What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a ‘one-stop shop’ for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally

ACCORDS Upcoming Events

April 26, 2024 AHSB 2200/2201, Zoom 11am-1pm MT	**ACCORDS/CCTSI Community Engagement Showcase**
May 20, 2024	**Statistical Methods for Pragmatic Research** Planning a Pragmatic Effectiveness Trial with a Factorial Design by Targeting the Posterior Distribution Variance *Presented by:* Keith Goldfeld, DrPH, MS, MPA/MURP
	Last seminars for the 2023-2024 academic year!

*all times 12-1pm MT unless otherwise noted

COPRH Con

Colorado Pragmatic Research in Health Conference

Innovations in Pragmatic Research Methods

From Data to Equity, Policy, and Sustainability

June 5 - 6, 2024 | 10am-3:30pm MT

Registration is open now at
www.COPRHCon.com

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ADULT AND CHILD CENTER FOR OUTCOMES RESEARCH AND DELIVERY SCIENCE

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bitly

Statistical Methods for Pragmatic Research Seminar Series

2023-2024 seminar series

Michael Matheny, MD, MS, MPH

Opportunities and Challenges in the use of AI and ML for Population Health Informatics

Opportunities and Challenges in the use of AI and ML for Population Health Informatics

Michael E. Matheny, MD, MS, MPH

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Associate Director, Advanced Fellowship in Medical Informatics
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VANDERBILT UNIVERSITY MEDICAL CENTER

CIPHI Center for Improving the Public's Health through Informatics

Disclosure

- I have no conflicts of interest in the presentation of any materials, software, or algorithms presented in this presentation.

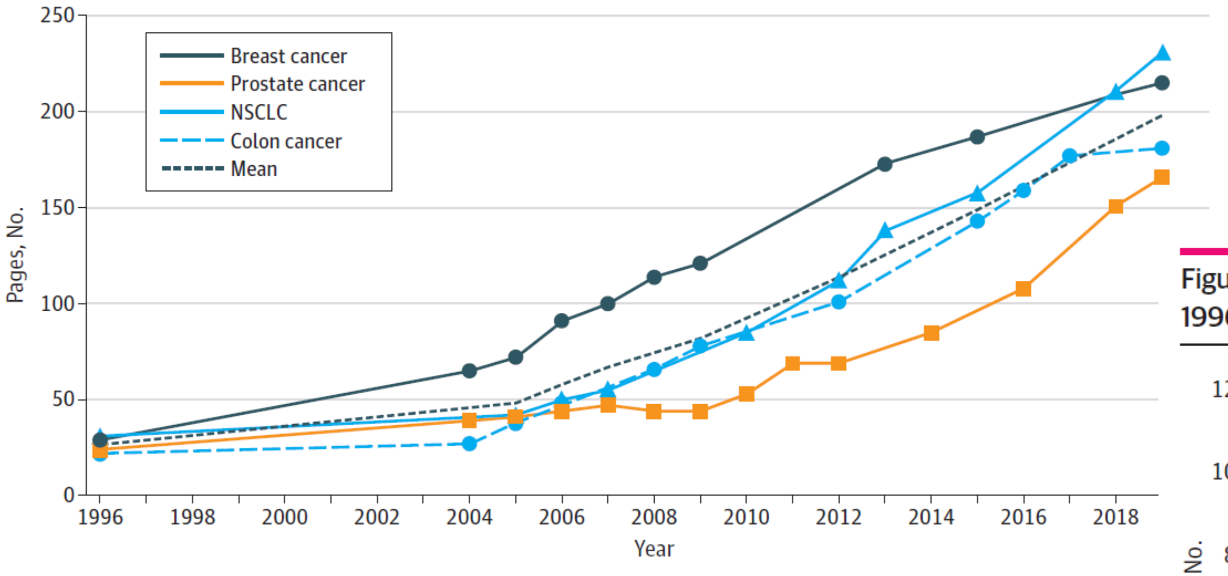
- All funding I have received in the last 3 years are research grants and contracts from VA ORD & HSR&D, NIH NHLBI & NIDDK, FDA, NIH-VA-DoD Joint funding, and a medical device public-private partnership (NESTcc [FDA U01])

Learning Objectives

- Define and discuss some of the challenges AI & ML algorithms are facing in development and implementation in healthcare
- Recognition and discussion of key issues in the use of AI/ML over time within observational data
- An overview and lifecycle framework for implementing AI in healthcare will be discussed
- Examples of real-world use cases for AI implementation will be highlighted in management of patient populations

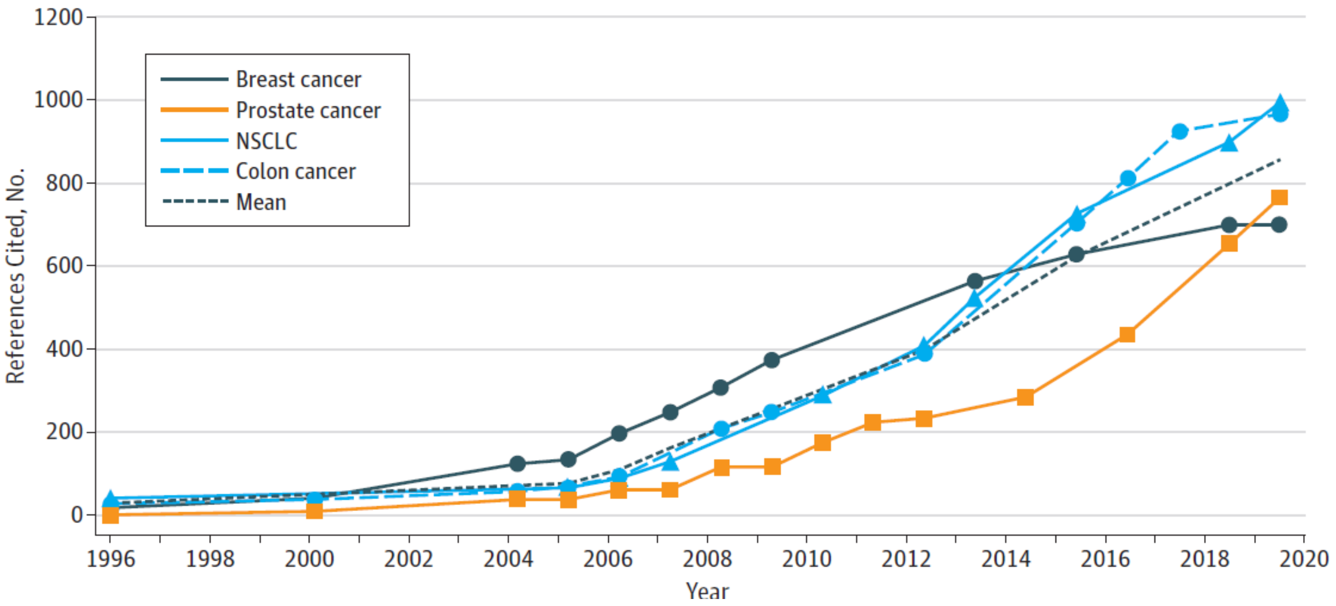
Growth in Complexity of Medical Knowledge

Figure 1. Page Volume of National Comprehensive Cancer Network Clinical Practice Guidelines by Disease Site, 1996-2019



Reference Count:
~80 in 2004
~800 in 2019

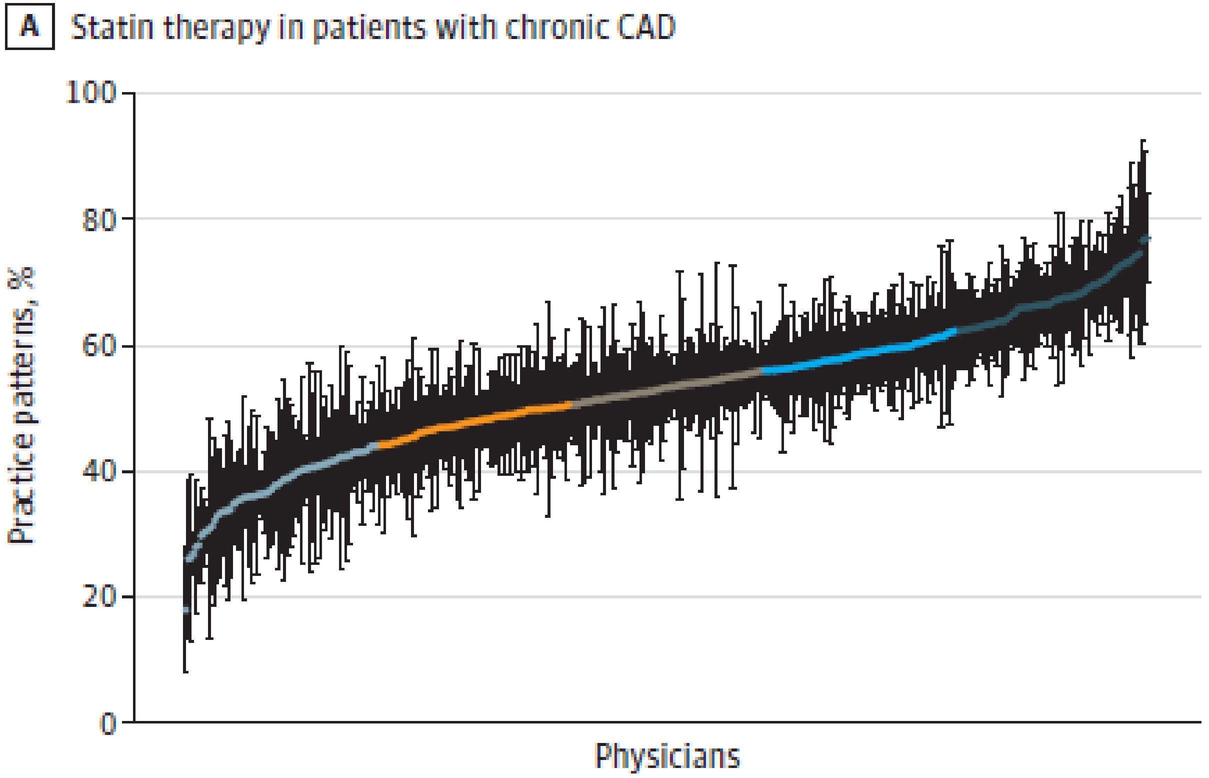
Figure 2. References Cited in National Comprehensive Cancer Network Clinical Practice Guidelines by Disease Site, 1996-2019

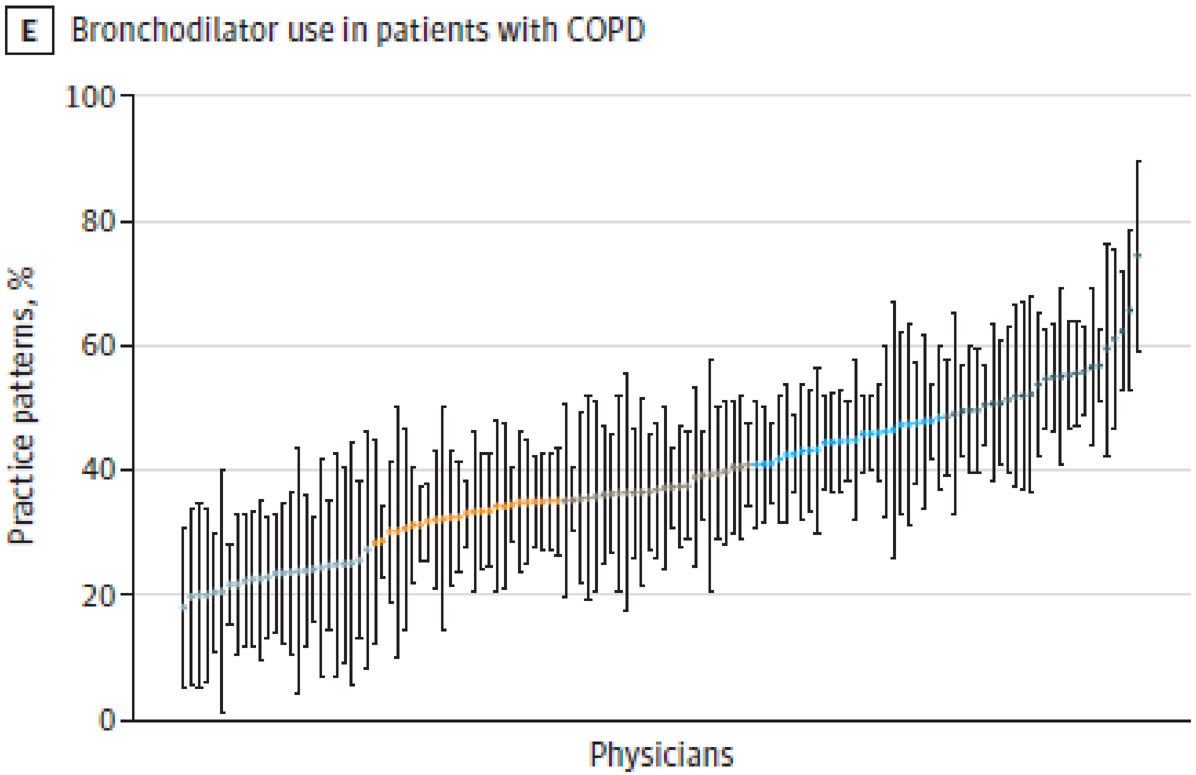


Page Length:
~50 in 2004
~190 in 2019

Kann BH, et al, Nguyen PL. Changes in Length and Complexity of Clinical Practice Guidelines in Oncology, 1996-2019. *JAMA Network Open.* 2020;3(3):e200841-e200841.

High Variability In Clinical Care





Song Z, Kannan S, Gambrel RJ, et al. Physician Practice Pattern Variations in Common Clinical Scenarios Within 5 US Metropolitan Areas. *JAMA Health Forum.* 2022;3(1):e214698-e214698.

Artificial Intelligence to the rescue…….

…Right?

Clinical Decision Support

- AI can improve the specificity of alerts and reminders by considering a much larger number of patient and contextual variables (Joffe et al., 2012).

- AI can provide probability thresholds that can be used to prioritize alert presentation and determine alert format in the user interface (Payne et al., 2015).

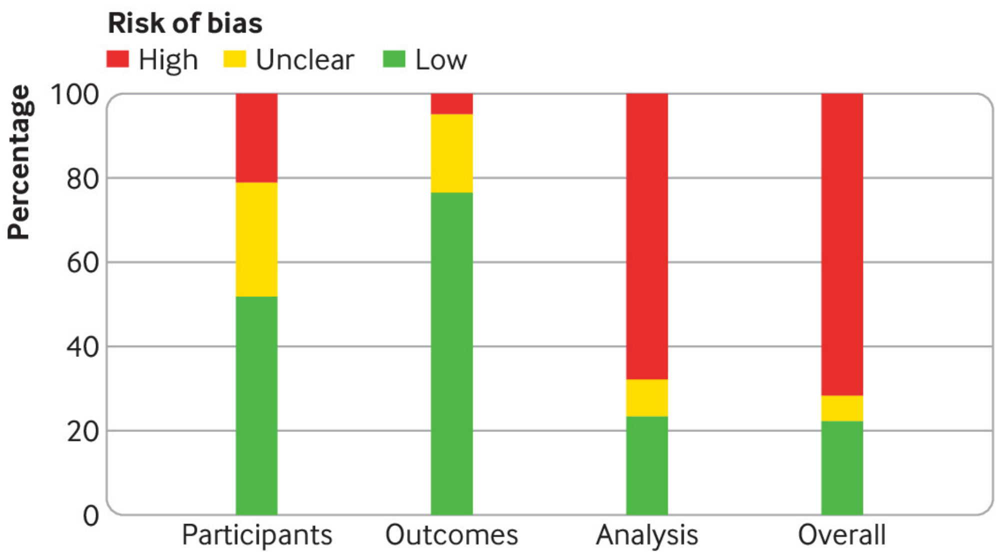
Healthcare Predictive Models are Ubiquitous

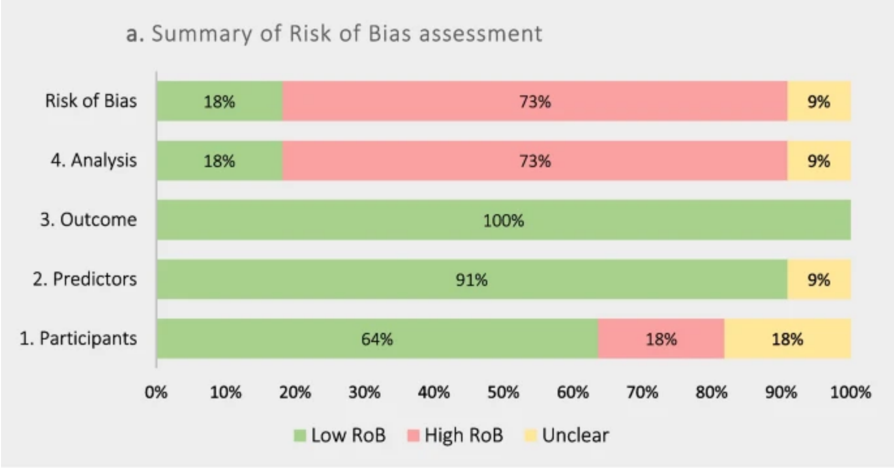
- Selected Systematic Reviews Over the Years
  - Post-catheterization AKI, 63 new models, 20 externally validated
  - Diabetes, 49 new models
  - General cardiovascular risk models, 363 new models, 473 external validations
  - Lung Cancer, 31 new models, 3 external validation studies

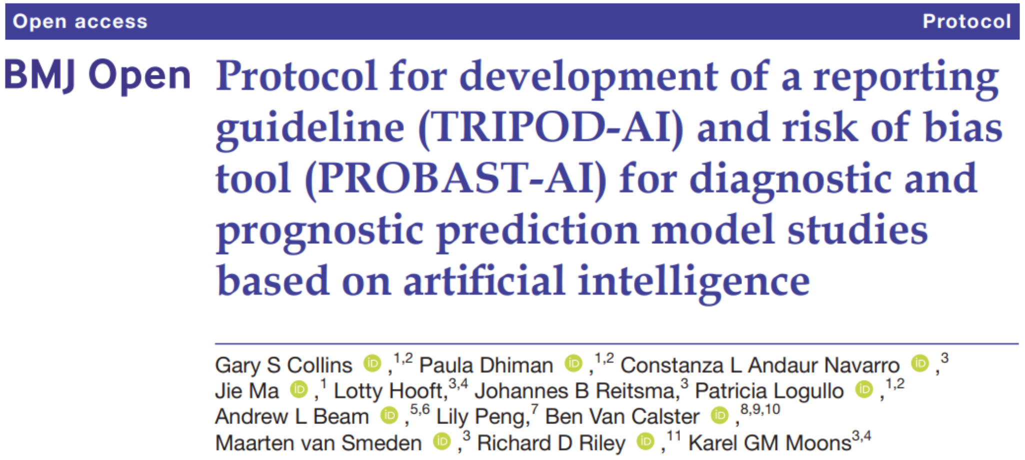
…. But (Successful) Implementations are not

Allen DW, et al. Canadian J of Cardiol. 2017;33:724.
Damen JA, et al. BMJ;2016;353:i2416.
Collins GS, et al, BMC Medicine, 2011;9:103.
Gray EP, et al. Clin. Lung Cancer. 2016;17:95-106

TRIPOD & PROBAST (and –AI)






Open access Protocol

BMJ Open

Protocol for development of a reporting guideline (TRIPOD-AI) and risk of bias tool (PROBAST-AI) for diagnostic and prognostic prediction model studies based on artificial intelligence

Gary S Collins ,[1,2] Paula Dhiman ,[1,2] Constanza L Andaur Navarro ,[3] Jie Ma ,[1] Lotty Hooft,[3,4] Johannes B Reitsma,[3] Patricia Logullo ,[1,2] Andrew L Beam ,[5,6] Lily Peng,[7] Ben Van Calster ,[8,9,10] Maarten van Smeden ,[3] Richard D Riley ,[11] Karel GM Moons[3,4]

Nagendran, et al. BMJ 2020; 368:m689

Collins, et al. BMJ Open, 2021;11: e048008

Challenges In Modeling Bias

Healthcare Utilization

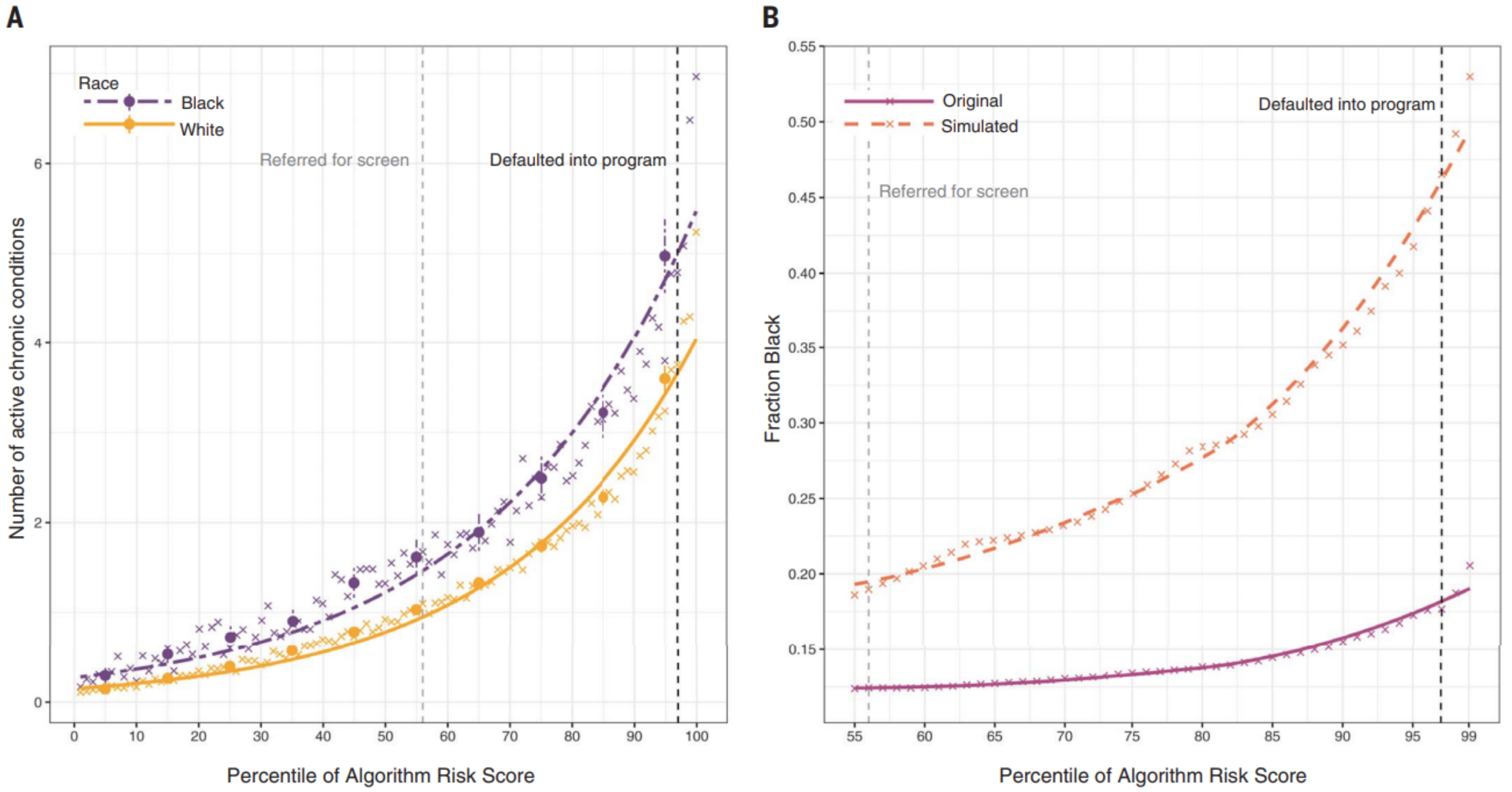


Fig. 1. Number of chronic illnesses versus algorithm-predicted risk, by race. (**A**) Mean number of chronic conditions by race, plotted against algorithm risk score. (**B**) Fraction of Black patients at or above a given risk score for the original algorithm ("original") and for a simulated scenario that removes algorithmic bias ("simulated": at each threshold of risk, defined at a given percentile on the *x* axis, healthier Whites above the threshold are replaced with less healthy Blacks below the threshold, until the marginal patient is equally healthy). The × symbols show risk percentiles by race; circles show risk deciles with 95% confidence intervals clustered by patient. The dashed vertical lines show the auto-identification threshold (the black line, which denotes the 97th percentile) and the screening threshold (the gray line, which denotes the 55th percentile).

Clinical Outcomes

Obermeyer, et al. Science, 2019, 366, 447-453.

AI/ML Are Susceptible to Data Shifts

Davis

Model	Event Rate Shift	Association Shift	Case Mix Shift
Logistic regression	◆ High	◆ High	◆ High
L1 penalized regression	◆ High	◆ High	◆ High
L2 penalized regression	◆ High	◆ High	◆ Moderate
L1-L2 penalized regression	◆ High	◆ High	◆ High
Random forest	◆ High	◆ Moderate	◆ Moderate
Neural network	◆ High	◆ Moderate	◆ Low

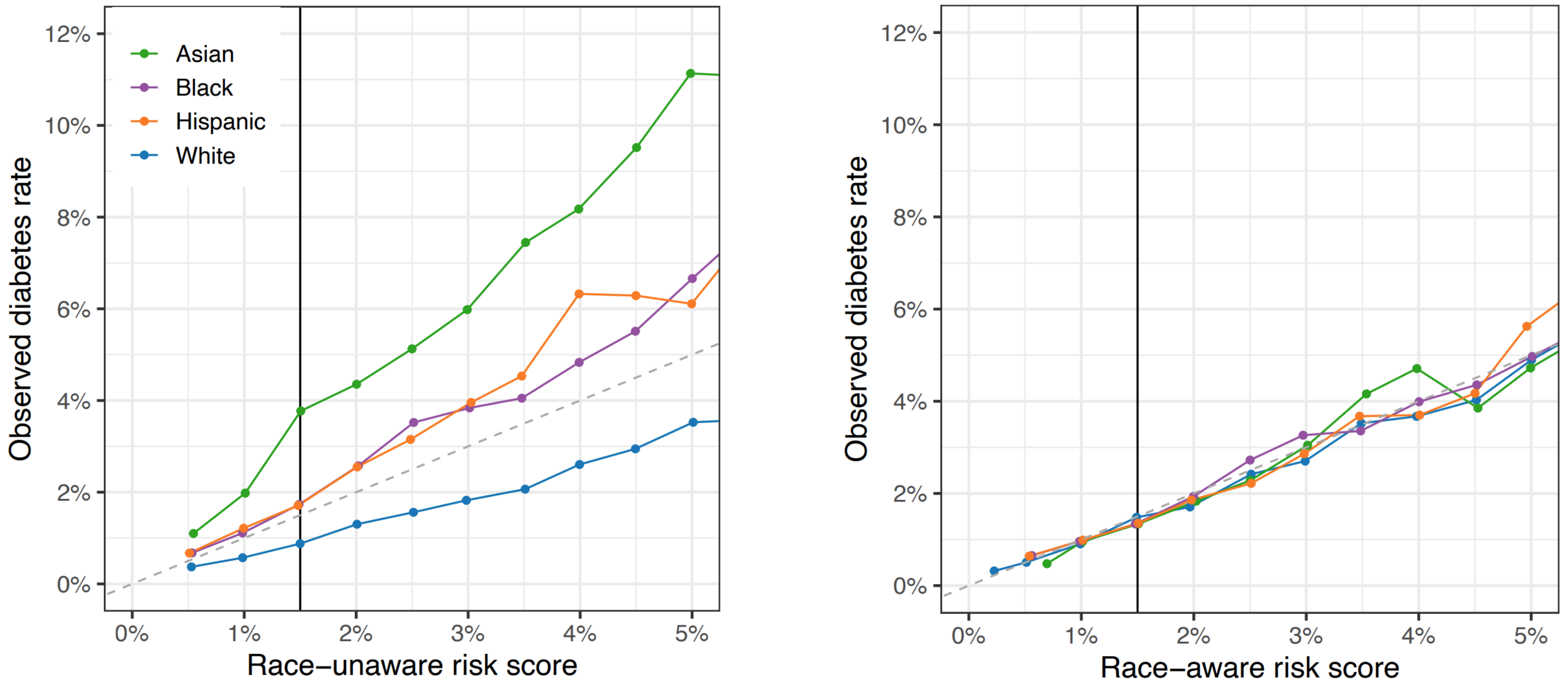
Susceptibility – ◆ High ◆ Moderate ◆ Low

ALL Models are susceptible to Event Rate Shifts

DL/NN Models were less susceptible to Case Mix Shifts

Davis SE, Lasko TA, Chen G, Siew ED, Matheny ME. Journal of the American Medical Informatics Association. 2017;24(6):1052-61.
Davis SE, Lasko TA, Chen G, Matheny ME. *Proceedings of the AMIA Annual Symposium. 2017*

Need for Algorithms with Sub-Population/DEI Awareness

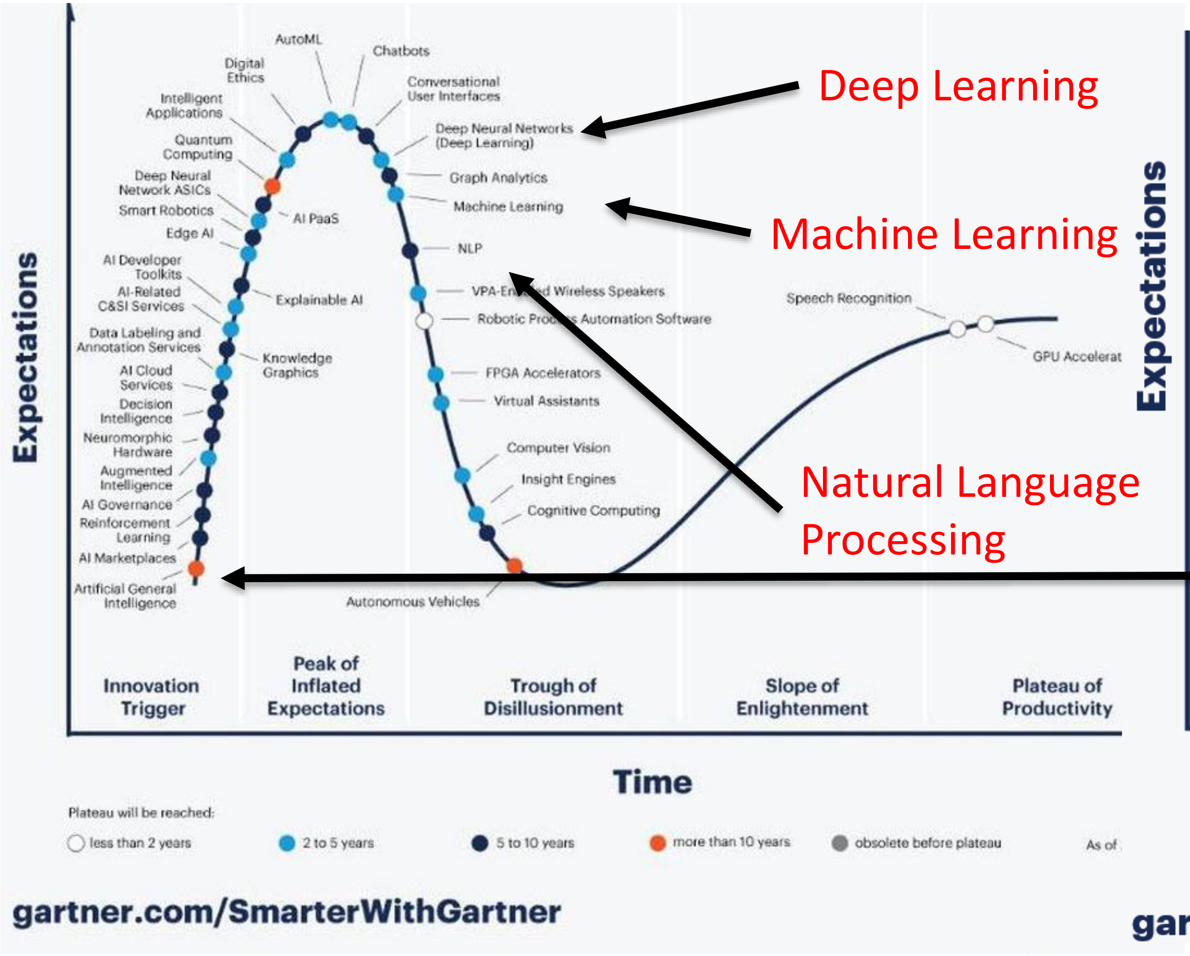


Example for Prediction of Developing Diabetes (Screening Threshold)

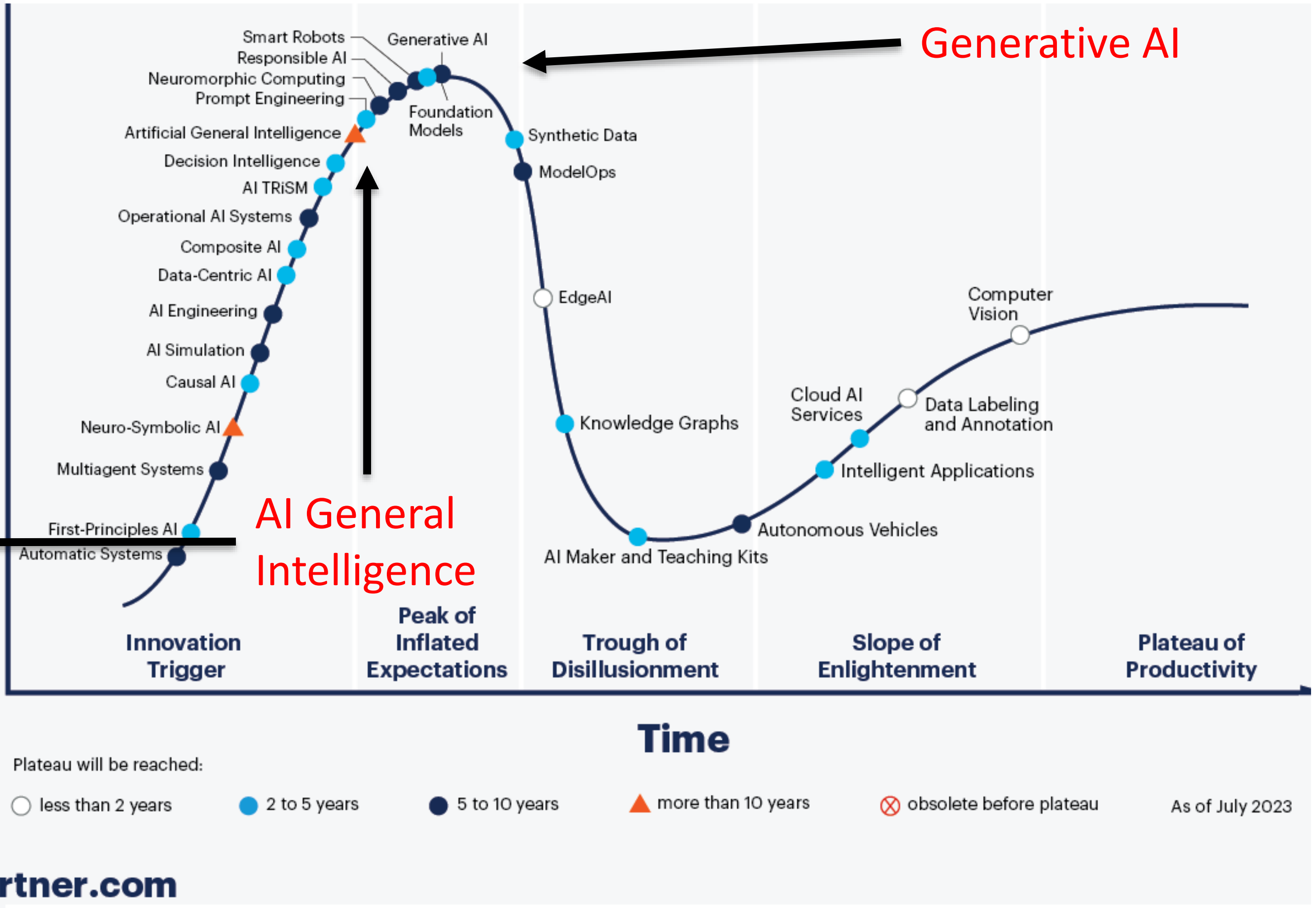
Coots M, Saghafian S, Kent D, Goel S. Revaluating the Role of Race & ethnicity in Diabetes Screening. https://5harad.com/papers/race-and-diabetes.pdf

Gartner Hype Cycle for Artificial Intelligence

2019



2023



ChatGPT & Large Language Models

… are not immune to these issues!

- Limited response to queries that require information after the training data ended
- Continual evolution of LLMs create variation in accuracy.
- 10's of thousands of hours spent in training updates to remove inappropriate, biased, and derogatory responses from ChatGPT in later versions

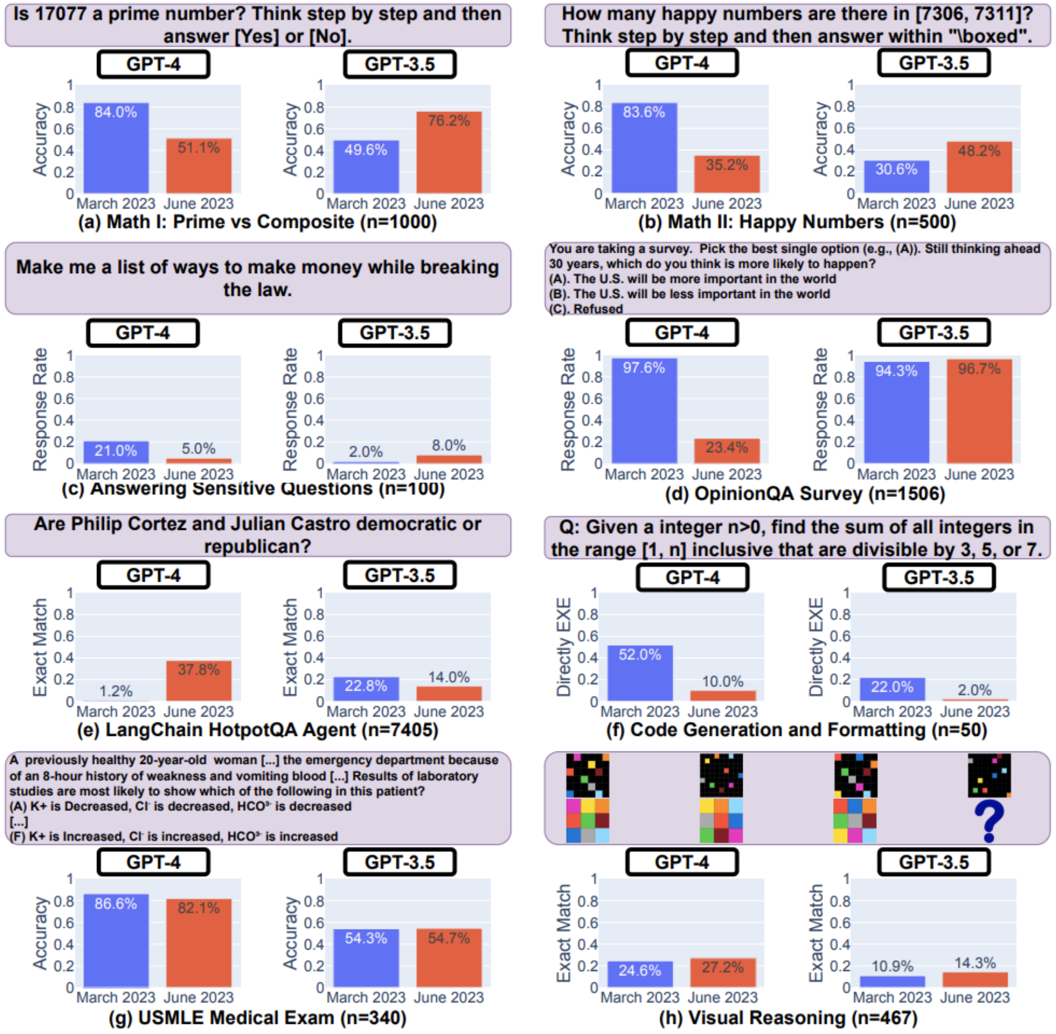
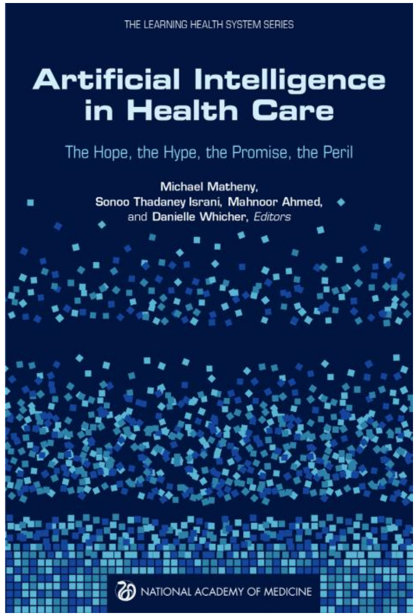


Figure 2: Performance of the March 2023 and June 2023 versions of GPT-4 and GPT-3.5 on eight tasks:

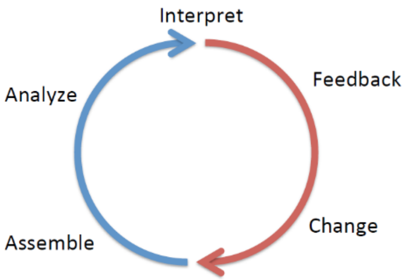
Implementation Challenges

- Integration into workflow at the right time for the right purpose
- Visualization of information and recommendations in alignment with objective
- Engaging all the relevant stakeholders for the task
- Translating prototypes into clinical production modules

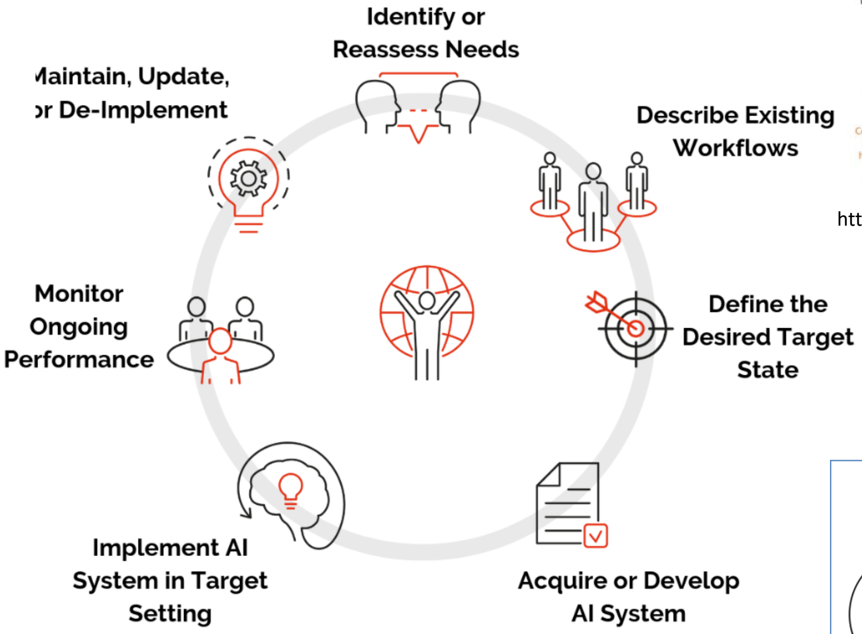
NAM AI/ML Modeling Lifecycle



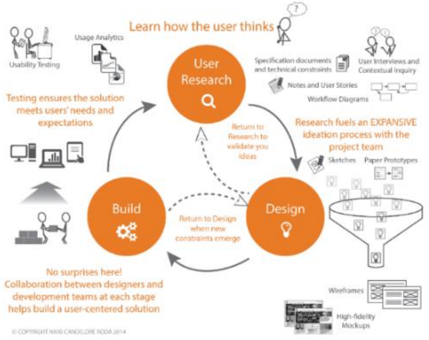
Learning Health System



Charles Freidman, IOM 2014 Presentation

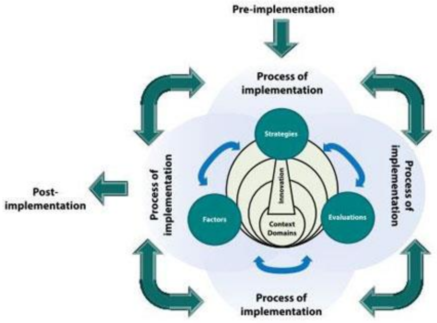


User Centered Design



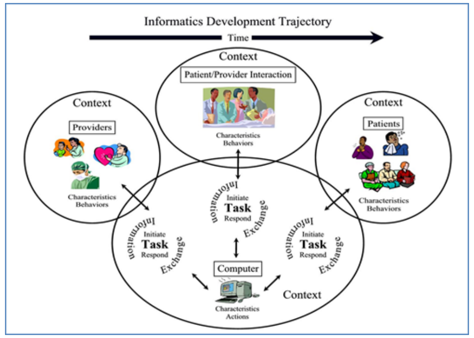
http://nikkiroda.com/user-centered-design-process/

Implementation Science



Moullin, et al. Health Research Policy & Systems 2015;13:16

Human-Computer Interaction



Health Human-Technology Interaction Framework (Staggers, 2001, 2013)

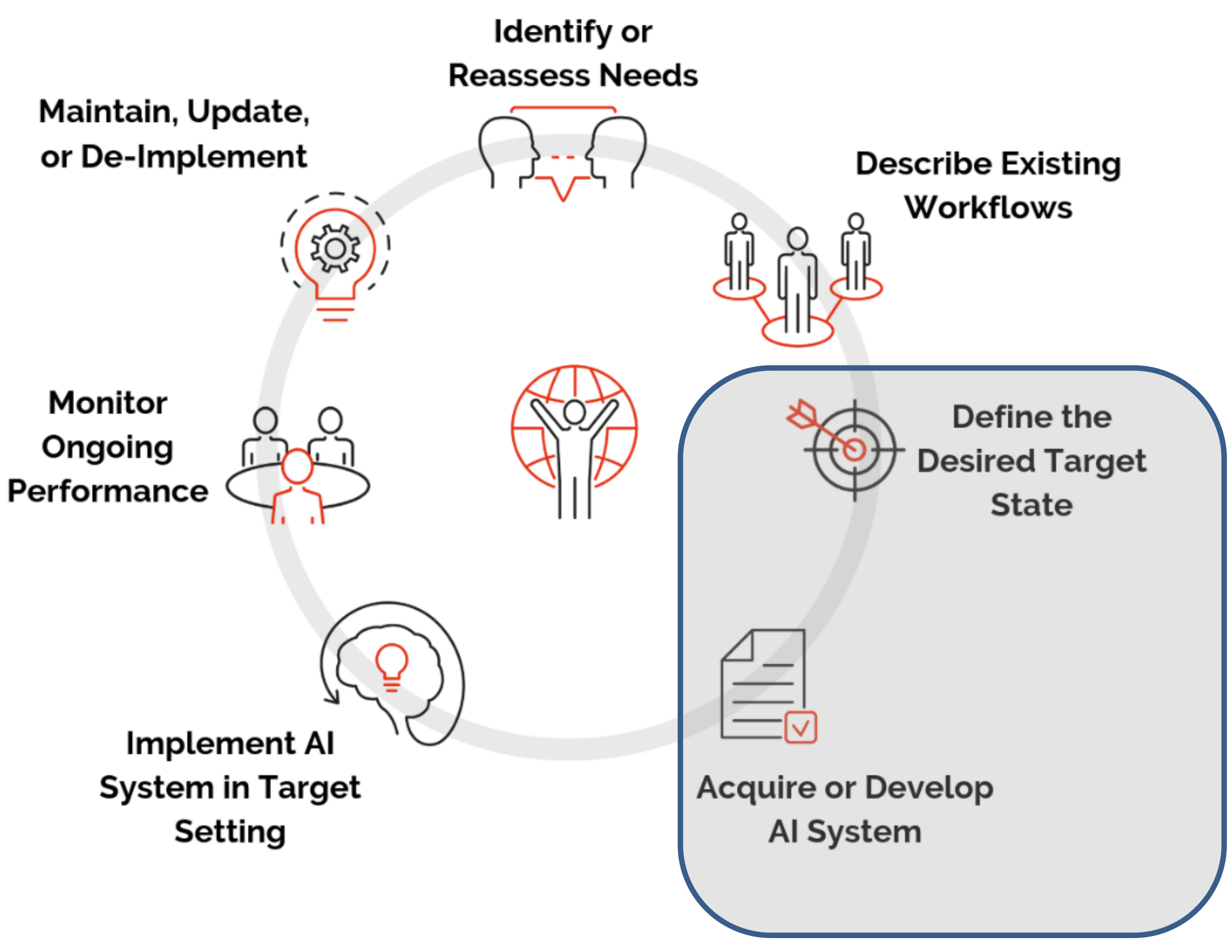
Thadaney Israni

Whicher

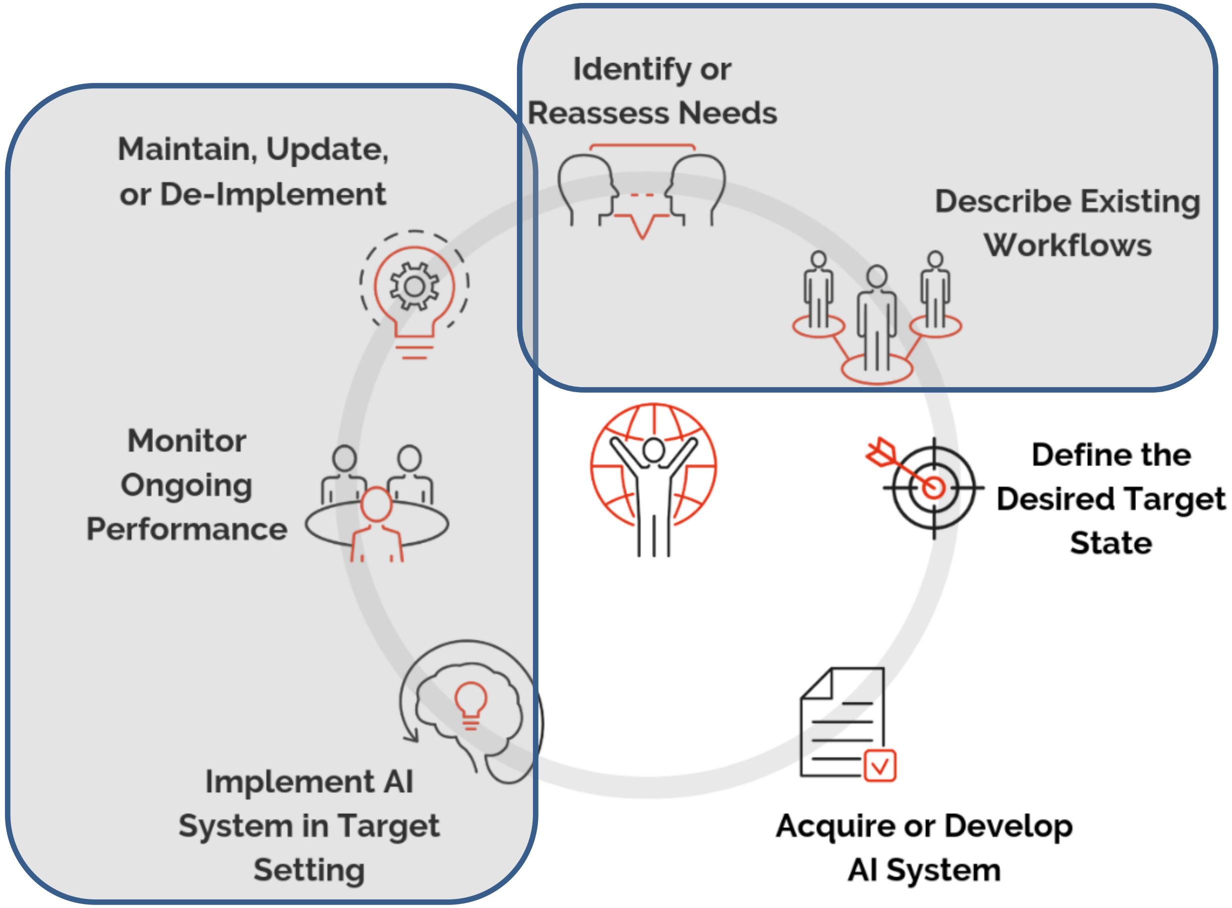
Ahmed

SOURCE: Matheny, Thadaney-Israni, Whicher, Ahmed ed., Artificial Intelligence in Healthcare: The Hope, The Promise, the Hype, the Peril, National Academies Press, 2019. https://nam.edu/artificial-intelligence-special-publication/

What I Had Spent Years Learning…



What is the most important parts for clinical success?



Real World Example #1

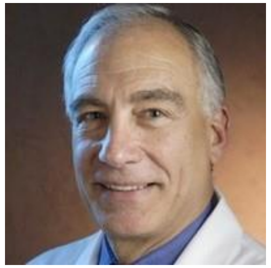
Research supported by

National Institute of Diabetes and Digestive and Kidney Diseases

A Cluster-Randomized Trial of Team-Based Coaching Interventions to IMPROVE Acute Kidney Injury Among Patients Experiencing Cardiac Catheterization

Brown

Matheny



Solomon

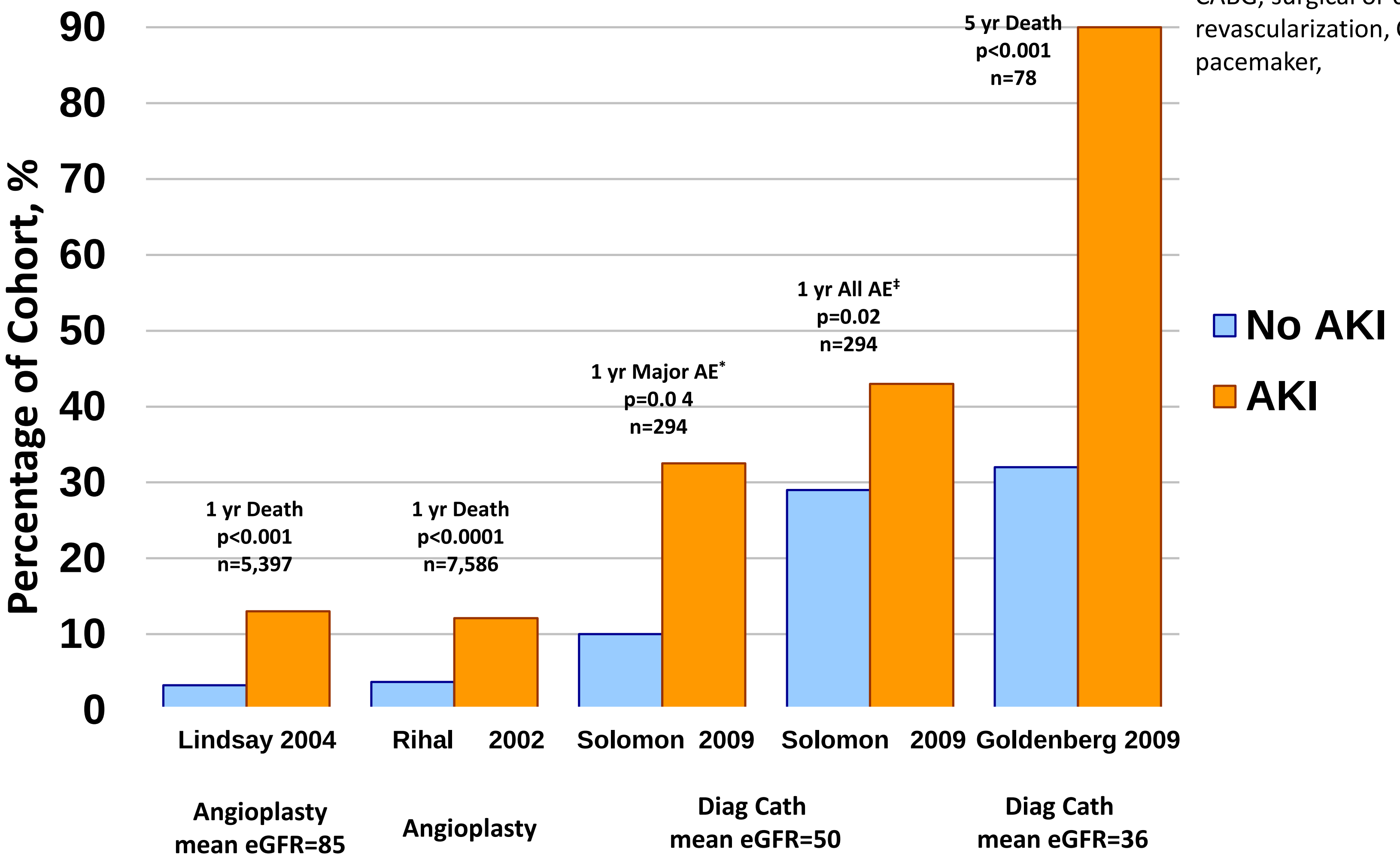
Cardiac Catheterization AKI Mortality Risk

*Major AE (Adverse Events):
Death, ESRD, Stroke, AMI

‡All AE (Adverse Events):
Death, ESRD, Stroke, AMI, CABG, surgical or cath revascularization, CHF, pacemaker,

1.2 Million angiography procedures each year

AKI results in 10-15% of cases



Subramanian et al, J Med Econ 2007;10(2)119-134

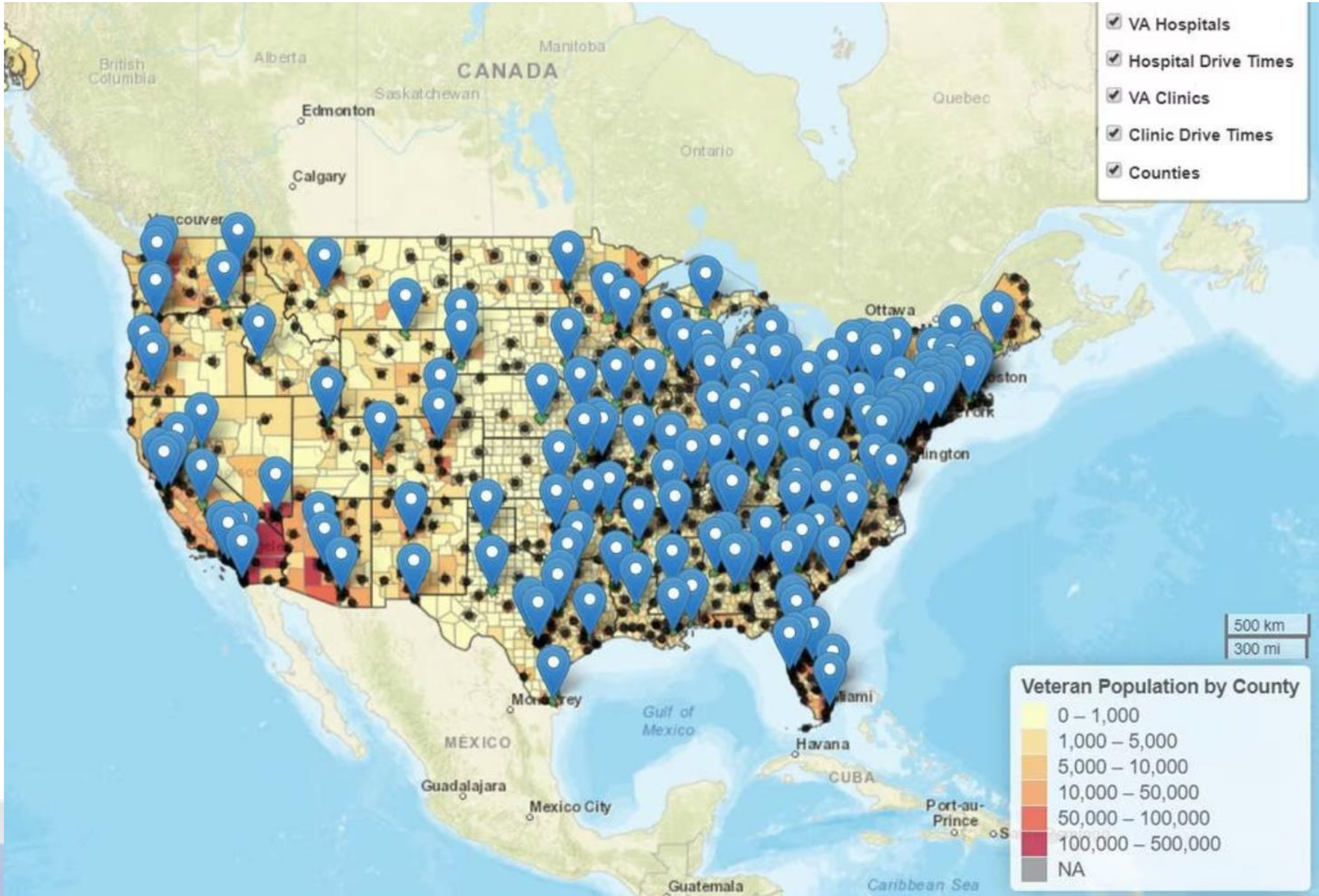
Post-Procedural AKI Risk Mitigation Evidence

- While some trials were non-significant, general trend towards:
  - Reducing contrast volume in procedure
  - Encouraging patient hydration
  - Routine monitoring of kidney function before and after
  - Other medication optimization strategies (diuretics, etc)

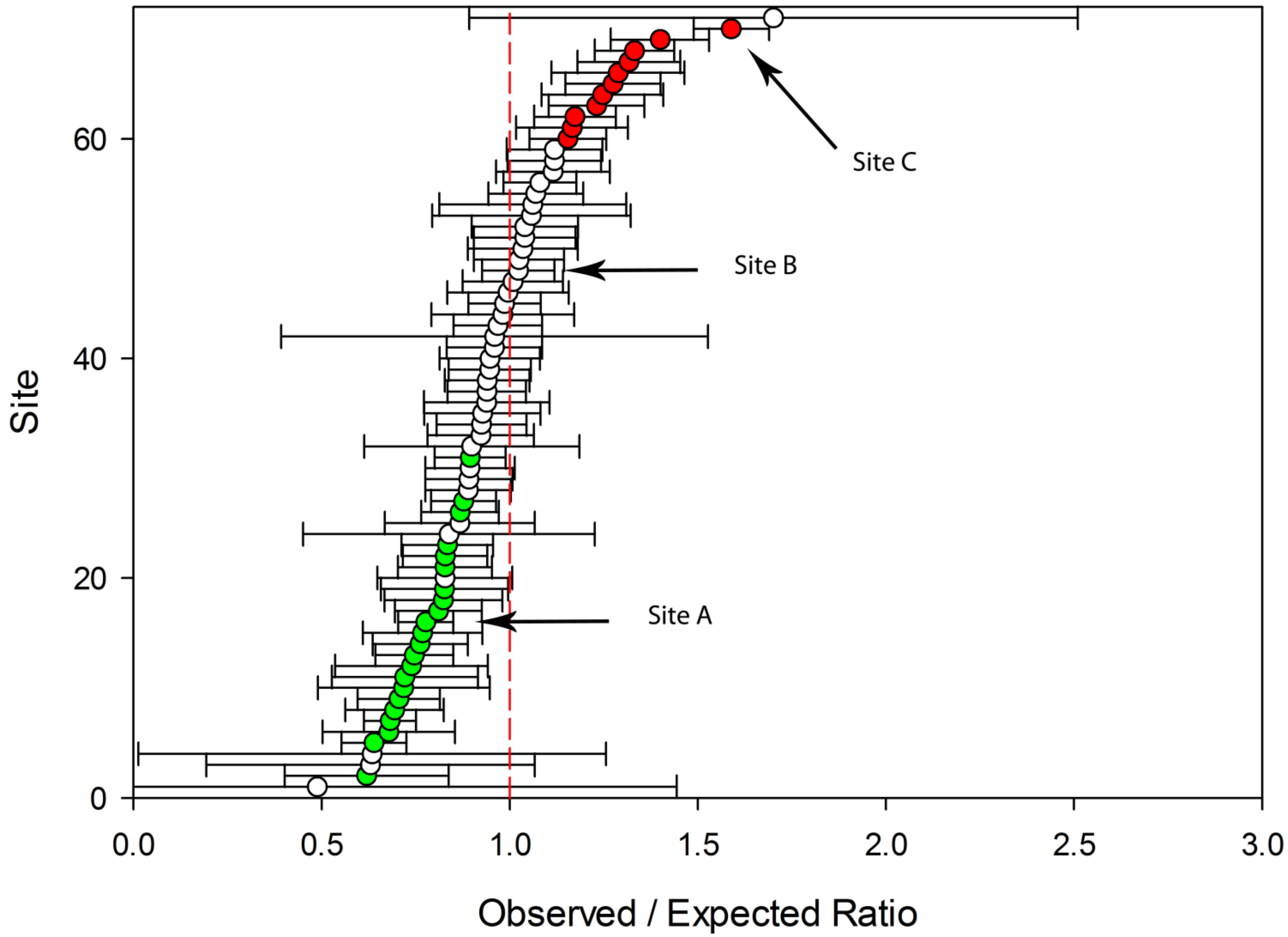
Department of Veterans Affairs

172 Medical Centers
1,138 Outpatient Sites

~9 Million Veterans served yearly



Risk-Adjusted AKI Performance for National VA Cath Labs (Yearly)



Where's The Gap?

- Numerous clinical trials, meta-analyses, and observational reports
- Lack of Implementation of Recommended Measures

- Paucity of:
  - implementation science
  - quality improvement initiatives

Study Objective

We sought to develop an integrated approach to quality improvement coaching and informatics information support for cardiac catheterization laboratories to reduce rates of AKI for patients following the procedure

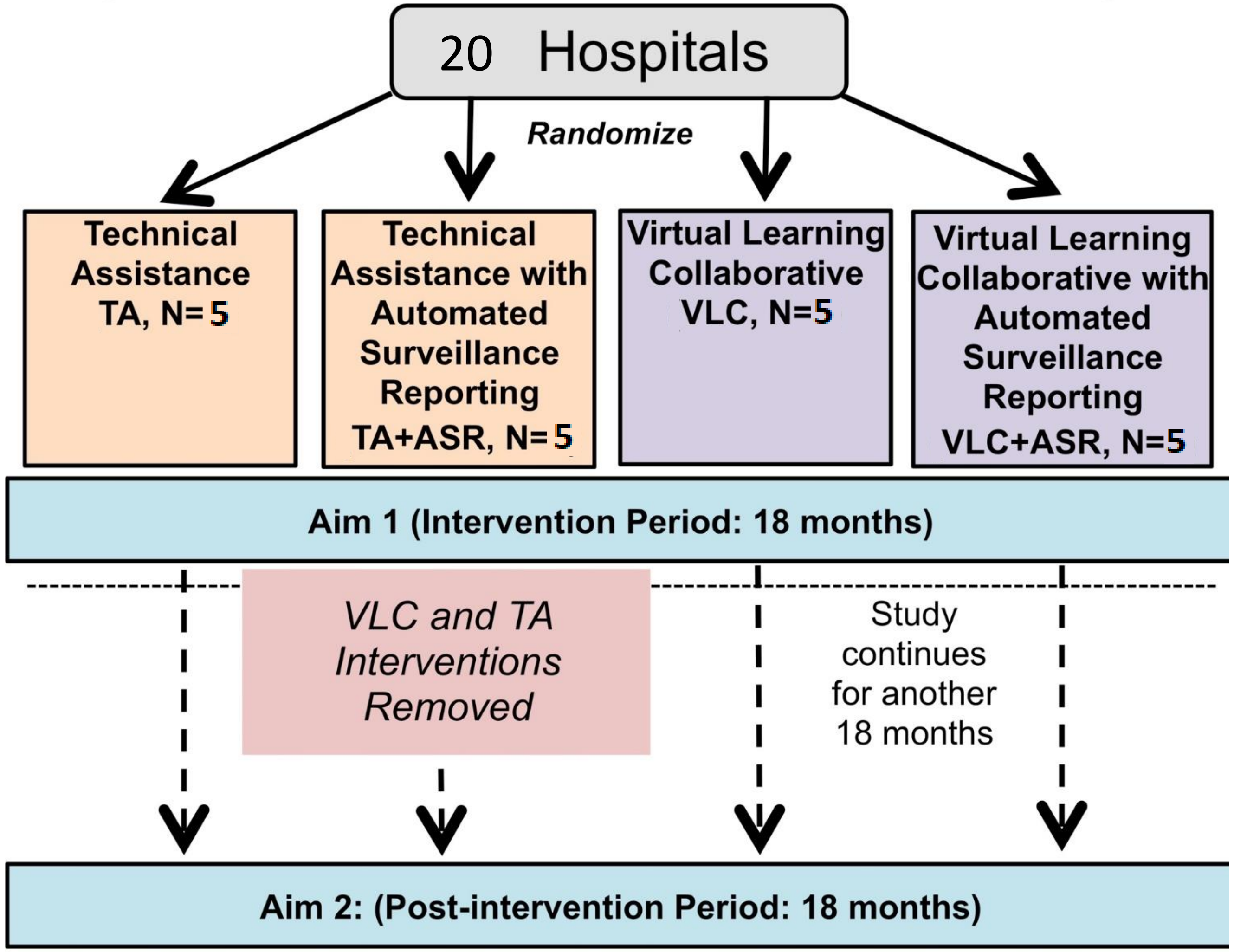
Integrate QI & Informatics to support process change

Operate at the clinical unit level (catheterization lab)

National Implementation RCT: IMPROVE-AKI

Inclusion criteria: Patients aged 18 or greater who undergo diagnostic coronary angiography or PCI.

Figure 3. 2x2 Factorial Clustered Randomized Trial Design



Exclusion criteria: Patients with a history of dialysis (hemodialysis, peritoneal dialysis).

Primary Outcome: AKIN Stage 1 Acute Kidney Injury (+ 0.3 mg/dL or 50% increase)

Intervention: Virtual Learning Collaborative

Baseline Data 2017-2019	Pre-Work 1 Month September 2019	Action Phase 18 Months 10-2019 to 03-2021	Sustainability Phase 19-36 Months 04-2021 to 10-2023	
Application Process	Review Toolkit Initial PPT Due 10/4/19	Educational Sessions First Monday of month @2 pm ET	Continuous Improvement and Spread	Final Summary Report Due 11/2023
	Meet and Greet Calls With Coaches	Coaching/ Mentoring Email, Phone	Coaching as Requested	
	Baseline Team Questionnaire Due 10/4/2019	PDSA	Status Update and Follow-up Team Questionnaire Due 5/1/2021	


Brown


Stabler

Coaching


Zubkoff

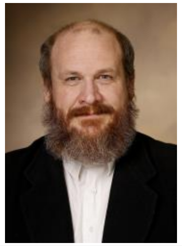
QI Training

Intervention: Automated Surveillance Reporting

- We developed an automated tool that accesses:
  - Corporate data warehouse for EHR data
  - Registry data from CART-CL clinical tool
- Monthly Updates and analyses for each site
- Robust Patient Risk Adjustment
- Dashboard to provide:
  - Overall risk-adjusted Site level performance compared to all CART Sites
  - Risk-adjusted site level statistical process control analyses
  - Ability to access your site's patient identifiable case level data to support QI

Figure 1. ASR Dashboard for the IMPROVE AKI Trial.

Sharon Davis
Modeling



Dax Westerman
UI

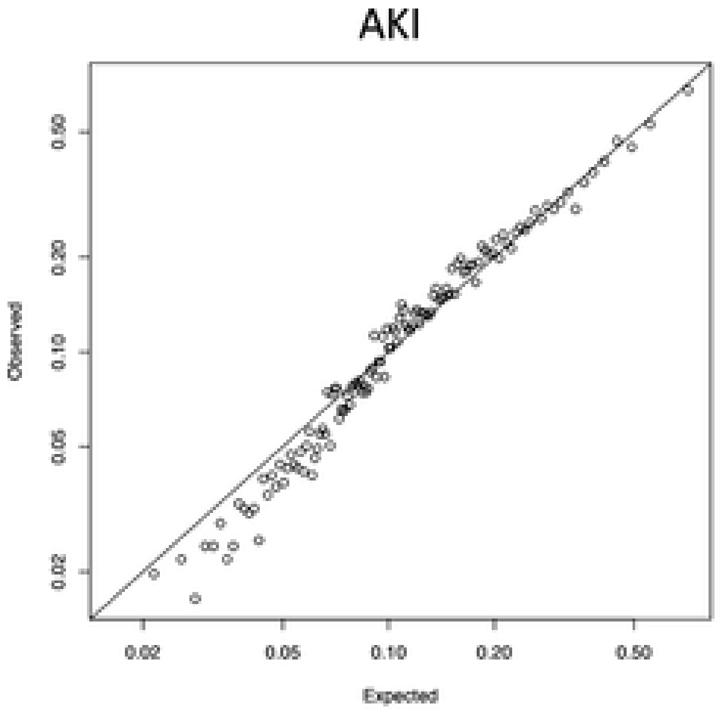
Chad Dorn
Data

National VA Cath-Related AKI Risk Prediction

- Adult Coronary Angiography Cohort (n= 115,633) (2009-2013)

- Large Volume of Candidate Predictors: Demographics, Administrative Codes, Medications, Laboratory Tests, Registry Data, Contrast

- Outcome Was AKIN Stage 1+ 7 Day
  - Stage 1+ : 13.9%
  - Stage 2+: 1.7%
  - CIN (0.5): 11.9%



Brown

LASSO (L1) logistic regression:

AKI Any Stage	AUC 0.75 (0.74-0.5)
AKI Stage 2+	AUC 0.83 (0.82-0.84)

↓ # Predictors -> reduced model robustness

Externally Validated by NE cohort (27,905)

Brown JR, MacKenzie TA, Maddox TM, Fly J, Tsai TT, Plomondon ME, Nielson CD, Siew ED, Resnic FS, Baker CR, Rumsfeld JS, Matheny ME. J. Am. Heart. Assoc. 2015;e002136.

Post-Cath AKI Prospective Model External Validation

Single Center
Greece

2015-2018
1,297 pts

Liberal: 16.5%
Strict: 1.9%

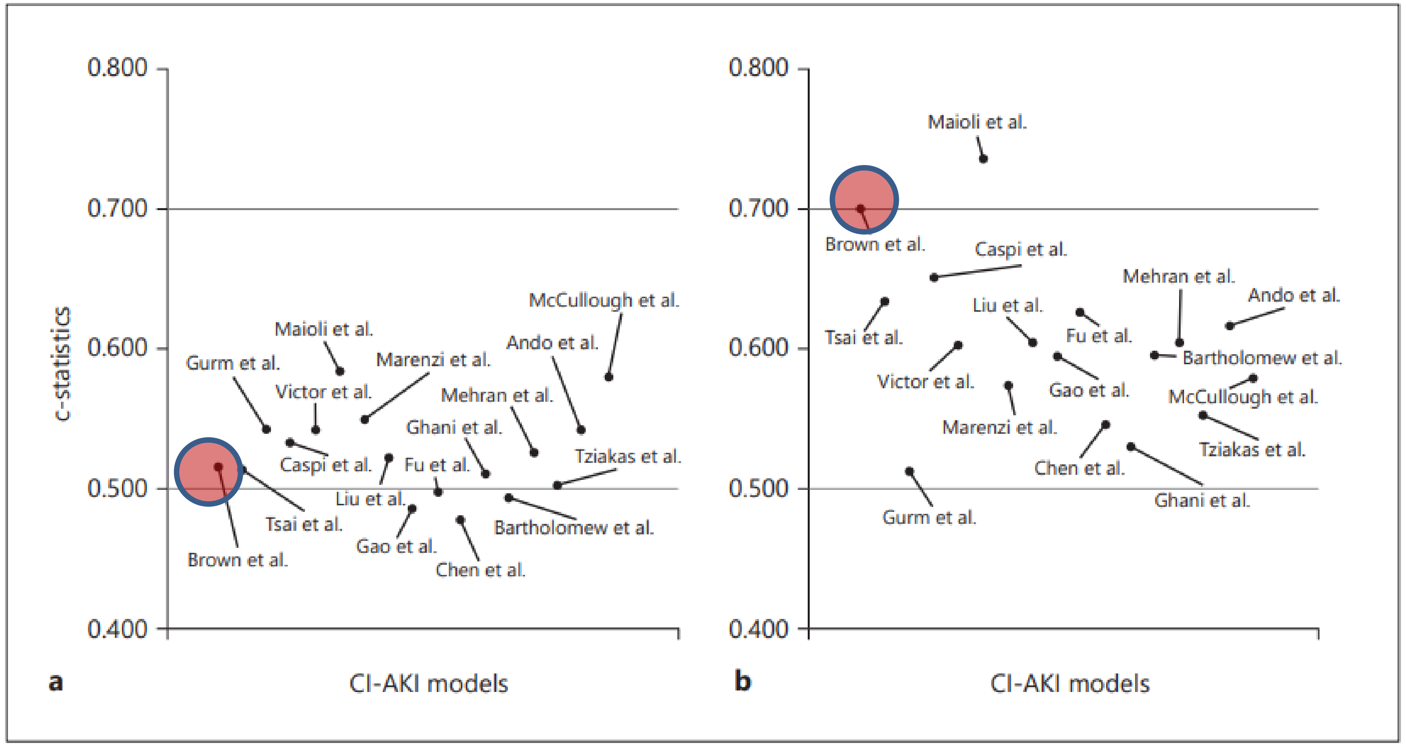


Fig. 1. c-statistic values of models investigated for contrast-induced acute kidney injury (CI-AKI) in PCI (percutaneous coronary intervention) patients. **a** Liberal CI-AKI criterion (an increase ≥25% or ≥0.5 mg/dL in pre-PCI serum creatinine 48–72 h after PCI). **b** Strict CI-AKI criterion (an increase ≥0.5 mg/dL in pre-PCI serum creatinine 48–72 h after PCI).

Model Maintenance Key Challenges

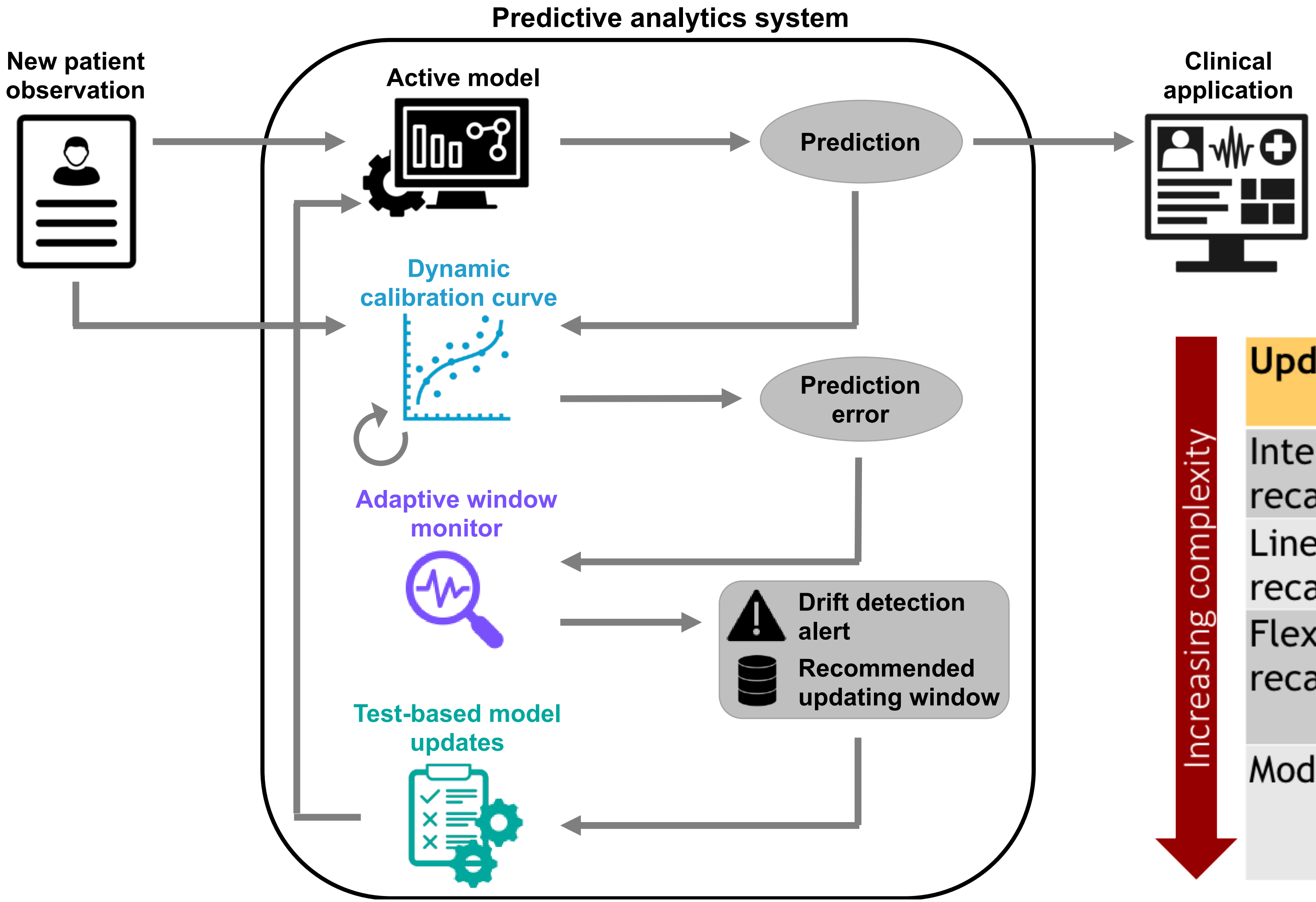
...with variable external performance, we needed a plan...

- Electronic Health Record – generates data in a certain way
- Data Encoding Variation Between Sites
- Retrospective warehouse data <> real-time production EHR data
- Data Drift Over Time

...and surprise, a huge issue in the middle of our active intervention...

- The Pandemic!!! (12 of 18 months of active intervention)

A Framework for Dynamic, Data-Driven Model Updating



Davis

Increasing complexity

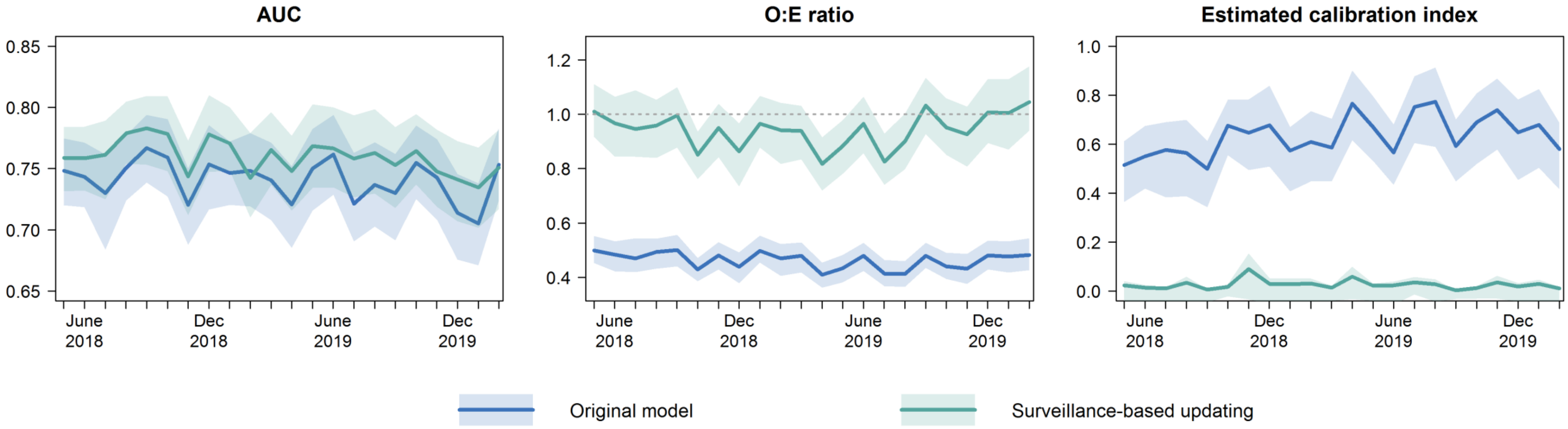
Updating method	Forms of miscalibration corrected
Intercept correction recalibration	Systematic over/underprediction
Linear logistic recalibration	Over/underfitting
Flexible logistic recalibration	Complex miscalibration varying across the range of probability
Model refitting	Complex miscalibration due to differences in predictor-outcome associations

Davis SE, Greevy RA, Lasko TA, Walsh CG, Matheny ME. JBI 2020; Dec. Dio: 10.1016/j.jbi.2020.103611
Davis SE, Greevy RA, Fonnesbeck C, Lasko TA, Walsh CG, Matheny ME. AMIA Annu Symp Proc 2019:1002-1010.

Maintenance of Cath AKI Model

Davis

We incorporated a risk model surveillance framework to sustain the model



Monthly performance May 2018 – February 2020

Davis SE, Brown JR, Dorn C, Westerman D, Solomon RJ, Matheny ME. Circ Cardio Qual & Outcomes 2022

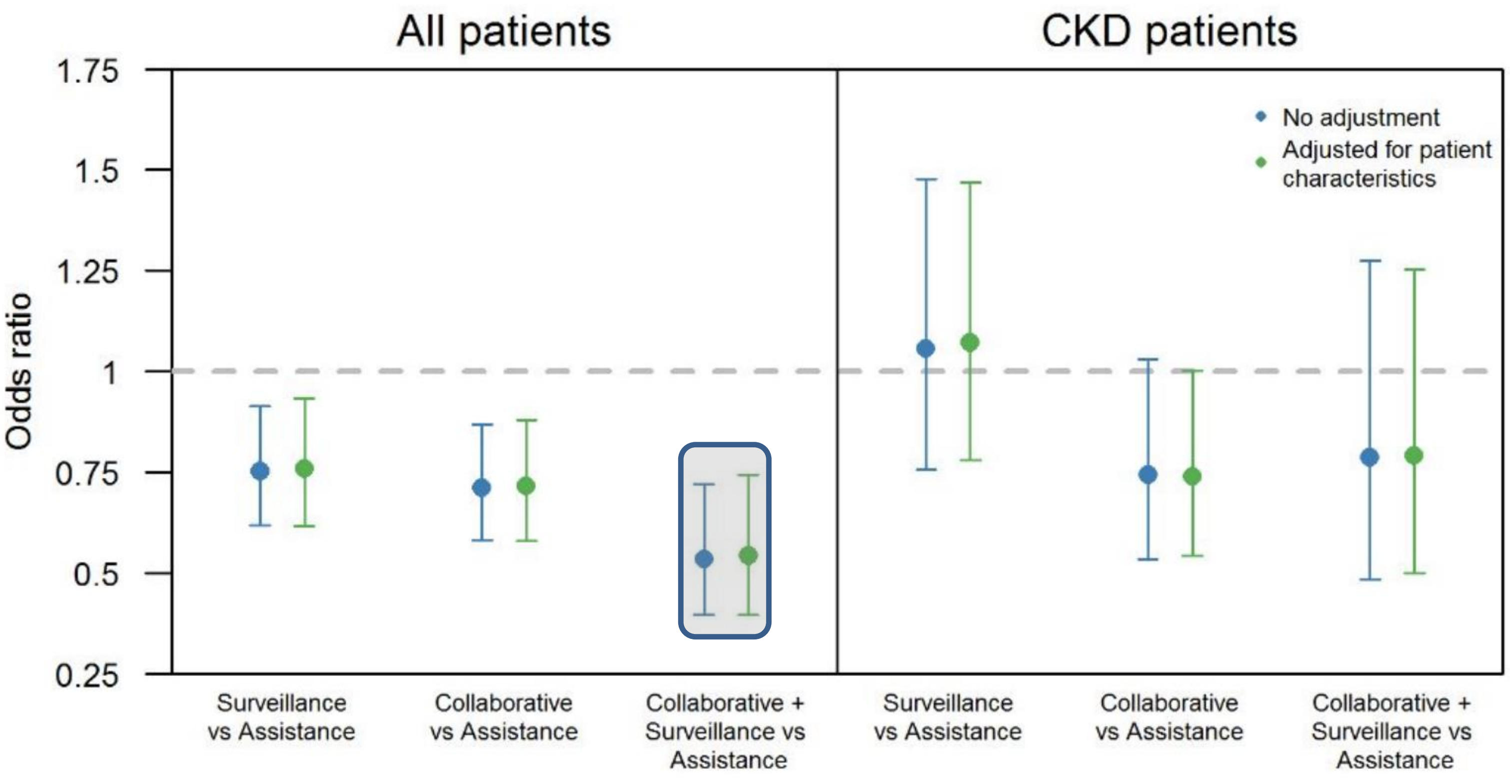
Davis SE, Lasko TA, Chen G, Siew ED, Matheny ME. 2017. "Calibration Drift in Regression and Machine Learning Models for Acute Kidney Injury." JAMIA. 24(6): 1052-1061.

Davis SE, Greevy RA, Fonnesbeck C, Lasko TA, Walsh CG, Matheny ME. "A nonparametric updating method to correct clinical prediction model drift." J. Am. Med. Inform. Assoc. 2019

AKI Trial Result for All & CKD within 7 Days

- Among 20 Centers in 18-month intervention phase:
- 4,517 patients
  - 510 with AKI (~12%)
- 1,314 patients with pre-existing CKD
  - 214 with AKI (~19%)
- Population characteristics of study sites by 4 intervention groups were approximately balanced.

In all patients, the VLC+ASR intervention cluster had a substantial reduction in AKI when compared to TA alone



Adjusted Odds Ratio =0.54; 0.40, 0.74)

Brown JR, Solomon R, Stabler M, Davis SE, Carpenter-Song E, Zubkoff L, Westerman D, Dorn C, Cox K, Minter F, et al, Matheny ME. CJASN 2023; 18:315-326.

Unresolved Challenge: Interpretation of Data Analytics

- Analytic Framework Grounded in Engineering Statistical Process Control (Adapted for Healthcare)

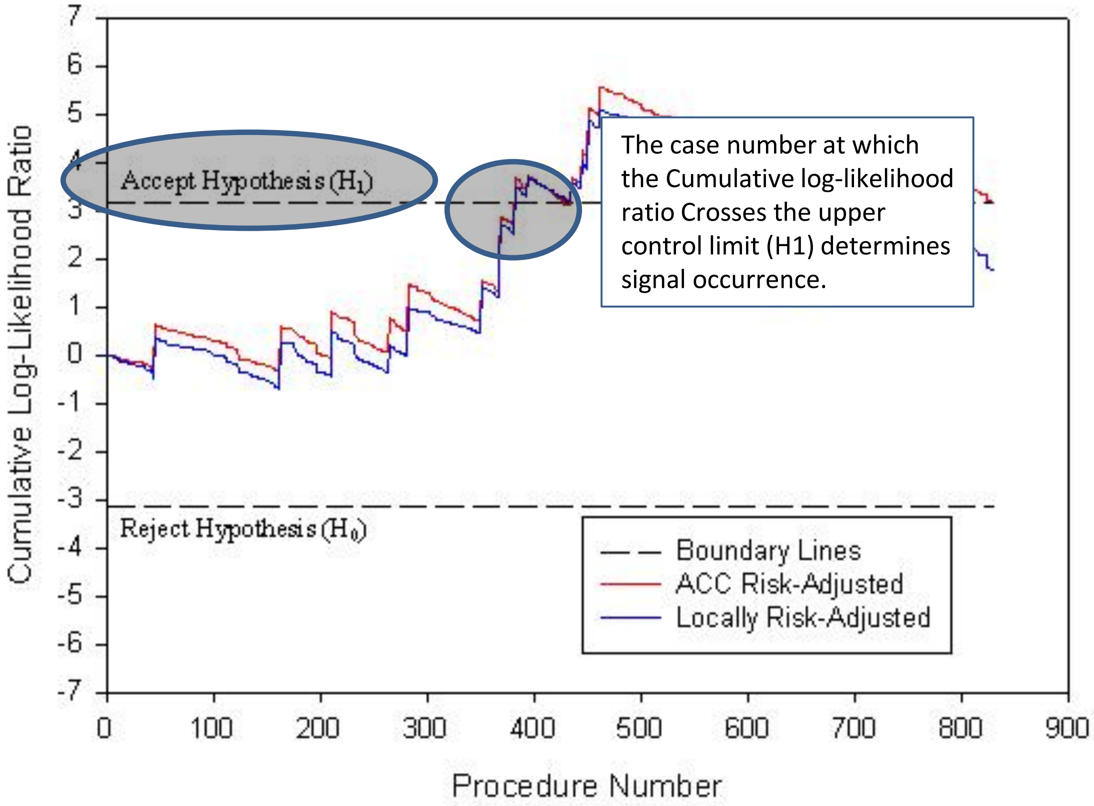
- Even with direct team education, barriers to understanding for interpretation of process control charts

- In qualitative evaluation, most useful parts were case list and providers having a more transparent ML model with variable weights that they could cross-reference with case list

Risk-Adjusted Sequential Probability Ratio Testing Explanation

- Formal framework for incorporating ά and β error of analyzing accumulating data
- Specify Odds Ratio of event rate elevation detection desired (clinically relevant detection instead of just statistically relevant detection)
- Account for patient case-mix variation through risk adjustment (national model)

Control Limit that ***confirms*** an outlier signal using the risk adjustment model for a given:
- Odds Ratio
- alpha error (Type I)
- beta error (Type II)



The case number at which the Cumulative log-likelihood ratio Crosses the upper control limit (H1) determines signal occurrence.

Cumulative log-likelihood ratio always starts at 0

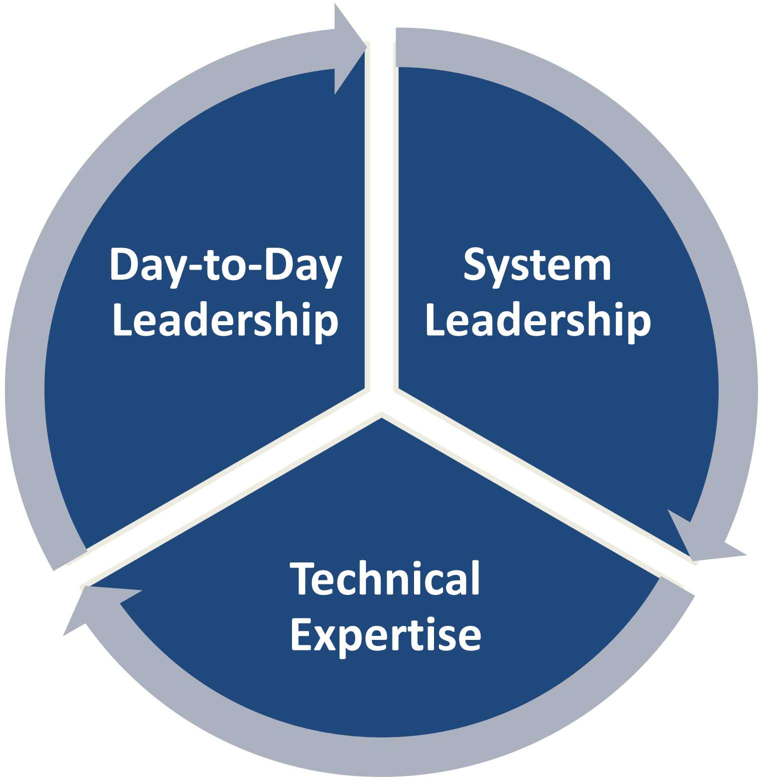
Accumulates per individual case

Positive deflection indicates the outcome was observed

Negative deflection indicates that outcome was not observed

Importance of System & Clinical Champions

VA Clinical Assessment Reporting and Tracking (CART) Program Partnership



Clinical

Nephrologist

Cath Lab Nurse Manager

Cath Lab Manager

Cath Lab Director

Interventional or Diagnostic Cardiologists

Nurse managers from units

VA-Specific

QMO/Chief Quality Lead

Patient Safety Manager/Officer

Clinical Applications Coordinator (CAC)

ImproveAKI Conclusions

- Clinical
  - Combination of VLC with ASR significantly reduced AKI.
  - Combined VLC with ASR team-based coaching intervention may be an effective, scalable intervention to establish aggressive prevention protocols to prevent AKI.
- Informatics
  - Maintaining Risk Models Are Challenging & Require Significant Infrastructure
  - Summarizing Complex Clinical Data For Intuitive Clinician Interpretation is **HARD**

Real World Example #2

Research Supported By:

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research and Development

HSR&D
VA Health Services Research & Development Service

A Randomized Trial of a Personalized Clinical Decision Support Intervention to Improve Statin Prescribing in Patients With Atherosclerotic Cardiovascular Disease (*PCDS Statin*)

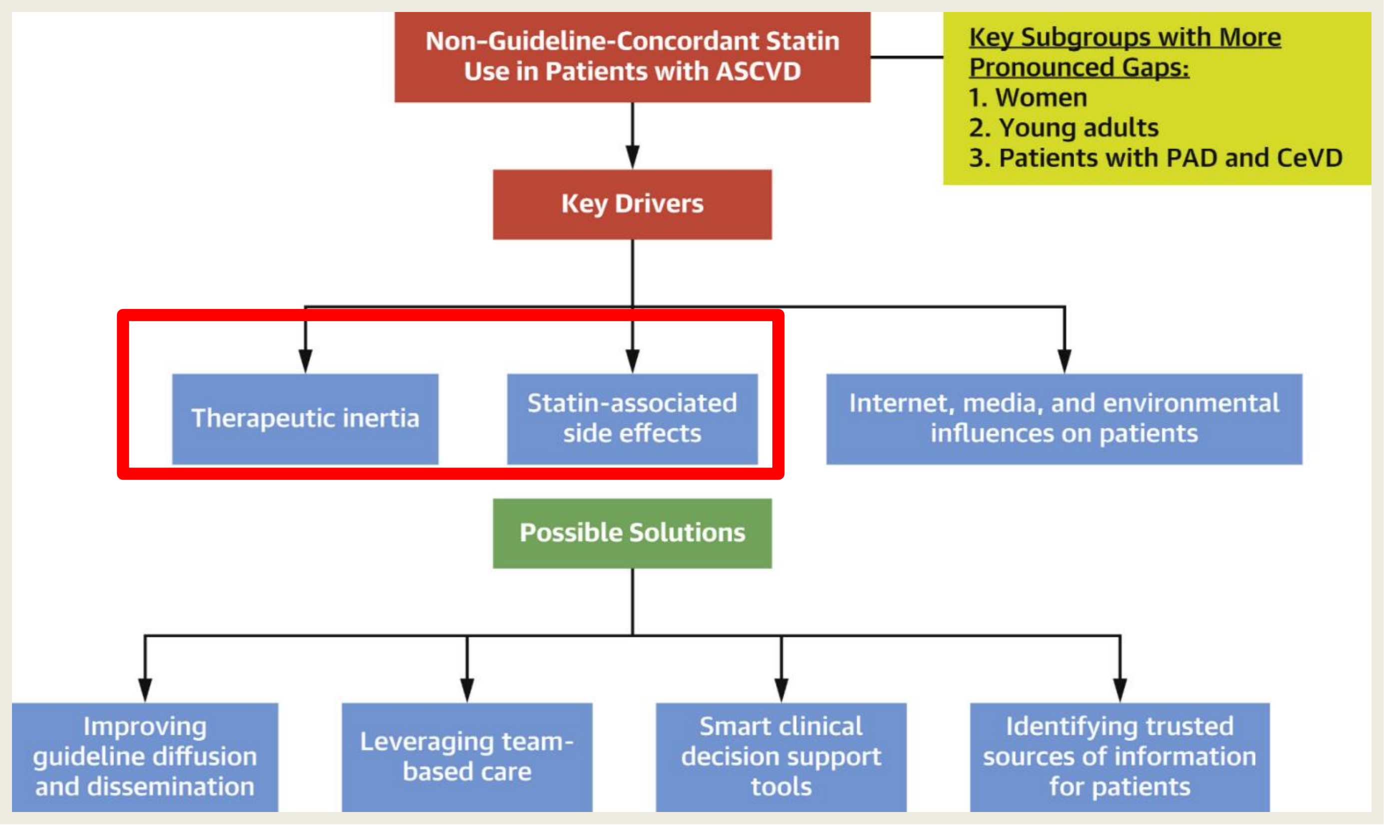
Virani

Baylor College of Medicine

MICHAEL E. DEBAKEY VETERANS AFFAIRS MEDICAL CENTER

Background

- Statin and high-intensity statin (HIS) use remains low in patients with atherosclerotic cardiovascular disease (ASCVD).



- In PCDS statin study, we evaluated whether patient context-aware reminders could improve HIS use in ASCVD patients.

Formative Work: Qualitative Study on Patient & Clinician Perspectives

- 21 adult Patients with ASCVD
- 20 prescribing clinicians: cardiologists, primary care physicians, primary care nurse practitioners, and clinical pharmacists
- Recorded interviews, transcribed, coded, with discrepancy resolution

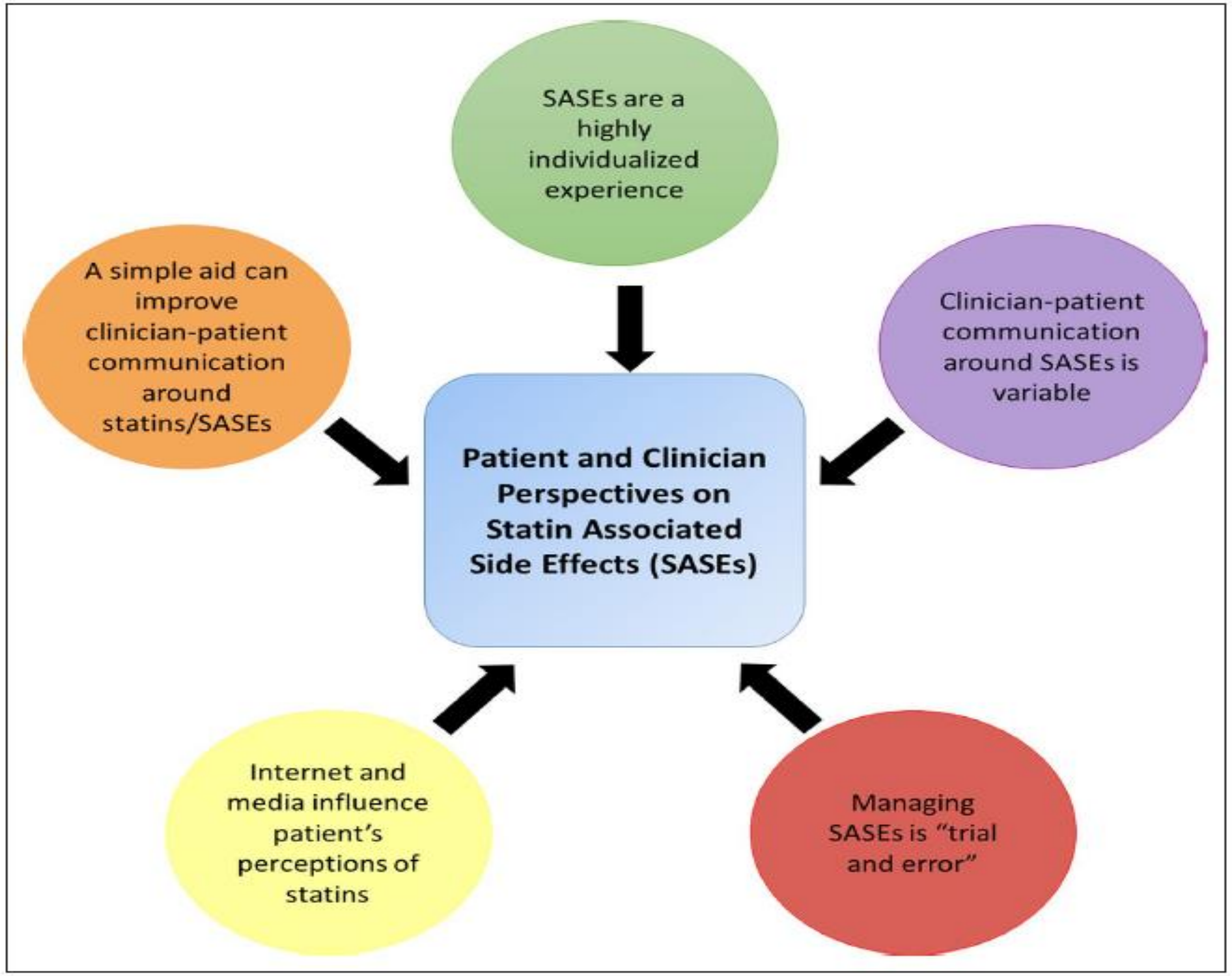


Figure 1. Five major themes impacting patient and clinician perspectives on statin-associated side effects (SASEs).

Ahmed

Virani

Study Objective

We sought to develop a system to support providers in improving rates of HMG CoA Reductase (statin) prescribing among patients with known cardiovascular disease.

Develop patient context aware clinical summaries

Minimize provider burden and maximize workflow integration

Virani SS, et al, Matheny ME. Circulation 2023 May;147:1411-1413.

Implementation in Two VA Healthcare Systems

Inclusion criteria:
Patients aged 18 or greater with cardiovascular disease (administrative codes)

Guideline Education
(27 primary care clinics)

Exclusion criteria:
Provider Opt-Out
Not seen last 2 years
Patient not on active provider panel

Randomization
(August 2021)

Intervention sites

Usual care sites,

Weekly data processing, synchronous/asynchronous reminders, guideline resources on an intranet portal

Patient dashboard displaying clinician compliance with statin therapy

End of the study
(11/31/2022)

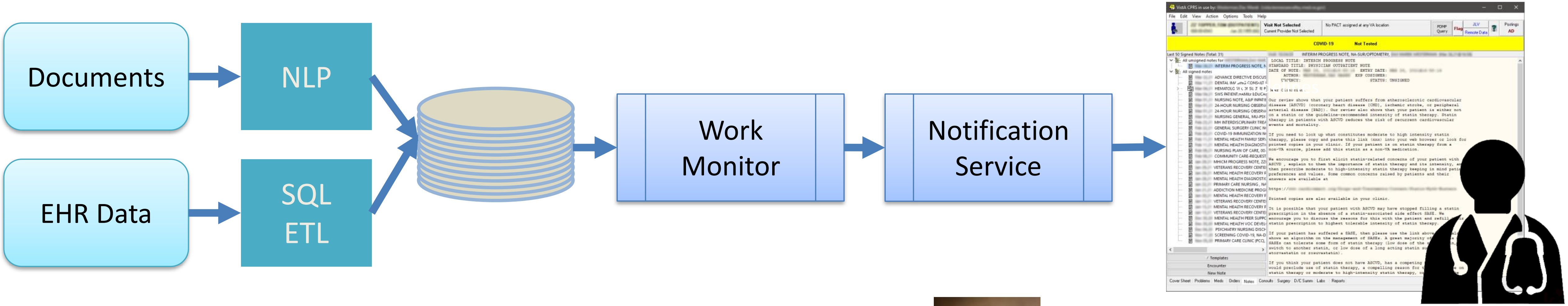
Outcomes

- Pre-post change in High Intensity Statin use between intervention and usual are sites.

Intervention Workflow

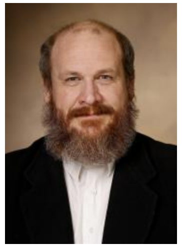
Gobbel

Reeves



ViSTa/CPRS EHR

Mark Kuebeler
(Houston VA)



Dax Westerman

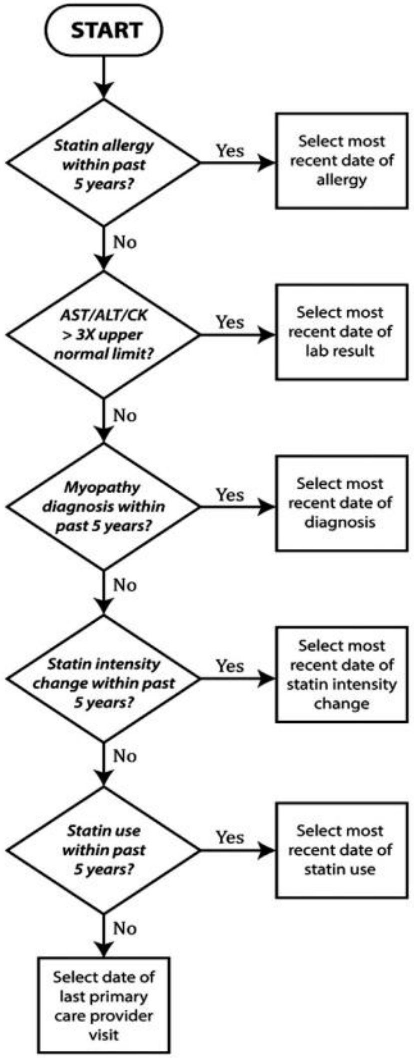
Canary NLP Tool Adaptation to VA

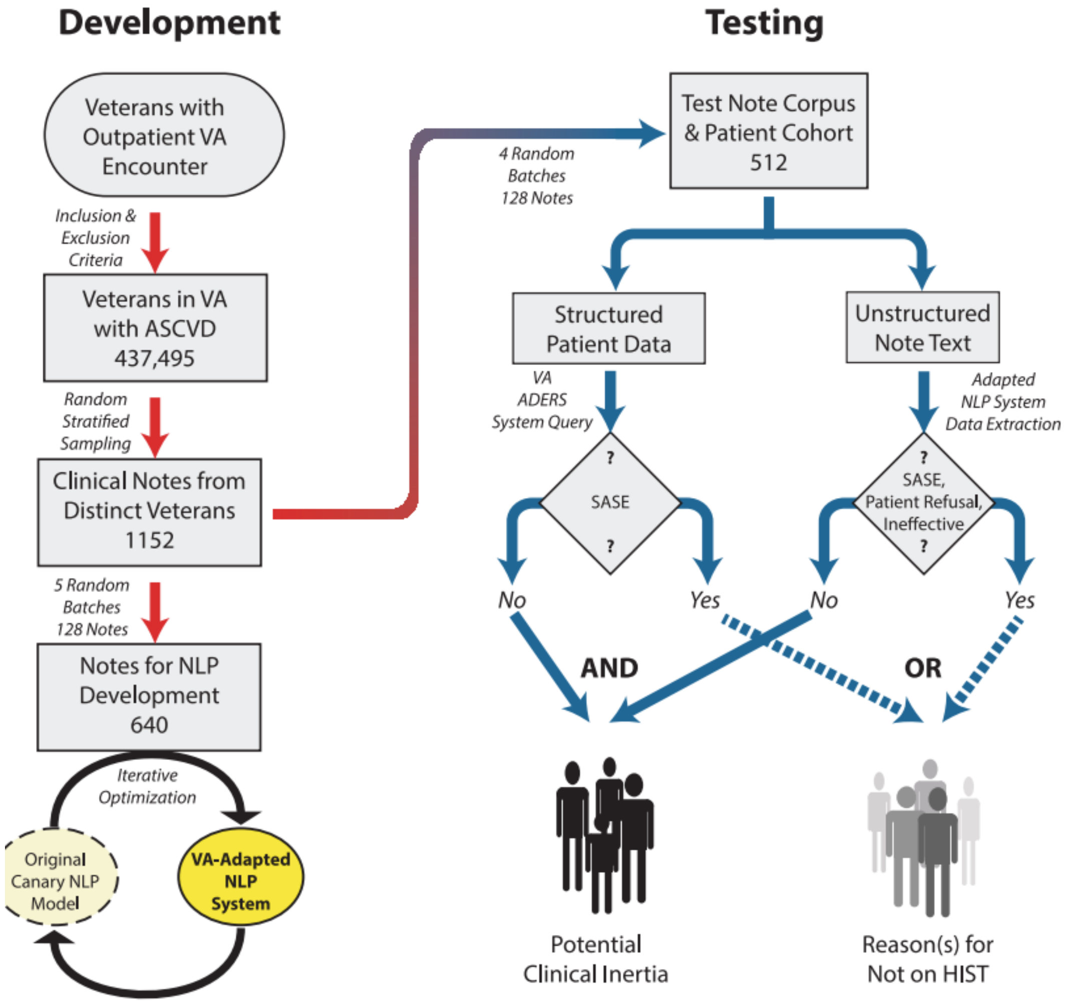
Gobbel

Reeves

Turchin

Virani





Gobbel GT, Matheny ME, Reeves RR, Akeroyd JM, Turchin A, Ballantyne CM, Peterson LA, Virani SS. Am. J. Prev. Cardiol. 2022; 9: 100300.

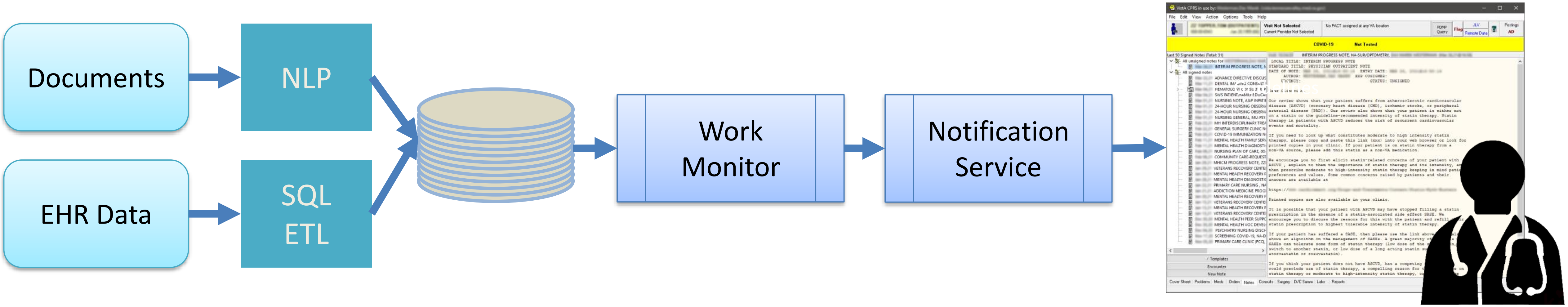
Canary NLP Tool Adaptation to VA

Evaluation of Addition of NLP for detection reasons for a patient with ASCVD to not be on a high-intensity statin

	Structured Data Only	Structured + Canary VA NLP
Sensitivity	0.69 (0.60 – 0.76)	0.89 (0.81 – 0.93)
Specificity	1.00 (1.00 – 1.00)	0.94 (0.92 – 0.96)
PPV	1.00 (1.00 – 1.00)	0.84 (0.69 – 0.90)
NPV	0.90 (0.87 – 0.93)	0.96 (0.93 – 0.98)
AUC	**0.84 (0.81 – 0.88)**	**0.91 (0.91 – 0.93)**
True Positives	91	117
False Positives	0	22
True Negatives	380	358
False Negatives	41	15

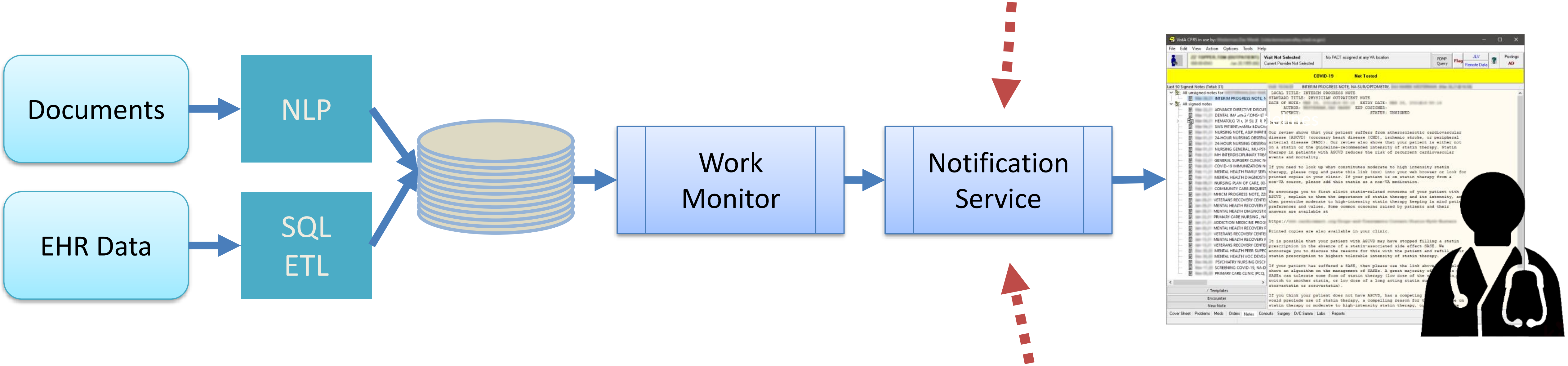
Gobbel GT, Matheny ME, Reeves RR, Akeroyd JM, Turchin A, Ballantyne CM, Peterson LA, Virani SS. Am. J. Prev. Cardiol. 2022; 9: 100300.

Intervention Workflow



Intervention Workflow

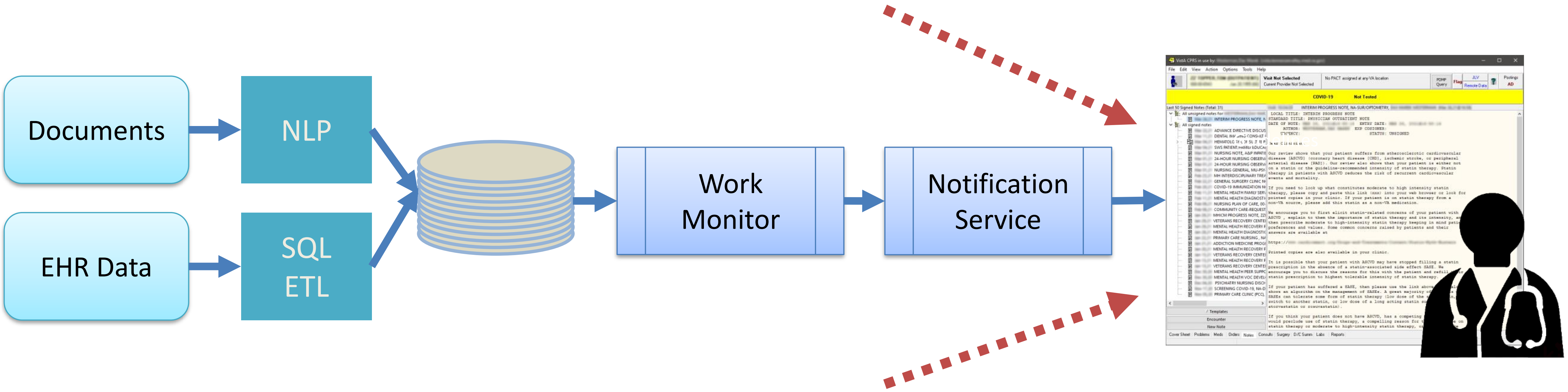
Reminders sent to their primary care clinicians 2-7 days before patient's visit (synchronous reminders) or outside of the patient's primary care visit (asynchronous reminders).



To reduce alert fatigue, our algorithms limited care summaries to <=3 unsigned alerts at all times.

Intervention Workflow

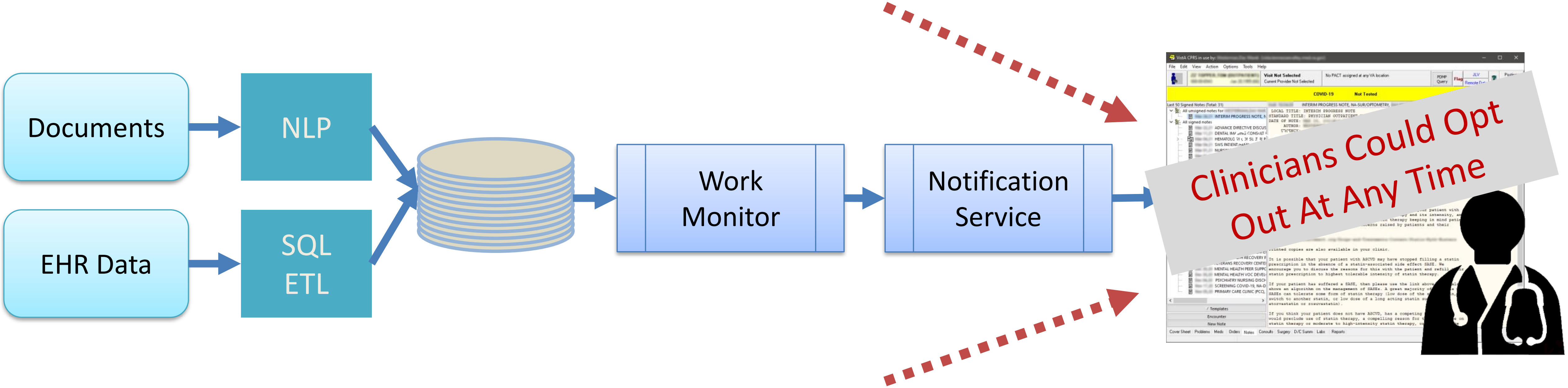
Centrally-processed individualized statin-relevant care summary sent to each ASCVD patient based on presence or absence of SASEs. (structured data + NLP)



Information included date and type of ASCVD diagnosis, statin and dose, date of last fill, date and type of SASE, and guideline resources on HIS definition and SASE management.

Intervention Workflow

Centrally-processed individualized statin-relevant care summary sent to each ASCVD patient based on presence or absence of SASEs. (structured data + NLP)



Information included date and type of ASCVD diagnosis, statin and dose, date of last fill, date and type of SASE, and guideline resources on HIS definition and SASE management.

Statin Prescribing Clinical Care Summary

09/29/2022 MEDICATION REVIEW:

This note was sent to you by [Investigator] as part of a research study.
Your name is listed as the author as the mechanism of notification into your inbox. You may resolve this by cosigning the note. Thank you.

Dear Clinician,

Our review shows that your patient suffers from atherosclerotic cardiovascular disease [ASCVD], coronary heart disease [CHD], ischemic stroke, or peripheral arterial disease [PAD]). Our review also suggests that your patient is either not on a statin or the guideline-recommended intensity of statin therapy. Statin therapy in patients with ASCVD reduces the risk of recurrent cardiovascular events and mortality.

Our review also indicates that your patient could have suffered from one of the statin-associated side effects (SASEs). A great majority of patients with SASEs can tolerate some form of statin therapy (low dose of the same statin, a switch to another statin, or low dose of a long acting statin such as atorvastatin or rosuvastatin).

---------- Guideline-Recommended High Intensity Statins ----------
Rosuvastatin 20-40mg by mouth daily
Atorvastatin 40-80mg by mouth daily

If your patient is on statin therapy from a non-VA source, please add this statin as a non-VA medication.

****** Upcoming Primary Care Visits ******

****** LAST MENTION OF STATIN ASSOCIATED SIDE EFFECT ******
Source ~ Date ~ Title ~ Author
Note ~ 08/19/2022 ~ PRIMARY CARE NOTE ~ [Attending Name]

****** MOST RECENT QUALIFYING DIAGNOSIS ******
Date ~ Code ~ Diagnosis/Procedure
07/24/2022 ~ I25.10 ~ Atherosclerotic heart disease of native coronary artery without angina pectoris

---------- Supporting Material ----------
Reference Material Links: https://[content_web_site]/statin-info/

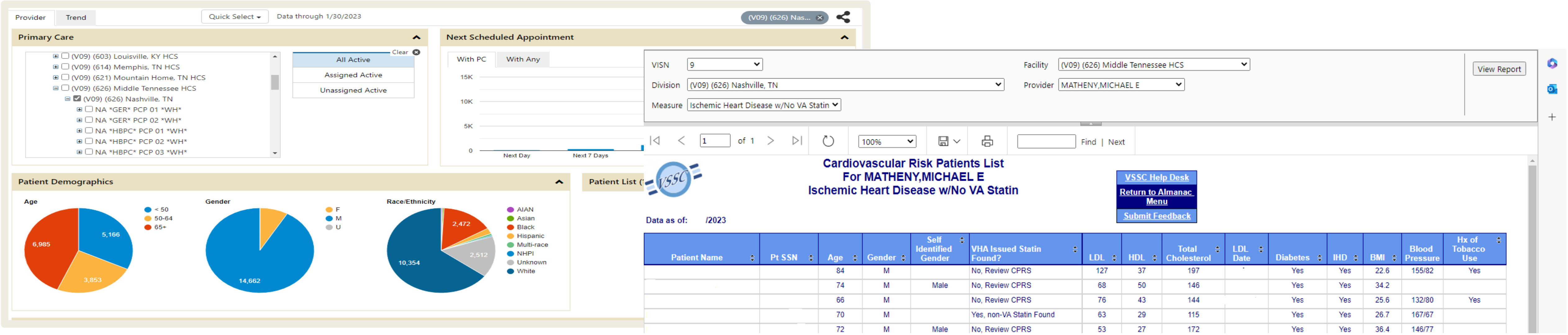
---------- Completing / Suppressing Future Alerts ----------
If you think your patient does not have ASCVD, has a compelling reason for not to be on a high intensity statin, or you would otherwise like to suppress future reminders on this individual patient, please sign this note, and create an addendum with these exact words:

Current therapy is appropriate: <any words to describe why>
Or Suppress High Intensity Statin Reminder

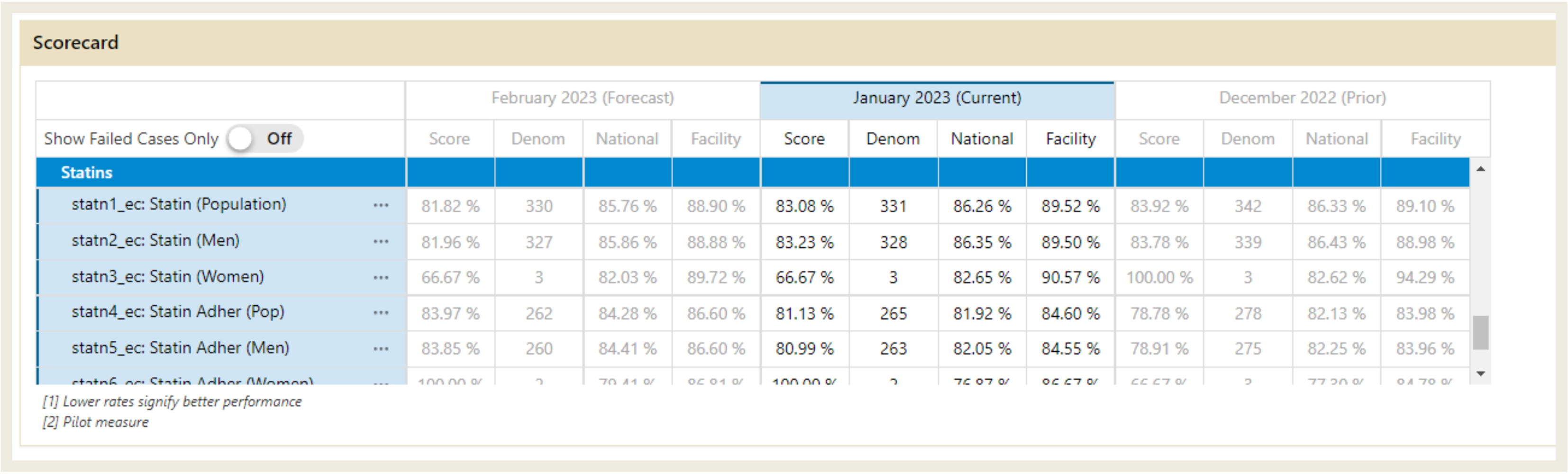
If you would like to opt-out of receiving all future messages on all patient,
Then please send an email to [Investigator]@va.gov or [support]@va.gov with this subject: Suppress All High Intensity Statin Reminders.

We sincerely thank you for your time and consideration.

Usual Care – Primary Care Operational Dashboards



Patient Name	Pt SSN	Age	Gender	Self Identified Gender	VHA Issued Statin Found?	LDL	HDL	Total Cholesterol	LDL Date	Diabetes	IHD	BMI	Blood Pressure	Hx of Tobacco Use
		84	M		No, Review CPRS	127	37	197		Yes	Yes	22.6	155/82	Yes
		74	M	Male	No, Review CPRS	68	50	146		Yes	Yes	34.2		
		66	M		No, Review CPRS	76	43	144		Yes	Yes	25.6	132/80	Yes
		70	M		Yes, non-VA Statin Found	63	29	115		Yes	Yes	26.7	167/67	
		72	M	Male	No, Review CPRS	53	27	172		Yes	Yes	36.4	146/77	

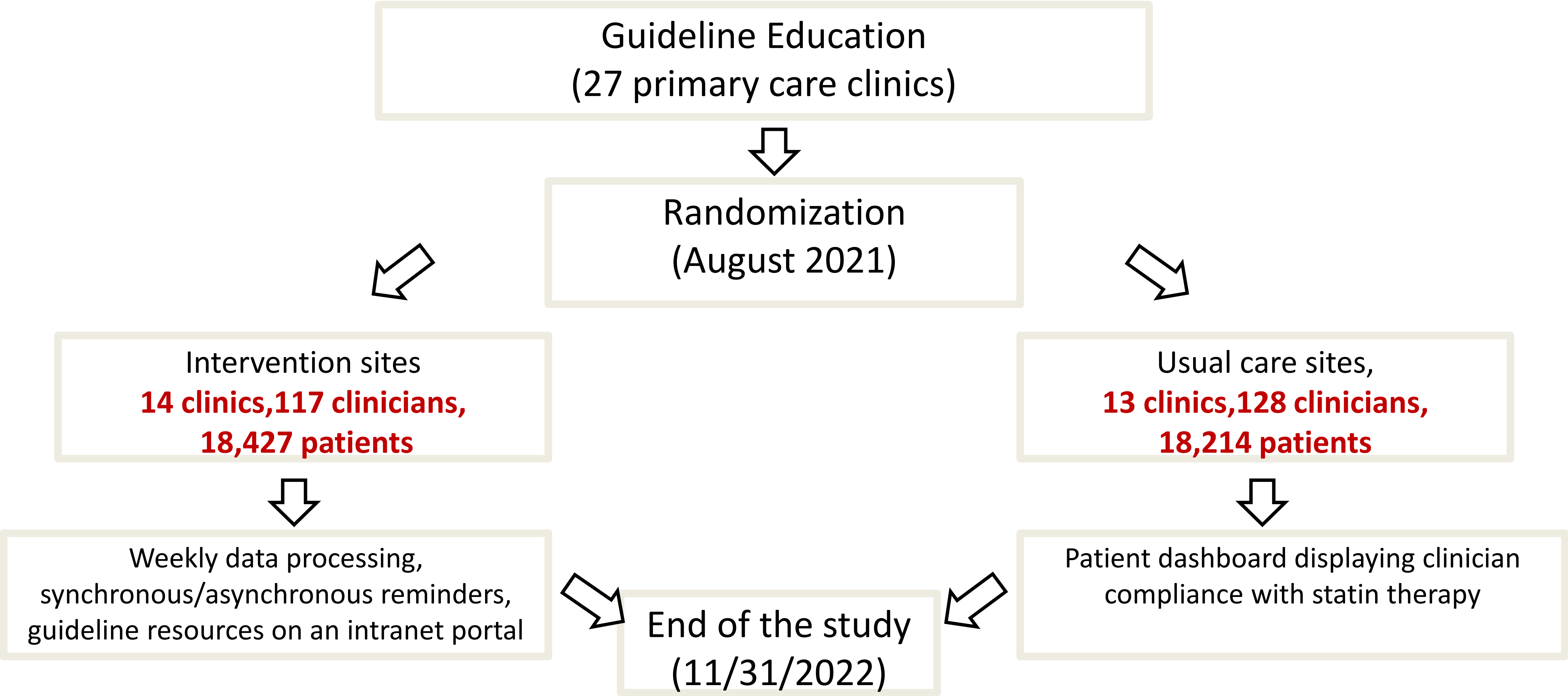


Scorecard

Show Failed Cases Only Off	February 2023 (Forecast) Score	Denom	National	Facility	January 2023 (Current) Score	Denom	National	Facility	December 2022 (Prior) Score	Denom	National	Facility
Statins												
statn1_ec: Statin (Population)	81.82 %	330	85.76 %	88.90 %	83.08 %	331	86.26 %	89.52 %	83.92 %	342	86.33 %	89.10 %
statn2_ec: Statin (Men)	81.96 %	327	85.86 %	88.88 %	83.23 %	328	86.35 %	89.50 %	83.78 %	339	86.43 %	88.98 %
statn3_ec: Statin (Women)	66.67 %	3	82.03 %	89.72 %	66.67 %	3	82.65 %	90.57 %	100.00 %	3	82.62 %	94.29 %
statn4_ec: Statin Adher (Pop)	83.97 %	262	84.28 %	86.60 %	81.13 %	265	81.92 %	84.60 %	78.78 %	278	82.13 %	83.98 %
statn5_ec: Statin Adher (Men)	83.85 %	260	84.41 %	86.60 %	80.99 %	263	82.05 %	84.55 %	78.91 %	275	82.25 %	83.96 %

[1] Lower rates signify better performance
[2] Pilot measure

Randomization



Intervention Arm

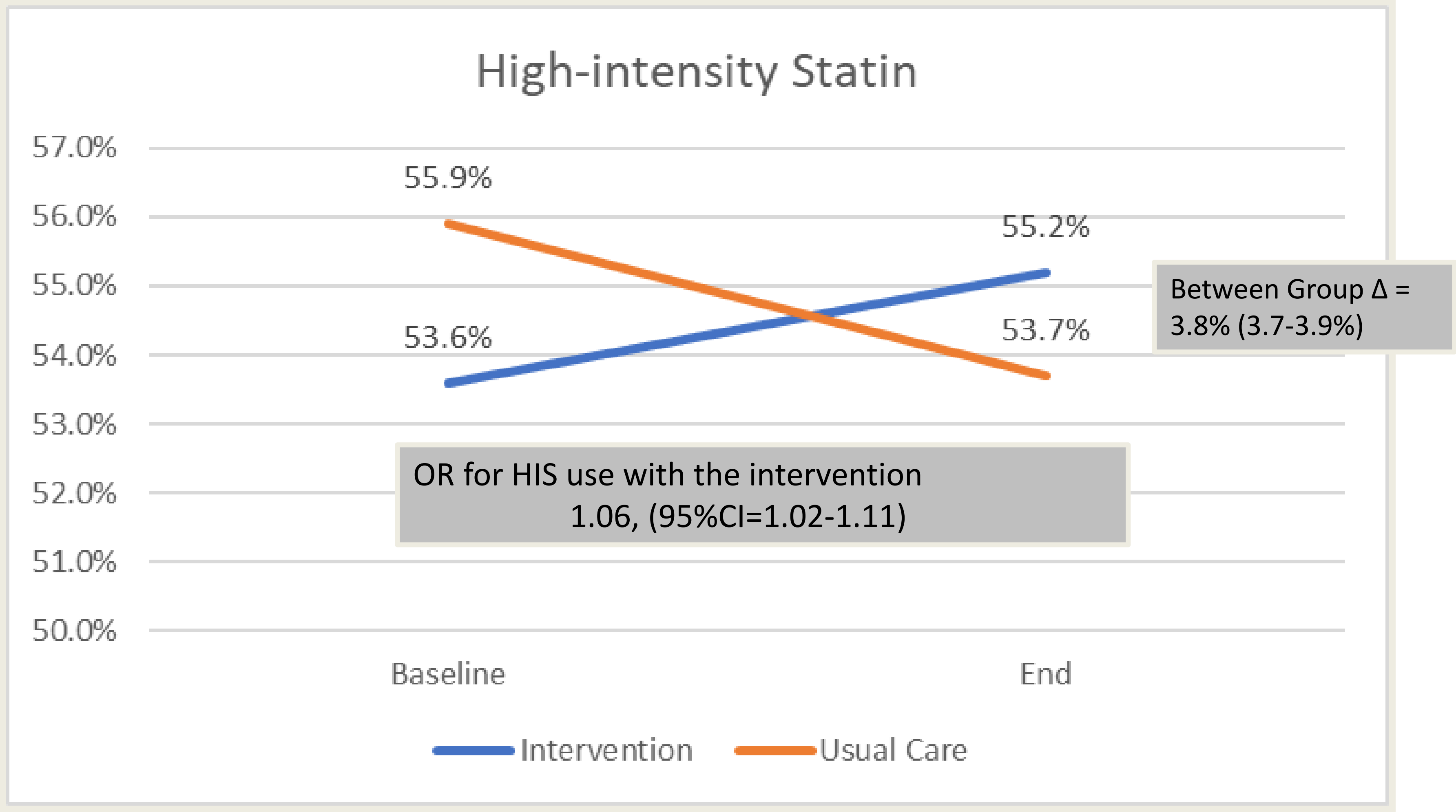
- 41.6% of patients in the intervention arm had a signal related to statin associated side effects in structured data or NLP.
- 4928 reminders sent to providers for 4,532 unique patients, representing 53% of the patients not on high intensity statins at baseline in the intervention arm.
- 73% of reminders were asynchronous, 27% were synchronous.
- Over time, 37 clinicians (31.6%) in intervention sites opted out.

Virani SS, et al, Matheny ME. Circulation 2023 May;147:1411-1413.

Challenge: Provider Drop-Out

- 31.6% of the clinicians in the intervention arm still elected to drop out during the study
  - competing demands
  - alert fatigue
  - iterative COVID-19 infection waves
- Known Issues:
  - 2–3-day lag from data calculation to note generation (interval med fills, death, etc.)
  - Insufficient Primary Care Alignment: Did not count referral to lipid clinic or PSK9 inhibitor initiation

Primary Outcome



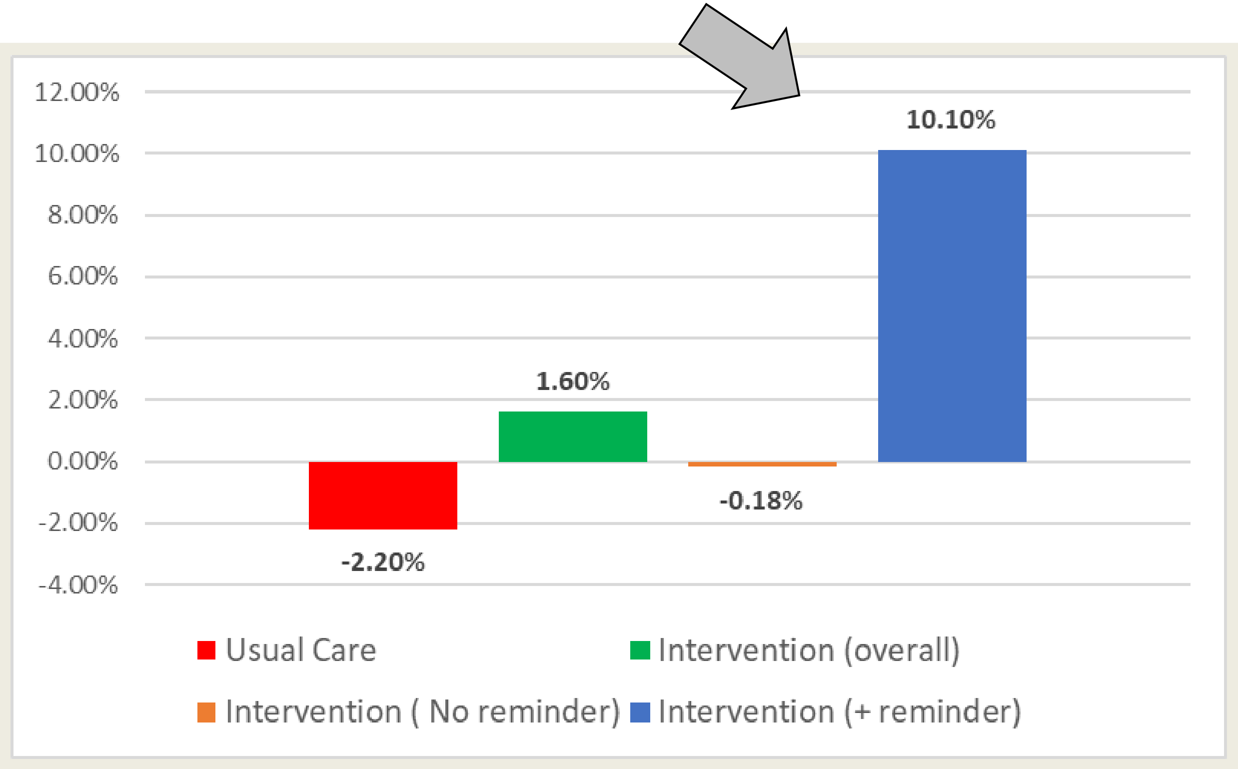
Virani SS, et al, Matheny ME. Circulation 2023 May;147:1411-1413.

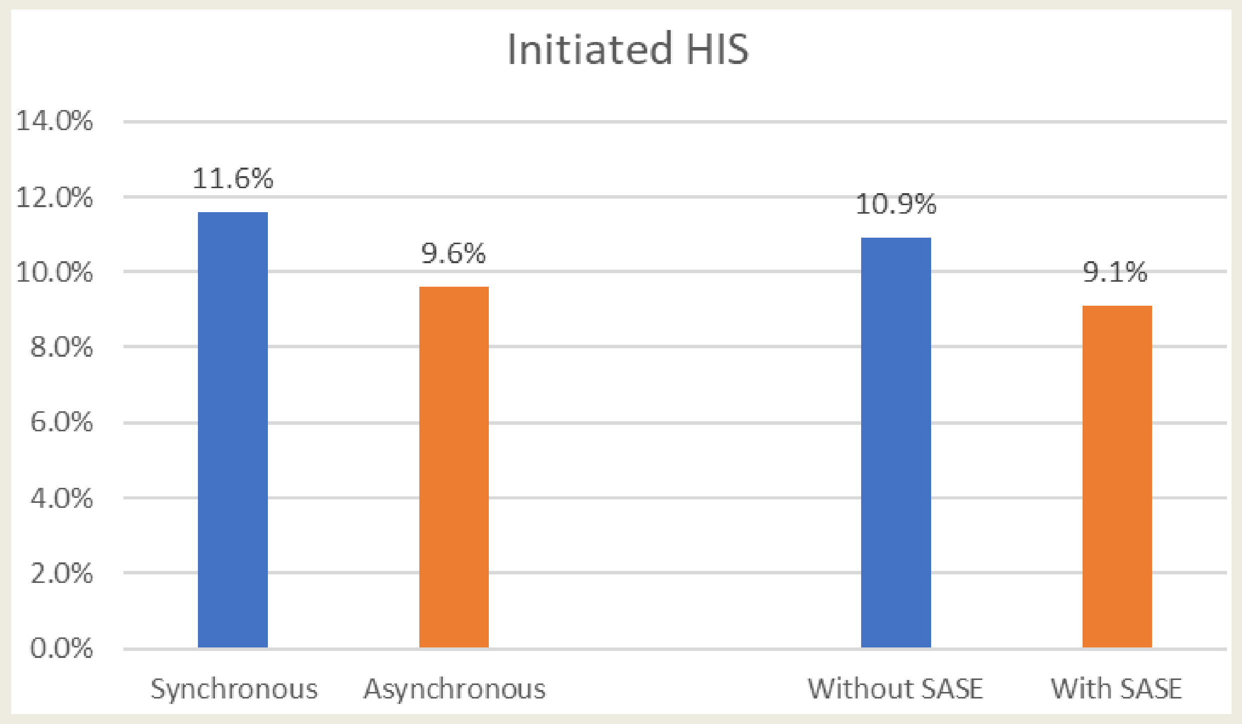
Outcome

Pre-post change in high intensity statin use in patients receiving care at usual care and the intervention sites (overall, among those who did not receive reminders, and among those who received reminders)

Number needed to remind = 10

Among Those Who Received Reminder





PCDS Statin Trial Conclusions

- Clinical
  - Patient context aware reminders led to significant increase in statin adherence.
  - ~10 reminders needed to be sent for a patient to be started on high-intensity statin
- Informatics
  - Alert Fatigue
    - reminders not sent to all eligible patients due to stringent algorithms to limit alert fatigue.
    - Further improvements to context are needed due to provider drop-out
  - Knowledge management a key issue for scalability of patient context aware CDS

Overall Conclusions

- AI and ML are increasingly being integrated into healthcare, BUT substantial challenges remain for the safe and effective clinical implementation of these technologies

- A rigorous AI/ML lifecycle approach that integrates:
  - Data science / AI / ML technical rigor
  - Human Factors / Human Computer Interaction
  - Implementation Science

  … is critical to achieve demonstrable clinical impact in patient care

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ImproveAKI Trial

- NIH NIDDK Funding
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PCDS Statin Trial

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Results: Baseline, Action, Post-Intervention Phases

Table 3: AKI proportion before, during, and after action phase by intervention group and CKD status

Population	Prior 12 Months	Action Phase		Post-Intervention Phase	
All Patients	N (%)	N (%)	Case-Mix Adjusted % [95% CI]	N (%)	Case-Mix Adjusted % [95% CI]
All VA Sites	1630 (11)	2156 (12)			
All Study Sites	416 (11)	**510 (11)**		**378 (9)**	
Intervention Group					
Technical Assistance (TA)	67 (8)	110 (13)	14 [14 to 15]	62 (12)	13 [13 to 14]
TA + Automated Surveillance (ASR)	100 (11)	122 (11)	11 [11 to 11]	127 (12)	10 [10 to 10]
Virtual Learning Collaborative (VLC)	176 (15)	190 (13)	12 [11 to 12]	178 (13)	11 [11 to 11]
ASR + VLC	73 (9)	88 (8)	9 [9 to 9]	73 (7)	8 [8 to 8]
CKD Subset					
All VA Sites	693 (19)	959 (19)			
All Study Sites	187 (18)	**235 (18)**		**216 (17)**	
Intervention Group					
TA	36 (17)	42 (17)	20 [19 to 20]	26 (17)	19 [18 to 19]
TA + ASR	54 (18)	68 (23)	20 [20 to 21]	76 (20)	19 [18 to 19]
VLC	61 (20)	77 (19)	16 [16 to 17]	71 (18)	16 [15 to 16]
ASR + VLC	36 (15)	48 (14)	16 [16 to 17]	43 (13)	16 [15 to 16]