Developing and Pilot Testing Quality Indicators in the Intensive Care Unit

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Purpose: **To develop and implement a set of valid and reliable yet practical measures of intensive care units (ICU) quality of care in a cohort of ICUs and to estimate, based on current performance, the potential opportunity to improve quality.**

Methods: We included 13 adult medical and surgical ICUs in urban community teaching and community hospitals. To monitor performance on previously identified quality measures, we developed 3 data collection tools: the Team Leader, Daily Rounding, and Infection Control forms. These tools were pilot tested, validated, and modified before implementation. We used published estimates of efficacy to estimate the clinical and economic effect of our current performance for each of the process measures: appropriate sedation, prevention of ventilator-associated pneumonia, appropriate peptic ulcer disease (PUD) prophylaxis, appropriate deep venous thrombosis (DVT) prophylaxis, and appropriate use of blood transfusions.

Results: **Performance varied widely among the 13 ICUs and within ICUs. The median percentage of days in which ventilated patients received therapies that ought to was 64% for appropriate sedation, 67% for elevating head of bed, 89% for PUD prophylaxis, and 87% for DVT prophylaxis. The median rate of appropriate transfusion was 33%. The failure to use these therapies may lead to excess morbidity, mortality, and ICU length of stay.**

Conclusion: To improve quality of care, we must measure our performance. This pilot study suggests that it is feasible to implement a broad set of ICU quality measures in a cohort of hospitals. By improving performance on these measures, we may realize reduced mortality, morbidity, and ICU length of stay.

MEDICAL PROFESSIONALS generally lack knowledge regarding the quality of care they provide. This is particularly troublesome because we now have evidence that specific therapies and organizational characteristics are associated with improved outcomes for patients in intensive care units (ICUs).[1,2] Nevertheless, there are barriers to measuring quality of ICU care. Providers must develop measures of quality, create data collection instruments, collect and analyze data, and then use these results to improve performance. A significant challenge in developing quality measures is to strike a balance between the validity and reliability of the measure and the burden of data collection. To reduce bias in the measures, providers must create standard data collection tools and protocols. In addition, if organizations wish to compare their performance (benchmark) they need common measures and methods of data collection.

The goal of this project was to develop and implement a set of valid and reliable yet practical ICU quality measures and to estimate, based on current performance, the potential opportunity to improve quality. The steps required to develop measures are provided in Table 1. We have described steps 1 through 3 previously: (1)conduct of a systematic review of the literature, (2) select specific types of outcomes to evaluate, and (3) select a list of potential ICU quality measures.[3] In this article, we describe the process used to develop and pilot test ICU quality measures as part of a collaborative project between the VHA, Inc. and the Institute for Healthcare Improvement to create the idealized design of an ICU. We also present the initial results from this project and estimate the potential impact of current performance on quality of ICU care.

METHODS

Design Specifications

For each measure, 3 ICU physicians worked closely with experts in quality of care to write explicit definitions (Table 2) and design specifications. Design specifications were similar to a research protocol and formulated to answer the fol-

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Table 1. Steps to Develop ICU Quality Measures

Steps	Considerations
1. Conduct literature review	Summarize the evidence regarding structure and processes of care associated with improved outcomes
2. Select specific types of outcomes to evaluate	Selection criteria: outcomes evaluated included morbidity, mortality, and cost of care; individual provider or hospitals had to vary on how they performed on these outcome measures; providers had to be able to impact the outcome measure
3. Select pilot indicators	Selection criteria: the strength of the evidence that a specific process would improve the outcomes; the feasibility of the data collection
4. Write the design specifications for the measures	For each measure, define who, what, where, when, and how: who will collect the measure? What will they measure? Where will they measure it? When in the course will they measure it? How will they measure it?
5. Evaluate the validity and reliability of the data	Validity: do providers believe that the measure evaluates an important aspect of quality of care? Reliability: reduce variation among data abstraction by writing detailed specifications for data collection
6. Pilot test the measures	Evaluate how the measures perform in the ICU

lowing questions: Who will collect the data? What will they measure? Where will they measure it? When will they measure it? How will they measure it? In addition, we described the methods of data analysis and summarized the specifications in a manual of operations or abstraction guide.

Data Collection Tools

To reduce bias in data collection, we created standardized data collection tools. We determined the data required for each quality measure and considered how that data might be practically collected, including the amount of staff time required, the need for training, and the marginal costs to abstract the data from ICU information systems. Because information systems vary among ICUs, we elected to collect data from primary clinical sources rather than from existing databases such as administrative data. To obtain the information required for the measures, we created 3 data collection tools: the Team Leader form, the Daily Rounding form, and the Infection Control form. The Team Leader form (Appendix 1) was completed daily by the charge nurse at approximately 8:00 AM to reflect the previous 24 hours. The Daily Rounding form (Appendix 2) was completed daily by the team making rounds. The Infection Control form (Appendix 3) was completed monthly by the infection control practitioner. Because of concerns with patient confidentiality, patient identifiers were not collected.

Pilot Testing

We pilot tested the data collection tools and the abstraction guide in 2 phases. In the first phase, staff in 2 surgical ICUs at The Johns Hopkins Hospital used the forms for 1 week. After this, we interviewed staff regarding the clarity of the data collection tools and abstraction guide, burden of data collection, usefulness of each measure, and suggested modifications of the measures. We modified the tools based on this feedback. To facilitate data entry, we placed the tools on Scantron forms (Irvine, CA) (bubble forms), which automatically import data elements into a database.

In phase 2, the revised data collection tools were distributed to the 13 adult ICUs participating in the VHA and Institute for Healthcare Improvement's idealized design of the ICU project. The characteristics of participating ICUs are provided in Table 3. We classified ICUs by type of population served (surgical, medical, mixed medical/surgical; demographic setting (urban if in a metropolitan statistical area, and rural if in a non–metropolitan statistical area); and status as a teaching unit (academic if the hospital was a member of the Council Of Teaching Hospitals, community teaching if the hospital had residents but was not a member of Council Of Teaching Hospitals, or community if the hospital did not have residents). Each participating ICU created a team, including physician and nurse leaders, as well as other staff. One staff member from each ICU was assigned to lead the data collection efforts. During one of the quarterly meetings for this project, representatives from each ICU were trained in data collection and asked to collect data for 4 weeks. The teams were instructed to mail completed scantron forms to an independent vendor who processed the forms and ensured capture of the data elements. Nonscantron forms

Table 2. Quality Measures, Definitions, and Design Specifications

Quality Measure	Definition	Specifications
Outcome measures		
ICU mortality rate	% of ICU discharges who die in the ICU (no risk adjustment; to be used for comparison over time within an ICU)	Numerator: Total no. of ICU deaths Denominator: Total no. of ICU discharges (including deaths and transfers)
% of ICU patients, with ICU LOS >7 days	% of ICU discharges with ICU LOS >7 days	Numerator: All ICU patients with ICU LOS >7 days Denominator: Total no. of ICU discharges (including deaths and transfers)
Average ICU LOS	Average ICU LOS	Numerator: Sum of ICU length of stay for all discharges Denominator: Total no. of ICU discharges (including deaths and transfers)
Average days on mechanical ventilation	Average days on mechanical ventilation	Numerator: Total no. ventilator days Denominator: Total number of intubated/trached patients, who were mechanically ventilated
Suboptimal management of pain	% of 4-hour intervals with a pain score >3	Numerator: No. of 4-hour intervals in which the pain score was >3 Denominator: Total no. of 4-hour intervals
Patient/family satisfaction	To be developed	To be developed
Access measures		
Rate of delayed admissions	Rate of delay admissions to the ICU	Numerator: Number of admissions that are delayed for ≥4 hours to ICU (exclude transfers from outside hospitals) Denominator: Total number of ICU admissions (exclude transfers from outside hospitals)
Rate of delayed discharges	Rate of delay discharges from the ICU	Numerator: Number of discharges that are delayed for ≥4 hours from ICU Denominator: Total number of ICU discharges
Canceled OR cases	Number of canceled OR cases due to lack of ICU bed	Numerator: Number of canceled OR cases owing to lack of ICU bed Denominator: None (if total number of OR cases are available, than these data can be presented as a rate)
Emergency department by-pass hours	Emergency department by-pass hours per month owing to lack of ICU bed	Numerator: Total by-pass hours per month that are caused by a lack of ICU bed Denominator: None
Complication measures		
Rate of unplanned ICU readmissions	Rate of unplanned ICU readmission	Numerator: No. of patients who had an unplanned ICU readmission within 48 h of ICU discharge Denominator: Total no. of ICU discharges
Rate of catheter-related bloodstream infections	Rate of catheter-related bloodstream infections per 1,000 catheter days	Numerator: No. of patients with catheter-related blood stream infections as defined by CDC Denominator: Total no. of catheter days in the ICU
Rate of resistant infections	Rate of new-onset resistant infections per ICU patient day	Numerator: No. patients who developed resistant infections in the ICU (defined as MRSA or VRE infections) Denominator: Total ICU patient days
Process measures		
Appropriate sedation	The percent of ventilator days on which: (1) sedation was held for at least 12 h or until patient could follow commands or (2) if patient followed commands without the need to hold sedation	Numerator: No. of ventilator days on which (1) sedation was held for ≥12 h or until patient followed commands or (2) patient followed commands without sedation held Denominator: Total ventilator days
Prevention of ventilator-associated pneumonia	The percent of ventilator days on which the head of bed is elevated ≥30°	Numerator: No. of ventilator days on which the head of the bed was elevated ≥30° Denominator: Total no. of ventilator days
Appropriate PUD prophylaxis	The percent of ventilator days on which patient received PUD prophylaxis	Numerator: No. of ventilator days on which patients received PUD prophylaxis Denominator: Total ventilator days
Appropriate DVT prophylaxis	The percent of ventilator days on which patient received DVT prophylaxis	Numerator: No. of ventilator days on which patients received DVT prophylaxis Denominator: Total ventilator days
Appropriate use of blood transfusions	The percent of packed red blood cell transfusions for which the hemoglobin level before transfusion was less than 8 g/dL	Numerator: No. of packed red blood cell transfusions for which the hemoglobin level immediately before transfusion was less than 8 g/dL (include transfusions during episodes of massive bleeding (≥4 U-h) and assume that these transfusions all had hemoglobin levels <8) Denominator: Total no. of transfusions
Effective assessment of pain	% of 4-hour intervals for which each patient had a pain score documented with the visual analogue scale	Numerator: No. of 4-hour intervals for which patients had a pain score measured with the visual analogue scale Denominator: Total number of 4-hour intervals

Abbreviations: LDS, Length of stay; OR; operating room; MRSA, methacillin resistant staph aureus; VRE, vancomycin resistant enterococcus.

Appendix 1
Team Leader Form

Team Leader Form

Complete this form for each participating ICU, daily b/f 8:00 & 10:00 am to reflect the prior 24 hrs.
Today's Date_____ Hospital ID#_____ ICU_____
Total number of admissions
How many admissions were transfers (from an outside hospital)?
How many admissions were unplanned?
Of the unplanned admissions, how many were readmissions within 48 hours of an ICU discharge?
How many admissions to the ICU [exclude transfers from outside hospital] were delayed for >four hours?
For the last 24 hours:
_____Total Nursing Hours _____Agency Nursing Hours
_____Overtime Nursing Hours _____Travel Nursing Hours
Total hours on ED by-pass due to lack of ICU beds
Conceled Operative cases due to lack of ICU beds
How many discharges from the ICU were delayed >four hours?
For each patient discharged from the ICU in the past 24 hours, what was their ICU length of stay (days)?

Patient	LOS	Discharge alive [Y/N]
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

were sent to the VHA for data entry, validation, and analysis. After the 4-week data collection effort, we held another meeting of all participating ICUs at which time feedback was obtained regarding the clarity of the data collection tools and abstraction guide, burden of data collection, usefulness of each measure, and suggested modifications of the measures. The teams then were given revised data collection tools and instructed to begin collecting data.

Evaluation of Validity and Reliability

We applied practical tests of construct and content validity. First, the ICU physicians and quality experts who developed the measures unanimously agreed that the measures identified an important domain of ICU quality. In addition, we asked the improvement team from each participating ICU if they believed the measure evaluated an important aspect of quality care and if they could use information regarding performance on this measure to improve quality of care. The assumption underlying this validity test was that providers must believe that each measure (as we defined it) evaluates an important aspect of care. In addition, all of the process measures are supported by evidence from randomized clinical trials that showed increased use of the therapy is associated with improved patient outcomes. As such, the randomized clinical trials provide predictive validity for our process measures.

To evaluate reliability, we had both a physician and nurse in one ICU independently collect data for the process measures for 1 week and we compared the results using a κ statistic to represent the percent agreement beyond chance. We did not evaluate intrarater reliability.

Estimates of Opportunity to Improve

To show staff the potential for improving quality, we estimated the potential improvements in quality if all ventilated patients received each of the 5 process measures compared with those currently receiving these therapies. To estimate this, we multiplied 1 minus our current performance by the published estimates of the efficacy for those

Appendix 2
Daily Rounding Form

Daily Rounding Form

Complete daily b/t 8.00 & 10.00 am to reflect the prior 24 hrs.

Today's Date _____ Hospital ID# _____ ICU _____

Bed No.	% of Control/ Arteriol lines (0–9)	VAS Scores [0–10] am or ND (not doc) NA (not ovoil) NR (not responsive) 8 am	12 pm	4 pm	8 am	12 am	4 am	Total # of RBC Transfusions (0-99)	# of transfusions w/Hgb <8 immed. prior to transfusion (0–99)	Intub/Trouch & Mech Vent las 24 hrs. Y/N	ONLY fill out if intubated/trouched & mech ventilated: 1st. day on Mech Ventilator Y/N	HOB Elev >=30 degrees Y/N/C	Sedation Held Y/N/C	PUD Proph. Y/N/C	DVT Proph. Y/N/C
1															
2															
3															
4															
5															
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therapies on clinical and economic outcomes. For clinical outcomes, we used the number needed to treat (NNT), which is 1 divided by the absolute risk reduction (the difference in outcomes between the 2 groups) and is interpreted as how many patients must be treated with the experimental intervention versus the control intervention to prevent one outcome. For economic outcomes, we used the NNT and the estimated reduction in hospital or ICU length of stay. Because baseline event rate affects the NNT, we obtained estimates of the NNT from the published literature that included only ICU patients. Although we created estimates for each ICU, for this study we used the mean or median performance of all 13 ICUs and a hypothetical ICU with 1,000 admissions per year.

The process measures included appropriate sedation, prevention of ventilator-associated pneumonia, appropriate peptic ulcer disease (PUD) prophylaxis, appropriate deep venous thrombosis (DVT) prophylaxis, and appropriate use of blood transfusions.

Appropriate sedation was defined as the percentage of ventilator days in which sedation was held such that the patient was able to follow commands. The potential clinical and economic impact of our performance on this measure is significant. To estimate the opportunity to improve for sedation, we used data from the randomized controlled trial by Kress et al,[4] who found that the daily interruption of sedative drug infusions until patients could follow commands reduced the duration of mechanical ventilation by 2.4 days (33%) and reduced ICU length of stay by 3.5 days (35%). There was no statistical difference in in-hospital mortality between the 2 groups (36% in the intervention group and 47% in the control group; $P = .25$).

Prevention of ventilator-associated pneumonia was defined as the percentage of group; $P = .25$ ventilator days in which the head of bed is elevated 30° or greater. To estimate the opportunity to improve, we used a randomized controlled trial by Drakulovic et al.[5] Patients who were ventilated mechanically in the ICU were randomized to receive a semirecumbent position—in which the head of bed is elevated to 30% or greater. Investigators found that the use of a semirecumbent position was associated with a 26% absolute re-

Appendix 3
Infection Control Form

Infection Control Information
ICU Idealized Design Project

As part of the VHA and Institute for Health Improvement's Idealized Design of the ICU project, we plan to monitor a set of quality measures that may provide insights into the performance of the ICUs at your institution, to help accomplish this, we ask that you provide the following information.

Hospital ID# Today's Date
□□□□□□ □□/□□/□□□□
(assigned ID# for hospital & ICU)
Time Period
□□/□□/□□□□ through
□□/□□/□□□□
During the time period above:
How many catheter-related blood stream infections were ascribed to the ICU?
□□
Do you use the definitions for catheter-related blood stream infections provided by National Nosocomial Infection Surveillance (NNIS)?
□ (y) □ (n)
How many resistant infections (MRSA and VRE only) were ascribed to the ICU?
□□
Do you use the definitions for resistant infections provided by the antibiotic MIC reporting guidelines from the National Committee for Clinical Lab Standards?
□ (y) □ (n)
Thank you for your time.

duction in the risk of clinically suspected nosocomial pneumonia, or NNT of 4.

To estimate the opportunity to improve after PUD prophylaxis, we used a study published by Cook et al.[6] Investigators conducted a randomized trial in which patients who were ventilated mechanically in the ICU were randomized to receive either ranitidine or sucralfate. These investigators found that the use of ranitidine compared with sucralfate was associated with a 2.1% absolute risk reduction and a 55% relative risk reduction for clinically important gastrointestinal (GI) bleeding. The NNT was 47, meaning that for every 47 patients we treat with ranitidine versus sucralfate, we would prevent one episode of upper GI bleeding.

Table 3. ICU Characteristics

Type of ICU n (%)	
Medical	3 (23)
Surgical	3 (23)
Medical/surgical	7 (54)
Patients n(%)	
Adult	13 (100)
Pediatric	0 (0)
Median number of ICU beds (interquartile range)	15 (12-22)
Location n (%)	
Rural	0 (0)
Urban	13 (100)
Affiliation n (%)	
Academic	0 (0)
Community teaching	9 (69)
Community	4 (31)

NOTE. n = 13.

To estimate the opportunity to improve DVT prophylaxis, we used the systematic review by Attia et al.[7] Although the method of DVT prophylaxis varied, the overall relative risk reduction in the incidence of DVT for patients receiving any prophylaxis compared with placebo was approximately 50% and the baseline incidence of DVT was approximately 30%. A 50% reduction would decrease this incidence to 15%. This absolute reduction of 15% translates into a NNT of 6.

Appropriate use of blood transfusions was defined as the percentage of packed red blood cell transfusions for which the hemoglobin level before transfusion is less than 8 g/dL. The evidence to support this measure comes from a multicenter trial by Hebert et al,[8] in which ICU patients were assigned randomly for transfused packed red blood cells when their hemoglobin level was 7 g/dL versus 10 g/dL. These investigators found that 30- and 60-day mortality were similar in both groups. Moreover, use of 7 g/dL as the transfusion trigger was associated with a decreased risk for mortality in the group of patients who were less ill.

Table 4. Baseline Results From 13 ICUs

	Median Performance	Range Among ICUs
Outcome measures		
ICU mortality rate	7.6%	2% to 15%
% of patients with ICU LOS >7 days	8.9%	2% to 24%
Average ICU LOS	3.6 d	2–10 d
Average days on mechanical ventilator	4.6 d	2–10 d
Suboptimal management of pain	15.8%	0% to 65%
Patient/family satisfaction	ND	ND
Access measures		
Rate of delayed admissions	7.8%	0% to 45%
Rate of delayed discharges	33.5%	0% to 56%
Canceled operating room cases	0.1	0–2 cases
Emergency department by-pass hours	10.0	0–59 h
Complication measures		
Rate of unplanned ICU readmissions	2.4%	0% to 10%
Rate of catheter-related BSI	0.3%	0% to 1.3%
Rate of resistant infections	0.3%	0% to 1.4%
Process measures		
Effective assessment of pain	84%	30% to 98%
Appropriate sedation	64%	2% to 100%
Prevention of ventilator-associated pneumonia	67%	42% to 99%
Appropriate PUD prophylaxis	89%	71% to 98%
Appropriate DVT prophylaxis	87%	48% to 98%
Appropriate use of blood transfusions	33%	9% to 66%

Abbreviations: LOS, Length of stay; ND, not developed; BSI, bloodstream infections.

Burden of Data Collection and Usefulness of the Quality Measures

To evaluate the burden of data collection, we conducted semistructured interviews with the 8 nurses and 5 ICU physicians who completed the data collection tools in our ICU. To further evaluate the burden of data collection and usefulness of the data, we conducted a focus group with physician and nurse representatives from the 13 participating ICUs.

Timeline of Study

The timeline of the study was as follows:

- April, 2001: conduct literature review;
- May, 2001: write design specifications;
- May, 2001: create data collection tools;
- June, 2001: pilot test data collection tools and abstraction guide;
- July, 2001: revise data collection tools and abstraction guide;
- August, 2001: pilot test measures (1 mo);
- October to December, 2001: initial data collection (1 quarter).

Statistical Analysis

Descriptive analyses were performed for the ICU characteristics, including type of ICU, number of staffed beds, location, and affiliation. Performance for each of the quality measures was calculated as a percentage or a ratio. All analyses were performed with Stata 7.0 (Houston, TX).

RESULTS

We obtained feedback from the ICU nurses and physicians who completed the data collection tools in our ICU. All nurses and physicians interviewed reported that the Daily Rounding form was easy to understand and could be completed in less than 2 minutes per patient. In addition, all of the data elements were available from the resident's presentation during bedside rounds. The charge nurses reported that the Team Leader form was easy to understand and was not burdensome to complete during the course of the day. A total of 100% of all data elements were completed on the data collection tools. We also found the process measures to be highly reliable. The κ statistic was 0.9 for appropriate sedation and 1.0 for each of the other process measures.

Results for the initial data collection at the 13 participating ICUs from August 23, 2001, through September 23, 2001, are presented in Table 4. There was wide variation in performance among quality measures within an ICU as well as wide

Table 5. Clinical and Economic Effect of Current Performance

Quality Measure	Performance	Excess ICU Days per Year	Excess Hospital Days per Year
Appropriate sedation	64%	1,260	—
Prevention of ventilator-associated pneumonia	67%	332	—
Appropriate PUD prophylaxis	89%	12	—
Appropriate DVT prophylaxis	87%	—	198
Appropriate use of blood transfusions	33%	—	—
Total	—	1,604	198

variation in performance among ICUs for individual measures. We estimated the clinical and economic effect of current performance for each of the process measures (Table 5). An example of these calculations is provided in Appendix 4. The median percentage of days in which ventilated patients were able to follow commands was 64% (range among ICUs, 2% to 100%). Given the performance on this measure in our pilot project, an ICU with 1,000 admissions per year would have an annual excess of 864 days (range, 0-2,352 d) of mechanical ventilation and 1,260 ICU days (range, 0-3,430 d).

The median percentage of ventilator days in which the head of the bed was increased 30° or more in our study was 67% (range among ICUs, 42% to 99%). Based on this evidence and the median performance of our 13 ICUs, an ICU with 1,000 admissions per year may be able to prevent 83 (range, 3-145) ventilator-associated pneumonias per year if all patients received this simple intervention. It has been shown that ventilator-associated pneumonia has a 24% attributable mortality and increases ICU length of stay by 4 days.[9] Given this, our performance may lead to 20 (range, 0-35) excess deaths and 332 (range, 12-580) additional ICU days per year. By elevating the head of the bed for patients who are ventilated mechanically, we can reduce their risk for ventilator-associated pneumonia and decrease morbidity, mortality, and costs of care.

The median percent of ventilator days on which patients received PUD prophylaxis was 89% (range among ICUs, 71% to 98%). Our performance, therefore, would translate into 2 (range, 0-6) episodes of significant upper GI bleeding owing to our failure to use PUD prophylaxis. If we assume that GI bleeding results in an additional 6 ICU days, our performance may have resulted in an additional 12 (range, 0-36) ICU days. Although our performance would not have lead to any preventable deaths from our failure to use PUD prophylaxis, the attributable mortality associated with significant upper GI bleeding in the ICU was 20%.[10]

The median percent of ventilator days on which patients received DVT prophylaxis in our study was 87% (range among ICUs, 48% to 98%). If we

Appendix 4
Toolkit for Estimating Impact of Current Performance on Process Measures

Excess DAYS of Mechanical Ventilation per year						
Admissions per year	×	100% − average % of days ventilated patients were able to follow commands	×	2.4 days	=	Excess days of MV per year
1,000	×	0.36	×	2.4	=	864
Excess ICU DAYS per year						
Admissions per year	×	100%−average % of days ventilated patients were able to follow commands	×	3.5 days	=	Excess ICU days per year
1,000	×	0.36	×	3.5	=	1260
Excess COSTS per year						
Excess ICU days per year	×	Marginal cost per ICU day	=	Excess costs per year		
1,260	×	$1,200	=	$1,512,000		

assume that thromboembolic events are associated with a 12% increased risk for in-hospital mortality and increased hospital length of stay by 5 days (S. Berenholtz, unpublished data), our performance may have led to an additional 22 (range, 3-87) DVTs, 3 (range, 0-10) deaths, and 198 (range, 15-435) excess hospital days per year because of our failure to use thromboprophylaxis.

The median rate of appropriate transfusion in our study was 33% (range among ICUs, 9% to 66%). If we assume that every patient is transfused once during their ICU admission, this would result in 670 (range among ICUs, 340-910) excess units of packed red blood cells transfused per year and the associated risks of blood transfusion.

Focus group participants felt that the burden of data collection was low. They also stated that the process measures were much more useful to them than the outcome measures and that the process measures could be used to help improve quality of care. They were generally skeptical about the results of the outcome measures, in particular mortality and length of stay, and stated that obtaining risk-adjusted mortality would not have increased their confidence in the outcome measures. The group felt that the sample sizes were too small to provide valid estimates of mortality and length of stay. In addition, the group felt that the burden of collecting outcome (mortality and length of stay) data was significantly greater than the burden of collecting process measures. They believed that future efforts should be made to obtain outcomes from discharge data.

DISCUSSION

Potential Opportunities to Improve

Quality of care is in need of improvement.[11] To improve, caregivers must have valid, reliable, and practical tools to evaluate quality design interventions to improve performance, and monitor the affect of the intervention on the quality measures. Given the expanding evidence for therapies that improve outcomes in critically ill patients, we need to ensure that patients receive the therapies they ought to. The results from our pilot project suggest that it is practical to design and implement measures of quality of care in a cohort of ICUs using primary data collection. Staff generally felt the burden of data collection was minimal and found process measures were more valuable for improvement than outcome measures. Moreover, there was a significant opportunity to improve the care that we provide to ICU patients.

We found that many patients are not receiving the therapies they ought to and our performance may result in significant, and preventable, morbidity, mortality, and costs of care. Given our performance on process measures in an ICU with 1,000 admissions per year and assuming that the results from randomized clinical trials apply to our patients, we may be able to prevent approximately one death every 2 weeks and an additional 1,800 ICU and hospital days if all eligible patients received these care processes. Interestingly, because these excess deaths were caused by errors of omission rather than commission, these types of deaths likely were excluded in the Institute of Medicine's reported estimate in "To Err Is Human".[11]

Performance on these process measures can be improved by relatively simple interventions. One type of intervention is to use redundancy to ensure that patients receive these therapies. That is, having independent assessments by different types of caregivers of whether the process was used. For example, most efforts to improve performance using guidelines focus on physicians alone and thus are not redundant.[12] We are developing interventions to provide nurses and family members with information regarding the 5 process measures related to ventilated patients. Nurses and family members will be asked to check and ensure that these processes were completed.

We placed less emphasis on risk-adjusted mortality than other studies of ICU quality. Although risk-adjusted hospital mortality rates are used commonly to evaluate quality of ICU care, they have limitations that inhibit their broad implementation. First, the risk-adjustment models generally require physiology data that are burdensome to collect. Second, ICU risk-adjustment models often perform poorly when applied to new datasets, limiting our ability to apply a common risk-adjustment model to all ICUs.[13] Third, risk-adjustment models perform poorly when developed on a sample size of less than 800 patients; more patients than many ICUs admit in a year.[14] Finally, our goal was to develop a tool that hospitals could use to evaluate their performance over time rather than to benchmark their performance against other hospitals. As such, we would only need to use risk-adjusted mortality if case-mix changed over time. Unless a

hospital adds a new product line, the case-mix of ICU patients changes little over time, eliminating the need for risk-adjusted mortality.[15]

We recognize several limitations of our project. One limitation was the extent to which we evaluated validity. It is important to distinguish between the validity of the indicator and the validity of the measure.[16] Our process indicators likely are valid because each intervention is supported by evidence from randomized clinical trials. To evaluate the validity of the measure, we could have reviewed medical records or observed providers during data collection. These interventions, however, would have increased significantly the burden of data collection. We intentionally focused on content and face validity. The ICU experts who developed the measures and the ICU physicians and nurses who pilot tested the measures believed the measures, as defined in our specifications, evaluated an important aspect of quality. In addition, staff from participating sites believed the measures evaluated the domain of quality they intended to measure and identified important opportunities to improve quality. Nevertheless, providers should ensure that these measures are important and that they have face validity at their institution before committing resources to data collection efforts.

Second, any data collection in the ICU is burdensome and we need to evaluate the feasibility of data collection for these measures in other ICUs. We believe that we have developed practical data collection tools that could be implemented in a wide variety of ICUs. Indeed, many of the ICUs continue to collect data for the process measures as part of the transformation of the ICU collaborative sponsored by the VHA, including 22 additional ICU teams. In addition, many of these teams have expanded their data collection to include information on patient/family satisfaction with ICU care. Nevertheless, providers will need to evaluate the resources available at their institution to collect the data.

Finally, the value of these measures will be determined by our ability to improve the quality of ICU care. For example, we measured ventilator days, as opposed to the number of patients that received each process measure and we estimated the clinical and economic effect of our performance using published estimates of efficacy. As a result, we may have overestimated the excess morbidity, mortality, and costs per year. Nevertheless, because we chose measures in which the evidence regarding the association between the process and outcome is strong, we increased the likelihood that improvement in the process measure will produce improvements in patient outcomes. Further work is needed to evaluate whether improvements in performance result in improvements in patient outcomes.

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