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Derivation and Validation of a Risk Model for Emergency Department Palliative Care Needs Assessment using the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) Tool

By

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Epidemiology

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Derivation and Validation of a Risk Model for Emergency Department Palliative Care Needs Assessment using the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) Tool

By

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Bachelor of Arts University of California - Berkeley 2009

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An abstract of A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Epidemiology 2014

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Abstract

Derivation and Validation of a Risk Model for Emergency Department Palliative Care Needs Assessment using the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED)

By Danielle Moulia

Background: A key setting for the provision of palliative care is the emergency department (ED) where important decisions regarding patient treatment and next site of care are determined. One barrier to the provision of palliative care in the ED is identifying patients who would benefit from a palliative care consult. The Screen for Palliative and End of Life Care Needs in the Emergency Department is a 5-question screening that can be completed either by a patient or proxy (SPEED informer). It assesses 5 domains of unmet palliative care needs – physical symptoms (pain), psychological distress, access to care, medication management, and goals of care alignment.

Objective: To derive and validate a risk model to predict a palliative care event (palliative care consult, discharge to hospice, or in-hospital death) for cancer patients with an ED visit and subsequent hospital admission using data available upon arrival, including data from the SPEED tool.

Methods: We performed a retrospective derivation and temporal validation of a risk model for a palliative care event (PCE). We developed a multivariate logistic regression model to predict PCEs based on SPEED data and other patient characteristics available upon arrival to the ED. We assessed model performance using a receiver operating characteristic curve and visual inspection of quintile plots.

Results: Eleven factors were identified as predictive of a PCE, including SPEED score, proxy SPEED informer, age, EMS arrival, emergent or immediate ED acuity, the number of ED visits within the last 90 days, metastatic cancer, cardiac arrhythmias, coagulopathy, depression and weight loss. In validation, the risk model had an area under the curve of 0.72 and calibration showed an underestimation of risk in the second and third quintiles.

Conclusions: A risk model based on SPEED score has been successfully derived, but needs a larger dataset for proper validation. If the predictive ability of the model is confirmed, a risk model can efficiently identify cancer patients arriving to the ED who may benefit from early initiation of a palliative care consult.

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Literature Review

Derivation and Validation of a Risk Model for Emergency Department Palliative Care Needs Assessment using the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) Tool

By Danielle Moulia

Palliative care is the comprehensive treatment of physical, psychological, social and spiritual needs of patients and families dealing with serious and life-limiting illness. Palliative care alleviates suffering and centers on meeting patient goals of care. Palliative care can be offered with or without live-saving therapies and can be provided to patients across the care continuum and trajectory of their illness (1). Due to palliative care's historical origins in the care of oncology patients and the debilitating nature of the disease (2), cancer is the most common diagnosis for which patients receive palliative care in the United Sates (3).

Cancer is the second leading cause of death in the United States (4). There are currently 13 million people living with cancer and 1.6 million new cancer diagnoses every year (4). Cancer is a heterogeneous group of diseases caused by unregulated cell growth. Survival rates differ drastically by type of cancer. While modern cancer therapies, such as surgery, chemotherapy and radiation therapy, are able to generally extend life and sometimes cure cancer, the physical and psychological burden on patients, caregivers and families can be tremendous. In most cases cancer patients do not die immediately. Instead, patients often live for extended periods of time with a progressively debilitating, life limiting illness (5). Palliative care can help patients and families on this disease trajectory. Among advanced cancer patients, palliative care is associated with increased quality of life (6-8), alleviation of symptoms (8, 9) and an increase in life expectancy (10).

Benefits of Palliative Care for Cancer Patients

The American Society of Clinical Oncology issued a provisional clinical opinion that palliative care, when combined with standard oncology care, leads to better patient and caregiver outcomes (11). There are 5 randomized controlled trials that form the basis of this provisional opinion.

In one landmark study by Temel et al., 151 newly diagnosed non-small-cell cancer patients were randomized to either early palliative care integrated with usual oncological care or usual oncological care. Those who received early palliative care had significant improvements in survival, living on average 2.7 months longer than non-palliative care patients. Patients who received early palliative care also had higher quality of life and mood scores than those who received only oncology care (10). In a secondary analysis of the same trial, researchers found that early palliative care optimized the timing of chemotherapy (12).

In a multicenter, randomized controlled trial conducted by Gade et al., 517 patients with life-limiting illness (of whom 159 were cancer patients) were randomized to either inpatient palliative care consult or usual hospital care. Patients who received inpatient palliative care had significantly greater satisfaction with care and provider communication, fewer ICU admissions on readmission, and an average six-month net cost savings of \$4,855 (7).

Brumley et al. randomized 298 homebound, terminally ill patients (prognosis 1 year or less) to usual care or usual care plus in-home palliative care. Patients

receiving usual care plus in-home palliative care had significantly higher patient satisfaction, reduced service utilization, and lower costs than those in usual care (6).

In a randomized controlled trial, Bakitas et al. recruited 322 advanced cancer patients and randomized them to usual oncology or usual oncology plus a palliative care intervention that addressed physical, social and care coordination needs. They found that patients with palliative care plus oncology care had significantly higher quality life and mood compared to patients who just had usual oncology care (8).

Zimmermann et al. cluster-randomized 24 medical oncology clinics to provide consultation and follow-up by a palliative care team in additional to usual oncology care, or usual oncology care. Among 461 patients, the researchers found that patients who received palliative care had higher satisfaction with their care, however there was no statistically significant differences in quality of life scores between intervention and control at the original 3 month endpoint. However, at 4 months there was a statistically significant difference between groups, indicating that benefits accrue over time (9).

Outside of randomized controlled trials there is numerous evidence supporting the effectiveness of palliative care for patients. Casarett et al. conducted a retrospective survey of family members of patients who received inpatient or outpatient palliative care in the last month of life from five Veteran's Affairs Medical Centers (or their nursing homes and outpatient clinics). Family members were to score nine aspects of patient care, including well-being and dignity, communication, respect for treatment preferences, emotional and spiritual support, symptoms, care at time of death, and access to services. Family members of patients who had received palliative care scored all nine aspects higher. In multivariable modeling, consults that occurred earlier were independently associated with higher overall scores (13).

Patients who have end of life care discussions with providers are more likely to receive care that fits with their goals (14, 15). In addition, families who receive palliative care interventions report higher satisfaction with communication and decision-making (16). As palliative care is most frequently provided on an inpatient basis, these early interventions are not widely available and many cancer patients do not receive adequate care.

State of Palliative Care for Cancer Patients

The Institute of Medicine has issued two reports on the quality of care of persons with cancer (2003 and 2013), where they reported that many persons living with cancer are unable to find care that adequately manages symptoms and aligns with their goals of care (17, 18). These reports highlight the national discrepancy between patient's goals of care and the care they actually receive. A majority of patients report a preference for supportive care that alleviates symptoms and helps them stay out of the hospital during the course of their disease (19). Additionally, when the time comes, most patients report that they prefer to die at home (20, 21). The reality, in contrast, is that 1 in 4 cancer patients die in the hospital and 62% are hospitalized in the last month of life (22). Breakthrough pain, dyspnea, nausea and other symptoms draw patients to the emergency department (ED) at a rate of over 500,000 visits per year (23). While some ED visits and hospitalizations are unavoidable, ED visits have been identified as an indicator of poor quality care for patients with advanced cancer (24).

Palliative Care in the ED

With increasing ED visits, long wait times and subsequent inpatient stays for over 60% of cancer patients (24, 25), the ED is an important care setting for cancer patients. The care provided in the ED influences the treatment trajectory and site of care for patients visiting the hospital (26). Communication with patients and families affects their understanding of their illness and choice of treatment options. Medical interventions, such as mechanical ventilation, may be initiated in the ED, and clinicians determine the site at which care will continue, such as ICU, inpatient unit, or home (26). These factors make the ED a natural setting to provide palliative care: patient-centered communication and advanced planning to ensure patients are receiving care that fits with their goals.

However current palliative care services in the ED are lacking. Families report inadequate communication and end of life decision-making taking place in the ED (16). In a survey of 350 patients with advanced cancer who were admitted to the hospital it was found that the most common reason for admissions was uncontrolled symptoms (66-70%), an issue palliative care is uniquely well-suited to address (13). Among the highly symptomatic population, 70% were discharged without palliative care services and only 18% were enrolled in hospice (27). One study at an urban academic medical center found that most patients who receive a palliative care consult during an inpatient stay were admitted through the ED. However there are relatively long waits for inpatient palliative care consultations, roughly 6 days (28, 29), suggesting the opportunity to upstream palliative care consults to the ED could lead to faster management of pressing palliative care needs. There is a small but growing number of studies that look at the effects of providing palliative care consults in the ED. In a retrospective analysis of administrative data, Wu et al find that those who had a palliative care consult in the ED had a significantly lower hospital length of stay (3.6 days less) than those who had a palliative care consult after inpatient admission (30). In a study of patient outcomes before and after the establishment of an ED palliative care triage, Mahoney et al. found that there was a significant decrease in median time from admission to palliative care consult, length of inpatient stay, and increase in referrals to hospice (11).

Barriers to Providing Palliative Care in the ED

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While the benefits of providing palliative care in the ED are being established, there are many barriers to its provision. Palliative care consult services are not available 24 hours daily (28, 31), due in part to palliative workforce shortages (32). In addition, primary palliative care skills, or the ability of non-palliative care specialized clinicians to provide palliative care, is often lacking among ED providers (33-35). In a qualitative study of emergency physician attitudes and beliefs regarding the provision of palliative care in the ED, providers identified the emergency medicine culture of stabilization of patients experiencing acute medical emergencies, limited knowledge of palliative care and discomfort with medico-legal issues as barriers to the provision of primary palliative care in the ED (36).

One commonly identified barrier is an efficient method to identify those ED patients who may benefit from a palliative care consult (36, 37). ED clinicians have a very short amount of time with each patient and limited knowledge of their medical history. While prior work has been done on identifying palliative care patients in other

acute care settings including inpatient wards (38, 39), the surgical intensive care unit (40), and medical intensive care unit (41), these tools would be hard to adapt to the ED as the required information is not readily available upon patient admission.

The SPEED Screen

One way to identify patients with palliative care needs is using symptom assessment tools. The Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) tool is designed to assess unmet palliative care needs among cancer patients presenting to the ED. The SPEED tool was formulated by an expert panel of emergency clinicians and validated in an urban, tertiary, teaching hospital among English-speaking patients, 21 years of age or older. The validated tool contains 13 questions that assess palliative care needs in 5 domains: social, therapeutic, physical, psychological and spiritual. The SPEED tool can be rapidly administered in the ED upon secondary assessment. Patients score each item on a 0-10 Likert scale, with 0 indicating the lowest need and 10 indicating the highest need. In validation, the tool showed high reliability (Cronbach's a: 0.7-0.9) (42). A national group of ED and palliative care experts have reviewed the SPEED questions and identified score thresholds that indicate that a patient may have substantial unmet palliative care needs and would benefit from further intervention in the ED (43). The SPEED tool is the first screening developed to identify patients in need of palliative care consults in the ED; used in conjunction with patient clinical and demographic information it has the promise to efficiently and accurately identify patients who would benefit from a palliative care consult in the ED.

Conclusion

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Research shows that cancer patients would likely benefit from early palliative care consults in the ED through more timely consults, direct hospice referral (44) and decreased length of stay (45). Up streaming palliative care consults to the ED will also likely result in earlier symptom alleviation, care that is in line with patient wishes and better understanding of disease and treatments for patients and their families (13). To achieve this, however, the ED needs a set of fast and accurate criteria to identify patients who will benefit from palliative care.

Manuscript

Derivation and Validation of a Risk Model for Emergency Department Palliative Care Needs Assessment using the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) Tool

By Danielle Moulia

Introduction

Palliative care aims to ease suffering and enhance the quality of life for patients with serious and life-limiting illness, as well as to provide care that is aligned with a patient's stated goals and wishes. Among advanced cancer patients, palliative care is associated with increased quality of life (6-8), alleviation of symptoms (8, 9) and an increase in life expectancy (10). In the United States, cancer is the second leading cause of death (46). Inpatient hospital admissions are recognized as an indicator of poor quality end-of-life care for cancer patients (47), as the majority of patients indicate that they would like to receive care that alleviates symptoms and reduces time spent in the hospital at the end of their lives (21). However, cancer patients visit the emergency department (ED) over 500,000 times per year due to breakthrough pain, dyspnea and other uncontrolled symptoms (23). In 2010, 62% of cancer patients were hospitalized and 24% of patients died in the hospital (22). Common reasons for hospitalization are uncontrolled pain, high symptom burden and family distress at symptoms (27).

With increasing ED visits and subsequent inpatient stays for advanced cancer patients (24) (48), the ED is an important care setting for patients. The care provided in the ED influences the treatment trajectory and site of care for patients visiting the hospital (26). Communication with patients and families affects their understanding of their illness and choice of treatment options. Medical interventions, such as mechanical ventilation, may be initiated in the ED and clinicians determine the site at which care will continue, such as ICU, inpatient unit, or home (26). These factors make the ED a natural setting to provide palliative care, patient-centered communication and advanced planning to ensure patients are receiving care that fits with their goals. One study found that initiation of palliative care in the ED is associated with a decreased length of stay, allowing patients to return home earlier and lowering hospital costs (49). However, the ED is a very busy setting, so the fast and accurate identification of patients is essential. One possible solution is the Screen for Palliative and End of Life Care Needs in the Emergency Department (SPEED) tool.

The SPEED tool is designed to identify cancer patients with unmet palliative care needs in a busy ED setting (42). In a preliminary study of 1,025 patients who presented to the ED of a southern tertiary academic medical center and completed the SPEED instrument between March of 2010 and December of 2011, higher SPEED scores were significantly associated with increased odds of receiving a palliative care consult (50). These results indicate that the SPEED tool could be an effective predictor of the eventual need of a palliative care consult, when used in conjunction with other clinical and demographic variables.

Further research is needed to facilitate early identification and triage of those who present to the ED with palliative care needs, especially cancer patients (37). The purpose of this study is to develop and validate a model that uses SPEED score to predict which cancer patients would benefit from a palliative care consult in the ED. A risk prediction model that performs well could facilitate early identification of patients who will benefit from palliative care services in the ED, ensuring earlier access to a palliative care consult and better care for cancer patients.

Methods

Study Design

We performed a retrospective derivation and temporal validation of a risk model for a palliative care event (PCE). Records that were missing a documented respondent to the SPEED assessment, ED acuity, and ED mode of arrival were removed.

Study Setting

This study was conducted at Emory University Hospital (EUH). EUH is 590-bed, acute care, academic medical center in the Atlanta metropolitan area with approximately 37,000 annual ED visits.

Study Participants

The study population consisted of all cancer patients admitted to the hospital from the ED between September 2011 and February 2014 who were given the SPEED screen during secondary assessment in the ED. Criteria for a SPEED assessment included ≥ 21 years of age, English-speaking and being an active cancer patient (diagnosis or treatment in the past 12 months) (42).

SPEED Tool

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The SPEED tool is a 5-question, rapid assessment of unmet palliative care needs among cancer patients in the ED. The SPEED tool was formulated by an expert panel of emergency clinicians and validated in an urban, tertiary, teaching hospital among English-speaking patients, 21 years of age or older (42). While the validated tool included 13 questions, it was shortened to 5 – one question for each of the 5 domains of the larger SPEED screen – for use in our ED. ED clinicians can use the SPEED tool to quickly assess five key areas of palliative care needs -- physical symptoms (pain), psychological distress, access to care, medication management and care alignment with patient goals. Patients score each item on a 0-10 Likert scale, with 0 indicating the lowest need and 10 indicating the highest need (Figure 1).

In June of 2010 the SPEED tool was deployed in the eligible population in our ED. During secondary assessment a nurse verbally asks the patient all 5 questions, instructing them to respond with a score from 0-10. The nurse enters the scores from each question into the patient's electronic medical record. If the patient is not able to verbally answer the questions, a proxy (informer) may respond on behalf of the patient. Currently, the SPEED tool is being used for research purposes only, not in the triage of care. A national group of ED and palliative care experts has reviewed the SPEED questions and identified score thresholds that indicate that a patient may have substantial unmet palliative care needs and would benefit from further intervention in the ED (43). We leveraged these expert-defined thresholds to build our predictive model, described below.

Study Outcome

The composite endpoint of our study, a palliative care event (PCE), was defined as either an inpatient palliative care consult during the stay subsequent to the ED visit, discharge to hospice or in-hospital death.

Data Collection

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We retrospectively reviewed the clinical and administrative records of all patients admitted to the hospital from the ED during the study period. Admissions from September 2011 to August 2013 were included in the derivation set. By the time the model derivation had been completed another six months of records were available (September 2013 to February 2014) for validation. Demographic data was missing for marital status (3%), race/ethnicity (4%), income quartile (3%), financial class (2%). These records were retained, as they were not included in multivariate analysis. Many patients (15%) had multiple hospital visits during the study period; records for all visits were retained.

We reviewed data on candidate predictors and patient demographics. Patient demographic characteristics included age, sex, race/ethnicity, marital status, financial class and income quartile. Income quartile was used as a proxy for socioeconomic status. It was classified using 2010 Census data on the median household income of residents in a patient's ZIP code, with Quartile 1 indicating the lowest income and Quartile 4 the highest.

Candidate predictors were identified by palliative care and ED experts as clinically relevant to a PCE and available upon arrival to the ED. Candidate predictors in the following areas were abstracted: SPEED screen, previous healthcare utilization, clinical variables. SPEED screen predictors included SPEED informer (patient vs. nonpatient) and scores on all five questions. SPEED score was classified as the number of questions for which the patient's score exceeded the expert-defined threshold indicating significant palliative care need. Prior utilization predictors included the number of ED visits and all cause hospitalizations within the preceding 90 days.

Clinical predictors included mode of arrival to the ED, ED acuity and patient comorbidities. ED acuity is used for triage and patients are rated on a 1 to 4 scale. ED acuity 1 refers to patients classified as emergent and highest priority, ED acuity 2 refers

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to patients classified as urgent and is the second highest priority and ED acuity 3 or 4 are non-urgent and stable patients. Patient's primary and secondary diagnoses (ICD-9 codes) were categorized into 31 comorbidities using the Elixhauser comorbidity classification system (51). Patients could have more than one comorbidity. Two physicians with ED and palliative care expertise selected comorbidities that could be clinically relevant to a PCE, including: metastatic cancer, fluid and electrolyte disorder, weight loss, cardiac arrhythmias, depression, coagulopathy, renal failure, congestive heart failure, chronic pulmonary disease, liver disease, complicated hypertension, pulmonary circulation disorders, paralysis, complicated diabetes, valvular disease, blood loss anemia and HIV/AIDs.

Statistical Analysis

Descriptive univariate analyses were used to characterize the derivation and validation cohorts. Bivariate analyses of the associations between PCE and all covariates were performed in both the derivation and validation cohorts. Differences were assessed using t-tests for continuous variables and chi-square tests for categorical variables. Time to PCE was not included in the outcome because the aim of the study was to identify patients who had a PCE, not when they happened.

Model Derivation

We constructed multivariate logistic regression models to examine the association between predictors and PCEs. Generalized estimating equations (GEE) models with a logit link (SAS Proc Genmod) were used to account for the correlation of repeated admissions for a single patient. Manual backward elimination based on *a priori* criteria was employed to reduce the model. Candidate predictors were retained during backwards elimination based on three criteria: 1) sufficient prevalence (>10%) in the derivation population; 2) strength of the adjusted association between the predictor and PCEs (OR>1.5); and 3) clinical relevance as determined by emergency department and palliative care experts. While it was not an explicit criterion in model reduction, all variables were statistically significant at p<0.05. Backwards elimination was stopped when all variables in the model met criteria leaving a final model.

The performance of the model was assessed based upon the discrimination and calibration of the model in the validation set. Discrimination indicates the model's ability to separate those who did and did not have a PCE and was assessed using the area under the receiver operating characteristic (ROC) curve. Model calibration (how well the predicted risk of PCE correlates with the actual risk of a PCE) was assessed using visual inspection of quintile plots. To generate quintile plots the predicted risks were grouped by quintiles expected and observed risks of PCE were then calculated and plotted for each quintile.

Model Validation

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For the validation study we applied the risk model created from the derivation set to the validation set to calculate the predicted risk of a PCE. Model performance in the validation set was assessed using the same discrimination and calibration methods employed to assess performance in the validation set.

SAS 9.3 (SAS Institute Inc., Cary, North Carolina) was used for all analyses. Statistical significance was defined as p<0.05 for all analysis.

Results

There were 1,576 admissions from the ED screened with the SPEED instrument during the 30-month study period. A total of 27 admissions (1.7%) were excluded due to missing data -- 15 admissions were excluded for missing SPEED informer, 11 admissions were excluded for missing ED arrival mode and 4 admissions were excluded for missing ED acuity (3 admission were missing both ED arrival mode and ED acuity). The final study population consisted of 1,549 admissions from the ED. The derivation and validation sets contained 1,357 and 192 admissions from the ED, respectively. Table 1 shows characteristics of patients in the derivation and validation datasets.

In the derivation set 19.2% (n=261) of visits had a PCE. The PCEs were comprised of 168 palliative care consults, 107 hospice discharges and 47 in-hospital deaths. Several of these patients had two or more PCEs: 51 patients had both a hospice discharge and palliative care consult and 14 patients who died in-hospital had a palliative care consult.

In the validation set 17.7% (n=34) had a PCE. PCEs were comprised of 19 palliative care consults, 15 hospice discharges, and 4 in-hospital deaths. Three patients had both a hospice discharge and palliative care consult and 1 patient who died in-hospital had a palliative care consult.

The mean age of patients was 58.8 years (std=14.4 years) in the derivation set and 59.6 years (std=13.8 years) in the validation set. There was a high prevalence of metastatic cancer among admissions from the ED in the derivation and the validation set,

45.3% and 44.3% respectively. There were no notable differences in prevalence of the patient characteristics between the two populations.

Table 2 presents the unadjusted association of 25 candidate predictors with PCE. The strongest unadjusted predictors of a PCE were weight loss (OR: 3.67; 95% CI: 2.73-4.94), depression (OR: 2.77; 95% CI: 1.99-3.86) and metastatic cancer (OR: 2.62; 95% CI: 1.98-3.47). ED variables were also crudely associated with PCEs, including EMS ED arrival (OR: 2.44; 95% CI: 1.83-3.25) and ED acuity 1 (OR: 2.16; 95% CI: 1.30-3.61).

Model Development

Variables were retained in the model after application of *a priori criteria* and manual backwards elimination (Appendix B). Table 3 shows the final model for risk of PCE. The final model contained 11 variables -- 5 comorbidities (cardiac arrhythmias, metastatic cancer, coagulopathy, depression and weight loss), 3 ED variables (ED arrival mode, ED acuity, prior ED visits), both SPEED variables (SPEED score and informer) and age. While age did not have a statistically significant association with PCEs, it was deemed clinically relevant and retained in the model. SPEED score showed a moderate, but statistically significant (OR: 1.18; 95% CI: 1.05-1.33) association with PCE and was retained in the model due to relevance to the primary research question. The strongest predictors of PCE were comorbidities, including metastatic cancer (OR: 3.21; 95% CI: 2.32-4.45), weight loss (OR: 3.24; 95% CI: 2.32-4.53), and depression (OR: 2.70; 95% CI: 1.88-3.87).

Model Performance

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Derivation set. Figure 2 shows the model calibration. There is a slight overestimation of risk in the lowest quintile. Actual and predicted risks were within 1% in the second through fifth quintiles. The area under the curve was 0.79 (Figure 6).

Validation set. Figure 3 shows the calibration achieved when the final derivation model is applied to the validation cohort. There is an overestimation of risk in the first and fifth quintiles and an under-prediction of risk in the second and third quintiles. The area under the curve was 0.72 (Figure 7).

Secondary Analysis

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To further understand the decreased performance in the validation set, we conducted a secondary analysis. In secondary analysis we took the following 4 steps: 1) compared the conditional probabilities of PCE for all predictors in the derivation and validation sets; 2) compared the adjusted associations in the derivation and validation sets for the 11 predictors selected during model derivation; 3) re-derived and re-validated a secondary model; and 4) compared the adjusted associations in the derivation and validation sets for the 9 predictors included in the second model.

Table 4 compares the prevalence of PCEs for each predictor in the derivation and validation sets. In the derivation set 17.2% of patients with a proxy SPEED informer had a PCE, while in the validation set only 2.9% of patients with a proxy SPEED informer had a PCE. There were approximately twice as many derivation set patients with weight loss who had a PCE compared to the validation set -- 40.6% vs. 23.5% respectively. There were also substantial changes in the prevalence of a PCE, given the number of ED visits in the previous 90 days. In the derivation set, patients 29.1% of patients had an ED visit in the last 90-days, while in the validation set 14.7% of patients had an ED visit in the last 90-days.

Table 5 compares the adjusted associations from the final model created from the derivation set with that same model structure run on the validation set. While proxy

SPEED informer was associated with increased risk of a PCE in the derivation set (OR: 1.64; 95% CI: 1.06-2.54), in the validation set it was associated with a decreased risk of PCE (OR: 0.42; 95% CI: 0.03-4.18). One and two prior ED visits also reversed association between the derivation and validation sets, while the effect of 3 or more prior ED visits in the derivation set (OR: 1.94 95% CI: 1.03-3.64) was nearly tripled in the validation set (OR: 6.01 95% CI: 1.83, 34.88), though the derivation effect estimate was included in the validation set's confidence interval. The effects of cardiac arrhythmias and metastatic cancer were stronger in the validation set, while the effects of EMS ED arrival, ED acuity 1 and 2, coagulopathy and weight loss were weaker.

Secondary Model

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Due to gross changes in associations between the derivation and validation sets, we decided to re-derive and re-validate a second model. Variables whose association had changed direction in the validation set (SPEED informer and number of prior ED visits) were dropped and the model performance was reassessed in the derivation and validation sets.

Derivation set. Figure 4 shows model calibration. Actual and predicted risks show no notable difference. The area under the curve was 0.76 (Figure 8).

Validation set. Figure 5 shows model calibration. The risk of a PCE was overestimated in the second and fourth quintiles and underestimated in the third. The area under the curve was 0.73 (Figure 9).

Table 6 compares the adjusted associations from the secondary model created from the derivation set with that same model structure run on the validation set. Variables that had showed strong differences in the original validation (EMS arrival mode, coagulopathy and weight loss) still showed large changes in association between the derivation and validation.

Discussion

Early palliative care has been associated with increased survival (10) and quality of life (6-8) for patients with cancer. The ED is emerging as a key setting for provision of palliative care (26), however little is known about how to best identify ED patients with palliative care needs. We developed and validated a predictive model for PCEs using variables readily available to ED clinicians upon a patient's admission. While the model performance in the derivation set was good, the model performance decreased when validated temporally in the following six months of admissions from the ED. The poor validation was further investigated in secondary analyses and deemed to be likely due to small sample size. Future work will include attempting to validate the model in a larger population.

Eleven factors were identified as predictive of a PCE, including the number of SPEED thresholds exceeded, having a proxy SPEED informer, age, arrival to the ED via EMS, having an emergent or immediate ED acuity, the number of prior ED visits in the last three months, cardiac arrhythmias, metastatic cancer, coagulopathy, depression and weight loss. We found that the strongest predictors of PCEs were clinical comorbidities common to advanced cancer etiology, including metastatic cancer, depression, weight loss and coagulopathy. Metastatic cancer and depression have been suggested as key triggers for an inpatient palliative care consult (20, 31, 32). Cachexia is a clinical feature of advanced cancer and is used in prognosis for cancer patients (52). Thromboembolic complications due to hypercoagulopathy are the second leading cause of death in cancer

patients (53, 54). ED acuity and EMS arrival have been identified as independent risk factors for care utilization in previous studies (55, 56).

SPEED variables were also identified as significant predictors of PCEs. SPEED proxy is hypothesized to be an indicator of severity of illness in the ED, as proxies are only used if the patient is unable to answer questions from the nurse. SPEED score was significantly, but not strongly associated with a PCE in adjusted analysis. A low adjusted effect estimate for SPEED score suggests that while the SPEED tool may have utility in identifying PCEs, clinical comorbidities and severity of illness upon arrival to ED have higher predictive utility.

Decreased model performance in the validation set, especially calibration, is expected due to overfitting in the derivation set (57). However, upon further examination it was determined that the decrease in model performance was not easily attributable to overfitting. While there were no notable differences in prevalence of predictors in the derivation and validation set, the conditional probability of a PCE shifted dramatically between the derivation and validation sets. This drove drastic changes in the associations between many predictors in the derivation and validation sets. Prior ED visit and SPEED informer which had been associated with an increased risk of PCEs in the derivation set.

Due to gross changes in associations between the derivation and validation sets, a secondary analysis was done. In this secondary analysis, variables whose association had changed direction in the validation set (SPEED informer and number of prior ED visits) were dropped and the model performance was reassessed in the derivation and validation sets. Predictably, discriminatory performance in the derivation set decreased, though

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visual inspection of quintile plots showed excellent fit. However fit in the validation set remained poor.

The poor calibration is likely due to persistent differences in the adjusted associations between predictors in the variables left in the model, notably in EMS transport, coagulopathy and weight loss.

Interestingly, the derivation and validation sets appeared descriptively similar in univariate analyses (Table 1). Possible factors that could lead to changes in association between PCEs and candidate predictors from the derivation to the validation include changes in hospital policies, treatments or patterns of care; changes in the patient population; and random variation. The authors identified no changes in hospital policies, treatments or patterns of care during this time. Changes in the patient population were deemed unlikely particularly given the descriptive results, but possible and warrant further investigation. Random variation was identified as the most likely cause of changes seen in the associations between PCEs and risk. The validation is therefore deemed inconclusive; additional data will be needed to accurately assess the external validity of the model.

This is the first study to use administrative data to identify cancer patients for a palliative care consult in the ED. While prior work has been done on identifying palliative care patients for other acute care settings including inpatient wards (38, 39), the surgical intensive care unit (40), and medical intensive care unit (41), none has been conducted in an ED setting. All predictors except SPEED are available in administrative datasets that are common in all acute care hospitals, increasing its generalizability and

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dissemination potential. The SPEED instrument is publicly available and designed for easy implementation in a busy ED setting.

Limitations

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The major limitation of this study is the inability to conclusively validate the PCE risk model. If there have been actual temporal changes in the association between the predictors in the model and PCEs, then the risk model is of little value. However, if the model performs well in a larger validation set, it could be used to identify palliative care patients presenting to the ED. To conclusively assess the external validity of the model, the researchers plan to collect an additional 12 months of data and rerun the validation analysis.

There are several limitations due to conducting this study at a single site, including lack of generalizability and underestimation for prior hospitalizations and ED visits. The generalizability of this study and model may be limited to similar hospitals. Additionally, we were only able to capture prior admissions and ED visits within our healthcare system. As patients may have visited other hospitals in the prior 90 days, prior hospitalization and prior ED visits may be undercounted.

Our model used only administrative data available upon admission, although providers have significantly more information to inform decision-making. However, for a tool to be useful in the ED it cannot rely on information that may not be available to clinicians or take a long time to collect. Additionally, our study was restricted to the population that the SPEED instrument was piloted in: English-speaking patients with active cancer. Therefore, it does not address the multitude of patients with end-of-life or palliative care needs who present to the ED with life limiting conditions other than cancer or are non-English speakers.

Conclusions

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Timely palliative care consult can reduce pain, alleviate symptoms and provide care that is in line with patient goals for those with cancer. With further validation, this predictive model may serve as the basis for a trigger to quickly identify cancer patients who would benefit from a palliative consult in the ED.

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Tables

February 28, 2014 (n=1,549)				
	Derivation (n=13		Validatio (n=19	
	No.	%	No.	%
Palliative Care Event*	261	19.2	34	17.7
SPEED Score (Mean, Std)	0.9	1.2	0.8	1.1
SPEED Informer				
Patient	1,200	88.4	175	91.1
Proxy	157	11.6	17	8.9
Gender				
Female	674	49.7	92	47.9
Male	683	50.3	100	52.1
Age (Mean, Std)	58.8	14.4	59.9	13.8
Marital Status				
Married/Partner	762	56.1	107	55.7
Single	552	40.7	78	40.6
Missing	43	3.2	7	3.6
Race/Ethnicity				
Non-Hispanic, White	729	53.7	112	58.3
Non-Hispanic, Black	513	37.8	59	30.7
Other	59	4.3	6	3.1
Missing	56	4.1	15	7.8
Financial Class				
Commercial	503	37.1	68	35.4
Medicaid	157	11.6	16	8.3
Medicare	574	42.3	80	41.7
Other	101	7.4	20	10.4
Missing	22	1.6	8	4.2
Income Quartile by Zip				
1	70	5.2	7	3.6
2	142	10.5	23	12.0
3	396	29.2	62	32.3
4	704	51.9	94	49.0
Missing	45	3.3	6	3.1
ED Arrival Mode				
Patient	1,019	75.1	135	70.3

Table 1. Characteristics of Admissions Subsequent to ED Visit Assessed withthe SPEED Tool by Derivation and Validation Set, September 1, 2011 toFebruary 28, 2014 (n=1,549)

ED Acuity				
1 Immediate	177	13.0	34	17.7
2 Emergent	983	72.4	127	66.1
3 Urgent/ 4 Stable	197	14.5	31	16.1
Prior ED Visits**				
0	785	57.8	114	59.4
1	347	25.6	50	26.0
2	139	10.2	17	8.9
≥3	86	6.3	11	5.7
Prior Hospitalizations**				
0	633	46.6	107	55.7
1	411	30.3	43	22.4
2	196	14.4	31	16.1
3	77	5.7	7	3.6
≥4	40	2.9	4	2.1
Comorbidities***				
Metastatic cancer	615	45.3	85	44.3
Fluid and electrolyte disorder	709	52.2	92	47.9
Weight Loss	278	20.5	29	15.1
Cardiac arrhythmias	325	23.9	47	24.5
Depression	195	14.4	24	12.5
Coagulopathy	277	20.4	36	18.8
Renal failure	225	16.6	26	13.5
Congestive heart failure	159	11.7	26	13.5
Chronic pulmonary disease	158	11.6	31	16.1
Liver Disease	152	11.2	21	10.9
Lymphoma	210	15.5	28	14.6
Hypertension, complicated Pulmonary Circulation	145	10.7	17	8.9
Disorders	95	7.0	13	6.8
Paralysis	31	2.3	3	1.6
Diabetes, complicated	58	4.3	8	4.2
Valvular disease	47	3.5	11	5.7
Blood loss anemia	33	2.4	2	1.0
AIDS/HIV	22	1.6	2	1.0

SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department OR=odds ratio | CI=confidence interval

* Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

**Prior hospitalizations or ED visits are 90-day all cause readmissions or prior ED visits

***Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

	Even	Palliative Care Event* (n=261) No Palliative Care Event* (n=1096)			U	nivariat	e Assoc	iations
	No.	%	No.	%	OR	95%	CI	P-Value**
SPEED Score (Mean, Std)	1.3	1.3	0.8	1.1	1.28	1.16	1.43	< 0.001
SPEED Informer								
Patient	216	82.6	984	89.8	1.00			-
Proxy	45	17.4	112	10.2	1.83	1.26	2.67	0.002
Age (Mean, Std)	58.6	14.4	59.0	14.4	1.00	0.99	1.01	0.96
ED Arrival Mode								
EMS	104	39.9	234	21.4	2.44	1.83	3.25	< 0.001
Walk-in	157	60.2	862	78.7	1.00	-	-	-
ED Acuity								
1 Immediate	48	18.3	129	11.8	2.16	1.30	3.61	0.18
2 Emergent	184	70.7	799	72.9	1.33	0.87	2.04	0.004
3 Urgent/ 4 Stable	29	11.0	168	15.3	1.00	-	-	-
Prior ED Visits***								
0	127	49.2	658	60.0	1.00	-	-	-
1	76	28.8	271	24.7	1.45	1.06	2.00	0.02
2	32	12.1	107	9.8	1.55	1.00	2.40	0.05
≥3	26	9.9	60	5.5	2.25	1.37	3.69	0.002

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Table 2. Univariate Associations Between Candidate Predictors and PCEs* Among Admissions Subsequent to ED Visit Assessed with the SPEED Tool, Derivation Set, September 1, 2011 to August 31, 2013 (n=1,357)

Prior	Hos	pitaliz	ation	1s***
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0	108	42.1	525	47.9	1.00	-	-	-
1	82	31.1	329	30.0	1.21	0.89	1.67	0.24
2	46	17.4	150	13.7	1.49	1.01	2.20	0.04
3	17	6.4	60	5.5	1.38	0.77	2.45	0.28
≥ 4	8	3.0	32	2.9	1.22	0.55	2.71	0.63
Comorbidities****								
Metastatic cancer	168	64.8	447	40.8	2.62	1.98	3.47	< 0.001
Fluid and electrolyte disorder	170	65.2	539	49.2	1.93	1.46	2.56	< 0.001
Weight Loss	106	40.2	172	15.7	3.67	2.73	4.94	< 0.001
Cardiac arrhythmias	99	37.9	226	20.6	2.35	1.76	3.14	< 0.001
Depression	69	26.9	126	11.5	2.77	1.99	3.86	< 0.001
Coagulopathy	77	29.6	200	18.3	1.88	1.38	2.55	< 0.001
Renal failure	57	22.0	168	15.3	1.54	1.10	2.16	0.01
Congestive heart failure	39	14.8	120	11.0	1.43	0.97	2.11	0.07
Chronic pulmonary disease	35	13.3	123	11.2	1.23	0.82	1.83	0.32
Liver Disease	42	15.9	110	10.0	1.72	1.17	2.53	0.006
Lymphoma	37	14.0	173	15.8	0.88	0.60	1.29	0.52
Hypertension, complicated	31	12.1	114	10.4	1.16	0.76	1.77	0.49
Pulmonary Circulation Disorders	23	8.7	72	6.6	1.37	0.84	2.24	0.20
Paralysis	12	4.6	20	1.8	2.37	1.12	5.00	0.02
Diabetes, complicated	12	4.6	46	4.2	1.10	0.57	2.11	0.77
Valvular disease	11	4.2	36	3.3	1.30	0.65	2.58	0.46
Blood loss anemia	9	3.5	24	2.2	1.60	0.73	3.48	0.24
AIDS/HIV	4	1.5	18	1.6	0.93	0.31	2.78	0.90

SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department | OR=odds ratio | CI=confidence interval

* Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

** Wald test

***Prior hospitalizations or ED visits are 90-day all cause readmissions or prior ED visits

****Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

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	Coefficient	OR	95%	CI	P-Value**
Intercept	-3.8799	-	-	-	-
SPEED Score	0.1676	1.18	1.05	1.33	0.005
SPEED Informer					
Patient		1.00	-	-	-
Proxy	0.4946	1.64	1.06	2.54	0.02
Age (Mean, Std)	-0.0032	1.00	0.99	1.01	0.58
ED Arrival Mode					
Non-EMS	0	1.00	-	-	-
EMS	0.829	2.29	1.66	3.17	< 0.001
ED Acuity					
1 Emergency	0.998	2.71	1.52	4.85	< 0.001
2 Immediate	0.4604	1.58	0.99	2.53	0.06
3 Urgent/ 4 Stable	0	1.00	-	-	-
Prior ED Visit***					
0	0	1.00	-	-	-
1	0.3075	1.36	0.96	1.93	0.08
2	0.7573	1.58	0.93	2.67	0.09
≥ 3	0.6638	1.94	1.03	3.65	0.03
Comorbidities****					
Cardiac arrhythmias	0.6883	1.99	1.42	2.79	< 0.001
Metastatic cancer	1.167	3.21	2.32	4.45	< 0.001
Coagulopathy	0.7725	2.17	1.51	3.11	< 0.001
Depression	0.9925	2.70	1.88	3.87	< 0.001
Weight Loss	1.1767	3.24	2.32	4.53	< 0.001

Table 3. Multivariate Associations Between Predictors and PCEs* Among Admissions Subsequent toED Visit Assessed with the SPEED Tool, Derivation Set, September 1, 2011 to August 31, 2013(n=1,357)

SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department OR=odds ratio | CI=confidence interval

* Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

** Wald test

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*** Prior 90-day, all cause ED visits

****Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

	Derivation (n=1,3		Validatio (n=19	92)	
	Number of PCEs*	% of PCEs*	Number of PCEs*	% of PCEs*	
SPEED Score (Mean, Std)	1.23	1.3	1.03	1.24	
SPEED Informer					
Patient	216	82.8	33	97 .1	
Proxy	45	17.2	1	2.9	
Age (Mean, Std)	58.7	14.4	56.0	17.	
ED Arrival Mode					
EMS	104	39.9	12	35	
Walk-in	157	60.2	22	64.	
ED Acuity					
1 Immediate	48	18.4	8	23.	
2 Emergent	184	70.5	21	61.	
3 Urgent/ 4 Stable	29	11.1	5	14.	
Prior ED Visits**					
0	127	48.7	21	61.	
1	76	29.1	5	14.	
2	32	12.3	1	2.	
<u>≥</u> 3	26	10.0	7	20.	
Prior Hospitalizations**					
0	108	41.4	17	50.	
1	82	31.4	5	14.	
2	46	17.6	10	29.	
3	17	6.5	2	5.	
≥4	8	3.1	0	0.	
Comorbidities***					
Metastatic cancer	168	64.4	22	64.	
Fluid and electrolyte disorder	170	65.1	17	50.	
Weight Loss	106	40.6	8	23.	
Cardiac arrhythmias	99	37.9	14	41.	
Depression	69	26.4	8	23.	
Coagulopathy	77	29.5	7	20.	
Renal failure	57	21.8	7	20.	
Congestive heart failure	39	14.9	4	11.	

 Table 4. Prevalence of PCEs* for Candidate Predictors among Admissions Subsequent to

 ED Visits Assessed with the SPEED Tool, Derivation and Validation Sets, September 1, 2011

 to February 28, 2014 (n=1,549)

Chronic pulmonary disease	35	13.4	4	11.8
Liver Disease	42	16.1	3	8.8
Lymphoma	37	14.2	9	26.5
Hypertension, complicated	31	11.9	4	11.8
Pulmonary Circulation Disorders	23	8.8	4	11.8
Paralysis	11	4.2	0	0.0
Diabetes, complicated	12	4.6	0	0.0
Valvular disease	11	4.2	1	2.9
Blood loss anemia	9	3.5	0	0.0
AIDS/HIV	4	1.5	0	0.0

SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department OR=odds ratio | CI=confidence interval

* Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

**Prior hospitalizations or ED visits are 90-day all cause readmissions or prior ED visits

`

***Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

]	Derivation (n=1,357					tion Set =192)	
	OR	95% (CI	P-Value**	OR	95%	CI	P-Value**
SPEED Score	1.18	1.05	1.33	0.005	1.26	1.14	2.19	0.01
SPEED Informer								
Patient	1.00	-	-	-	1.00	-	-	-
Proxy	1.64	1.06	2.54	0.02	0.42	0.03	4.18	0.39
Age (Mean, Std)	1.00	0.99	1.01	0.58	0.99	0.95	1.02	0.40
ED Arrival Mode								
Walk-in	1.00	-	-	-	1.00	-	-	-
EMS	2.29	1.66	3.17	< 0.001	1.56	0.58	3.02	0.51
ED Acuity								
1 Emergency	2.71	1.52	4.85	< 0.001	1.15	0.33	6.72	0.60
2 Immediate	1.58	0.99	2.53	0.05	0.72	0.31	3.96	0.88
3 Urgent/4 Stable	1.00	-	-	-	1.00	-	-	-
Prior ED Visit***								
0	1.00	-	-	-	1.00	-	-	-
1	1.36	0.96	1.93	0.08	0.25	0.13	1.36	0.15
2	1.58	0.93	2.67	0.09	0.32	0.02	2.96	0.28
≥3	1.94	1.03	3.65	0.03	6.01	1.83	34.88	0.01
Comorbidities****								
Cardiac arrhythmias	1.99	1.42	2.79	< 0.001	2.73	1.06	7.04	0.04
Metastatic cancer	3.21	2.32	4.45	< 0.001	4.07	1.72	9.64	< 0.001
Coagulopathy	2.17	1.51	3.11	< 0.001	1.31	0.45	3.85	0.62
Depression	2.70	1.88	3.87	< 0.001	2.10	0.62	7.20	0.23

Table 5. Comparison of Multivariate Associations Between Predictors and PCEs* Among Admissions Subsequent to ED
Visit Assessed with the SPEED Tool, Derivation and Validation Sets, September 1, 2011 to February 28, 2014 (n=1,549)

Weight Loss	3.24	2.32	4.53	< 0.001	1.22	0.38	3.91	0.74
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SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department

OR=odds ratio | CI=confidence interval

* Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

** Wald test

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***Prior 90-day, all cause ED visits

****Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

February 28th, 2014 (n=1,549)	Derivation	. Sat			Validatio	n Sat	
	OR	95% C	CI	P-Value	OR	95% C	I	P-Value
SPEED Score	1.22	1.08	1.37	0.001	1.49	1.08	2.04	0.01
Age	1.00	0.99	1.01	0.52	0.98	0.94	1.01	0.22
ED Arrival Mode								
Walk in	1.00	-	-	-	1.00	-	-	-
EMS	2.47	1.80	3.38	<.001	1.53	0.65	3.62	0.34
ED Acuity								
1 Emergency	2.61	1.48	4.59	0.001	1.74	0.39	7.77	0.47
2 Immediate	1.63	1.04	2.54	0.03	1.10	0.36	3.33	0.87
3 Urgent/ 4 Stable	1.00	-	-	-	1.00	-	-	-
Comorbidities*								
Cardiac arrhythmias	2.21	1.60	3.05	< 0.001	2.58	1.06	6.27	0.04
Metastatic cancer	3.32	2.42	4.56	< 0.001	3.78	1.60	8.94	< 0.001
Coagulopathy	2.14	1.51	3.02	< 0.001	1.32	0.49	3.57	0.59
Weight Loss	3.21	2.31	4.47	< 0.001	1.57	0.59	0.62	0.67
Depression	2.89	2.03	4.12	< 0.001	2.18	0.72	6.59	0.17

Table 6. Comparison of Adjusted Odds Ratios in Derivation and Validation Sets, Emory University Hospital, September 1, 2011 to February 28th, 2014 (n=1,549)

SPEED=Screen for Palliative and End of Life Care Needs in the ED | ED=Emergency Department

OR=odds ratio | CI=confidence interval

* Wald test

•

** Palliative care event=inpatient palliative care consult, discharge to hospice or in-hospital death

***Prior hospitalizations or ED visits are 90-day all cause readmissions or prior ED visits

****Categorized into Elixhauser Comorbidities using primary and secondary diagnoses (ICD-9)

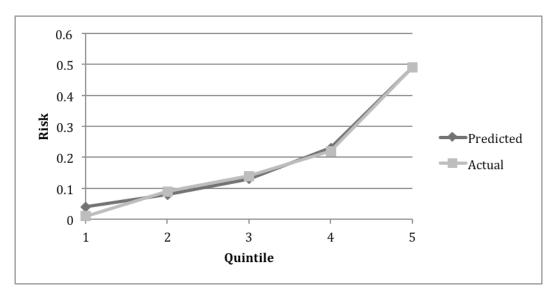
Figures

Figure 1. Screen for Palliative Care and End-of-life Care Needs in the Emergency Department (SPEED) Instrument

Questions are scored by the SPEED informer (patient or their proxy) on a 0-10 scare with 0 indicating the lowest need and 10 indicating the highest need.

- Q1. How much are you suffering from **pain**? (threshold \geq 4)
- Q2. How much difficulty are you having getting your **care needs** met at home? (threshold \geq 3)
- Q3. How much difficulty are you having with your **medications**? (threshold \geq 3)
- Q4. How much are you suffering from feeling **overwhelmed**? (threshold \geq 5)
- Q5. How much difficulty are you having difficult getting medical care that fits with your **goals**? (threshold \geq 3)

Figure 2. Calibration Plot, Derivation Set



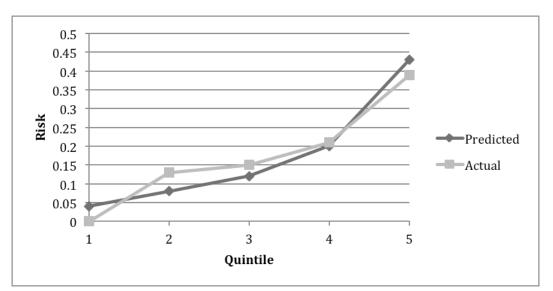


Figure 3. Calibration Plot, Validation Set

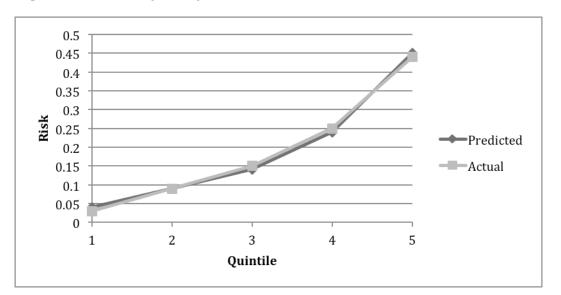


Figure 4. Secondary Analysis Calibration Plot, Derivation Set

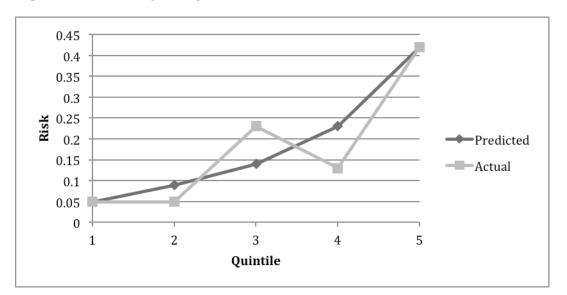


Figure 5. Secondary Analysis Calibration Plot, Validation Set

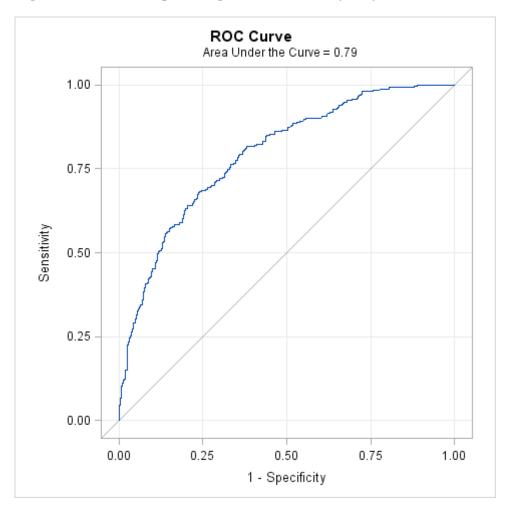


Figure 6. Receiver Operating Characteristic (ROC) Curve, Derivation Set

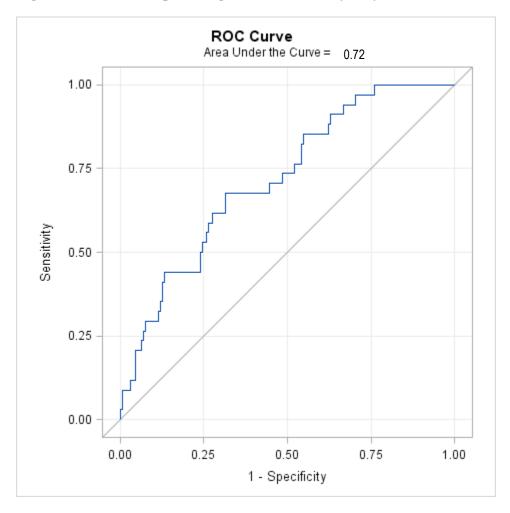


Figure 7. Receiver Operating Characteristic (ROC) Curve, Validation Set

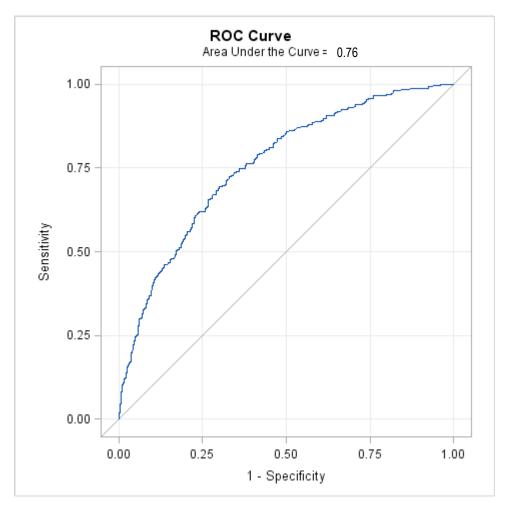


Figure 8. Receiver Operating Characteristic (ROC) Curve, Secondary Derivation

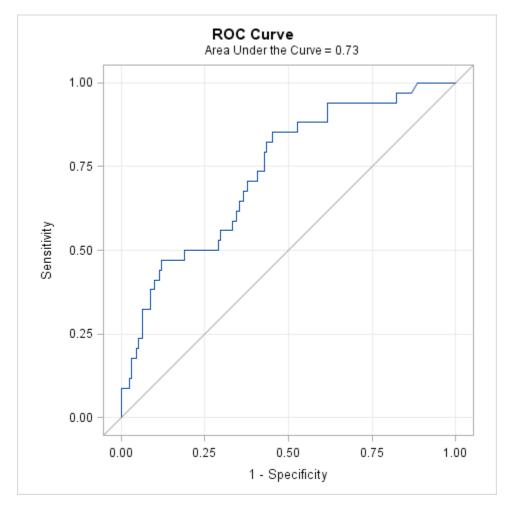


Figure 9. Receiver operating characteristic (ROC), Secondary Validation

Appendix A: IRB Approval

IRB Approval

TO: Danielle Moulia Principal Investigator Public Health

DATE: February 20, 2014

RE: **Expedited Approval**

IRB00070873

The SPEED Study: Assessment of the Predictive and Etiologic Value of the Screening for Palliative and End of Life Care Needs in the Emergency Department (SPEED) Instrument

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the regulatory categories F(5) and F(7) as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on 2/20/2014 and granted approval effective from 2/20/2014 through2/19/2015. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- The IRB grants a waiver of all elements of informed consent for this study
- The IRB grants a waiver of HIPAA authorization for the purposes of identifying cases and conducting the protocol

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at <u>www.irb.emory.edu</u>, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, and study design), you must submit an

amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you

Sam Roberts, BA CIP Senior Research Protocol Analyst *This letter has been digitally signed*

Appendix B: Modeling Strategy

	Exclude: Pulmonary Cicrulatory Disorder, Complicated Diabetes, Valvular Disease, Blood Loss Anemia, Paralysis, HIV/AIDS	<u>M</u> e AUC=	odel 1:									tension		Heart	op Cor Failur	ngestive re	Model 5: Drop COPD AUC= 0.81				
	Prevalence in Derivation Set (%)	OR	95%	CI	P-value	OR	95%	CI	P-value			CI	P-value	OR	95%	CI	P-value	OR	95%	CI	P-value
Speed Score	100	1.1	1.0		0.15	1.1	1.0		0.15		1.0			1.1	1.0		0.09	1.158	1.02	1.31	0.02
SPEED Informer	100	1.1	1.0	1.5	0.15	1.1	1.0	1.5	0.15	1.1	1.0	1.5	0.09	1.1	1.0	1.5	0.09	1.156	1.02	1.51	0.02
Patient	88.4	1.0				1.0	-			1.0	-			1.0		-		1.0		-	
Not Patient	11.6	1.5	0.9	2.5	0.09	1.5	0.9	2.5	0.09	1.6		2.6	0.07	1.6	1.0	2.6	0.07	1.6	1.0	2.6	0.06
Age (Mean, Std)	11.0	1.0	1.0		0.03	1.0	1.0		0.09					1.0	1.0		0.16	1.0	1.0	1.0	
ED Arrival Mode	100	1.0	1.0	1.0	0.54	1.0	1.0	1.0	0.54	1.0	1.0	1.0	0.10	1.0	1.0	1.0	0.10	1.0	1.0	1.0	0.20
Patient	75.1	1.0				1.0	-			1.0				1.0				1.0			
EMS	24.9	2.3	1.6	3.4	<.0001	2.3	1.6	3.4	<.0001	2.2	1.5	3.1	<.0001	2.2	1.5	3.1	<.0001	2.2	1.6	3.1	<.0001
ED Acuity	24.3	2.3	1.0	5.4	<.0001	2.5	1.0	5.4	10001	2.2	1.5	5.1	<.0001	2.2	1.5	5.1	\$.0001	2.2	1.0	5.1	<.0001
1 Immediate	13	2.5	1.3	4.7	0.01	2.5	1.3	4.7	0.01	2.7	1.5	5.1	0.002	2.7	1.5	5.1	0.00	2.6	1.4	4.7	0.002
2 Emergent	72.4	1.4	0.8	2.4	0.01	1.4	0.8	2.4	0.01			2.4		1.5	0.9	2.4	0.12	1.6	1.4	2.5	
3 Urgent/ 4 Stable	14.5	1.4	0.0	2.4	0.19	1.4	0.0	2.4	0.19	1.5	0.9	2.4	0.12	1.0	0.9	2.4	0.12	1.0	1.0	2.3	0.07
Prior Hospitalizations	14.5													1.0	-	-	-	1.0	-	-	-
	46.6	1.0				Drive he	omitalia	ntion (dropped d	 	offerst	antim	ataa (11	3							
1	30.3	1.0	0.8	1.7	0.52	Filor no	spitaliz	ation	nopped d		w effect	estim	ates (~1	2							
2	14.5	1.1	0.3	2.0	0.32																
3	5.7	0.9	0.4	2.0	0.49																
>=4	2.9	1.5	0.4	3.7	0.35																
Prior ED Visits	2.3	1.5	0.0	5.1	0.55																
	57.8	1.0				1.0		-		1.0				1.0				1.0		-	
1	25.6	1.0	0.9	2.1	0.16	1.0	0.9	2.1	0.16		1.0	2.1	0.05	1.5	1.0	2.1	0.05	1.0	1.0	2.1	0.05
2	10.2	1.4	1.0	3.2	0.10	1.4	1.0	3.2	0.10	1.9	1.0	3.2		1.9	1.0	3.2	0.03	1.4	1.0	3.2	
>=3	6.3	2.9	1.0	5.8	0.00	2.9	1.4	5.8	0.00			5.2		2.8	1.5	5.2	0.00	2.5	1.1	4.7	
Comorbidities	0.3	2.7	1.4	5.0	0.00	2.9	1.4	5.0	0.00	2.0	1.5	5.2	0.00	2.0	1.5	5.2	0.00	2.5	1.4	4.7	0.00
Fluid Electrolyte Imbalance	52.2	1.4	1.0	2.0	0.06	1.4	1.0	2.0	0.06	1.4	1.0	2.0	0.04	1.4	1.0	2.0	0.04	1.4	1.0	2.0	0.05
Metastatic cancer	45.3	4.2	2.8	6.2	<.0001	4.2	2.8	6.2	<.0001	4.2	2.9	6.3		4.2	2.9	6.3	<.0001	3.9	2.7	5.7	
Cardiac arrythmias	23.9	4.2	1.2	2.6	0.01	1.7	1.2	2.6	0.01	1.8	1.2	2.6		1.8	1.2	2.6	0.003	1.8	1.2	2.6	
Weight Loss	23.5	3.2	2.1	4.8	<.0001	3.2	2.1	4.8	<.0001	3.2	2.2	4.7		3.2	2.2	4.7	<.0001	3.1	2.2	4.5	
Coagulopathy	20.5	2.0	1.3	3.1	0.001	2.1	1.3	3.1	0.0009		1.4	3.2		2.2	1.4	3.2	0.0002	2.1	1.4	3.1	
Renal failure	16.6	1.4	0.8	2.6	0.001	1.4	0.9	2.2	0.0009		0.8	2.0		1.3	0.8	2.0	0.0002	1.3	0.8	1.9	
Lymphoma	15.5	1.4	0.8	2.5	0.20	1.4	0.9	2.2	0.13	1.5	0.8	2.0		1.3	0.8	2.0	0.19	1.3	0.8	2.2	
Depression	15.5	2.6	1.7	3.8	<.0001	2.6	1.7	3.8	<.0001	2.6	1.8	3.9		2.6	1.8	3.9	<.0001	2.7	1.9	4.0	
Congestive heart failure	14.4	1.1	0.6	1.9	0.76	1.1	0.6	1.9	0.76		0.6	1.9					lure dropp				
Congestive heart landre	11.7	1.1	0.0	1.5	0.70	1.1	0.0	1.2	0.70	1.1	0.0	1.5	0.70	Congesti	IVE ITE	arran	iaie aropp				ue to low
COPD	11.6	1.4	0.8	2.5	0.23	1.4	0.8	2.5	0.23		0.7	2.3		1.3	0.7	2.3	0.37	effect es			00 10 10W
Liver Disease	11.2	1.4	0.8	2.4	0.23	1.4	0.8	2.4	0.22			2.3		1.4	0.8		0.25	1.5	0.9	2.5	0.13
Hypertension, complicated	10.7	0.9	0.5		0.87	0.9	0.6	1.9	0.85	Compl	icated h	yperte	ension dro	pped due	e to lo	w effec	t estimate:	(<1.5)			
Pulmonary Circulatory Disorde	e 7.0		monary																		
Diabetes, Complicated	4.3		sorder,																		
Valvular Disease	3.5	Diabe	etes, Va	lvular I	Disease,																
Blood loss anemia	2.4	Blood I	Loss At	iemia, I	Paralysis,																
Paralysis	2.3	HIV/	AIDS e	xcluded	due to																
HIV/AIDs	1.6	1	prevale	nce <10)%																

		<																	
	Model 6: Drop Fluid and Electrolyte Imbalance			Model 7	Failure	Mode	18: Dro	p Liver	Disease	Model	p Lym	phoma	Final Model						
	AUC= 0	0.80			AUC= (0.80			AUC=	0.80	80		AUC= 0.79						
	OR	95%	CI	P-value	OR	95% (CI	P-value	OR	95%	CI	P-value	OR	95%	CI	P-value			
peed Score	1.2	1.1	1.3	0.005	1.2	1.1	1.3	0.005	1.2	1.0	1.3	0.01	1.2	1.1	1.3	0.01	Keep	Sp	peed Score due to clinical relevance
PEED Informer																		T	
Patient	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-			
Not Patient	1.7	1.1	2.6		1.7	1.1	2.6	0.02	1.6	1.1	2.5	0.03	1.6	1.1	2.5	0.02	Keep	Sp	peed Informer due to effect estimate > 1.5
ge (Mean, Std)	1.0	1.0	1.0	0.57	1.0	1.0	1.0	0.68	1.0	1.0	1.0	0.63	1.0	1.0	1.0	0.58	Keep	A A	ge due to clinical relevance
D Arrival Mode																			
Patient	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-			
EMS	2.2	1.6	3.1	<.0001	2.3	1.7	3.2	<.0001	2.3	1.7	3.2	<.0001	2.3	1.7	3.2	<.0001	Keep	EI	D Arrival Mode due to effect estimate > 1.5
D Acuity																			
1 Immediate	2.6	1.5	4.7		2.7	1.5	4.7	0.00	2.7	1.5	4.7	0.001	2.7	1.5	4.9	0.050	Keep	EI	D Acuity due to effect estimate > 1.5
2 Emergent	1.6	1.0	2.5	0.06	1.5	1.0	2.4	0.06	1.5	1.0	2.5	0.07	1.6	1.0		<.0001			
3 Urgent/ 4 Stable	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-			
rior Hospitalizations																			
0																			
1																			
2																			
3																			
>=4																			
rior ED Visits																			
0	1.0	-	-	-	1.0	-	-	-	1.0	-	-	-	1.0	-	-		Keep	Pr	rior ED Visits due to effect estimate > 1.5
1	1.4	1.0	2.0		1.4	1.0	2.0	0.06	1.4	1.0	2.0	0.07	1.4	1.0	1.9	0.08			
2	1.6	1.0	2.8		1.6	0.9	2.7	0.08	1.6	0.9	2.7	0.08	1.6	0.9	2.7	0.09			
>=3	2.2	1.2	3.9	0.01	2.1	1.2	3.9	0.01	2.1	1.2	3.9	0.01	1.9	1.0	3.7	0.02			
omorbidities							~~												
	Fluid and																		
Metastatic cancer	3.5	2.5		<.0001	3.5	2.4	5.0		3.5	2.5	5.0	<.0001	2.0	1.4	2.8				letastatic cancer due to effect estimate > 1.5
Cardiac arrythmias	2.0	1.4		<.0001	2.0	1.4	2.8	<.0001	2.0	1.4	2.8	<.0001	3.2	2.3	4.5				ardiac arrythmias due to effect estimate > 1.5
Weight Loss	3.3	2.3		<.0001	3.3	2.3	4.6	<.0001	3.3	2.4	4.6	<.0001	3.2	2.3	4.5				eight Loss due to effect estimate > 1.5
Coagulopathy	1.9	1.3		0.0008	2.0	1.3		0.0005	2.1	1.4	3.0	0.0001	2.2	1.5	3.1	<.0001	кеер	Co	oagulopathy due to effect estimate > 1.5
Renal failure	1.4	0.9	2.1					lue to low				0.14	Tarrat				66		insta (21.5)
Lymphoma	1.4	0.9	2.2	0.19	1.4	0.9	2.3	0.14	1.4	0.9	2.3								imate (<1.5)
Depression	2.7	1.9	3.9	<.0001	2.1	1.9	3.9	<.0001	2.7	1.9	5.9	<.0001	2.7	1.9	3.9	<.0001	кеер	De	epression due to effect estimate > 1.5
Congestive heart failure COPD																			
Liver Disease	1.4	1.0	2.6	0.06	1.4	1.0	2.6	0.06	Liver di	isease dro	opped d	ue to low e	ffect estin	nate (<1	5)				
Hypertension, complicated																			
Pulmonary Circulatory Disorde																			
Diabetes, Complicated																			
Valvular Disease																			
Blood loss anemia																			
Paralysis																			
HIV/AIDs																			

Appendix B: Modeling Strategy, Continued