. Disease evaluation factors include the psychometrics of a diagnostic screen, invasive and noninvasive testing, or a range of different preventive or therapeutic interventions. Treatment variables include the available options, costs, and risk of complications. Medical context variables evolve as evidence-based medicine and biomedical knowledge increase and new treatment options emerge.

Each of the 3 circles operates within the same environmental frame, such as an inpatient medicine ward, which itself operates within a hospital and the broader healthcare system. This frame exerts overt and subtle influences on providers, patients, and even the medical context. Features of the environmental frame include culture (eg, values, preferences, social norms), university versus community setting,

incentives, formularies, quality improvement campaigns, regulations, and technology use.

The dynamic interactivity of the environmental frame and the 3 circles inform the process of SDM and highlight key differences that may occur between care settings. Certain features may predominate in different situations, but all will influence and be influenced by features of other circles during the course of SDM.

Application of the SDM 3 Circle Model

As shown in the Figure, the multistep SDM pathway begins with information gathering and processing, where the provider solicits medical history as well as patient preferences for decision-making. This "processing" of patient decision-making preferences is less commonly described. The next steps, sharing information and decision discussion, include patient education about the medical issue and available treatments. Discussions may involve the pros/cons of each option, alternative diagnostic or management strategies, and how these decisions fit with a patient's preferences, abilities (eg, health literacy)[58] and resources, or what has been called "contextualizing care."[7,8] Framing and other provider behaviors, including the use of decision aids and decision guides,[15] may influence these conversations. Finally, after gathering, sharing, and discussing information (as influenced by the environment and 3 circles), a medical decision is made and patient understanding is verified. Detailed examples of how this model might be applied are illustrated with case scenarios in supplemental Appendix B.

Although the SDM process is similar across clinical settings, its operationalization varies in important ways for hospital decision-making. In some situations, patients may defer all decisions to their providers or decisions may be considered with multiple providers concurrently. In the hospital, SDM may not be possible, such as in emergency surgery for an obtunded patient or when the patient and surrogate are not available or able to participate in the decision. Therefore, providers may bypass the steps of information sharing and discussion of the decision (big arrow in the Figure and supplemental Appendix B), proceeding directly to decision making.

DISCUSSION

The SDM 3 Circle Model provides a concise, ecologically valid, contextually sensitive representation of SDM that synthesizes and extends beyond recent SDM models.[3,7,40] Each circle represents the forces that influence SDM across settings. Although the multistep SDM pathway occurs similarly in outpatient and inpatient settings, how each step is operationalized and how each "circle" exerts its influence may differ and warrants further consideration throughout the SDM process. For example, hospitalized patients may have greater stress and anxiety, have more family involvement, be more motivated to adhere to treatment, and may be under greater financial and social pressures. Unlike outpatient primary care, patients are less likely to have an existing relationship with their inpatient providers, potentially compromising patient confidence in the provider, and necessitating expeditious trust building.

The SDM 3 Circle Model captures "setting" in both the broader environmental frame and within the provider/team category of variables. The frame also captures health system and broader community variables that may influence the practicality of some medical decisions. Within this essential frame, all 3 categories of patient, provider, and medical context are included as part of the SDM process. A better understanding of their interplay may be of great value for clinicians, researchers, administrators, and policy makers who wish to further study and promote SDM. Both the SDM 3 Circle Model and its accompanying pathway (Figures 1 and 2) highlight opportunities for intervention and research, and may drive quality improvement initiatives to improve clinical outcomes.

Limitations

We did not perform a new systematic review, potentially omitting lesser-known publications. We mitigated this risk by using recent systematic reviews, searching multiple databases, hand searching citation lists, and making inquiries to SDM experts. Our selection of models used as a foundation for the synthesized model was based on consensus, which included an element of subjective, clinical judgment. Our SDM expert sample was small and limited to authors of the papers we reviewed, potentially restricting the range of viewpoints received. Lastly, the SDM 3 Circle Model highlights key concept areas rather than all possible factors that influence SDM.

CONCLUSIONS

We present a peer-reviewed, literature-based SDM model capable of accounting for the unique circumstances and challenges of SDM in the hospital. The SDM 3 Circle Model identifies the primary categories of variables thought to influence SDM, places them in a shared environmental frame, and visually represents their interactive nature. A multistep representation of the SDM process further illustrates how the unique features and challenges of hospitalization might exert influence at various points as patients and providers reach a shared decision. As the interrelationships of patient and provider/team, medical context, and the environmental frame in which they occur are better understood, more effective and targeted interventions to promote SDM can be developed and evaluated.

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Reconsidering Hospital Readmission Measures

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Current hospital readmission measures are part of the Centers for Medicare & Medicaid Services Five-Star Quality Rating System but are inadequate for reporting hospital quality. We review potential biases in the readmission measures and offer policy recommendations to address these biases. Hospital readmission rates are influenced by multiple sources of variation (eg, mix of patients served, bias in the performance measure); true differences in quality of care are often a much smaller source of this variation. Thus, variation from caring for large proportions of socioeconomically disadvantaged or tertiary-care patients will bias a hospital's ratings. Ratings aside, readmission measures may indirectly harm patients because low readmission rates do not correlate with reduced mortality, yet the Five-Star Quality Rating System weighs readmission equally with mortality. We propose that hospital quality rankings not use readmission measures as currently constructed. *Journal of Hospital Medicine* 2017;12:1009-1011. Published online first August 23, 2017.

Hospital readmission rates are a consequential and contentious measure of hospital quality. Readmissions within 30 days of hospital discharge are part of the Centers for Medicare & Medicaid Services (CMS) Value-Based Purchasing Program and are publicly reported. Hospital-wide readmissions and condition-specific readmissions are heavily weighted by *US News & World Report* in its hospital rankings and in the new CMS Five-Star Quality Rating System.[1] However, clinicians and researchers question the construct validity of current readmission measures.[2,3]

The focus on readmissions began in 2009 when Jencks et al.[4] reported that 20% of Medicare patients were readmitted within 30 days after hospital discharge. Policy makers embraced readmission reduction, assuming that a hospital readmission so soon after discharge reflected poor quality of hospital care and that, with focused efforts, hospitals could reduce readmissions and save CMS money. In 2010, the Affordable Care Act introduced an initiative to reduce readmissions and, in 2012, the Hospital Readmission Reduction Program was implemented, financially penalizing hospitals with higher-than-expected readmission rates for patients hospitalized with principal diagnoses of heart failure, myocardial infarction, and pneumonia.[5] Readmission measures have since proliferated and now include pay-for-performance metrics for hospitalizations for chronic obstructive pulmonary disease (COPD), coronary artery bypass grafting, and total hip or knee arthroplasty. Measures are also reported for stroke patients and for "hospital-wide readmissions," a catch-all measure intended to capture readmission rates across most diagnoses, with various exclusions intended to prevent counting planned readmissions (eg, hospitalization for cholecystectomy following a hospitalization for cholecystitis). These measures use claims data to construct hierarchical regression models at the patient and hospital levels, assuming that variation among readmission rates are due to hospital quality effects. The goal of this approach is to level the playing field to avoid penalizing hospitals for caring for sicker patients who are at higher risk for readmission for reasons unrelated to hospital care. Yet hospital readmissions are influenced by a complex set of variables that go well beyond hospital care, some of which may be better captured by existing models than others. Below we review several potential biases in the hospital readmission measures and offer policy recommendations to improve the accuracy of these measures.

Variation in a quality measure is influenced by the quality of the underlying data, the mix of patients served, bias in the performance measure, and the degree of systemic or random error.[6] Hospital readmission rates are subject to multiple sources of variation, and true differences in the quality of care are often a much smaller source of this variation. A recent analysis of patient readmissions following general surgery found that the majority were unrelated to suboptimal medical care.[7] Consider 3 scenarios in which a patient with COPD is readmitted 22 days after discharge. In hospital 1, the patient was discharged without a prescription for a steroid inhaler. In hospital 2, the patient was discharged on a steroid inhaler, filled the prescription, and elected not to use it. In hospital 3, the patient was discharged on a steroid inhaler and was provided medical assistance to fill the prescription but still could not afford the $15 copay. In all 3

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scenarios, the hospital would be equally culpable under the current readmission measures, suffering financial and reputational penalties.

Yet the hospitals in these scenarios are not equally culpable. Variation in the mix of patients and bias in the measure impacted performance. Hospital 1 should clearly be held accountable for the readmission. In the cases of hospitals 2 and 3, the situations are more nuanced. More education about COPD, financial investment by the hospital to cover a copay, or a different transitional care approach may have increased the likelihood of patient compliance, but, ultimately, hospitals 2 and 3 were impacted by personal health behaviors and access to public health services and financial assistance, and the readmissions were less within their control.[8]

To be valid, hospital readmission measures would need to ensure that all hospitals are similar in patient characteristics and in the need for an availability of public health services. Yet these factors vary among hospitals and cannot be accounted for by models that rely exclusively on patient-level variables, such as the nature and severity of illness. As a result, the existing readmission measures are biased against certain types of hospitals. Hospitals that treat a greater proportion of patients who are socioeconomically disadvantaged; who lack access to primary care, medical assistance, or public health programs; and who have substance abuse and mental health issues will have higher readmission rates. Hospitals that care for patients who fail initial treatments and require referral for complex care will also have higher readmission rates. These types of patients are not randomly distributed throughout our healthcare system. They are clustered at rural hospitals in underserved areas, certain urban health systems, safety net hospitals, and academic health centers. It is not surprising that readmission penalties have most severely impacted large academic hospitals that care for disadvantaged populations.[2] These penalties may have unintended consequences, reducing a hospital's willingness to care for disadvantaged populations.

While these biases may unfairly harm hospitals caring for disadvantaged patients, the readmission measures may also indirectly harm patients. Low hospital readmission rates are not associated with reduced mortality and, in some instances, track with higher mortality.[9-11] This may result from measurement factors (patients who die cannot be readmitted), from neighborhood socioeconomic status (SES) factors that may impact readmissions more,[12] or from actual patient harm (some patients need acute care following discharge and may have worse outcomes if that care is delayed).[11] Doctors have long recognized this potential risk; empiric evidence now supports them. While mortality measures may also be impacted by sociodemographic variables,[13] whether to adjust for SES should be defined by the purpose of the measure. If the measure is meant to evaluate hospital quality (or utilization in the case of readmissions), adjusting for SES is appropriate because it is unrealistic to expect a health system to reduce income inequality and provide safe housing. Failure to adjust for SES, which has a large impact on outcomes, may mask a quality of care issue. Conversely, if the purpose of a measure is for a community to improve population health, then it should not be adjusted for SES because the community could adjust for income inequality.

Despite the complex ethical challenges created by the efforts to reduce readmissions, there has been virtually no public dialogue with patients, physicians, and policy makers regarding how to balance the trade-offs between reducing readmission and maintaining safety. Patients would likely value increased survival more than reduced readmissions, yet the current CMS Five-Star Rating System for hospital quality weighs readmissions equally with mortality in its hospital rankings, potentially misinforming patients. For example, many well-known academic medical centers score well (4 or 5 stars) on mortality and poorly (1 or 2 stars) on readmissions, resulting in a low or average overall score, calling into question face validity and confounding consumers struggling to make decisions about where to seek care. The Medicare Payment Advisory Commission's Report to the Congress[14] highlights the multiple significant systematic and random errors with the hospital readmission data.

REVISITING THE HOSPITAL READMISSION MEASURES

Given significant bias in the hospital readmission measures and the ethical challenges imposed by reducing readmissions, potentially at the expense of survival, we believe CMS needs to take action to remedy the problem. First, CMS should drop hospital readmissions as a quality measure from its hospital rankings. Other hospital-rating groups and insurers should do the same. When included in payment schemes, readmissions should not be construed as a quality measure but as a utilization measure, like length of stay.

Second, the Department of Health & Human Services (HHS) should invest in maturing the hospital readmission measures to ensure construct, content, and criterion validity and reliability. No doubt the risk adjustment is complex and may be inherently limited using Medicare claims data. In the case of SES adjustment, for example, limited numbers of SES measures can be constructed from current data sources.[8,13] There are other approaches to address this recommendation. For example, HHS could define a preventable readmission as one linked to some process or outcome of hospital care, such as whether the patient was discharged on an inhaler. The National Quality Forum used this approach to define a preventable venous thromboembolic event as one occurring when a patient did not receive appropriate prophylaxis. In this way, only hospital 1 in the 3 scenarios for the patient with COPD would be penalized. However, we recognize that it is not always simple to define specific process measures (eg, prescribing an inhaler) that link to readmission outcomes and that there may be other important yet hard-to-measure interventions (eg, patient and family education) that are important components of patient-centered care and readmission prevention. This is why readmissions are so challenging as a quality measure. If experts cannot define clinician behaviors that have a strong theory of change or are causally related to re-

duced readmissions, it is hard to call readmissions a modifiable quality measure. Another potential strategy to level the playing field would be to compare readmission rates across peer institutions only. For instance, tertiary-care safety net hospitals would be compared to one another and rural community hospitals would be compared to one another.[14] Lastly, new data sources could be added to account for the social, community-level, public health, and personal health factors that heavily influence a patient's risk for readmission, in addition to hospital-level factors. Appropriate methods will be needed to develop statistical models for risk adjustment; however, this is a complex topic and beyond the scope of the current paper.

Third, HHS could continue to use the current readmission measures as population health measures while supporting multistakeholder teams to better understand how people and their communities, public health agencies, insurers, and healthcare providers can collaborate to help patients thrive and avoid readmissions by addressing true defects in care and care coordination.

While it is understandable why policy makers chose to focus on hospital readmissions, and while we recognize that concerns about the measures were unknown when they were created, emerging evidence demonstrates that the current readmission measures (particularly when used as a quality metric) lack construct validity, contain significant bias and systematic errors, and create ethical tension by rewarding hospitals both financially and reputationally for turning away sick and socially disadvantaged patients who may, consequently, have adverse outcomes. Current readmission measures need to be reconsidered.

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Opportunities and Challenges for Improving the Patient Experience in the Acute and Post–Acute Care Setting Using Patient Portals: The Patient's Perspective

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Efforts to improve the patient experience are increasingly focusing on engaging patients and their "care partners" by using patient portals. The Acute Care Patient Portal Task Force was supported by the Gordon and Betty Moore Foundation to convene a national meeting of an interdisciplinary group of stakeholders, including patient advocates, to consider how the acute and postacute care patient experience can be improved by using patient-facing technologies. We identified key opportunities and challenges for enhancing cognitive support, promoting respect while maintaining boundaries, and facilitating patient and family empowerment through the lens of the patient. Institutions, clinicians, and vendors would benefit tremendously by considering these 3 patient-centered themes when partnering with patients and family advisors to implement and realize the full potential of patient portals to enhance the acute and postacute care experience. *Journal of Hospital Medicine* 2017;12:1012-1016. Published online first October 18, 2017. © 2017 Society of Hospital Medicine

To realize the vision of patient-centered care, efforts are focusing on engaging patients and "care partners," often a family caregiver, by using patient-facing technologies.[1-4] Web-based patient portals linked to the electronic health record (EHR) provide patients and care partners with the ability to access personal health information online and to communicate with clinicians. In recent years, institutions have been increasing patient portal offerings to improve the patient experience, promote safety, and optimize healthcare delivery.[5-7]

DRIVERS OF ADOPTION

The adoption of patient portals has been driven by federal incentive programs (Meaningful Use), efforts by the Center for Medicare and Medicaid Services, and the Office of the National Coordinator for Health Information Technology to improve patient outcomes and the transition toward value-based reimbursement.[2,8,9] The vast majority of use has been in ambulatory settings; use for acute care is nascent at best.[10] Among hospitalized patients, few bring an internet-enabled computer or mobile device to access personal health records online.[11] However, evidence suggests that care partners will use portals on behalf of acutely ill patients.[4] As the Caregiver Advise, Record, Enable Act is implemented, hospitals will be required to identify patients' care partners during hospitalization, inform them when the patient is ready for discharge, and provide self-management instructions during the transition home.[12] In this context, understanding how best to leverage acute care patient portals will be important to institutions, clinicians, and vendors.

CURRENT KNOWLEDGE

The literature regarding acute care patient portals is rapidly growing.[4,10] Hospitalized patients have unmet information and communication needs, and hospital-based clinicians struggle to meet these needs in a timely manner.[13-15] In general, patients feel that using a mobile device to access personal health records has the potential to improve their experience.[11] Early studies suggest that acute care patient portals can promote patient-centered communication and collaboration during hospitalization, including in intensive care settings.[4,16,17] Furthermore, the use of acute care patient portals can improve perception of safety and quality, decrease anxiety, and increase understanding of health conditions.[3,14] Although early evidence is promising, considerable knowledge gaps exist regarding patient outcomes over the acute episode of care.[10,18]

OUTSTANDING QUESTIONS

A clear area of interest is accessing acute care patient portals via mobile technology to engage patients during recovery from hospitalization.[4,11] Although we do not yet know whether use during care transitions will favorably impact outcomes, given the high rate of harm after discharge, this seems likely.[19] The few studies evaluating the effect on validated measures of engagement (Patient Activation Measure) and hospital readmissions have not shown demonstrable improvement to date.[20,21] Clearly, optimizing acute care patient portals with regard to patient-clinician communication, as well as the type, timing, and format of information

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delivered, will be necessary to maximize value.[4,22]

From the patient's perspective, there is much we can learn.[23] Is the information that is presented pertinent, timely, and easy to understand? Will the use of portals detract from face-to-face interactions? Does greater transparency foster more accountability? Achieving an appropriate balance of digital health-information sharing for hospitalized patients is challenging given the sensitivity of patient data when diagnoses are uncertain and treatments are in flux.[4,24] These questions must be answered as hospitals implement acute care patient portals.

ACUTE CARE PATIENT PORTAL TASK FORCE

To start addressing knowledge gaps, we established a task force of 21 leading researchers, informatics and policy experts, and clinical leaders. The Acute Care Patient Portal Task Force was a subgroup of the Libretto Consortium, a collaboration of 4 academic medical centers established by the Gordon and Betty Moore Foundation to design, develop, and implement technologies to engage patients, care partners, and providers in preventing harm in hospital settings. Initially, we were challenged with assessing stakeholders' perspectives from early adopter institutions. We learned that acute care patient portals must offer an integrated experience across care settings, humanize the patient-clinician relationship, enable equitable access, and align with institutional strategy to promote sustainability.[19]

In 2016, we convened the conference Acute Care Patient Portals 2020: Opportunities and Challenges for Development, Implementation, and Innovation. A total of 71 individuals participated, including chief medical informatics officers, chief nursing informatics officers, chief medical officers, chief nursing officers, quality and safety officers, executive directors, researchers, informatics experts, software developers, clinicians, patient and family advocates, entrepreneurs, policy leaders, and vendor representatives. The purpose of the meeting was multipronged; a key goal was to understand the patient's perspective during hospitalization. To achieve this, we led a panel composed of 3 patients who served on patient and family advisory councils at early adopter institutions. Panelists were asked to discuss how the use of patient-facing technologies could address current gaps. Meeting transcripts and notes were synthesized, summarized, and reviewed by task force members. By using a group consensus approach, we identified 3 main themes (Table 1). These themes confirm many of the opportunities and challenges reported in the literature but through the lens of the patient. We believe the insight gained will be valuable as institutions start implementing acute care patient portals.

Cognitive Support

The opportunities identified include acclimatizing and assimilating to the hospital environment (reviewing policies and patient rights) and facilitating self-education and preparation by linking to personal health information and providing structured guidance at transitions.[4] For example, a care partner of an incapacitated patient may watch a video to orient to the intensive care unit, navigate educational content linked to the patient's admission diagnosis (pneumonia) entered in the EHR, view the timing of an upcoming imaging study (chest computed tomography scan), and complete a standardized checklist prior to discharge.

The main challenges we identified include ensuring accuracy of hospital-, unit-, and patient-level information, addressing information overload, configuring notification and display settings to optimize the user experience, presenting information at an appropriate health literacy level,[4,21] and addressing security and privacy concerns when expanding access to family members.[24]

Respect and Boundaries

Opportunities identified include supporting individual learning styles by using interactive features of mobile devices to improve comprehension for visual, auditory, and tactile learners and reinforcing learning through the use of various types of digital media.[25-27] For example, a visual learner may view a video tutorial for a newly prescribed medication. A tactile learner may prefer to use interactive graphical displays that exploit multidimensional touch capabilities of mobile devices to learn about active conditions or an upcoming procedure. An auditory learner may choose to use intelligent personal assistants to navigate their plan of care ("Hey Siri, what is my schedule for today?"). By addressing the learning preferences of patients and time constraints of clinicians, institutions can use acute care patient portals to promote more respectful interactions and collaborative decision-making during important care processes, such as obtaining surgical consent.[28,29]

We also identified opportunities to facilitate personalization by tailoring educational content and by enabling the use of patient-generated health data collected from wearable devices. For example, patients may prefer to interact with a virtual advocate to review discharge instructions ("Louis" in Project Re-Engineered Discharge) when personalized to their demographics and health literacy level.[30-32] Patients may choose to upload step counts from wearable devices so that clinicians can monitor activity goals in preparation for discharge and while recovering afterwards. When supported in these ways, acute care patient portals allow patients to have more meaningful interactions with clinicians about diagnoses, treatments, prognosis, and goals for recovery.

The main challenges we identified include balancing interactions with technology and clinicians, ensuring clinicians understand how patients from different socioeconomic backgrounds use existing and newer technology to enhance self-management, assessing health and technology literacy, and understanding individual preferences for sharing patient-generated health data. Importantly, we must remain vigilant that patients will express concern about overdependence on technology, especially if it detracts from in-person interaction; our panelists emphasized that technology should never replace "human touch."

TABLE 1. Opportunities and Challenges for Improving the Acute and Post-Acute Care Patient Experience

Themes	Opportunities	Challenges	Examples
Cognitive Support – *"Can help enhance communication in your own language, not just the language of the clinician."*			
Acclimatization and assimilation	Understand policies, procedures, unit protocols, the rights of patients, families, and care partners, and clinical staff roles	Ensure hospital information is accurate, up-to-date, and easy to understand	View videos to orient patients, families, and care partners upon admission to the intensive care unit
	Timely and relevant clinical updates for patients and care partners, including bedside and distant family members	Address cognitive burden from information overload and alert fatigue; ensure security and privacy when expanding access to care partners	Designate access for proxies when patients are incapacitated; view updated schedule of planned procedures and imaging studies
Self-education and preparation	Enable on-demand access to personal health information and educational materials linked to patient's problems, medications, and test results in the EHR	Ensure clinical information is optimally presented for all health literacy levels and languages; ensure EHR is routinely updated	View educational content specific to patient's medical conditions, medications, and test results
	Review standardized checklists and guides to prepare for complex clinical conversations with clinicians and transitions to and from the hospital	Ensure patients of all literacy levels can easily access, navigate, and comprehend information	Prompt patient to review a predischarge checklist prior to their expected discharge date
Respect and Boundaries – *"There is a happy compromise, but info should be delivered and utilized in a way that you would want."*			
Individual learning styles	Support individual preferences for using interactive features (high-definition video, intelligent personal assistants, multidimensional touch)	Balance online and in-person interactions with clinicians; minimize overdependence on technology	Perform automated teach-back in patients' preferred language and format (text, audio, video)
	Improve comprehension for visual, auditory, and tactile learners; reinforce learning by using digital media (graphics, video tutorials, avatars)	Ensure clinicians understand how patients use the portal to engage in learning and care processes (electronically signing consent form)	Provide the option of viewing an educational video or taking an interactive tutorial about a procedure prior to meeting with the surgeon
Personalization	Tailor educational content, features, and functionality to patient's age, gender, primary language, and health literacy level; provide cultural context in interactive self-care instructions	Assess health and technology literacy of patients; respect time necessary to review and understand clinical information prior to making decisions	Provide options for selecting a virtual or live interpreter based on the patient's primary language when reviewing informed consent forms
	Connect to personal wearable devices (activity tracker) to upload patient-generated health data for medical decision-making	Understand individual preferences and comfort with sharing patient-generated health data	Prompt patient to connect a bluetooth activity tracker prior to discharge to monitor health data (step-counts, heart rate) during recovery
Patient and Family Empowerment – *"Weekends are scary. It is hard to find someone [with whom] to communicate. You are watching your loved one get passed from team to team. You HOPE that the last care team thinks what the last team thought."*			
Patient-centered communication	Support real time (video conferencing) and asynchronous (secure messaging) communication among patients, care partners, and care team members	Encourage appropriate use of communication tools; minimize conversational silos among clinicians	Synchronize message recipients to current care team role assignments in the EHR
	Display pictures, names, roles, and availability of all care team members	Maintain accuracy of care team member identities and availability	Prompt the patient to add their ambulatory specialist to the care team
Transparency	Share clinical information and documentation typically maintained by clinicians (progress notes, sign-outs) with patients and care partners to facilitate shared decision-making; hold clinicians accountable to a single care plan at shift-change/handoff	Overcome fear of sharing information in the EHR entered by clinicians; acknowledge patients as equal partners; manage expectations about the diagnostic process and therapeutic options when multiple clinicians are involved or team members change	Invite patients, care partners, and family members to review standardized handoff information (I-PASS) from the EHR at shift change and handoffs
Real-time feedback	Provide tools to react to or rate newly displayed information and report safety concerns to the care team	Address patient and care partner concerns quickly and respectfully; support patients who fear retaliation for voicing complaints	Invite patients to provide input about their expected discharge date and options for skilled nursing facilities

NOTE: Abbreviations: EHR, electronic health record; I-PASS; illness severity, patient summary, action list, situational awareness and contingency plans, and synthesis by receiver.

Patient and Family Empowerment

The opportunities identified include promoting patient-centered communication by supporting a real-time and asynchronous dialogue among patients, care partners, and care team members (including ambulatory clinicians) while minimizing conversational silos[4,33]; displaying names, roles, and pictures of all care team members[4,34]; fostering transparency by sharing clinician documentation in progress notes and sign-outs[35]; ensuring accountability for a single plan of care spanning shift changes and handoffs, and providing a mechanism to enable real-time feedback.

Hospitalization can be a vulnerable and isolating experience, perpetuated by a lack of timely and coordinated communication with the care team. We identified opportunities to mitigate anxiety by promoting shared understanding when questions require input from multiple clinicians, when team members change, or when patients wish to communicate with their longitudinal ambulatory providers.[4,34] For example, inviting patients to review clinicians' progress notes should stimulate more open and meaningful commu-

TABLE 2. Goals and Recommendations for Institutions, Clinicians, and Vendors Implementing Acute Care Patient Portals to Support, Respect, and Empower Hospitalized Patients

	Goals	Recommendations
Institutions	Comply with federal regulations (CARE Act)	Develop sustainable strategy to identify care partners for both current enrollees and nonenrollees of institutional patient portals upon hospital admission
	Maximize value-based reimbursement via key programs (HRRP, HVBP, MACRA)	Ensure acute care patient portals address key patient experiences of care domains that are targets of quality reporting: communication with MD and RN, communication about medications, and discharge information and instructions
Clinicians	Enhance patient-centered bedside rounding experience	Encourage reliable use of core EHR functionality (problem-based charting, care team role assignments) by clinicians to tailor self-management education and facilitate accurate identification of care team members for patients via EHR-linked acute care patient portals
	Extend reach of concurrent transitional care interventions	Encourage transitional teams to empower patients and care partners to use acute care patient portals to participate in discharge preparation, disease management, medication reconciliation, and self-management education during hospitalization and after discharge
Vendors	Enhance and develop offerings to support broad-based patient engagement	Work with patient networks and advocacy groups to ensure existing and forthcoming functionality, meaningfully support language, health literacy, access, and technology barriers for patients, family caregivers, and care partners
	Ensure support for technology standards and new requirements under MACRA	Use open APIs and emerging standards (FHIR) to facilitate data exchange with third-party applications that address current gaps in functionality (eg, applications capturing patient reported outcomes)

NOTE: Abbreviations: API, Application Programming Interface; CARE, Caregiver Advise Record and Enable Act; EHR, electronic health record; FHIR, Fast Healthcare Interoperability Resources; HRRP, Hospital Readmission Reduction Program; HVBP, Hospital Value-Based Purchasing Program; MACRA, Medicare Access and CHIP Reauthorization Act (Merit-Based Incentive Payment System, Alternative Payment Models).

nication.[35] Furthermore, requesting that patients state their wishes, preferences, and goals could improve overall concordance with care team members.[36,37] Empowering patients and care partners to voice their concerns, particularly those related to miscommunication, may mitigate harm propagated by handoffs, shift work, and weekend coverage.[38,39] While reporting safety concerns represents a novel mechanism to augment medical-error reporting by clinicians alone,[23,40] this strategy will be most effective when aligned with standardized communication initiatives (I-PASS) that have been proven to reduce medical errors and preventable adverse events and are being implemented nationally.[41] Finally, by leveraging tools that facilitate instantaneous feedback, patients can be empowered to react to their plan (ranking skilled nursing facility options) as it is developed.

The main challenges we identified include managing expectations regarding the use of communication tools, accurately and reliably identifying care team members in the EHR,[34] acknowledging patients as equal partners, ensuring patients receive a consistent message about diagnoses and therapies during handoffs and when multiple consultants have conflicting opinions about the plan,[37] and addressing patient concerns fairly and respectfully.

RECOMMENDATIONS AND CONCLUSIONS

As hospitals start implementing acute care patient portals, how should we prepare? We offer several recommendations to guide key stakeholders (Table 2). Institutions would benefit from aligning implementation with forthcoming regulations and value-based reimbursement initiatives. Clinicians would benefit from using acute care patient portals to enhance concurrent patient engagement initiatives (patient-centered bedside rounds, transitional care interventions). Vendors would benefit by recognizing that current offerings fall short of the desired features and functionality, from partnering formally with patients and advocacy groups to enhance their offerings, especially when incorporating new technologies (artificial intelligence); and from enabling the use of open-application programming interfaces and emerging technology standards that allow third-party applications addressing existing gaps to exchange data quickly and securely.[42]

In summary, the patient-centered themes we identified serve as guiding principles for institutions, clinicians, and vendors who wish to use patient portals to improve the acute and postacute care patient experience. One central message resonates: Patients do not simply want access to their health information and the ability to communicate with the clinicians who furnish this information; they want to feel supported, respected, and empowered when doing so. It is only through partnership with patients and their advocates that we can fully realize the impact of digital technologies when patients are in their most vulnerable state.

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Cardiac Biomarkers—Are We Testing Wisely?

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Cardiac biomarker testing, along with a thorough patient history, physical exam, and an electrocardiogram, is required for the diagnosis of patients with suspected acute coronary syndrome (ACS). For nearly 3 decades, 2 cardiac biomarkers, troponin (I or T) and creatine kinase-MB fraction (CK-MB), have been ordered together to evaluate ACS patients out of concern that utilizing a single biomarker might be less diagnostically accurate than using 2 biomarkers. However, subsequent studies have shown that troponin is far more sensitive and specific for myocardial injury than CK-MB.[1,2] Troponin testing offers important prognostic information irrespective of whether the CK-MB is normal or abnormal.[3,4] In 2015, the American Society of Clinical Pathology released a Choosing Wisely® recommendation against ordering CK-MB (or myoglobin) for the diagnosis of acute myocardial infarction (AMI).[5] This reflects an emerging consensus that CK-MB testing represents low-value care while troponin testing alone is the appropriate diagnostic strategy for ACS patients.

Remarkably, we know very little about patterns of cardiac biomarker utilization in clinical practice. In this issue of the *Journal of Hospital Medicine*, Prochaska et al.[6] provide a valuable snapshot of troponin and CK-MB utilization at 91 U.S. academic medical centers (AMCs) for 18 months prior to and following the release of the 2015 Choosing Wisely® recommendation. From a retrospective review of 106,954 inpatient discharges with a principal diagnosis of AMI, they report a 29.2% rate of troponin-only testing in 2013 with a gradual increase over 3 years to 53.5% in 2016. Interestingly, the study's baseline troponin-only utilization rate is consistent with a 2013 College of American Pathologists survey, which estimated that 23% of U.S. clinical laboratories no longer process CK-MB (and therefore run troponins alone).[7]

Did the 2015 Choosing Wisely® recommendation have an impact on providers choosing cardiac biomarkers wisely? The authors answer this question in a novel way by stratifying hospitals into performance tertiles for each study quarter and then further classifying them into groups that were consistently high, middle, and low performers throughout the study period. Using an interrupted time series design, they identify 26 hospitals who improved their troponin-only testing performance tertile during the study period and examine their average quarterly rate of change. As illustrated in Figure 3, they report a sharp increase in the rate of change of troponin-only testing shortly after the release of the 2015 Choosing Wisely® recommendation. The authors reasonably conclude that the Choosing Wisely® campaign "appeared to facilitate accelerated adoption of troponin-only testing" among these hospitals.

However, we should interpret these results with caution. The authors highlight several limitations, including the absence of causality common in observational studies and insufficient time to follow-up to capture the full (or transient) impact of the intervention. There are factors external to the Choosing Wisely® campaign that may have influenced cardiac biomarker testing patterns observed. Examples include variation in hospital leadership, financial drivers, and local culture that promote high-value care. We also note that (1) there are several published interventions to improve troponin-only ordering that predate the Choosing Wisely® campaign[8,9]; (2) a prominent cardiology guideline endorsed the use of troponin as a preferred cardiac biomarker in 2012[10]; and (3) a widely cited opinion by prominent researchers called for the elimination of CK-MB from clinical practice in 2008.[11] These publications suggest there was already an awareness of and efforts underway to improve cardiac enzyme testing contributing to the results described by Prochaska et al.

Limitations notwithstanding, we commend Prochaska et al. for conducting the first-known description of patient-level trend rates of troponin and CK-MB testing. Finally, it is worth noting that where there is accomplishment, there is also opportunity. At the end of the study period, nearly 50% of institutions had yet to adopt a troponin-only strategy. While there has been an overall trend towards improvement, this number remains high. We may conjecture as to possible explanations: Providers may be unconvinced that a single troponin is sufficient in the diagnosis of ACS (ie, lack of knowledge or debate over the interpretation of available science), stakeholders may be slow to de-adopt practices using appropriate systems levers (eg, laboratories delisting CK-MB processing), and incentives may be lacking to motivate AMCs. The results of this study should be used as a burning platform to those who wish to "test wisely" in cardiac biomarker use.

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Keeping It Simple in Sepsis Measures

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"*I didn't have time to write a short letter, so I wrote a long one instead.*"
-Mark Twain

Sepsis is a logical target for quality measures. Specifically, sepsis represents the perfect storm of immense public health burden[1-3] combined with unexplained practice[4-6] and outcomes[7] variation. Thus, it is not surprising that in October 2015, the Centers of Medicare and Medicaid Services (CMS) adopted a sepsis quality measure.[8] More surprising were the complex contents of the CMS Sepsis Core Measure "SEP-1" quality measure.[9] CMS had written a "long letter."

The multiple processes targeted with the CMS SEP-1 quality measure can best be understood with a brief account of history. SEP-1 arose from the National Quality Forum's (NQF) project #0500: "Severe Sepsis and Septic Shock: Management Bundle," a measure based upon Rivers et al.'s[10] single-center, randomized, controlled trial of early goal-directed therapy (EGDT) for severe sepsis. EGDT was an intervention that consisted of fluid resuscitation and hemodynamic management based upon fulfilling specific targets of central venous pressure, superior vena cava oxygen saturation (or lactic acid), and hemoglobin and mean arterial pressures.[11] The large mortality benefits, physiological rationale, and algorithmic responses to a variety of abnormal clinical values provided an appealing protocol to critical care and emergency physicians trained to normalize measured values, as well as policy makers looking for quality measures. Observational studies consistently showed associations between adoption of guideline-based "sepsis bundles" and improved patient outcomes,[12-14] setting the stage for the transition of NQF #0500 into SEP-1.

However, the transition from EGDT-based NQF #0500 to SEP-1 has been tumultuous. Soon after adoption of SEP-1, the consensus definitions of sepsis changed markedly. Sepsis went from being defined as the presence of infection with concomitant systemic inflammatory response syndrome (sepsis), organ dysfunction (severe sepsis), and/or shock,[15] to being defined as a dysregulated response to infection resulting in life-threatening organ dysfunction (sepsis) and/or fluid-resistant hypotension requiring vasopressors and lactate greater than 2 mmol/L.[16] As the study by Barbash et al.[17] in this issue clearly outlines, conflicting definitions of "sepsis" have left clinicians confused regarding whom the SEP-1 measure should apply. At the same time, results of 3 large, international, randomized trials investigating the efficacy of EGDT were published, providing strong evidence that EGDT did not provide improved patient outcomes over usual care.[18] SEP-1 adapted with the evolving evidence base, adding putative "usual care" processes such as evaluation of skin and peripheral pulses, and use of dynamic measures of fluid responsiveness, as quality measures.[19] However, as Barbash et al. also outline, the resulting process measure was incredibly complex, with potentially more than 50 data elements collected over 6 hours in the initial management of sepsis.

In addition to its unprecedented complexity, SEP-1 received criticism for the weak evidence base of its individual components. The general concepts behind SEP-1 are well-accepted tenets of sepsis management: rapid recognition, assessment and treatment of underlying infection, and institution of intravenous fluids and vasopressor support for septic shock. However, the "all or none" prescriptive nature of the SEP-1 bundle was based on a somewhat arbitrary set of measures and targets. For example, patients with septic shock must receive 30 cc/kg of intravenous fluids to be "SEP-1 compliant." The value "30 cc/kg" was taken from the average volume of fluids reported in prior sepsis trials, essentially based on a very low level of evidence.[20] The strict 30 cc/kg cutoff did not take into account that "the median isn't the message"[21] in fluid management: optimal resuscitation targets are unclear,[22] and selecting the median as a target ignores the fact that 50% of patients enrolled in international trials of EGDT received less than 30 cc/kg of initial fluid resuscitation (the interquartile range was 16-42 cc/kg).[18] Thus, most participants in trials upon which the SEP-1 fluid measure was based would ironically not have met the SEP-1 measure. Mandates for physical exam and physiological measures were based on similarly low levels of evidence.

Into this context, Barbash et al. use a representative sample of US hospitals to explore the opinions of hospital quality leaders regarding the SEP-1 measure. First, the qualitative methods used by Barbash et al. warrant some explanation. Much of biomedical research is characterized by hypothe-

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sis-driven, deductive reasoning: theories are tested using observations. In contrast, the methods of Barbash et al. use inductive reasoning: observations are used to develop theories within a systematic approach called "grounded theory" that explores common themes emerging from structured interviews.[23] Inductive reasoning can later inform deductive reasoning, feeding theories into testable hypotheses. However, qualitative, inductive research is not meant to test hypotheses and is not subject to typical notions of "power and sample size" often expected of quantitative statistical analyses. Qualitative studies reach sufficient sample size when no further themes emerge, a situation called "thematic saturation"; the sample size here of 29 participants rests comfortably in the range of participants commonly needed for thematic saturation.[23]

Barbash et al. identified common themes in opinions of quality leaders regarding SEP-1. Namely, the complexity of SEP-1 necessitated a major resource investment into sepsis care and data collection. The major infrastructure investments needed to comply with SEP-1 also bred frustration regarding lack of perceived fairness around the "all or none" nature of the measure and raised multiple additional challenges including lack of clinician buy-in and resistance to protocolized care. Prior qualitative studies evaluating hospital quality leaders' opinions on performance measures identified similar concerns about lack of "fairness,"[24] but the implementation of SEP-1 has raised additional concern regarding the large burdens of instituting major infrastructure changes to monitor processes of care required to report on this measure. Despite the major challenges of responding to SEP-1, quality leaders expressed optimism that increased attention to sepsis would ultimately lead to better patient outcomes.

How might future sepsis quality measures achieve the adequate balance between focusing attention on improving care processes for high-impact diseases, without imposing additional burdens on the healthcare system? Lessons from Barbash et al. help us move forward. First, rather than taxing hospitals with administratively complex process measures, initial attempts at quality measures should start simply. Policy makers should consider moving forward into new areas of quality measurement in 2 ways: (1) pursue 1 or 2 processes with strong etiological links to important patient outcomes (eg, timely antibiotics in septic shock),[25-28] and/or (2) use risk-adjusted outcomes and allow individual hospitals to adopt processes that improve local patient outcomes. Evidence suggests that the introduction of a quality measure may result in improved outcomes regardless of adoption of specific target processes,[29] although results are mixed.[30,31] In either case, complex "all or none" measures based upon weak evidence run a high risk of inciting clinician resentment and paradoxically perpetuating poor quality by increasing healthcare costs (decreased efficiency) without gains in safety, effectiveness, timeliness, or equity.[32] It has been estimated that hospitals spend on average $2 million to implement SEP-1,[33] with unclear return on the investment. The experience of SEP-1 is a reminder that, as evidence evolves, quality measures must adapt lest they become irrelevant. However, it is also a reminder that quality measures should not sit precariously on the edge of evidence. Withdrawal of process-based measures due to a changing evidence landscape breeds mistrust and impairs future attempts to improve quality.

Sepsis quality measures face additional challenges. If recent experience with interpretation of sepsis definitions can serve as a guide, variable uptake of newer sepsis definitions between/across hospitals will impair the ability to risk-adjust outcome measures and increase bias in identifying outlier hospitals.[34] In addition, recent studies have already raised skepticism regarding the effectiveness of individual SEP-1 bundle components, confirming suspicions that the 30 cc/kg fluid bolus is not a magic quality target. Rather, the effectiveness of prior sepsis bundles has likely been driven by improved time to antibiotics, a process unstudied in sepsis trials, but driven by increased attention to the importance of early sepsis recognition and timely management.[28] Timeliness of antibiotics can act as an effect modifier for more complex sepsis therapies, with quicker time to antibiotics associated with reversal of previously described effectiveness of activated protein C,[35] and EGDT.[28]

Sepsis has a legacy in which improving simple processes (ie, time to antibiotics) obviates the need for more complex interventions (eg, activated protein C, EGDT). To the extent that CMS remains committed to using process-based measures of quality, those focused on sepsis are likely to be most effective when pared down to the simplest and strongest evidence base—improved recognition[36] and timely antibiotics (for patients with infection-induced organ dysfunction and shock). Taking the time to start simply may best serve our current patients and preserve stakeholder buy-in for quality initiatives likely to benefit our future patients.

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Improving Handoffs: Teaching beyond "Watch One, Do One"

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In this issue of the *Journal of Hospital Medicine*, Lee et al.[1] describe a randomized trial to assess the effectiveness of four different approaches to teaching handoffs with the goal of improving process measures related to interns' handoffs. The Society of Hospital Medicine (SHM), The Joint Commission (TJC), Accreditation Council for Graduate Medical Education (ACGME), and others have all emphasized the importance of high-quality handoffs as an essential component of safe patient care.[2-4] The ACGME specifically requires that all institutions that sponsor ACGME-accredited programs provide both structure and monitoring, and the SHM complements this with evidence-based guidelines for handoffs.

Lee's team trained 4 groups of residents in handoffs using 4 different hour-long sessions, each with a different focus and educational format. A control group received a 1-hour didactic, which they had already heard; an I-PASS–based training group included role plays; and Policy Mandate and PDSA (Plan, Do, Study, Act) groups included group discussions. The prioritization of content in the sessions varied considerably among the groups, and the results should be interpreted within the context of the variation in both delivery and content.

Consistent with the focus of each intervention, the I-PASS–based training group had the greatest improvement in transfer of patient information, the policy mandate training group (focused on specific tasks) had the greatest improvement in task accountability, and the PDSA-training group (focused on intern-driven improvements) had the greatest improvement in personal responsibility. The control 60-minute didactic group did not show significant improvement in any domains. The lack of improvement in the control group doesn't imply that the content wasn't valuable, just that repetition didn't add anything to baseline. One takeaway from the primary results of this study is that residents are likely to practice and improve what they are taught, and therefore, faculty should teach them purposefully. If residents aren't taught handoff skills, they are unlikely to master them.

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The interventions used in this study are neither mutually exclusive nor duplicative. In the final conclusions, the authors described the potential for a curriculum that includes elements from all 3 interventions. One could certainly imagine a handoff training program that includes elements of the I-PASS handoff bundle including role plays, additional emphasis on personal responsibility for specific tasks, as well as a focus on PDSA cycles of improvement for handoff processes. This likely could be accomplished with efficiency and might add only an hour to the 1-hour trainings. Evidence from the I-PASS study[5] suggests that improving handoffs can decrease medical errors by 21% and adverse events by 30%; this certainly seems worth the time.

Checklist-based observation tools can provide valuable data to assess handoffs.[6] Lee's study used a checklist based on TJC recommendations, and the 17 checklist elements overlapped somewhat with the SHM guidelines,[2] providing some evidence for content validity. The dependent variable was total number of checklist items included in handoffs, a methodology that assumes that all handoff elements are equally important (eg, gender is weighted equally to if-then plans). This checklist also has a large proportion of items related to 2-way and closed-loop communication and therefore, places heavy weight on this component of handoffs. Adapting this checklist into an assessment tool would require additional validity evidence but could make it a very useful tool for completing handoff assessments and providing meaningful feedback.

The ideal data collection instrument would also include outcome measures, in addition to process measures. Improvements in outcome measures such as medical errors and adverse events, are more difficult to document but also provide more valuable data about the impact of curricula. In designing new hybrid curricula, it will be extremely important to focus on those outcomes that reflect the greatest impact on patient safety.

Finally, this study reminds us that the delivery modes of curricula are important factors in learning. The control group received an exclusively didactic presentation that they had heard before, while the other 3 groups had interactive components including role plays and group discussions. The improvements in different domains with different training formats provide evidence for the complementary nature. Interactive curricula involving role plays, simulations, and small-group discussions are more resource-intense than simple didactics, but they are also likely to be more impactful.

Teaching and assessing the quality of handoffs is critical to the safe practice of medicine. New ACGME duty hour

requirements, which began in July, will allow for increased flexibility allowing longer shifts with shorter breaks.[7] Regardless of the shift/call schedules programs design for their trainees, safe handoffs are essential. The strategies described here may be useful for helping institutions improve patient safety through better handoffs. This study adds to the bulk of data demonstrating that handoffs are a skill that should be both taught and assessed during residency training.

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