Personalized VTE Risk Prediction in Cancer Patients using Clinical Informatics

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Anticoagulation FORUM

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Disclosure

- None

Objectives

- Overview the advantages and limitations of modern curated electronic health record (EHR) research in cancer and thrombosis
- Provide case study on natural language processing (NLP) algorithms in classifying unstructured text for venous thromboembolism (VTE)
- Provide case study on derivation and validation of risk prediction models of VTE among cancer patients
- Provide case study on implementing patient centered clinical decision support (PC-CDS) tools for pharmacologic thromboprophylaxis

I. Introduction of Cancer Associated Thrombosis (CAT)

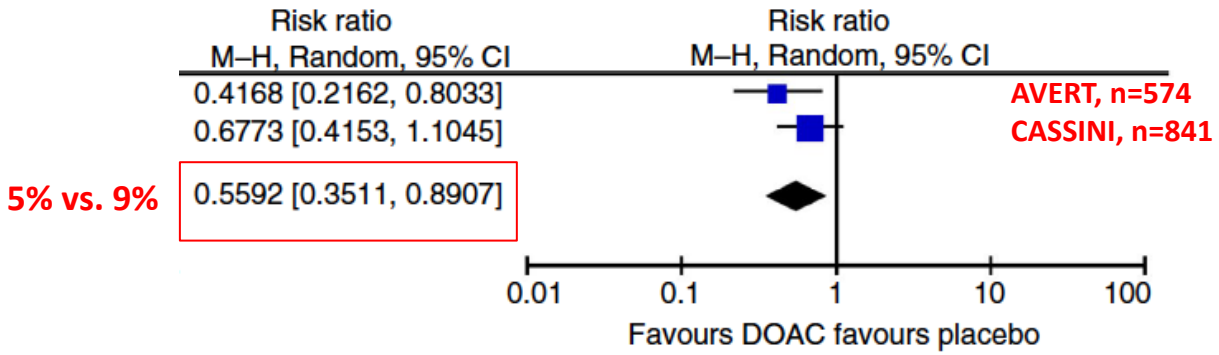
Importance of VTE Prediction in Cancer Patients

- VTE occurs 7-9 times more in cancer vs. non-cancer patients
- Incidence of VTE varies significantly by cancer type
- Thrombosis (venous + arterial) is 2nd leading cause of death in ambulatory patients with cancer along with infection (9%)
- Patients with active cancer have a one-year mortality of 65% after VTE diagnosis

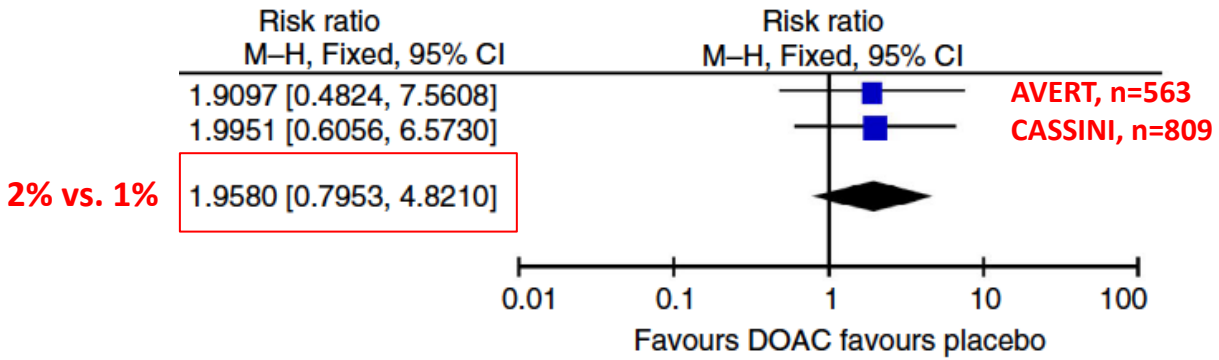
Blom, JAMA 2005. Khorana, J Thromb Haemost 2007. Cohen, Thromb Haemost 2017. Mulder, Blood 2021

Data Supporting VTE Prevention in Selective High-risk Cancer Patients

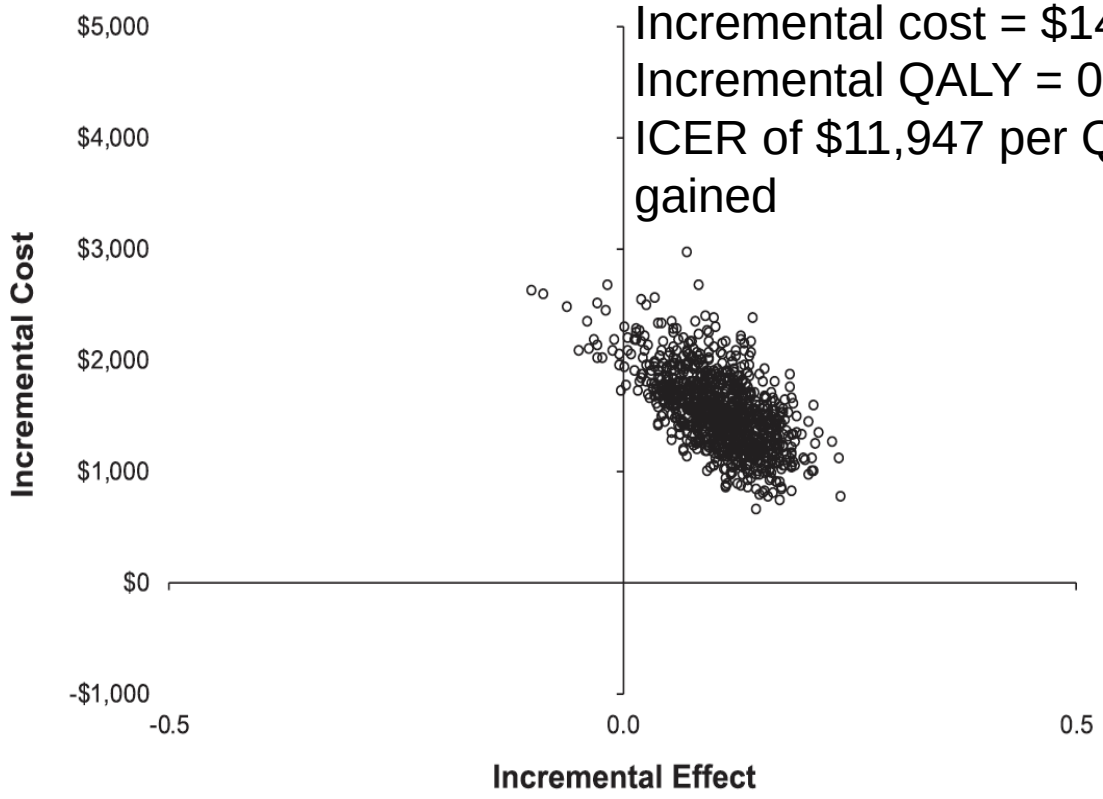
Incident VTE at <u>6 months</u> for Low-Dose DOAC vs. Placebo



Major Bleeding at <u>6 months</u> for Low-Dose DOAC vs. Placebo



Meta-analysis of randomized controlled trials enrolling patients with Khorana Score 2+



Cost Effectiveness Analysis

Li, J Thromb Haemost 2019. Li, Cancer 2020

Existing Risk Models in Cancer Associated Thrombosis

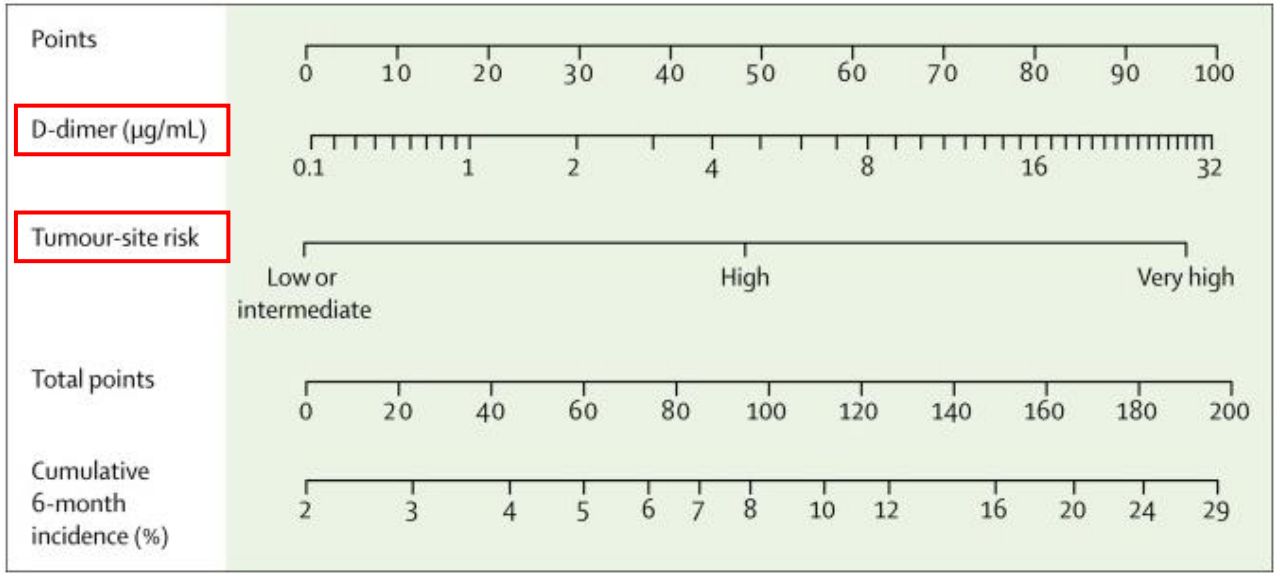
Khorana Score, Blood 2008

Variable	Score
Very high-risk tumor (stomach, pancreas)	2
High-risk tumor (lung, gynecologic, genitourinary excluding prostate)	1
Hemoglobin level <100 g/L or use of red cell growth factors	1
Prechemotherapy leukocyte count >11 × 10^9/L	1
Prechemotherapy platelet count 350 × 10^9/L or greater	1
Body mass index 35 kg/m^2 or greater	1

A score of 0 = low-risk category. A score of 1–2 = intermediate-risk category. A score of >2 = very high-risk category.

Only ~50% of VTE is classified as high-risk

Pabinger nomogram, Lancet Haematology 2018



Difficult to incorporate non-standard biomarker

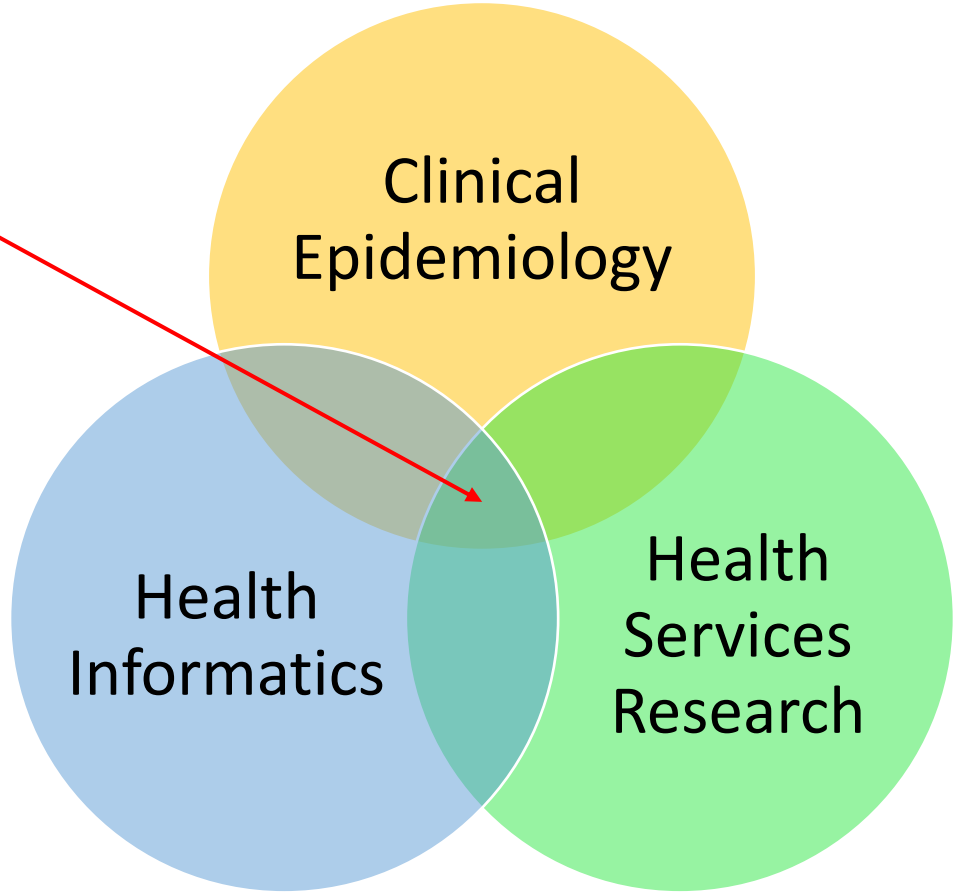
Key: Khorana Score is the most commonly used clinical risk model. D-dimer is the most commonly used biomarker

Ambulatory Pharmacologic Prophylaxis is Rarely Implemented

- Lack of precision: **Improved VTE prediction model**
  - "Khorana score complemented by clinical judgment and experience"
- Fear of bleeding: **Automated exclusion for bleeding risk**
  - "Used with caution in those with a high risk of bleeding"
- Lack of time: **Clinical decision support**
  - High volume clinic, not integrated into EHR
- Lack of awareness: **Simpler access to evidence**
  - Hematologist vs. oncologist; not comfortable to discuss

Intersection of Medicine, Research and Technology

Physician-led research team with clinically relevant and meaningful research questions



Etiology & pattern of disease

Use of technology (AI/ML) to improve healthcare delivery

Access & cost of healthcare to address disease

II. EHR Database Overview

Demographics from Different EHR Databases

Harris County Census (Houston)
- Non-Hispanic White: 29%
- Non-Hispanic Black: 20%
- Hispanic: 44%
- Asian/API: 7%

US Census (2020)
- Non-Hispanic White: 58%
- Non-Hispanic Black: 12%
- Hispanic: 19%
- Asian/API: 6%

Harris Health System (HHS)
- Non-Hispanic White: 16%
- Non-Hispanic Black: 28%
- Hispanic: 50%
- Asian/API: 5%

Uninsured/underinsured
~2,000 incident cancer annually
EPIC linkage 2010
2 hospitals (safety-net)
Immigrants without prior history

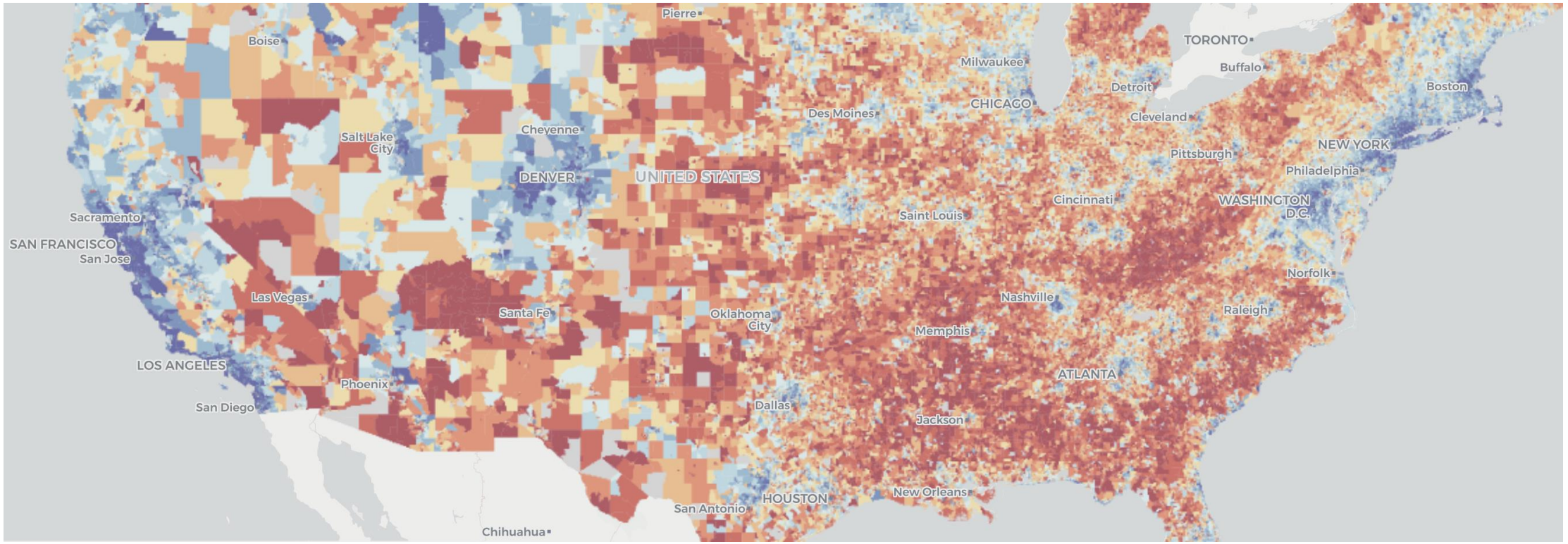
MD Anderson Cancer Center
- Non-Hispanic White: 70%
- Non-Hispanic Black: 10%
- Hispanic: 14%
- Asian/API: 6%

Selective private insurance
~10,000 incident cancer annually
EPIC linkage 2017
1 hospital (tertiary referral)
Referral & follow-up bias

VA National Healthcare System
- Non-Hispanic White: 72%
- Non-Hispanic Black: 21%
- Hispanic: 5%
- Asian/API: 2%

Veteran benefit insurance
~30,000 incident cancer annually
VINCI/CDW linkage 2002
100+ hospitals (primary care)
97% male with unique comorbidity

Area of Deprivation Index

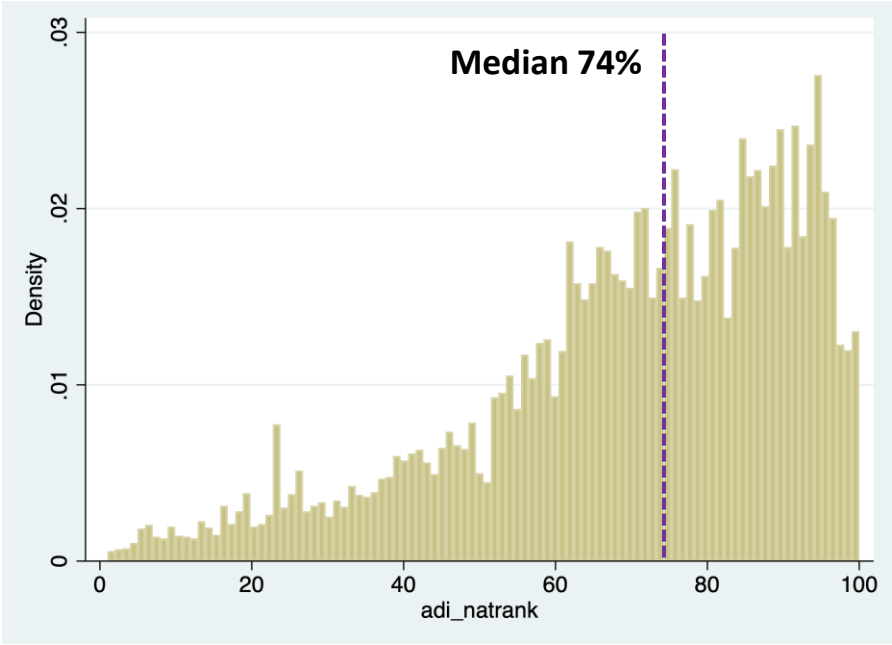


Small neighborhood social determinants of health estimated from Block Group level data from American Community Surveys
4 domains: poverty, housing, employment, education

Kind AJH, Buckingham W. The Neighborhood Atlas. *NEJM*, 2018

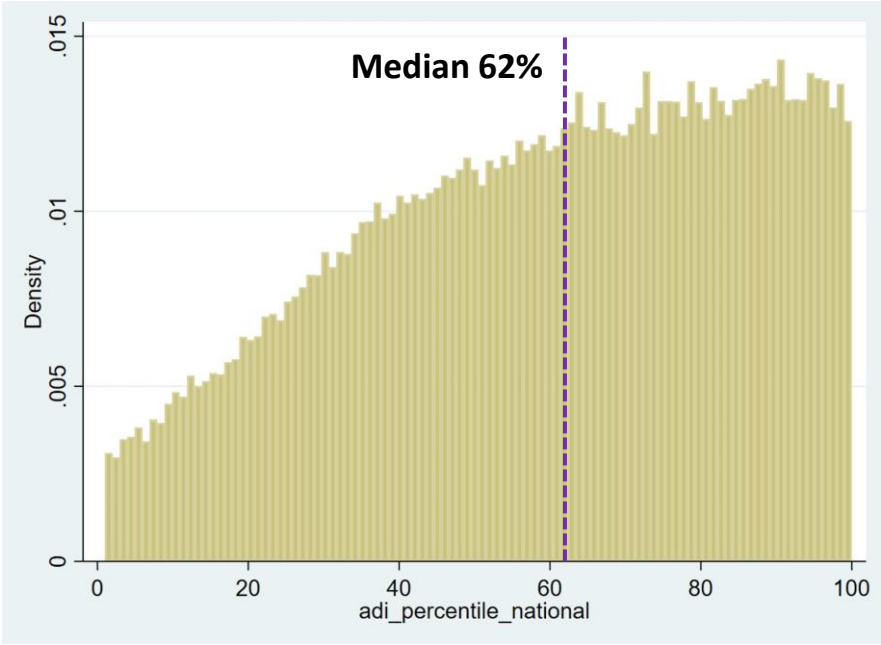
National ADI Distribution in Cancer Databases

HHS 2011-2021 (N=19,667)



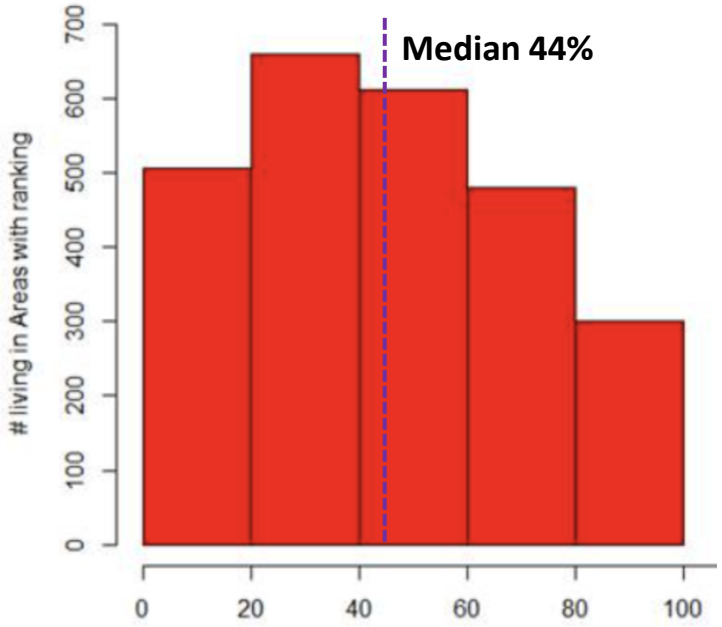
Uninsured/underinsured

VA 2006-2021 (N=434,203)



Veteran benefit insurance

MDACC 2017-2021 (N=36,542)



Selective private insurance

Low number = least deprived; high number = most deprived

Unpublished data from Li and Nze

Data Abstraction & Linkage

Hospital system cancer registry (Cancer Registry)

- Cancer registry data
  - Sequence
  - Diagnosis
  - Histology
  - Stage
  - Demographics
  - Mortality
  - Annual update with 1 year delay

+

Electronic Health Record (EPIC Caboodle/VINCI CDW)

- Claims-level data
  - ICD/CPT/HCPCS codes
- Encounter-level data
  - Encounter appointments/codes
  - Medical/surgical history
  - Medications prescribed/administered
  - Laboratory/transfusion/micro
  - Imaging/procedures
  - Hospital/clinic notes
  - Daily update

Extensive data validation, cleaning, filtering, and linkage

Integrated Cancer Data Warehouse (n=20,000 at HHS)

- Diagnosis, histology, staging
- Annually updated mortality
- Demographics at diagnosis
- Address => **geo-coded ADI**
- Comorbidities => **CCI / NCI**
- Encounter/appointment
- Scheduled/performed surgeries
- Prescribed/administered medication => **lines of therapy**
- Vitals: weight/height
- Laboratory: lab, micro, transfusion

- ICD diagnosis codes (facility)
- ICD diagnosis codes (encounter)
- ICD diagnosis codes (problem list, medical history, surgical history)
- ICD procedure codes (facility coded)
- CPT/HCPCS procedure codes (facility transaction)

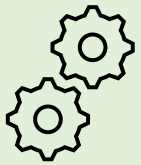
- Radiology impression
- Discharge summary
- Clinic progress notes
- Procedure: TTE, PFT, EGD

NLP

Key: clinician validated & cleaned data from electronic health record is paramount for ANY methodology!

Health Informatics in Cancer Care Delivery

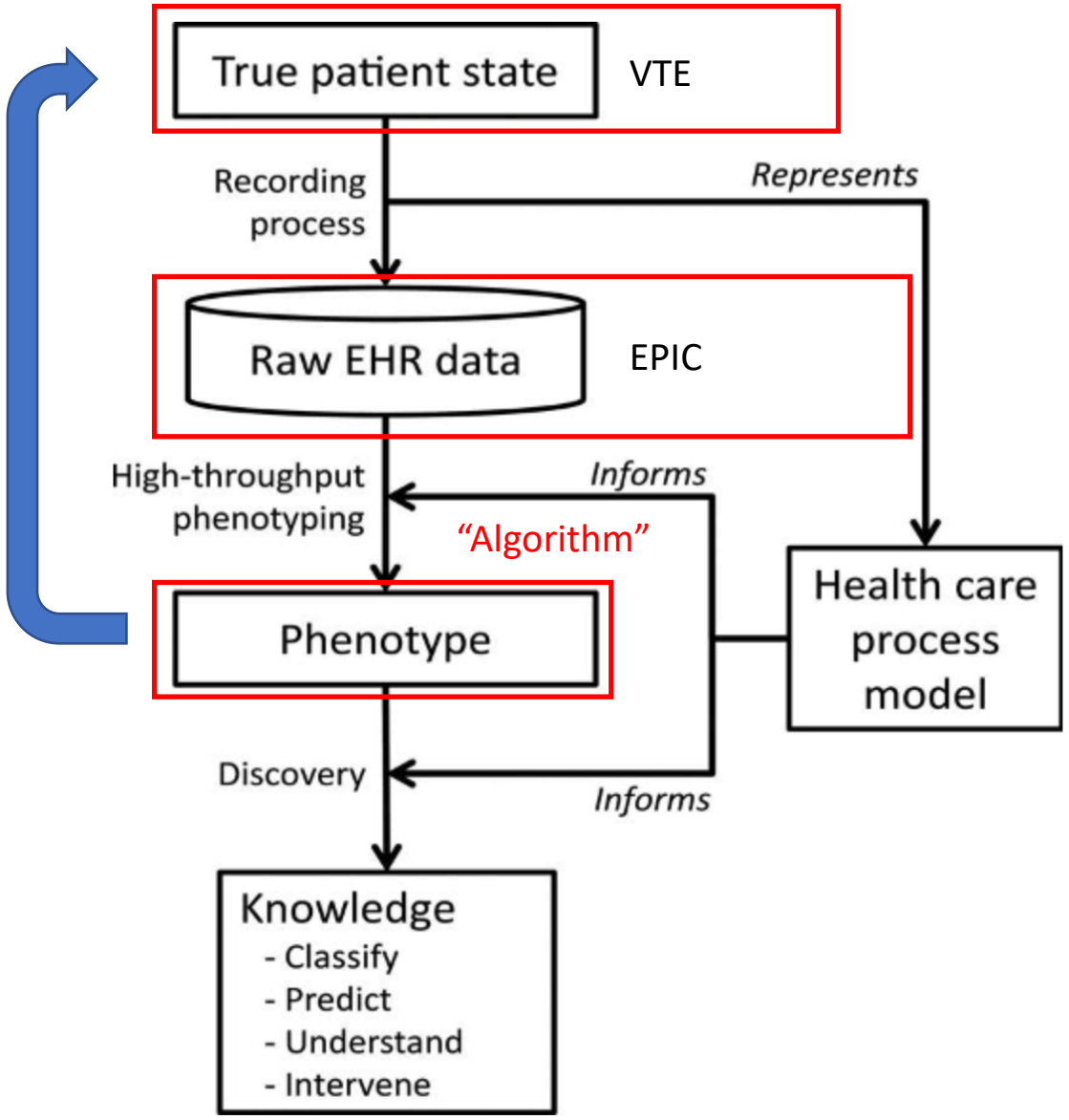
- **Research Methods**
  - Develop machine learning methods to address health disparity research
- Examples:
  - Computable phenotype of VTE via NLP
  - Goal = accurate/precise phenotyping of disease



- **Research Application**
  - Apply traditional & novel prediction models in different healthcare systems
- Examples:
  - Risk prediction model for VTE and bleeding
  - Goal = reproducible & generalizable model

- **Clinical Application**
  - Integrate risk prediction models at point of care decision making in EHR databases
- Example:
  - PC-CDS for VTE prophylaxis
  - Goal = user friendly unintrusive decision aid

III. Phenotyping VTE & Epidemiology of Cancer Associated Thrombosis (CAT)



Source: Hripcsak and Albers 2013. (Used under a Creative Commons license.)

https://rethinkingclinicaltrials.org/chapters/conduct/electronic-health-records-based-phenotyping/definitions/

How to determine the VTE phenotype

- Structured data
  - ICD codes
    - Billing: inpatient vs. outpatient
    - Encounter
    - ~~Problem list~~
  - CPT codes
    - Radiology studies
    - IVC filter
  - Medications
    - Anticoagulant

- Unstructured data (NLP)
  - Sequence in repeated notes
  - Region of interest
    - Radiology report: impression
    - Discharge note: hospital course
    - Office progress note: A/P
  - Rule-based vs. ML-based
    - VTE keyword
    - Assertion negation
    - Deep learning model

Key: EHR database (billing + charting) provides much more granularity than claims database (billing)

Defining VTE Computable Phenotype – Validation

HHS: Predicted vs. observed VTE at 12 months (selective review)

	Predicted No.	Reviewed No.	True+ VTE	True- VTE	PPV
ICD- NLP-	8,957 (92%)	300	**1**	299	0.33%
NLP+ only	115 (1.2%)	115	88	**27**	76.5%
ICD+ only	127 (1.3%)	127	78	**49**	61.4%
ICD+ NLP+	570 (5.9%)	200	192	**8**	96.0%

HHS: Performance of prediction algorithms (weighted sample)

	True+ VTE		True- VTE		
ICD- NLP-	8,957 x 0.33%	30	8,957 x 99.7%	8,927	NPV 100%
NLP+ only	115 x 76.5%	710	115 x 23.5%	102	PPV 87%
ICD+ only	127 x 61.4%		127 x 38.6%		
ICD+ NLP+	570 x 96.0%		570 x 4.0%		
	Sensitivity 96%		Specificity 99%		

ICD/medication: PPV 90%, sensitivity 84%
NLP/radiology: PPV 92%, sensitivity 84%
ICD or NLP: PPV 87%, sensitivity 96%

VA: Predicted vs. observed VTE at 12 months (selective review)

	Predicted No.	Reviewed No.	True+ VTE	True- VTE	PPV
ICD- NLP-	74,145 (93%)	300	**1**	299	0.33%
NLP+ only	799 (1.0%)	200	159	**41**	79.5%
ICD+ only	1,758 (2.2%)	200	161	**39**	80.5%
ICD+ NLP+	2,813 (3.5%)	200	198	**2**	99.0%

VA: Performance of the prediction algorithms (weighted sample)

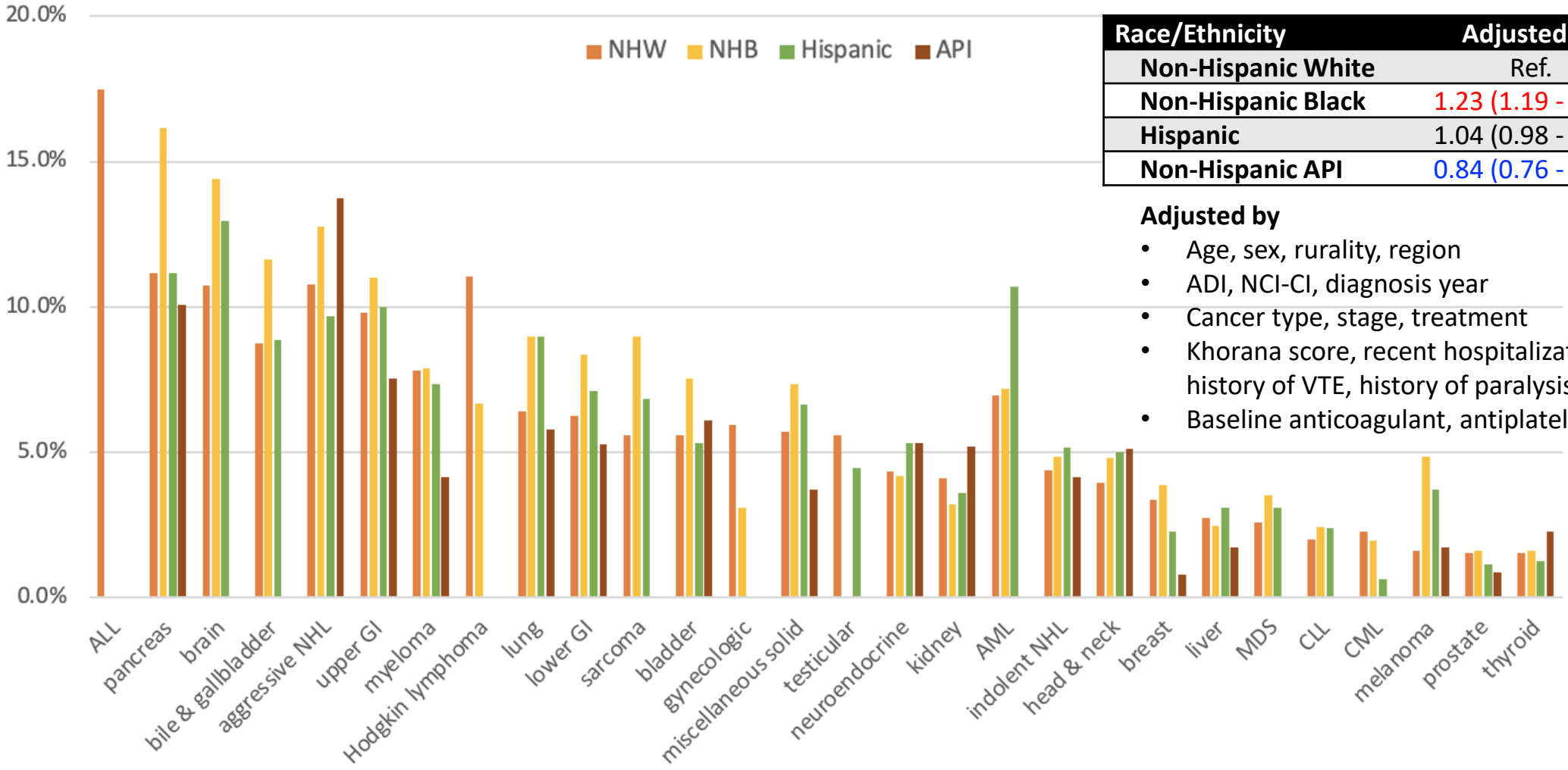
	True+ VTE		True- VTE		
ICD- NLP-	74,145 x 0.3%	222	74,145 x 99.7%	73,923	NPV 100%
NLP+ only	799 x 79.6%	4,836	799 x 20.4%	534	PPV 90%
ICD+ only	1,758 x 80.5%		1,758 x 19.5%		
ICD+ NLP+	2,813 x 99.0%		2,813 x 1.0%		
	Sensitivity 96%		Specificity 99%		

ICD/medication: PPV 89%, sensitivity 83%
NLP/radiology: PPV 95%, **sensitivity 68%**
ICD or NLP: PPV 90%, sensitivity 96%

Key: NLP is system-specific but can greatly augment accuracy of structured phenotyping algorithm

Li, J Clin Oncol 2023

Incidence of CAT by Cancer Type and Race/Ethnicity in 434,203 Veterans



Race/Ethnicity	Adjusted HR
Non-Hispanic White	Ref.
Non-Hispanic Black	1.23 (1.19 - 1.27)
Hispanic	1.04 (0.98 - 1.10)
Non-Hispanic API	0.84 (0.76 - 0.93)

Adjusted by

- Age, sex, rurality, region
- ADI, NCI-CI, diagnosis year
- Cancer type, stage, treatment
- Khorana score, recent hospitalization, history of VTE, history of paralysis
- Baseline anticoagulant, antiplatelet

Key: CAT incidence is specific to patient (race, weight, comorbidity) and cancer (type, stage, treatment)

Martens, JAMA Netw Open 2023

IV. VTE Risk Prediction Modeling

Creating Validated, Optimized, and Inclusive Risk Prediction Model for CAT

- Population:
  - First cancer diagnosis receiving first-line systemic therapy within 1 year
  - Exclude if recent acute VTE last 6 months or on therapeutic AC
  - Assess VTE from index treatment until loss of follow-up (90+ day gap)
- Derivation cohort:
  - HHS (N=9,769, 2011-2020, VTE 6.2% at 6-month)
- Validation cohorts:
  - VA national (N=79,517, 2011-2020, VTE 5.1% at 6-month)
  - MD Anderson (N=21,142, 2017-2020, VTE 5.7% at 6-month)

Clinical Knowledge is Important for Initial Variable Selection

Khorana score (KS) factors	Cancer site/histology subtype
	Pre-therapy body mass index >=35
	Pre-therapy white blood cell count >11
	Pre-therapy hemoglobin <10
	Pre-therapy platelet >=350
Cancer-specific risk factors	Cancer Stage
	Treatment initiation timing
	Treatment regimen
Patient-demographic factors	Age
	Sex
	Race/Ethnicity
Additional clinical factors	History of PE/LE-DVT
	Recent prolonged hospitalization >3d last 3 months
	Anticoagulant prescription in last 3 months
	Antiplatelet prescription in the last 3 months
	Surgery within last 3 months
Additional lab factors	Creatine
	Total bilirubin
	Alanine transaminase

Patient Comorbidities	Congestive heart failure
	Myocardial infarction
	Cardiac arrhythmia
	Cardiac valvular disease
	Peripheral vascular disease
	Cerebral vascular disease
	Chronic obstructive pulmonary disease
	Paralysis or immobility
	Diabetes
	Hypertension
	Renal Disease
	Liver disease
	HIV/AIDS
	Rheumatologic disease
	Coagulopathy

A priori selected risk predictors for VTE

Interpretable vs. Black Box Machine Learning models

- Linear regression, logistic regression, Cox regression
- Generalized linear models: non-Gaussian outcomes (family/link)
- Generalized additive models: non-linear outcomes (splines)

```
##  [1] "SL.bartMachine"      "SL.bayesglm"         "SL.biglasso"
##  [4] "SL.caret"            "SL.caret.rpart"      "SL.cforest"
##  [7] "SL.earth"            "SL.extraTrees"       "SL.gam"
## [10] "SL.gbm"              "SL.glm"              "SL.glm.interaction
## [13] "SL.glmnet"           "SL.ipredbagg"        "SL.kernelKnn"
## [16] "SL.knn"              "SL.ksvm"             "SL.lda"
## [19] "SL.leekasso"         "SL.lm"               "SL.loess"
## [22] "SL.logreg"           "SL.mean"             "SL.nnet"
## [25] "SL.nnls"             "SL.polymars"         "SL.qda"
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## [31] "SL.rpart"            "SL.rpartPrune"       "SL.speedglm"
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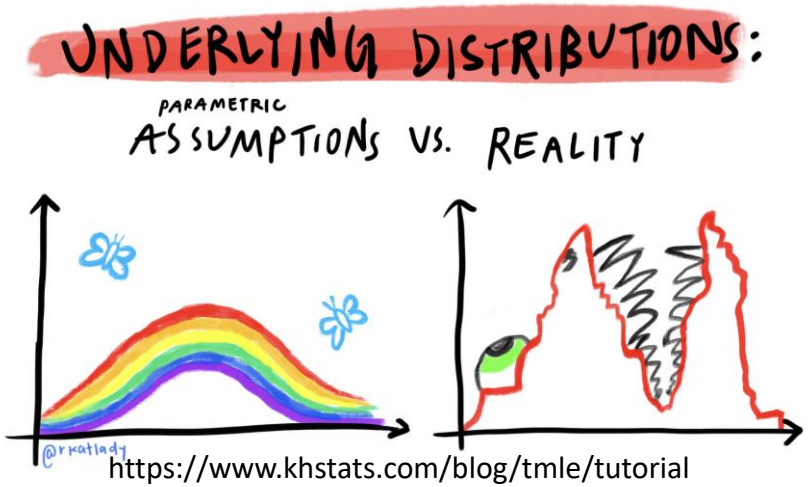
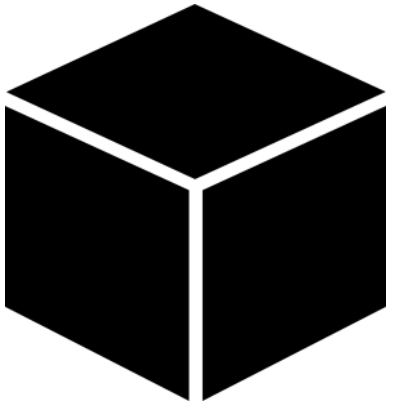


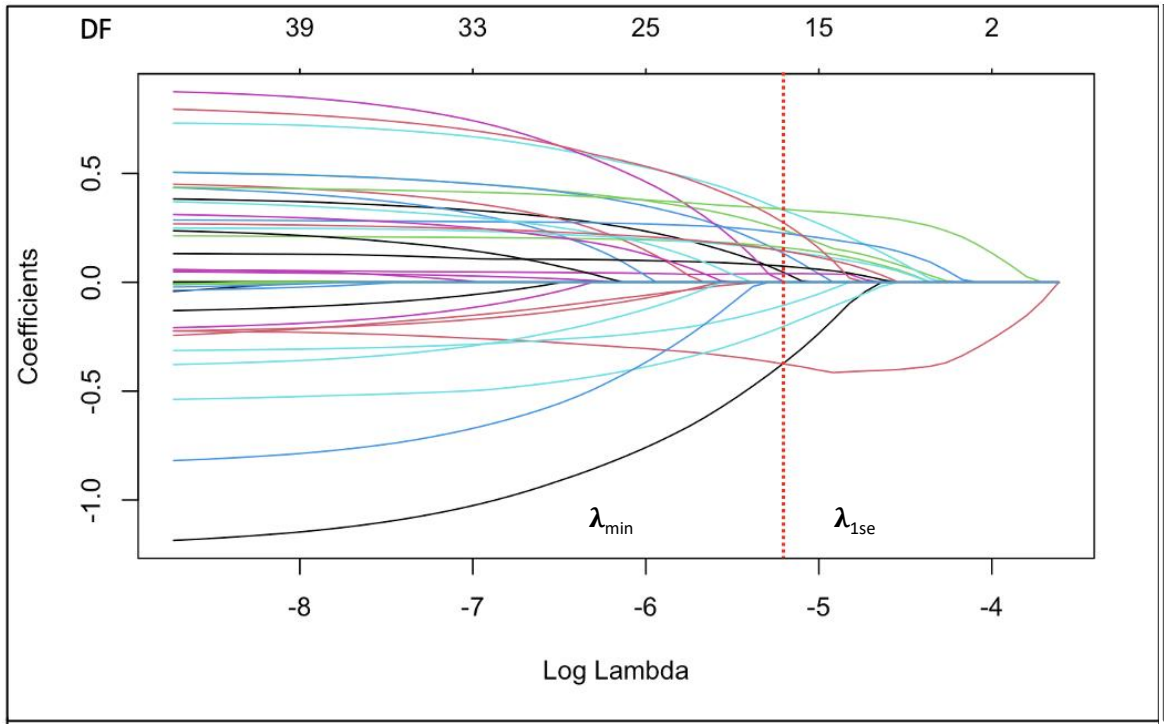
https://www.khstats.com/blog/tmle/tutorial

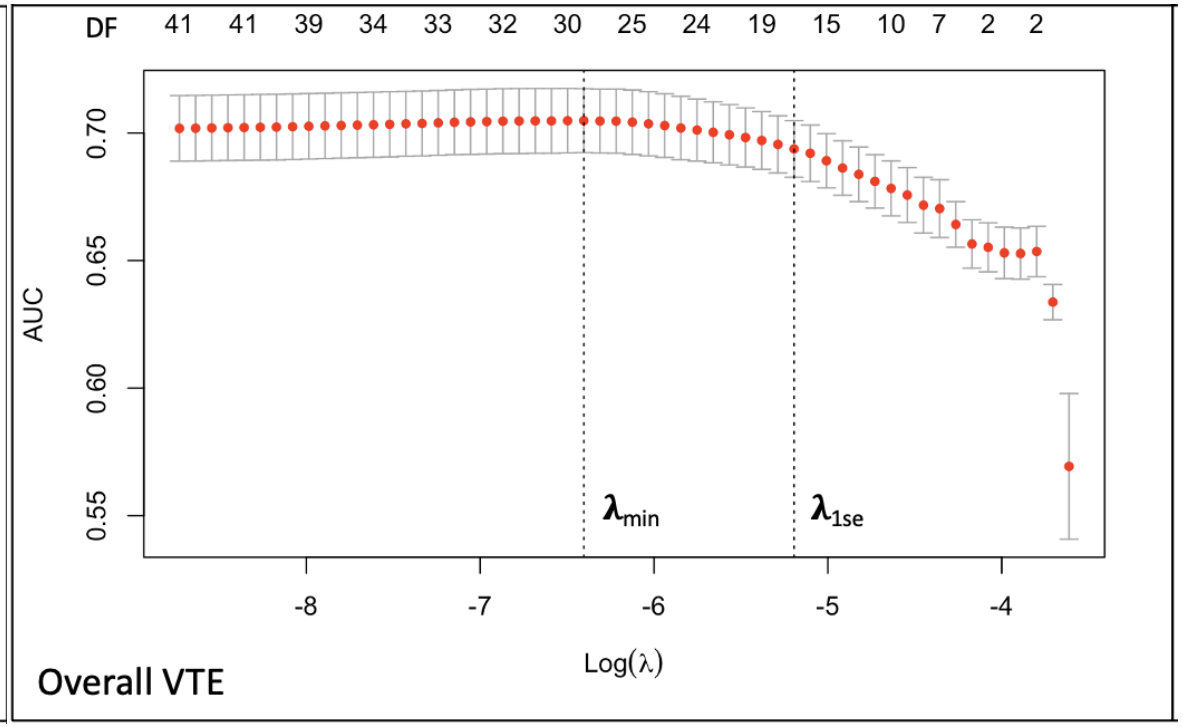
Features



Outcome

Feature Selection via LASSO Penalized Shrinkage





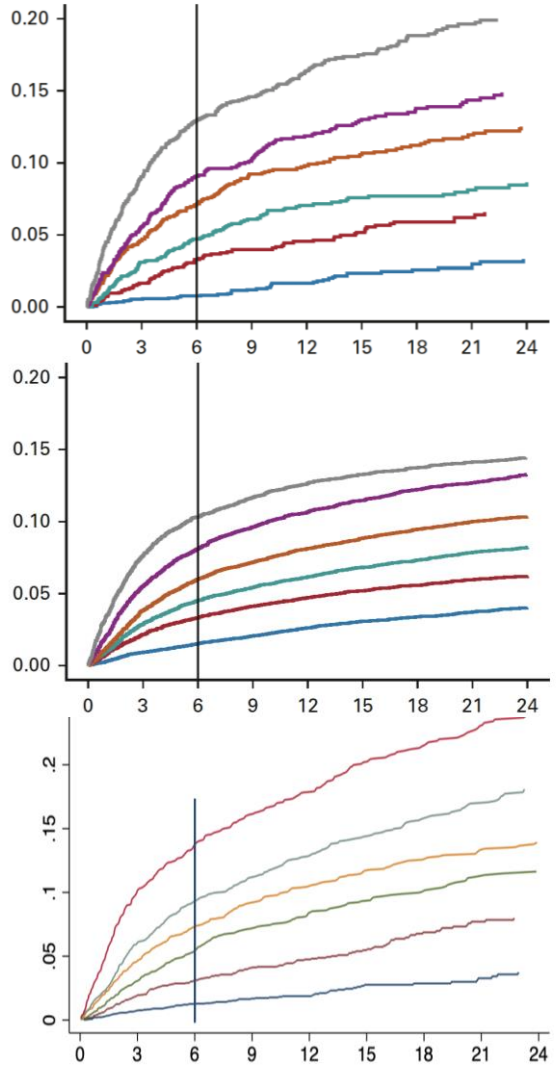
Goal is to optimize prediction with the most parsimonious model (trade-off between complexity & fit)

Logistic Regression Model Fitted from LASSO Selection

	Risk Predictors	Number (%)	OR for VTE (95% CI)	Point
Khorana score risk factors	**Modified cancer subtype risk**			
	- Other solid or heme cancer [a]	5,206 (53.3%)	Reference	0
	- Colorectal cancer	1,152 (11.8%)	1.36 (1.01-1.82)	1
	- Lung, ovarian, uterine, bladder, kidney, testicular, aggressive NHL, myeloma, brain, soft tissue sarcoma	2,644 (27.1%)	2.23 (1.81-2.74)	2
	- Pancreas, gastric, esophageal, cholangiocarcinoma, gallbladder	767 (7.9%)	2.26 (1.69-3.03)	3
	Pre-therapy BMI ≥35	1,318 (13.5%)	1.45 (1.14-1.83)	1
	Pre-therapy WBC >11	1,652 (16.9%)	1.34 (1.09-1.65)	1
	Pre-therapy hemoglobin <10	2,042 (20.9%)	1.49 (1.23-1.80)	1
	Pre-therapy platelet ≥350	2,700 (27.6%)	1.24 (1.03-1.49)	1

Discrimination of Novel Risk Prediction Model

Dataset	Risk score	VTE % at 6 mo	Classification	VTE % at 6 mo	TD-C statistic (95% CI)
HHS Derivation Cohort	0- (1,938)	0.8% (14)	Low-risk 50.8% (4,958)	2.8% (131)	**0.71 (0.69-0.72)**
	1 (1,483)	3.3% (47)			
	2 (1,537)	4.7% (70)			
	3 (1,644)	7.2% (114)	High-risk 49.2% (4811)	9.8% (459)	
	4 (1,523)	9.1% (135)			
	5+ (1,644)	13.0% (210)			
VA Validation Cohort	0- (18,022)	1.5% (267)	Low-risk 54.2% (43,894)	3.0% (1,272)	**0.68 (0.67-0.69)**
	1 (12,551)	3.3% (411)			
	2 (13,321)	4.5% (594)			
	3 (14,969)	6.0% (888)	High-risk 44.8% (35,623)	7.8% (2,755)	
	4 (11,381)	8.1% (915)			
	5+ (9,273)	10.3% (952)			
MDACC Validation Cohort	0- (5,661)	1.3% (59)	Low-risk 60.0% (12,681)	2.6% (325)	**0.71 (0.69-0.72)**
	1 (3,558)	3.1% (99)			
	2 (3,462)	5.4% (167)			
	3 (3,489)	7.3% (232)	High-risk 40.0% (8,461)	8.8% (742)	
	4 (2,918)	9.3% (250)			
	5+ (2,054)	13.8% (260)			



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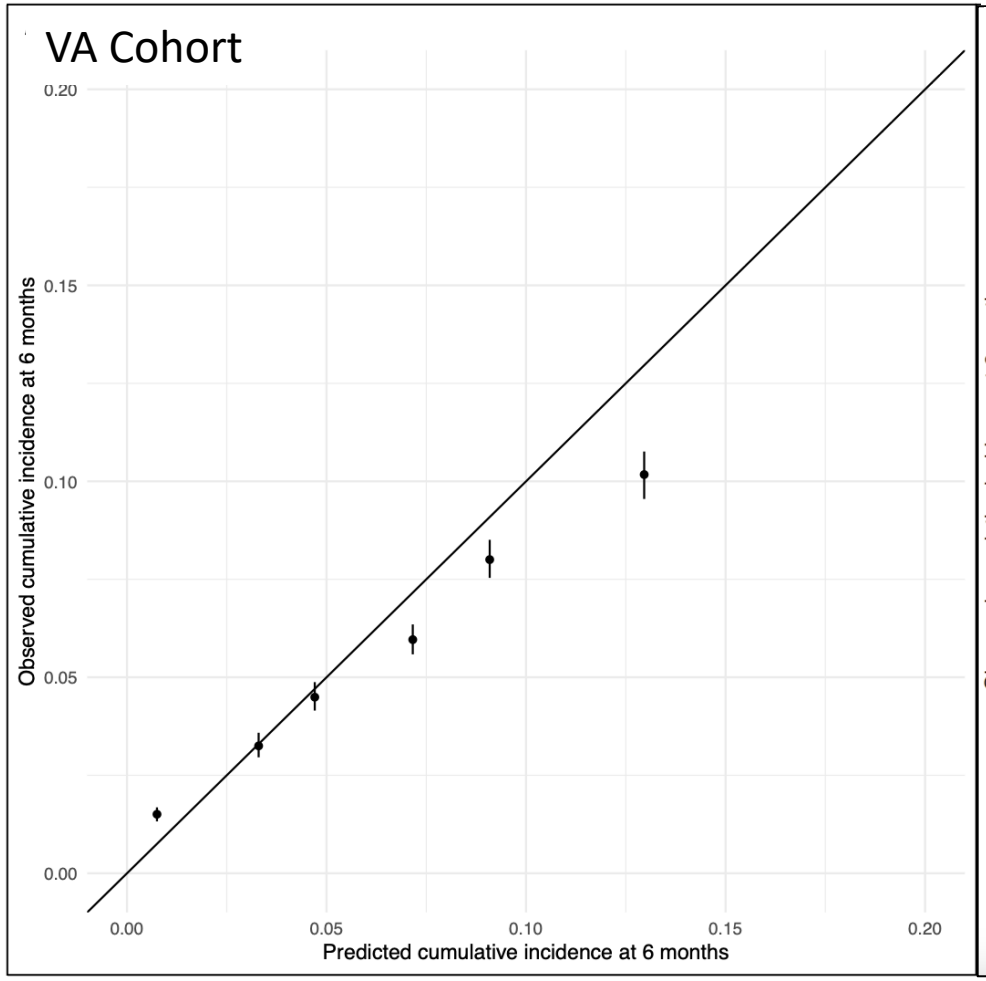
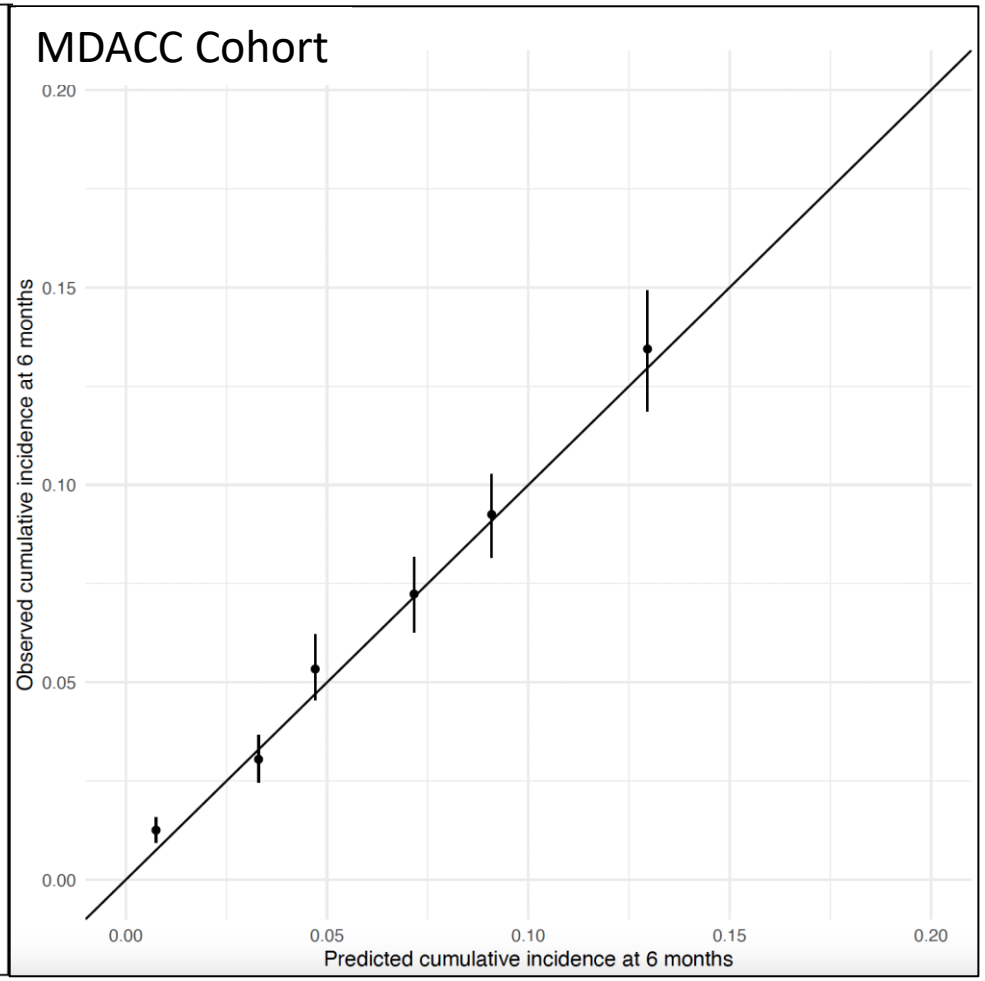
Calibration Curves in Validation Cohorts





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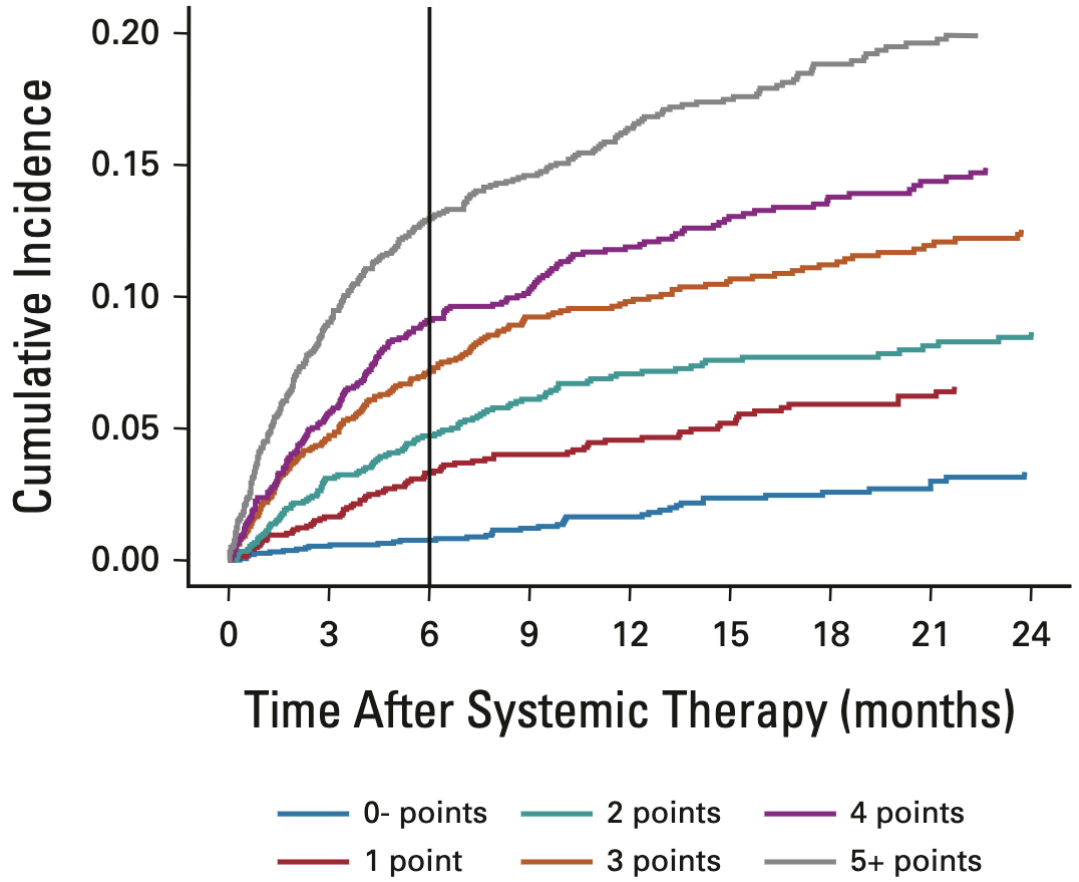
Comparison with Khorana Score

Dataset	Category	Khorana Score	New RAM	Number	VTE % at 6 mo
HHS Derivation Cohort	Concordant (78%)	Low-risk	Low-risk	4,495	2.6% (112)
		High-risk	High-risk	3,107	10.5% (321)
	Reclassified (22%)	Low-risk	High-risk	1,704	8.4% (138)
		High-risk	Low-risk	463	4.3% (19)
VA Validation Cohort	Concordant (72%)	Low-risk	Low-risk	40,360	3.0% (1,184)
		High-risk	High-risk	17,242	8.2% (1,406)
	Reclassified (28%)	Low-risk	High-risk	18,381	7.4% (1,349)
		High-risk	Low-risk	3,534	2.5% (88)
MDACC Validation Cohort	Concordant (80%)	Low-risk	Low-risk	11,947	3.0% (303)
		High-risk	High-risk	4,931	10.0% (451)
	Reclassified (20%)	Low-risk	High-risk	3,530	9.0% (291)
		High-risk	Low-risk	734	3.4% (22)

Key: New risk model increases VTE % in high-risk group by ~25% & improves overall C statistic ~0.07

Available Online Calculator



https://dynamicapp.shinyapps.io/EHR-CAT/

Cancer site/histology (choose one from the following)

Other cancers (0)

Cancer stage (AJCC)

- Early stage (I-II) (0)
- Advanced stage (III-IV) (+1)

Type of systemic therapy

- Cytotoxic chemotherapy (chemo) and/or immune checkpoint inhibitor (ICI) (0))
- Targeted and/or endocrine therapy without chemo/ICI (-1)

Patient race

- All other race (0)
- East/South Asian, Pacific Islander, American Indian or Alaskan Native (-1)

Pretherapy body mass index ≥ 35

No (0) Yes (+1)

Pretherapy white blood cell count > 11 x 10^9/L

No (0) Yes (+1)

Pretherapy hemoglobin < 10 g/dL

No (0) Yes (+1)

Pretherapy platelet count ≥ 350 x 10^9/L

No (0) Yes (+1)

History of VTE

No (0) Yes (+1)

History of paralysis/immobility

No (0) Yes (+1)

Recent/current hospitalization >3 days in the past 3 months

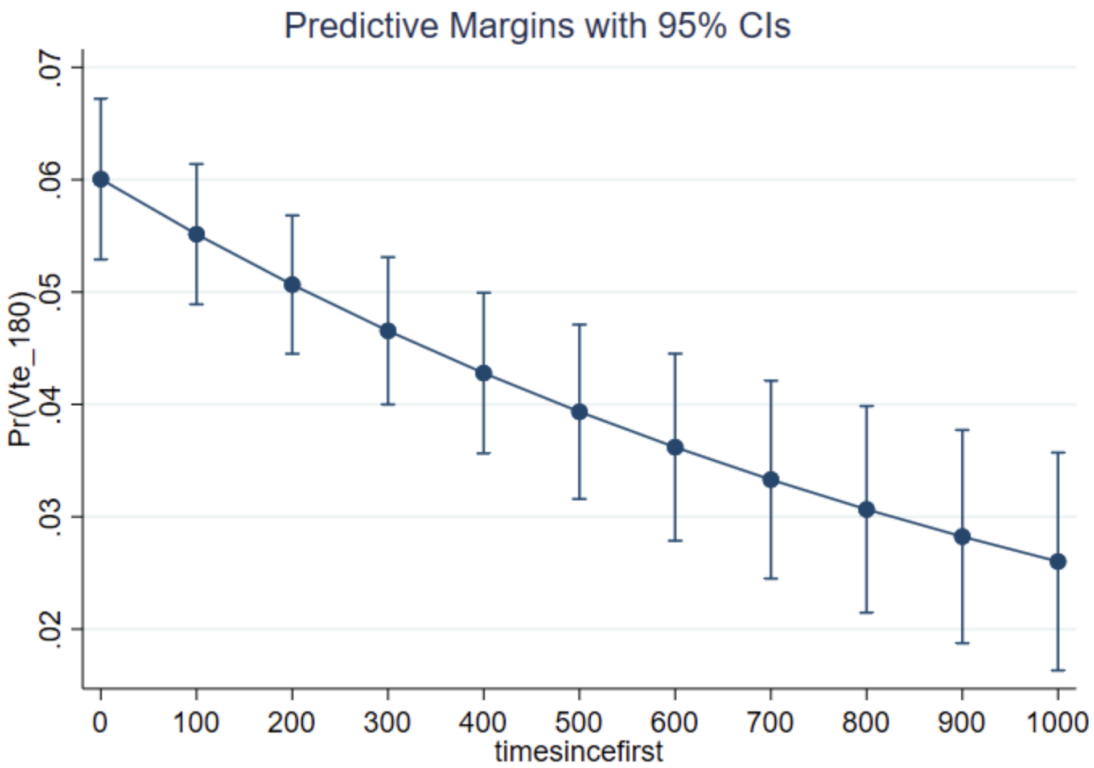
No (0) Yes (+1)

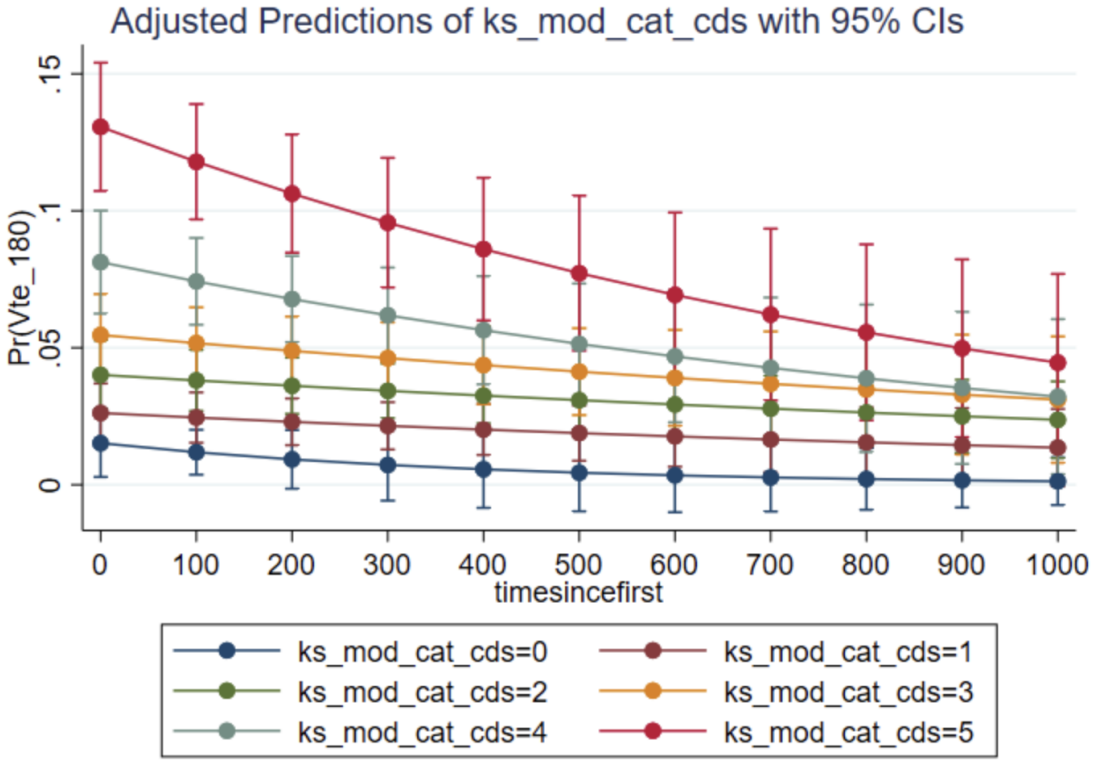
V. Dynamic Modeling & Implementation of PC-CDS

Ambulatory Pharmacologic Prophylaxis is Rarely Implemented

- Lack of precision: **Improved VTE prediction model**
  - "Khorana score complemented by clinical judgment and experience"
- Fear of bleeding: **Automated exclusion for bleeding risk**
  - "used with caution in those with a high risk of bleeding"
- Lack of time: **Clinical decision support**
  - high volume clinic, not integrated into EHR
- Lack of awareness: **Simpler access to evidence**
  - hematologist vs. oncologist; not comfortable to discuss

CAT Risk Decreases Over Time





Key: a time adjustment factor is needed to apply a static model over time

Li, unpublished data

Patient Specific Risk Factors Change Over Time

id	plan_n	cancer_type	dx_date	treat_date	chemo_class_regimen_cds	risk_score	vte_180d	vte_date	vte_type
1	1	breast	5/26/20	07/23/20	chemo+/−others (no immuno)	2	0	.	.
1	2	breast	5/26/20	11/17/20	chemo+/−others (no immuno)	4	0	.	.
1	3	breast	5/26/20	03/09/21	chemo+/−others (no immuno)	2	0	.	.
2	1	breast	6/27/18	08/17/18	target+/−endo (no chemo/immmuno)	1	0	.	.
2	2	breast	6/27/18	10/19/18	target+/−endo (no chemo/immmuno)	2	0	.	.
2	3	breast	6/27/18	12/27/19	target+/−endo (no chemo/immmuno)	1	0	.	.
24	1	lung	10/27/16	12/12/16	chemo+/−others (no immuno)	5	1	4/20/17	Acute PE
29	1	colorectal	6/23/17	08/04/17	chemo+/−others (no immuno)	5	0	7/6/18	Acute PE
29	2	colorectal	6/23/17	12/12/17	chemo+/−others (no immuno)	4	1	7/6/18	Acute PE
29	3	colorectal	6/23/17	03/19/18	chemo+/−others (no immuno)	2	1	7/6/18	Acute PE
105	1	lung	8/29/19	10/11/19	chemo/immuno+others	7	0	7/16/20	Acute PE
105	2	lung	8/29/19	01/22/20	immuno+/−others (no chemo)	6	1	7/16/20	Acute PE

Automate Patient Selection & Exclusion in EHR Prospectively

Overview of Data flow in EPIC EHR

1. Data extraction

2. Risk model calculation
VTE % = X + Y + Z

EPIC Hyperspace

Relational database

4. Risk model visualization
VTE risk = 10%

3. Data linkage

Patients with **signed treatment plan** -14d/+30d from today (n=129)

Missing data (6%)
- Unknown or multiple cancer type (n=3)
- Missing cancer staging (Epic, note) (n=5)
- Missing systemic treatment type (n=0)
- Missing CBC, BMI, or other covariates (n=0)

Patients with **no missing data** (n=121) (94%)

Trial exclusion criteria (17%)
- Acute leukemia (n=5)
- ALT >5x, Bili >2x, eGFR <30, Weight <40 kg (n=9)
- Drug interaction with DOAC (n=0)
- Anticoagulant or dual antiplatelet (n=8)
- High-risk for bleeding (?)

Patients **with no missing data or exclusions** (n=99) (77%)

N=48 high-risk
N=51 low-risk

Provide risk-stratified education to provider & patient

Patient Centered Clinical Decision Support (PC-CDS)

- **Design/assess/optimize usage:**
  - Time consuming process
  - Design provider- & patient-specific surveys & education fliers
  - Assess barriers to implementation (<25%): time, cost, difficulty, annoyance
  - Assess outcomes after implementation
  - Modify implementation strategy
- **BCM VCG QI project 2023**

Blumenfeld, PCCDS LN, AHRQ 2017

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