



## Deficits in the Palliative Care Process Measures in Patients with Advanced Pancreatic Cancer Undergoing Operative and Invasive Nonoperative Palliative Procedures

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### ABSTRACT

**Background.** Given survival measured in months, metrics, such as 30-day mortality, are poorly suited to measure the quality of palliative procedures for patients with advanced cancer. Nationally endorsed process measures associated with high-quality PC include code-status clarification, goals-of-care discussions, palliative-care referral, and hospice assessment. The impact of the performance of these process measures on subsequent healthcare utilization is unknown.

**Methods.** Administrative data and manual review were used to identify hospital admissions with performance of palliative procedures for advanced pancreatic cancer at two tertiary care hospitals from 2011 to 2016. Natural language processing, a form of computer-assisted abstraction, identified process measures in associated free-text notes. Healthcare utilization was compared using a Cox proportional hazard model.

**Results.** We identified 823 hospital admissions with performance of a palliative procedure. PC process measures were identified in 68% of admissions. Patients with documented process measures were older (66 vs. 63;  $p = 0.04$ ) and had a longer length of stay (9 vs. 6 days;  $p < 0.001$ ). In multivariate analysis, patients treated by surgeons were less likely to have PC process measures performed (odds ratio 0.19; 95% confidence interval 0.10–0.37). Performance of PC process measures was associated with decreased healthcare utilization in a Cox proportional hazard model.

**Conclusions.** PC process measures were not performed in almost one-third of hospital admissions for palliative procedures in patients with advanced pancreatic cancer. Performance of established high-quality process measures for seriously ill patients undergoing palliative procedures may help patients to avoid burdensome, high-intensity care at the end-of-life.

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Pancreatic cancer remains a devastating disease with an 8.5% 5-year survival.<sup>1</sup> The majority of patients have metastatic disease at diagnosis. Localized disease and surgical resection improve survival; however, even after resection median 3-year survival is only 34.8%.<sup>2</sup> Before death, patients are at risk for multiple conditions associated with distressing symptoms, including biliary obstruction, gastric outlet obstruction, and malignant bowel obstruction, as well as complications of chemotherapy. Thus, palliative procedures, including nonoperative and operative

interventions, represent a substantial portion of care for patients with advanced disease.<sup>3</sup> The goal of these procedures is to reduce symptom burden and improve quality of life. Given survival measured in months, quality metrics, such as 30-day survival, may not be relevant.<sup>4</sup> Instead, previously established standards for cancer and palliative care endorsed by the National Quality Forum may be more appropriate in evaluating the quality of care delivery.<sup>5,6</sup>

Relevant processes measures associated with high-quality palliative procedures include clarification of code status, goals of care discussions, specialist palliative care consultation, and assessment for hospice.<sup>7</sup> Early discussions of code status and goals of care are associated with improved quality of life, reductions in burdensome care, and better alignment of treatments with patients' preferences.<sup>8–10</sup> Nonetheless, these conversations frequently occur late in the disease trajectory.<sup>11</sup> Palliative procedures provide a critical pause point in which these conversations can—and should—occur.

Identifying palliative care process measures using large datasets has been hampered by the cost and time constraints of manual chart review and the poor sensitivity of administrative coding.<sup>12,13</sup> Burgeoning technological advances in artificial intelligence and natural language processing (NLP), coincident with the growth of electronic health records (EHR), have provided a rich new source of data from unstructured clinical notes.<sup>14–16</sup> This represents an opportunity for the novel application of NLP to identify important processes measures of palliative care.<sup>7,17,18</sup>

In this study, we identified a cohort of patients with advanced pancreatic cancer (metastatic or unresectable) undergoing invasive palliative procedures performed by surgeons and other specialists. Using NLP, our goal was to quantify documentation of palliative care process measures and identify associated patient and admission characteristics. Finally, by linking these data with administrative claims, we sought to measure the association between palliative care process measures and subsequent 180-day healthcare utilization. We chose to focus on healthcare utilization as measured through emergency department (ED) evaluation, hospital readmission, and intensive care unit (ICU) utilization as this may represent burdensome care for patients at the end-of-life.

## METHODS

### *Data Source*

The Partners Research Patient Data Registry (RPDR) is a centralized repository of clinical and administrative data for Partners Healthcare, which serves one-third of all hospitalized patients in the Boston metropolitan area. The

database captures all inpatient encounters and contains mortality data through linkage with the Social Security Death Index. Claims data, including *International Classification of Disease, Ninth revision and Tenth revision diagnosis/procedure* (ICD-9-CM/PCS, ICD-10-CM/PCS) and current procedure terminology (CPT) codes, are available for all encounters. These data are linked to the EHR, providing admission notes, progress notes, procedure/imaging reports (operative, radiology, and endoscopy), and discharge summaries. This study was approved by the Partners Human Research Committee.

### *Study Population*

The cohort included adults ( $\geq 18$  years) with pancreatic cancer (ICD-9-CM 157 or ICD-10-CM C25) who underwent a qualifying palliative procedure during an in-hospital admission from January 1, 2011, to April 30, 2016. We did not include patients who underwent outpatient procedures, because they did not have the opportunity for assessment by an inpatient team and to avoid variability in documentation. We chose pancreatic cancer, because, despite advances in treatment, 5-year survival is  $< 10\%$ , and many patients suffer from high symptom burden at the end-stage of disease.<sup>1,3</sup>

We included procedures that were performed to palliate common sequelae of advanced pancreatic malignancies. Indications included biliary obstruction, gastric outlet obstruction, malignant bowel obstruction, failure to thrive, pleural effusion, malignant ascites, and cancer-related pain.<sup>19</sup> Invasive nonoperative and operative procedures were included, such as biliary stenting, paracentesis, celiac axis block, and hepaticojejunostomy. A full list of the procedures and associated administrative codes are provided in Supplementary Table 1. Procedures codes were identified from the RPDR database. Two physician researchers reviewed procedure codes to identify potentially palliative treatments for these conditions. To reduce the likelihood of including patients who may be receiving these procedures in conjunction with nonpalliative treatment, we excluded patients who had a pancreatic resection during or after the qualifying procedure admission (ICD-9-PCSS 52.5–52.7; CPT 48140, 48145–48146, 14850, 48152–48155, 48160; ICD-10-PCS 0FBG). Finally, two physicians manually reviewed operative and procedure notes to ensure a palliative intention for each procedure. We excluded procedures that were nonpalliative at the onset but were converted to palliative due to the discovery of occult metastatic or unresectable disease during the procedure. Any procedures in which the two reviewers were unable to determine the intent (palliative vs. nonpalliative) were reviewed by a surgical oncologist to determine appropriateness for inclusion.

### *Exposure: Palliative Care Process Measures*

Four distinct and previously endorsed process measures were included: code status clarification, goals of care discussions, referral to a palliative care specialist, and hospice assessment. NLP code to capture performance of these processes measures was developed by members of the research team using keyword and phrase libraries, as previously described by Lilley et al.<sup>7</sup> Performance assessment of NLP keyword and phrase libraries was validated in a sample of 241 notes. Definitions of all processes appear in Supplementary Table 2 with examples of keywords and phrases, representative quotations from EHR notes, and discriminative performance of NLP. Using NLP we reviewed all clinical notes associated with an admission. Palliative care process measures were identified in notes generated by prescribing clinicians (MDs, physician assistants, and nurse practitioners). The dates of note entry were used to determine when the process of care was first documented, relative to the qualifying procedure: before (including the day of the procedure), after, or never.

### *Outcomes: Mortality and Healthcare Utilization*

Survival duration was measured in days following the procedure and was used to compute 180-day mortality rates. Among live discharges, we measured the following healthcare utilization domains within the 180 days of discharge: ED evaluations, hospital readmissions, and ICU utilization during a readmission. ED evaluations, hospital readmission, and ICU utilization were identified using administrative data for encounter location and source of admission.

### *Covariates: Patient and Admission Characteristics*

Patient demographics were obtained to describe the cohort, including age, gender, marital status, and race/ethnicity. Admission characteristics included the type of admission (elective vs. nonelective), palliative procedure indication, proceduralist specialty, and length of hospital stay.

### *Statistical Analysis*

Data were analyzed at the admission level, with each hospital stay representing a discrete observation. The performance of palliative care process measures was assessed during each admission for a palliative procedure. Because patient goals and priorities change over the course of their illness, we sought to capture reassessment at the time of each hospital admission for patients with terminal illness undergoing a palliative procedure. If a patient had more

than one qualifying palliative procedure during a single hospital admission, the first procedure was used to determine the timing of the process measure performance (e.g., before or after the palliative procedure). In longitudinal analysis, we excluded patients who died in-hospital after a palliative procedure, because they were not eligible for ED evaluation, hospital readmission, or ICU utilization during a readmission.

Categorical variables were compared using Pearson's Chi-square analysis and continuous variables with the Wilcoxon rank-sum test. Logistic regression was performed to identify factors associated with process measure performance. Clinically appropriate variables with a  $p$  value  $\leq 0.1$  on univariate analysis including patient demographics and admission characteristics were manually entered in multivariable analysis. The analysis was performed at the patient-procedure level with clustering by patient and reported as an odds ratio (OR). To avoid assumptions of linearity, we categorized continuous variables in multivariable analysis. In addition, we performed a sensitivity analysis focused on the timing of palliative care process measures performance as well as analysis focused solely on the performance of hospice referral.

Healthcare utilization was compared through univariable analysis and a Cox proportional hazard model. The Cox proportional hazard model controlled for differences in length of follow-up with censoring for death and end-of-study period. Given the potential for performance of process measures at the time of each palliative procedure, we censored for each recurrent palliative procedure. Covariates in the model included demographics and admission characteristics with a  $p$  value  $\leq 0.1$  on univariate analysis. All analysis was performed at the patient-procedure level with clustering by the patient and reported as hazard ratios (HR) with associated 95% confidence intervals (CI). Computations were performed using Stata software, version 15.1 (StataCorp, College Station, TX). Two-tailed  $p$  values  $< 0.05$  were considered to be statistically significant.

## **RESULTS**

There were 675 patients, and 2185 identified procedures among patients with a diagnosis of pancreatic cancer. We excluded 311 procedures, in which the procedure was performed on patients with resectable disease. We further excluded 960 procedures in which the procedure was performed as an outpatient, for nononcology related indications, or occurred during the same hospital admission as an earlier palliative procedure. Finally, we excluded 91 procedures in which the patient was discovered to have

occult metastatic or unresectable disease at the time of the procedure. The final study cohort included 523 patients and 823 procedures (Fig. 1).

*Performance of Palliative Care Process Measures*

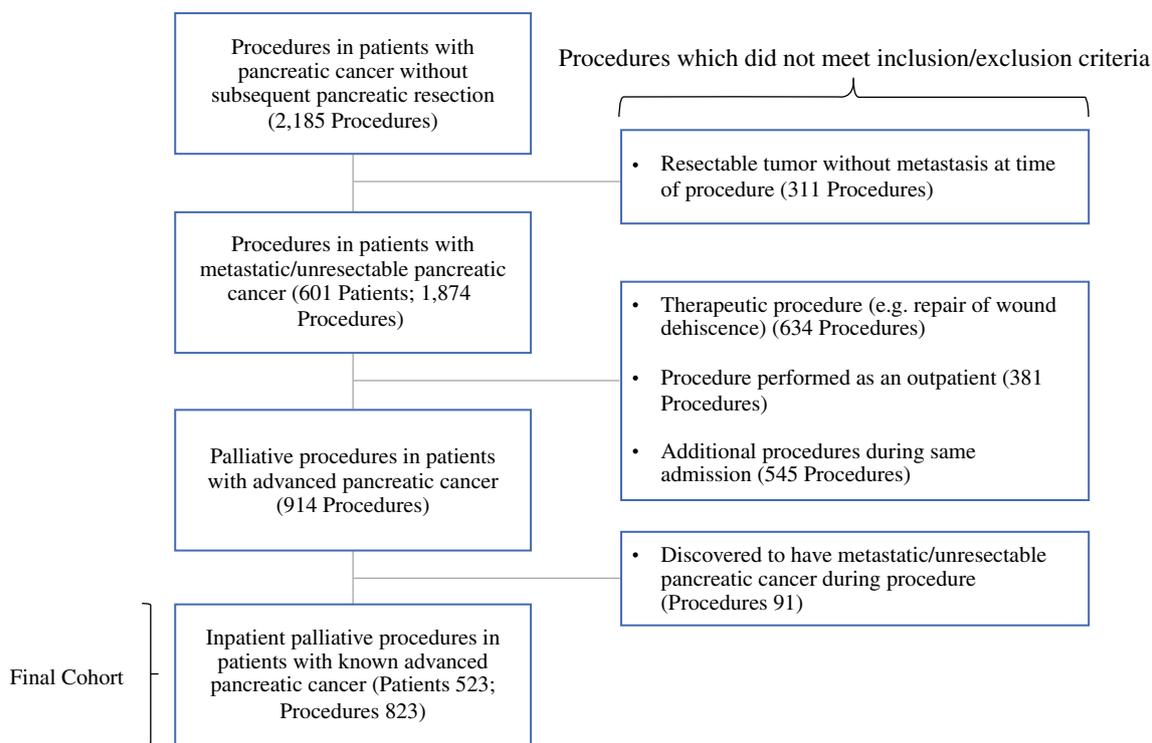
Of the 823 procedures, 68% were associated with at least one palliative care process measure. The median number of process measures documented per procedure was 2 with an interquartile range (IQR) of 0–3 (Table 1). Only 25% of admissions had documentation of all four process measures. The most common process measure was referral for specialist palliative care consultation, which occurred in 56% of all procedures. Hospice assessment was the least frequent and was associated with 33% of palliative care procedures. Code status clarification and goals of care discussion occurred in association with 54% and 49% of all procedures, respectively. For all four process measures, documentation most commonly occurred before the procedure (80–94%).

*Patient and Admission Characteristics Associated with Palliative Care Process Measures*

Median patient age was 65 (interquartile range 57, 73), 52% were male, and 86% were non-Hispanic white. Patients with palliative care process measures were older (66 vs. 63;  $p = 0.04$ ), had longer hospital lengths of stay (9

vs. 6 days;  $p < 0.001$ ), and were more likely to have a nonelective admission (90% vs. 74%;  $p < 0.001$ ; Table 2). Those with process measure documentation were more likely to have malignant ascites or a malignant pleural effusion ( $p < 0.001$ ). Correspondingly, there was variation in process measures performance based on the proceduralist. Procedures performed by surgeons were less commonly associated with process measure documentation (45%) compared with procedures performed by other specialists (63–81%;  $p < 0.01$ ; Fig. 2). The specific procedures performed by surgeons and other proceduralists are listed in Supplementary Table 3. In sensitivity analysis, patients who had process measures performed after a palliative procedure had a longer median length of stay compared with those that had process measures performed before the palliative procedure (11 vs. 9 days;  $p < 0.001$ ) but were otherwise similar (Supplementary Table 4).

In multivariate analysis, age  $> 75$  years was associated with palliative care process measure performance (OR 1.83; 95% CI 1.06–3.14;  $p = 0.04$ ; Table 3). Admission factors associated with process measures were nonelective admission (OR 1.88; 95% CI 1.18–2.97;  $p = 0.01$ ), length of stay 6–12 days (OR 2.67; 95% CI 1.185–3.86;  $p < 0.001$ ), and length of stay  $\geq 13$  days (OR 6.41; 95% CI 3.88–10.6;  $p < 0.001$ ). Indications associated with palliative care process measure performance included malignant ascites, malignant bowel obstruction, and malignant pleural effusion. Procedures performed by



**FIG. 1** Inclusion and exclusion criteria

**TABLE 1** Presence of palliative care process measure documentation during admission for palliative procedure

	Palliative procedures ( <i>n</i> = 823)
Median number of process measures per procedure (IQR)	2 (0, 3)
Documentation of $\geq 1$ processes measures (%)	68
<i>Code status clarification (%)</i>	
Before procedure	49
After procedure	5
<i>Goals of care discussion (%)</i>	
Before procedure	39
After procedure	10
<i>Palliative care referral (%)</i>	
Before procedure	52
After procedure	3
<i>Hospice assessment (%)</i>	
Before procedure	28
After procedure	5

*IQR* interquartile range

surgeons were significantly less likely to have associated palliative care process measures (OR 0.19; 95% CI 0.10–0.37;  $p < 0.001$ ). In sensitivity analysis, patient and hospital factors associated with just hospice assessment were like those associated with other palliative care process measures and included older age, increased length of stay, and certain indications, such as malignant ascites and bowel obstruction. As with other palliative care process measures, hospice assessment was inversely associated with procedures performed by surgeons (Supplementary Table 5).

#### *Mortality and Healthcare Utilization*

Overall, 180-day mortality was 73%. Mortality was higher after procedures in which palliative care process measures were performed (Table 2). Palliative care process measures were associated with a decrease in ED evaluation, hospital readmission, and ICU utilization during readmission. The timing of the palliative care process measure (e.g., before or after the palliative procedure) was not associated with significant differences in healthcare utilization. However, same admission death was associated with patients who had palliative care process measures performed after the palliative procedure (17.9% vs. 8.2%;  $p < 0.01$ ; Supplementary Table 3).

To account for differences in survival that might contribute to differences in healthcare utilization, a Cox proportional hazard model was used. When accounting for differences in survival, there remained an association between palliative care process measures and decreased healthcare utilization (Table 4). Specifically, goals of care discussion were associated with decreased ICU utilization

(HR 0.69; 95% CI 0.48–0.99;  $p = 0.046$ ). Likewise, hospice assessment was associated with a decrease in ED evaluations (HR 0.53; 95% CI 0.039–0.74;  $p < 0.001$ ), hospital readmissions (HR 0.58; 95% CI 0.43–0.75;  $p < 0.001$ ), and ICU utilization (HR 0.39; 95% CI 0.22–0.69;  $p < 0.001$ ). Finally, code status clarification was associated with decreased hospital readmission (HR 0.79; 95% CI 0.64–0.95;  $p = 0.02$ ). Increased 180-day mortality was expectedly associated with all four palliative care process measures.

#### **DISCUSSION**

In this multi-institutional study of patients with advanced pancreatic cancer, we used NLP to identify nationally endorsed palliative care process measures (code status clarification, goals of care discussion, specialist palliative care referral, and hospice assessment) during hospitalization for palliative procedures. We found that 68% of admissions for a palliative procedure had one or more processes measures performed, but only 25% had all four. Adjusting for differences in survival, having palliative care process measures performed during the admission was associated with fewer ED visits, hospital readmissions, and ICU admissions in the subsequent 180 days.

The association between palliative care processes measures and subsequent healthcare utilization is important. In a multi-institutional, prospective cohort study, patients with advanced cancer who reported having conversations with clinicians about goals of care in the outpatient setting received less invasive care near death compared with a propensity-score weighted control, including less ICU use.<sup>10</sup> Moreover, patients who report conversations about

**TABLE 2** Demographics, admission characteristics, mortality, and healthcare utilization for patients undergoing inpatient palliative care procedures with advanced pancreatic cancer stratified by performance of process measures

	Palliative care process measures		<i>p</i> value
	No ( <i>n</i> = 185)	Yes ( <i>n</i> = 338)	
Female (%)	44	50	0.17
Age <sup>a</sup> , median (IQR)	63 (57, 71)	66 (57, 74)	0.04
Race/ethnicity (%)			
Non-Hispanic white	90	84	0.21
Black	3	3	
Hispanic	4	4	
Asian	2	4	
Other/unknown	2	5	
Married or long-term relationship (%)	69	62	0.12
	No (procedures = 263)	Yes (procedures = 560)	<i>p</i> value
Nonelective admission (%)	74	90	< 0.001
Length of stay (days), median (IQR)	6 (3, 9)	9 (6, 14)	< 0.001
Indication (%)			
Biliary obstruction	42	30	< 0.001
Malignant ascites	20	32	
Gastric outlet obstruction	19	11	
Malignant pleural effusion	7	10	
Cancer-related pain	7	9	
Malignant bowel obstruction	4	5	
Failure to thrive	2	2	
Specialty of proceduralist (%)			
Interventional radiology	35	51	< 0.001
Gastroenterology	39	32	
Surgery	22	8	
Other <sup>b</sup>	4	9	
Mortality (%)			
Prior to discharge	2	11	< 0.001
30 days	13	38	< 0.001
90 days	37	69	< 0.001
180 days	56	82	< 0.001
Healthcare utilization (%)			
Intensive care unit utilization	33	16	< 0.001
Emergency department evaluation	56	35	< 0.001
Hospital readmission	75	49	< 0.001

*IQR* interquartile range

<sup>a</sup>Age at time of first palliative procedure

<sup>b</sup>Includes internal medicine, emergency medicine, and intervention pulmonology

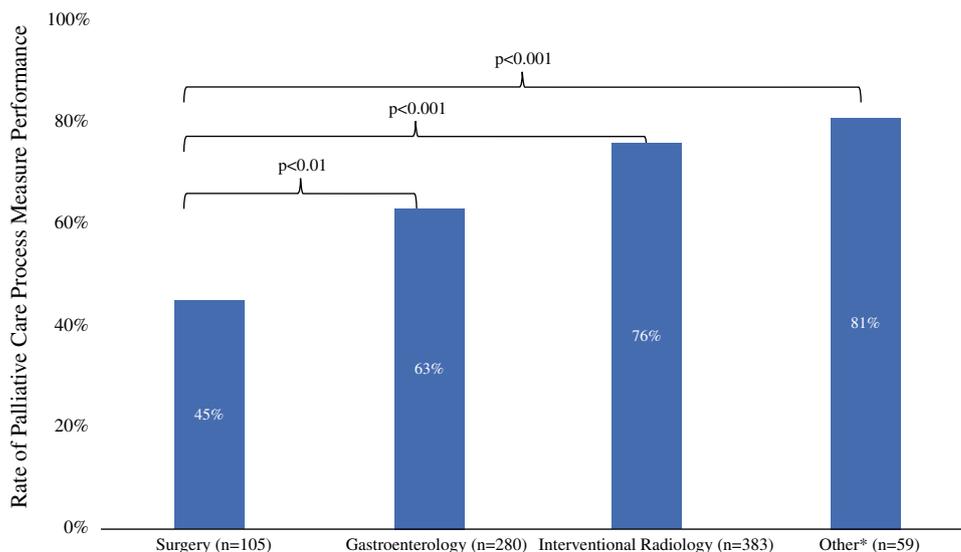
goals of care have a better quality of life, whereas their bereaved caregivers have less risk for major depressive disorder.<sup>9,20,21</sup> Our study builds upon prior work by demonstrating reduced healthcare utilization after the performance of palliative care process measures during an acute hospitalization for a palliative procedure. These data

suggest that the impact of performing palliative care process measures extends beyond the immediate palliative treatment and may assist with future care decisions.

The reduced survival among patients with palliative care process measures likely represents selection bias. Patients with higher disease burden and closer to end-of-life are more likely to have palliative care process measures

**FIG. 2** Rate of palliative care process measures performance stratified by proceduralist.

\*Other includes anesthesiology, emergency medicine, internal medicine, and interventional pulmonology



**TABLE 3** Association of patient and procedure characteristics with performance of  $\geq 1$  palliative care process measures during inpatient admission with a palliative procedure

	Odds ratio (CI)	<i>p</i>
Nonelective admission	1.88 (1.18–2.97)	0.01
Non-Hispanic white	0.74 (0.45–1.24)	0.25
Age (years)		
< 65	Ref.	
65–75	1.00 (0.68–1.48)	0.99
> 75	1.79 (1.04–3.08)	0.04
Length of stay during admission for palliative procedure (days)		
$\leq 5$	Ref.	
6–12	2.67 (1.85–3.86)	< 0.001
$\geq 13$	6.41 (3.88–10.6)	< 0.001
Indication		
Biliary obstruction	Ref.	
Malignant ascites	2.15 (1.15–4.01)	0.02
Gastric outlet obstruction	1.51 (0.86–2.62)	0.15
Malignant pleural effusion	4.22 (1.89–9.46)	< 0.001
Cancer related pain	1.69 (0.78–3.66)	0.18
Malignant bowel obstruction	3.31 (1.16–9.49)	0.03
Failure to thrive	2.63 (0.89–7.74)	0.08
Specialty of proceduralist		
Interventional radiology	Ref.	
Gastroenterology	1.02 (0.58–1.81)	0.87
Surgery	0.19 (0.10–0.37)	< 0.001
Other <sup>a</sup>	1.02 (0.58–1.81)	0.93

CI confidence interval

<sup>a</sup>Includes internal medicine, emergency medicine, and intervention pulmonology

performed. These findings corroborate prior studies showing that conversations about palliative care mainly occur close to death.<sup>8,11</sup> The difference in mortality also may be explained by patients electing for less invasive treatments and prioritizing comfort over longevity.<sup>22,23</sup> Nonetheless, half of those without performance of palliative care process measures died within 180 days of the procedure, highlighting that in these cases, admission for a palliative procedure was a missed opportunity to have this dialogue. While code status and treatment limitations should be assessed in the outpatient setting, proceduralist and inpatient teams should clarify and confirm patient goals during an admission, which may be dynamic depending on the patient's health state.<sup>8,24–26</sup>

We noted significant variation in process measures performance with procedure and proceduralist. Procedures performed by surgeons were less likely to be associated with process measure performance. This may be partially explained by surgeons treating patients earlier in the disease course; however, even among patients treated by surgeons, median survival was only 140 days (Supplementary Table 6). An alternate explanation for the reduced rate of palliative care process measure performance among surgeons may be discomfort around end-of-life discussion. Several studies have shown that surgeons may be hesitant in initiating conversations about end-of-life care, especially in the perioperative setting.<sup>27,28</sup> Likewise, there may be multiple structural and logistic limitations, such as increased acuity and busier clinical workload that make it more difficult for surgeons to have and document these conversations.<sup>29</sup> The high overall mortality of this cohort

**TABLE 4** Association of palliative care process measures with healthcare utilization and 180-day mortality

	ICU utilization		ED evaluation		Readmission		Mortality (180 day)	
	HR (CI)	<i>p</i>	HR (CI)	<i>p</i>	HR (CI)	<i>p</i>	HR (CI)	<i>p</i>
Code status clarification	0.87 (0.62–1.24)	0.45	0.97 (0.77–1.21)	0.78	0.79 (0.64–0.95)	0.02	1.73 (1.46–2.03)	< 0.001
Goals of care discussion	0.69 (0.47–0.99)	0.046	0.87 (0.81–1.34)	0.30	0.89 (0.73–1.10)	0.29	1.64 (1.39–1.95)	< 0.001
Palliative care referral	1.35 (0.95–1.94)	0.09	1.19 (0.92–1.54)	0.17	1.17 (0.96–1.42)	0.13	1.59 (1.33–1.92)	< 0.001
Hospice assessment	0.39 (0.22–0.69)	< 0.01	0.53 (0.39–0.74)	< 0.001	0.58 (0.43–0.75)	< 0.001	2.22 (1.78–2.78)	< 0.001

ICU intensive care unit, ED emergency department, HR hazard ratio, CI confidence interval

Table represents output of separate regressions for each outcome. Variables with a *p* value < 0.10 on univariate analysis were included in the model. These factors included age, race/ethnicity, type of admission (elective vs. nonelective), length of stay, indication for procedure, and proceduralist

suggests that any palliative admission provides an opportunity for advance care planning, setting expectations, and determining the desire for subsequent interventions.

Unexpectedly, we did not observe a significant association between specialist palliative care referral and subsequent healthcare utilization. This may in part be explained by selection bias, in that patients with the greatest symptomatic burden of disease were more likely to receive palliative care referral and more likely to require subsequent ED evaluation, hospital readmission, and ICU utilization. Furthermore, while we captured referral to palliative care specialists, patients and families may have declined the consultation or recommendations.

There are several limitations to this study. First, data were not available on care received outside the Partners Healthcare System, so data in this study may not capture all healthcare utilized after the index hospitalization. Second, our NLP methodology only captures documented discussions and may underreport the true rate of goals of care discussions for each patient over the course of their illness. Nonetheless, documentation of palliative care process measures, such as code status and goals of care are inherent to their utility. Additionally, documented palliative care may not be reflective of the care a patient and their family believe they receive.<sup>30</sup> As with all retrospective cohort studies we are able to demonstrate associations, but not causality. Randomized, prospective studies will be needed to demonstrate a causal relationship between the performance of palliative care process measures and decreased healthcare utilization. Likewise, further studies are necessary to develop aids for clinicians, whether through checklists or other methods, to perform efficiently these important process measures.

Finally, end-of-life care is complex and nuanced. The palliative care process measures explored in this work represents only one aspect and the benefits may be both existential and emotional. There are many challenges to performing these process measures, including patient

distress, cultural barriers, and prognostic uncertainty.<sup>29</sup> In this retrospective study, we were unable to determine the reason process measures were not performed in approximately one-third of hospital admissions for a palliative procedure.

## CONCLUSIONS

Palliative care process measures are absent in almost one-third of palliative procedures performed for advanced pancreatic cancer. Performance of palliative care process measures during hospital admissions for palliative procedures may assist with future care decisions and help patients to avoid unwanted, high-intensity care at the end-of-life.

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**AUTHOR CONTRIBUTIONS** EJM and BVU had access to all data in this study and take full responsibility for the integrity of the data and accuracy of the analyses. Study concept and design: EJM, BVU, CL, ZC. Acquisition of data: EJM, ZC, BVU. Analysis and interpretation of the data: All authors. Drafting of the manuscript: EJM, BVU. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: EJM, BVU.

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