AI SUMMIT

CINCINNATI, OH • NOVEMBER 14–16, 2023

Cultivating a Community of Practice to Ensure the Safe, Effective, and Equitable Use of AI

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Population Health & Data Science Lead

Duke Institute for Health Innovation

Co-Lead, Health AI Partnership

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

Inspiring Collaboration. Leading Innovation. Making a difference.

Duke Institute for Health Innovation	**2 mins**
Health AI Partnership	**2 mins**
Trustworthy AI Throughout the Lifecycle	**10 mins**

Duke Institute for Health Innovation
health ai partnership

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HEALTHCARE PRODUCTS COLLABORATIVE

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Duke Institute for Health Innovation

Our Mission: **Catalyze innovations at Duke**

Catalyze transformative innovation in health and healthcare through high-impact research, leadership development and workforce training and the cultivation of a community of entrepreneurship

Our Approach: **Innovation by design**

Understand user workflow, desired outcomes and problems (needs) and then collaboratively develop concepts and prototypes, and iterate through to finalize solution

DIHI domains of innovation

DIHI

Duke Institute for Health Innovation

Implementation and Health Delivery Science

- Catalyze multidisciplinary teamwork
- New care models
- Structured interface to Duke Health
- Living laboratory to incubate, refine, validate, and scale new ideas

Health Technology Innovation

- Leverage a growing health data infrastructure
- Create a connected digital health ecosystem
- Collaboration and co-development of technology
- Responsible development of datascience solutions

Leadership and Workforce Development

- Train current and future leaders across health care :
  - Leadership
  - Management
  - Innovation
  - Quantitative health sciences
- Contribute to developing the workforce of the future

Best Practices Development and Dissemination

- Disseminate best practices derived through internal R&D to elevate health innovation across ecosystem
- Convene stakeholders across settings to address common challenges in health innovation

Industry Best-practice Approach to Catalyzing innovation

RFA

Structured

DIHI RFA approach

“Top-down + Bottom-Up” approach to sourcing innovations

- Duke Health leadership develops mission-aligned strategic themes for innovation
- Front-line faculty and staff propose “problems” aligned with strategic themes and novel solutions
- Systematic review and due diligence: Assessments on team, feasibility, resource needs, impact and value to patients
- Operational Lead engaged right from the proposal stage
- 8-12 innovations funded each year; Duration: 12-15 months
- DIHI members embedded within project innovation teams to rapidly catalyze the innovations
- Pivots as needed to support rapid evolution to create value
- Metrics: clinical utility, economic utility, cultural impact, IP and academic outputs

11 Years Catalyzing Innovations | **90+** Innovation Projects | **740+** Proposals

IJ

Unstructured

DIHI Innovation Jam

A Health focused Shark Tank at Duke

- Solicits and identifies high-potential healthcare and health **innovations ready for commercialization**
- **Duke Leadership as Sharks:**
  - DUHS leaders, Department Chairs, Deans of School of Medicine, Nursing, Engineering, OLV, I&E, MedBlue, Center and Institute Directors
- Innovation proposals from students, faculty, trainees and staff across campus
- **Funding** to support entrepreneurship / **formation of company** and also **develop the product/service** etc.
- Inventors offer portion of their share of Duke internal returns for investment from the sharks
- Internal syndicated investment agreements documented through MOUs.

6 Years of Jamming | **30+** Pitches | **12** Companies Incubated

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DIHI Spectrum of Value Creation

Inpatient Innovations	Transition Setting	Outpatient/ Gaps in Care	Patient & Community
Hospital at Home		HIV Pre-Exposure Prophylaxis Identification	Community COVID-19 Support
Mortality Models (inpatient / 30-day)	High-utilizer dashboard	CKD Patient Education Dissemination	Patient Reported Outcomes for Cancer Patients
Operational Enhancement	Complex Care Plans	Community-Based Palliative Care	Outpatient Procedure Concierge Program
Procedure Safety	Index Admissions with MSSP	High Value Analyte Ordering	Cancer Distress Coach
Medication Safety	Readmissions (Social Drivers for HF)	NAFLD population health rounding	Autism and Beyond
Early Detection of Deterioration	SNF transition	CKD population health rounding	Voices of Duke

Immersion in innovation and data science

- **Medical Students Scholarship**
- **Data Science in Health** masters course in BME
- **Summer Fellowship** in Data Science
- **Case Studies** and Data Camp
- **Journal Club**

Technology Infrastructure | Research and Dissemination | Education and Training

Duke Institute for Health Innovation [DIHI] – Spectrum of value creation across the ecosystem

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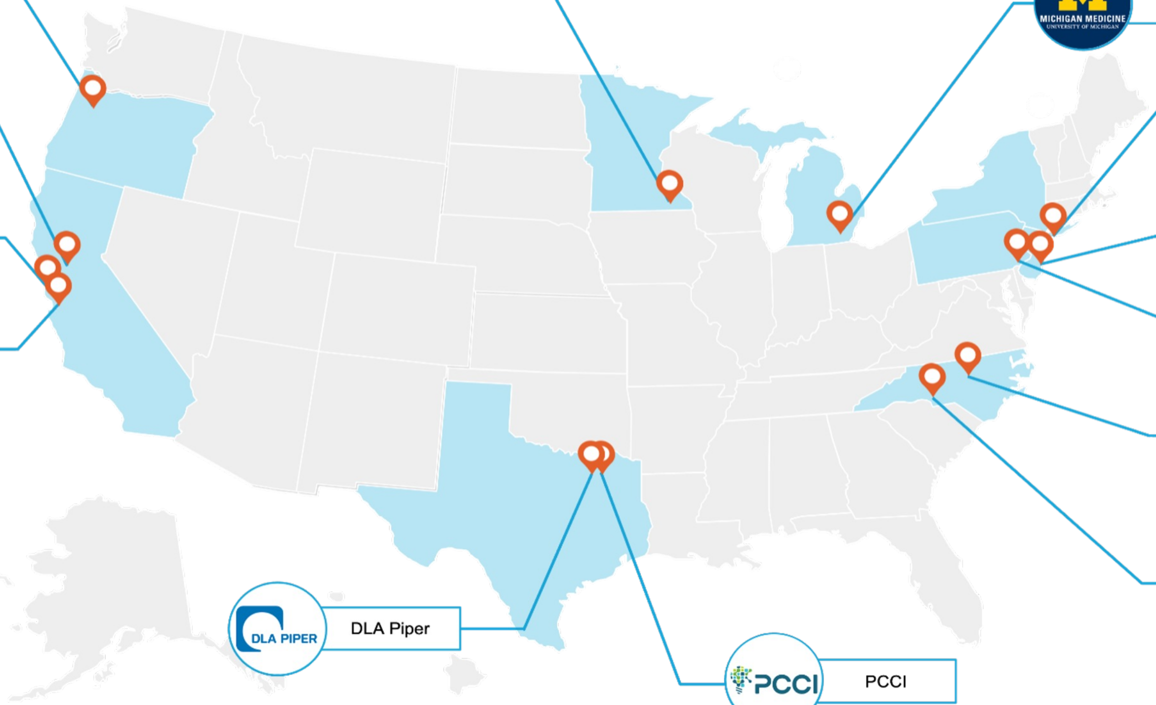
HAIP Corps



AMA American Medical Association

ONC* Office of the National Coordinator for Health Information Technology

*Participating as a federal observer

AFDO RAPS Healthcare Products Collaborative

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Inspiring Collaboration. Leading Innovation. Making a difference.

Our Mission: Empowering healthcare professionals to use AI effectively, safely, and equitably through **community-informed up-to-date standards**

Our Values:

advance health equity	improve patient care	improve the workplace	build community
prioritize solutions that advance health equity and eliminate the AI digital divide	ensure that AI adoption is driven by patient care needs, not technical novelty	surface socio-technical challenges in AI use and foster a positive work environment	create safe spaces to share learnings and consult peers

Phase One (Apr 22 – Aug 23) Milestones

Standard AI Solution Procurement Milestones

- Community-informed best practices sourced from across the network of organizations
- Multiple co-design workshops with IDEO.org
- Focused on AI solutions used for:
  - Diagnosis or treatment decisions for individual patients
  - Prioritization of patients for healthcare services (e.g., surgery scheduling, care management prioritization, ED triaging)

Health Equity Across the AI Lifecycle (HEAAL) Framework

- Developed to answer the question: “our health system is considering adopting a new solution that uses AI; how do we assess the potential future impact on health inequities?”
- Convened multi-stakeholder workshop featuring case studies, expert discussants, and framework developers
- Developed detailed procedures for healthcare organizations to follow for AI procurement

8 Key Decision Points

85+ Interviews

31 Topic Guides

3 Case Studies

75+ Participants

38 Procedures

Duke Institute for Health Innovation	2 mins
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8 Key Decision Points in AI Adoption Process

Procurement	Development & Adaptation	Clinical Integration	Lifecycle Management
1 Identify and prioritize a problem	3 Develop measures of outcomes and success of the AI product	6 Execute change management, workflow integration, and scaling strategy	7 Monitor and maintain the AI product
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AFDO RAPS

Align Front-Line Staff and Organizational Leaders

Create Alignment Throughout Project Selection

	Strategic Priorities	Proposal Solicitation	Project Selection	Scoping	Solution Development	Implementation & Evaluation
C-Suite	Specify 4-5 organizational innovation priorities	Publicize RFA	Rate oral pitches to select ~10 projects			Evaluate and determine impact and sustainability plans
Clinical and Operational Leaders (control resources)		Publicize RFA and work with front-line staff on proposal	Provide written reviews to select ~20 projects for oral pitches	Define problem, solution, stakeholders, metrics, and measures	Design and develop solution with DIHI	Define operationalization and dissemination, including communication and training
Front-Line Staff		Iterate on proposal with buy-in from clinical and operational leaders				

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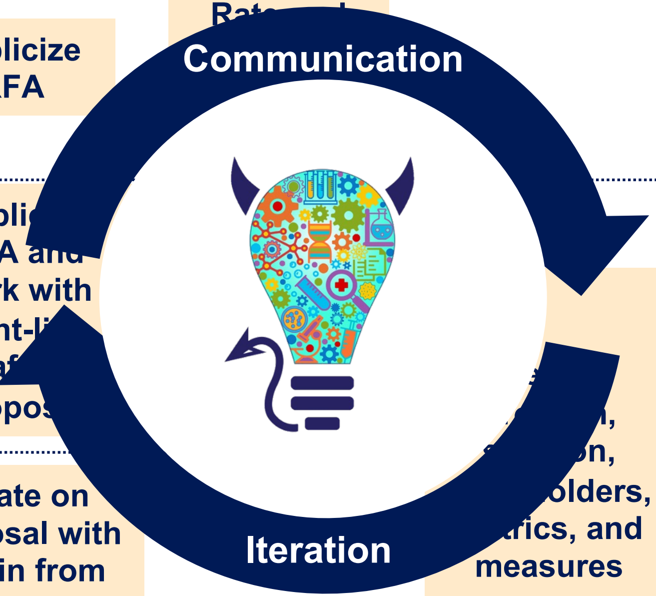

HEALTHCARE PRODUCTS COLLABORATIVE

8 Key Decision Points in AI Adoption Process

Procurement

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2. **Evaluate AI as a viable component of the solution**

Development & Adaptation

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Clinical Integration

6. Execute change management, workflow integration, and scaling strategy

Lifecycle Management

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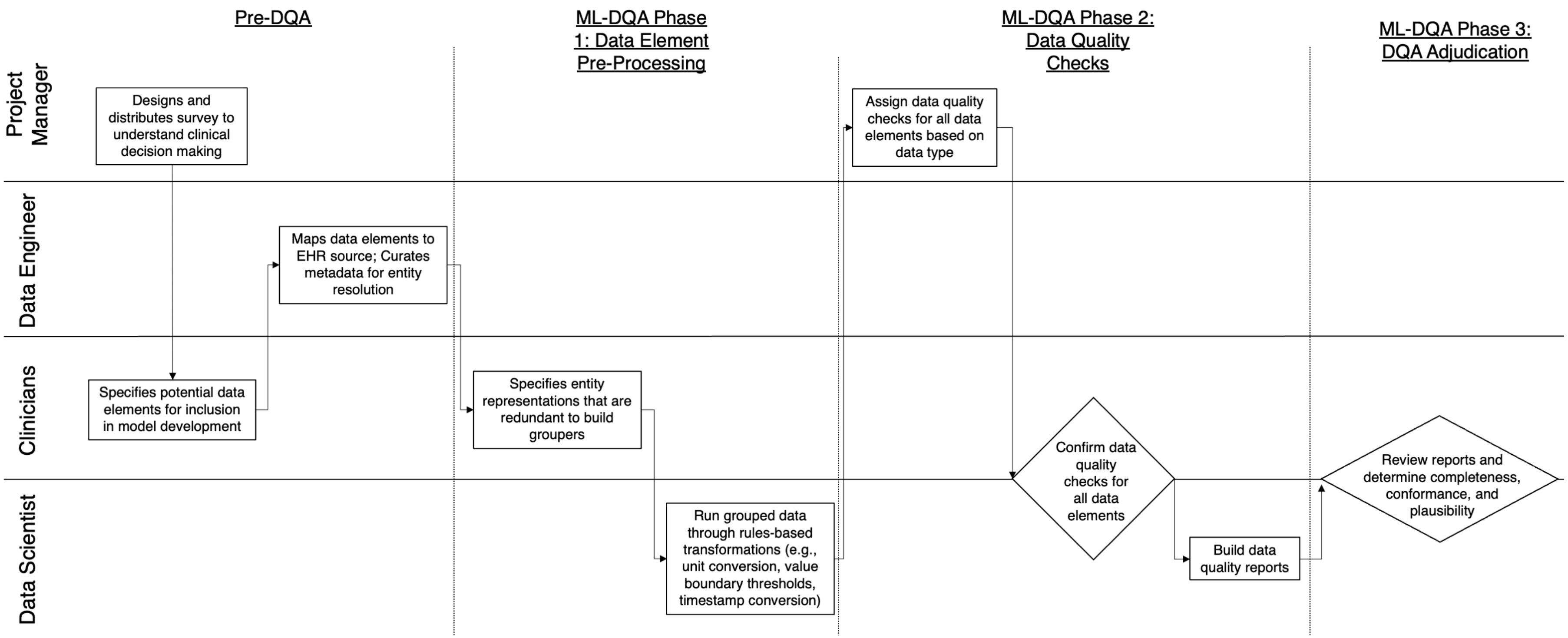
ML Data Quality Assurance for Healthcare

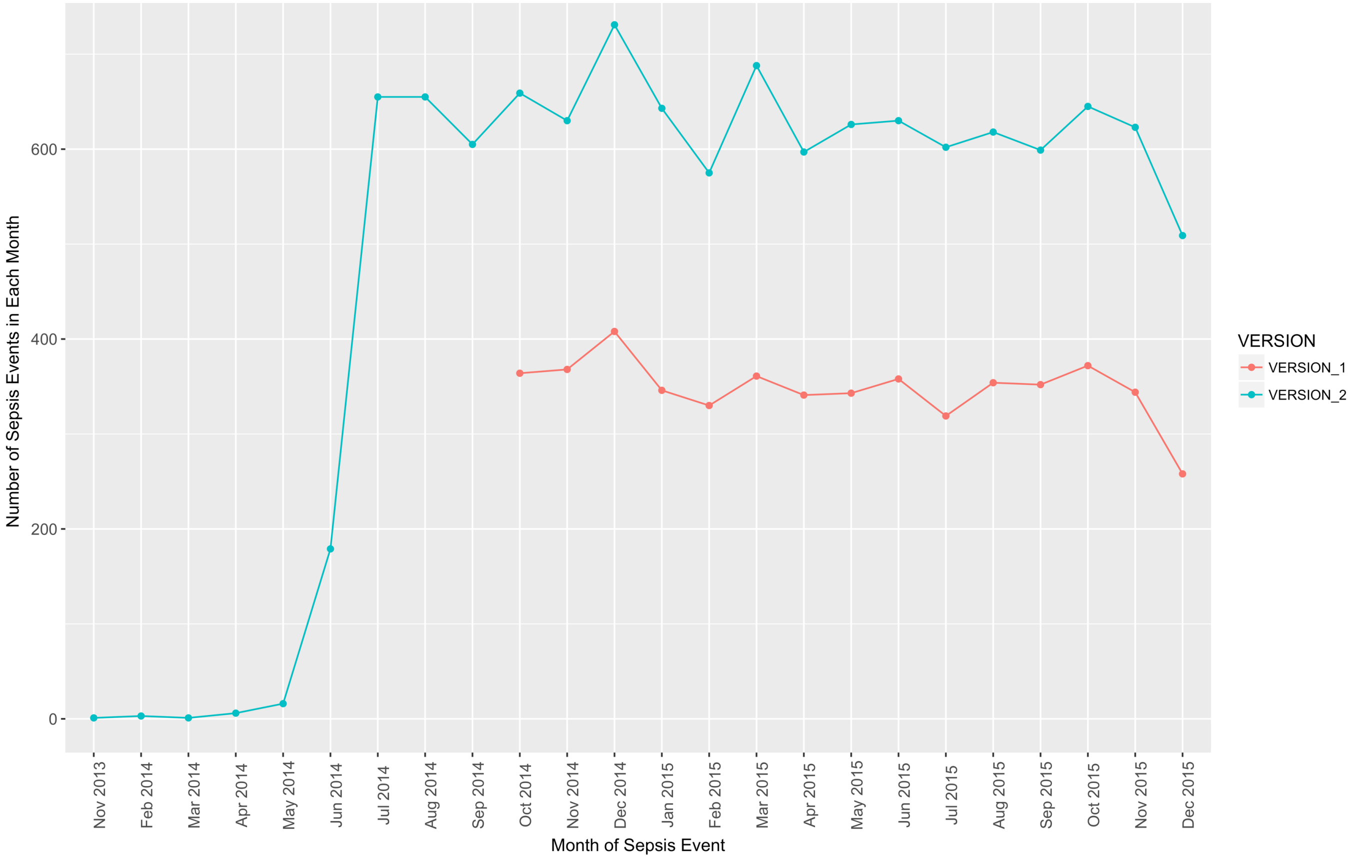


Development and Validation of ML-DQA

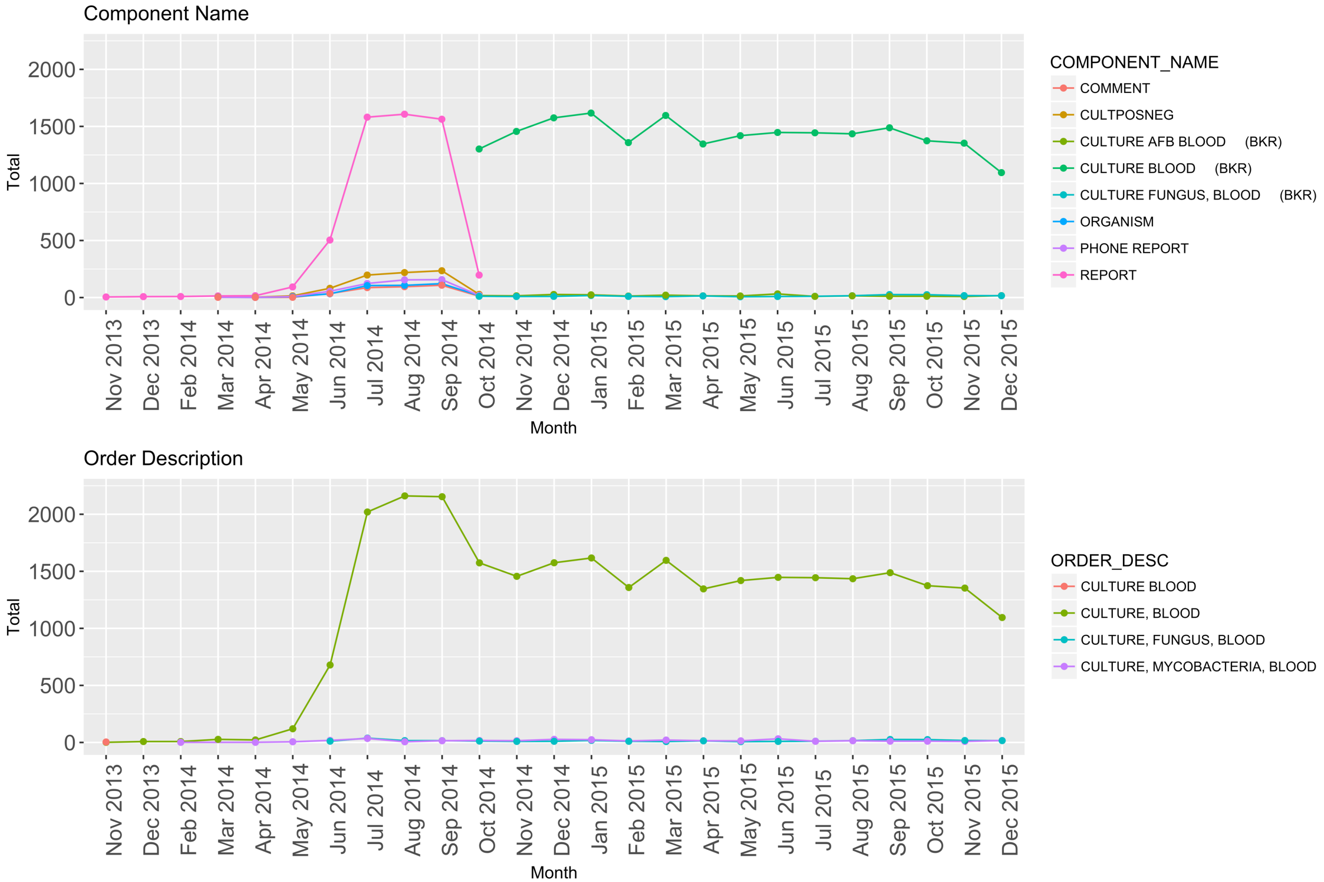
	Pediatric Sepsis Prediction	Lung Transplant Complication Prediction	Sepsis Prediction at Jefferson Health	Immune-Related Adverse Event Prediction	Maternal Morbidity and Mortality Prediction
Phase I: Data Element Pre-Processing					
Pre-existing groupers	108	109	30	39	310
Project-specific groupers	73	35	59	41	12
Phase II: ML-DQA Checks					
Completeness checks	144	144	70	508	404
Conformance checks	122	144	132	225	69
Plausability checks	123	144	61	301	404
Total quality checks	389	432	267	1,034	877

https://proceedings.mlr.press/v182/sendak22a.html

Disappearing Sepsis Events



Disappearing Sepsis Events



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Example Categories of Measures

Category	Definition	Example Metrics
Model performance	**Effectiveness, accuracy, and reliability of the AI model** or algorithm in fulfilling its intended tasks within the clinical or healthcare context.	Sensitivity (recall, true positive rate), Specificity (true negative rate), Area Under the ROC Curve (AUC-ROC), F1 Score, Precision (positive predictive value).
Software performance	**Efficiency and responsiveness of processing tasks**, delivering results, and overall performance of the software components and its interactions.	Inference time, throughput, model latency, response time, resource utilization, scalability.
Clinical effectiveness	Assessment of impact of product use on healthcare outcomes.	**Mortality rate, intensive care unit requirement, complication rate**
Usability	**Quality of users' interactions with the AI-based medical software.**	Clinician satisfaction, user error rates, ease of use.
Safety and security	Safely and securely operating software, evaluating harm to patients and protection against unauthorized access, data breaches, and cyber threats.	Number of identified safety risks and mitigations, adherence to cybersecurity standards, detection of adversarial attacks, incident response time.
Business	Business objectives and outcomes	**Reduction in diagnostic time, cost savings.**

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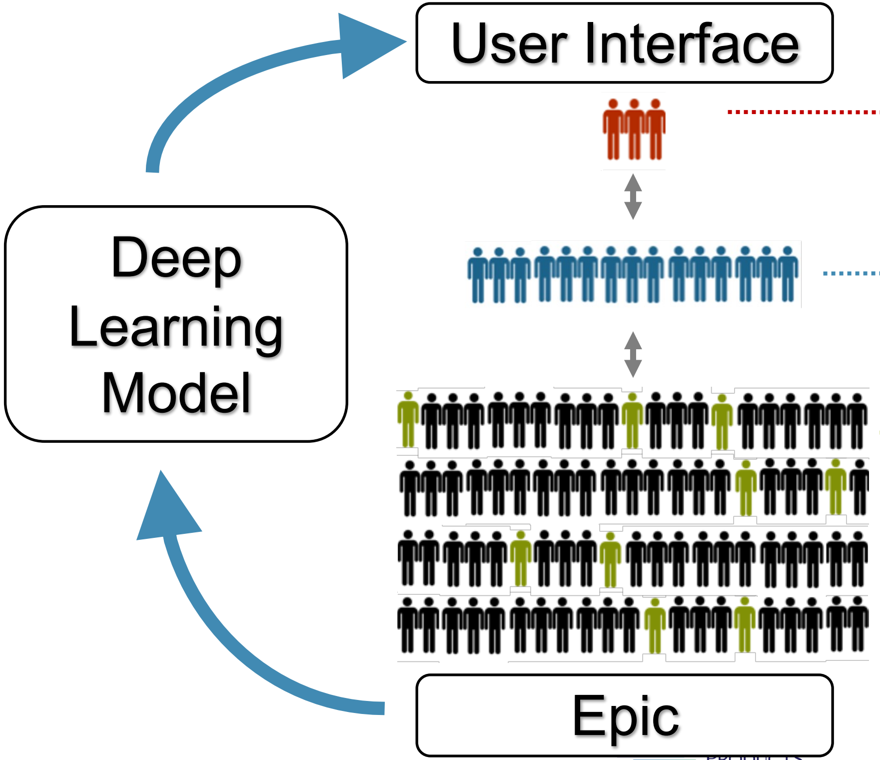
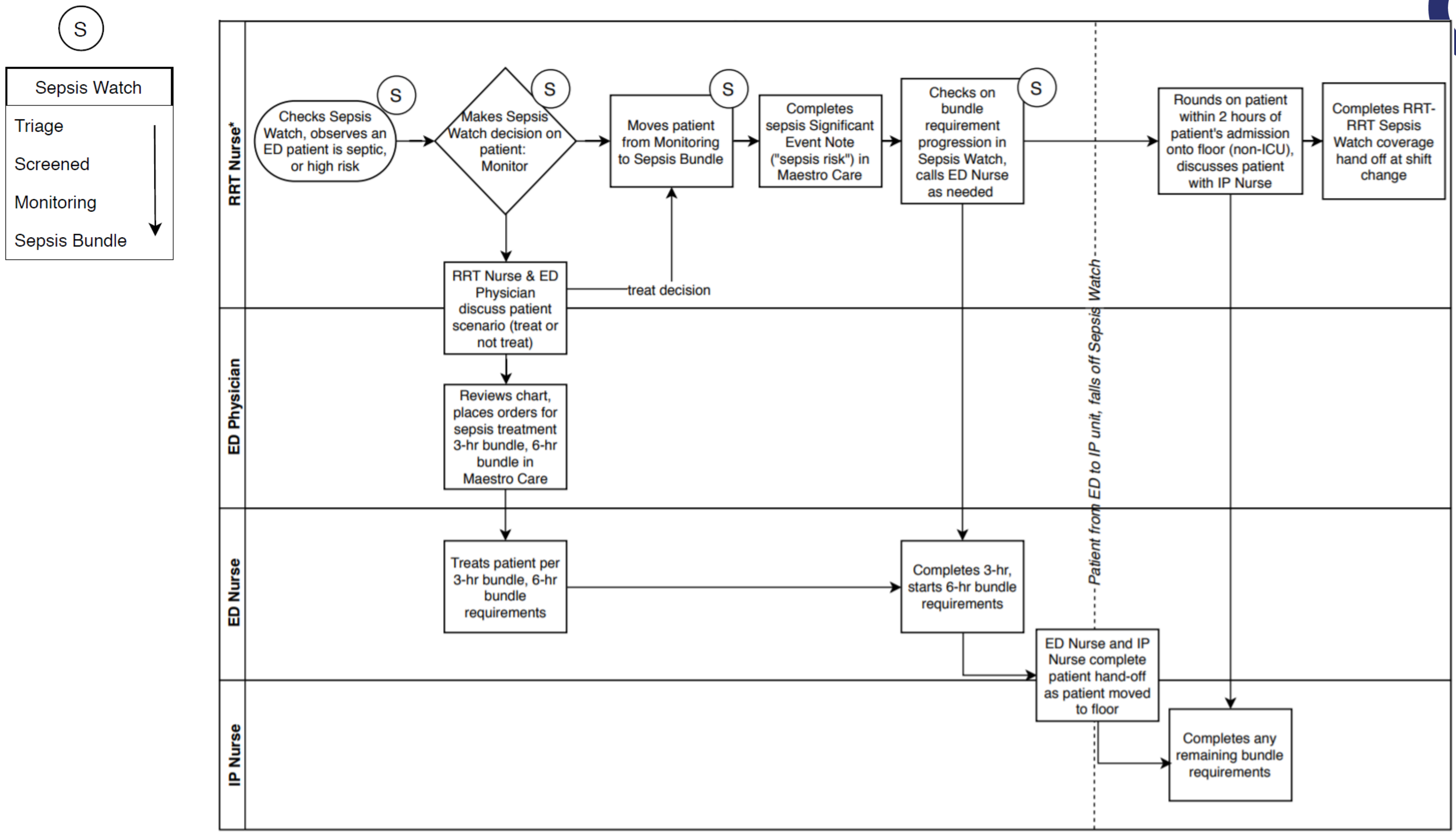
Custom Workflow to Reduce Alarm Fatigue

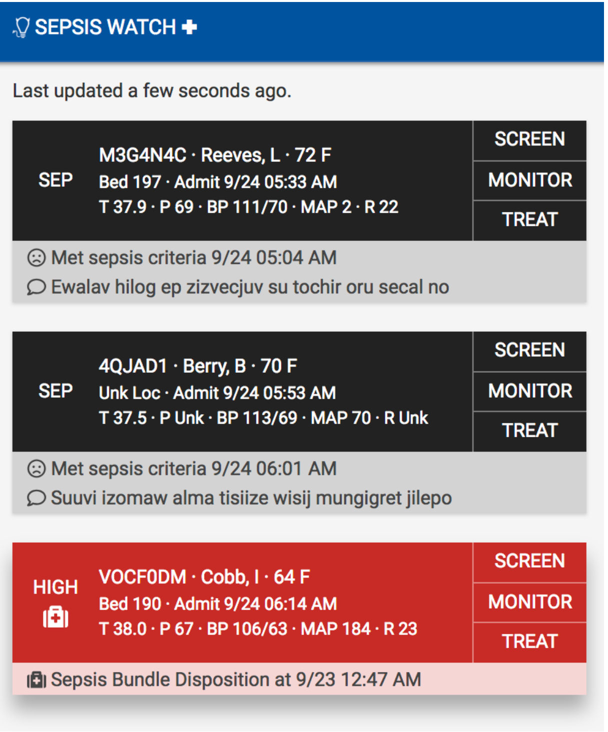


- *Leverage Sepsis Care Team*
  RRT nurses and hospitalists
- *Support primary providers*
  …without causing alarm-fatigue
- *Improve patient care over entire cycle*
  high risk through treatment



*An RRT or patient consult is the top priority of the RRT nurse

Sepsis Watch User Interface



Triage

- Sepsis identified every 5 minutes and sepsis risk computed every hour
- System normalizes data, groups clinically related concepts into meaningful features, and ensures valid inputs to deep learning model
- Deployed on-premise cloud with Docker containers
- **Black** = meets sepsis criteria
- **Red** = high risk of sepsis

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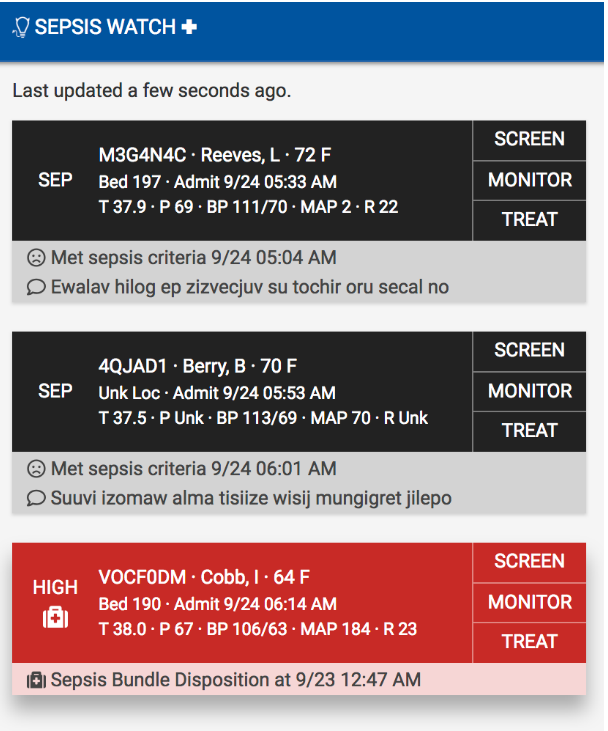
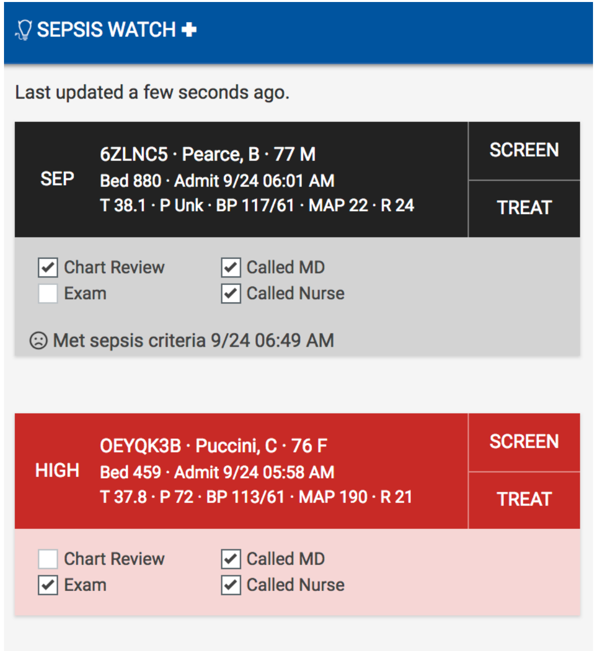
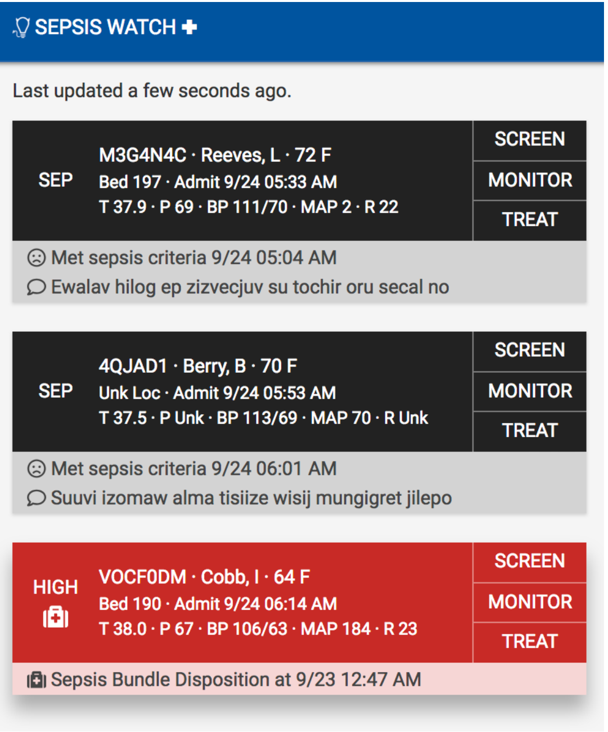
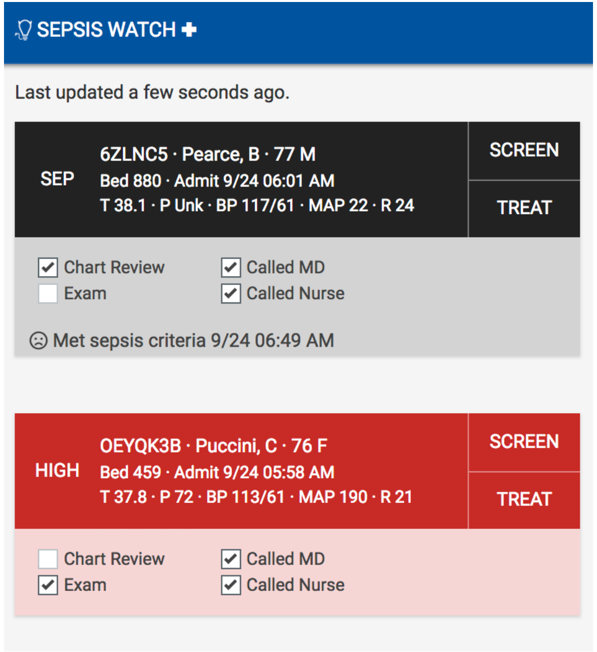


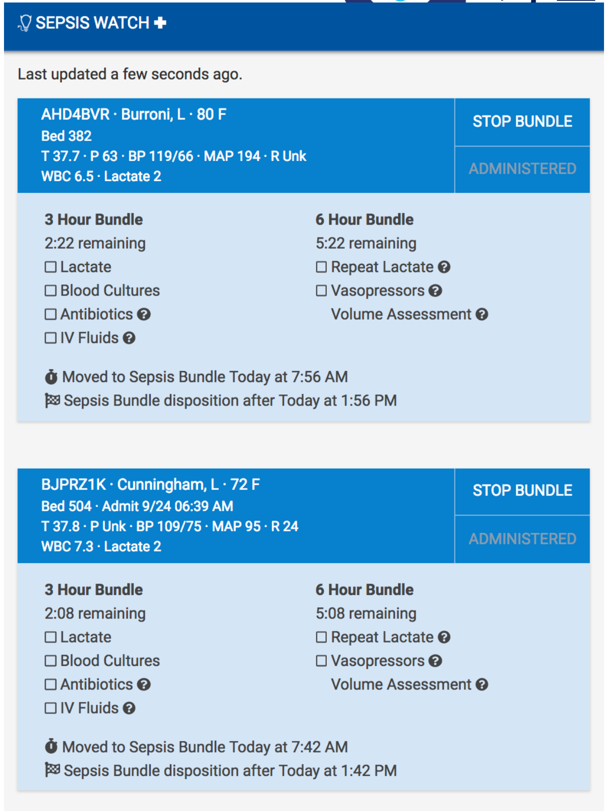


Triage **Monitor**

Sepsis Watch User Interface







Triage **Monitor** **Treat**

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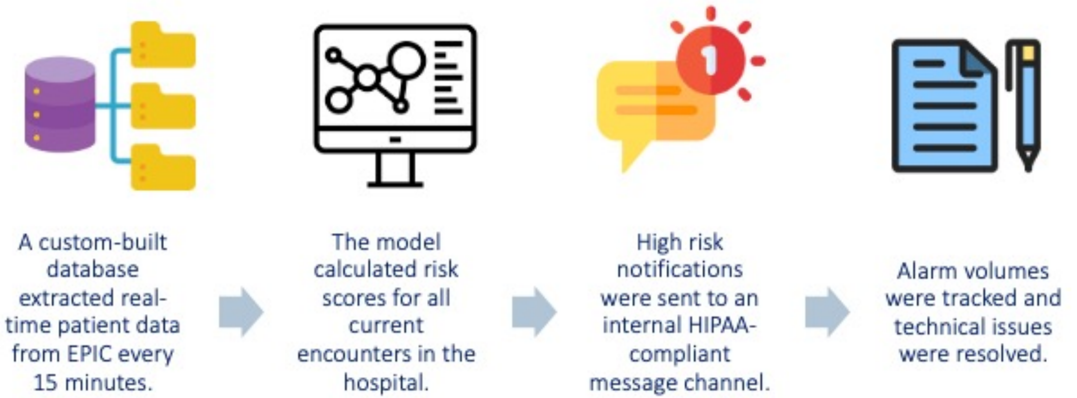
Identifying Label Leakage During a Silent Trial

- Pediatric sepsis prediction
  - Outcome definition: Blood Culture ∩ Antibiotics for 4 days ∩ Acute organ dysfunction
  - LSTM with 6-hour prediction window and 3-hour snooze
  - Retrospective training set: 17,491 unique encounters for children between 30 days old and 18 years old between November 1, 2016 – December 31, 2020
  - Temporal validation set: 6,545 unique encounters for children between 30 days old and 18 years old between January 1, 2021 – June 30, 2022

Identifying Label Leakage During a Silent Trial

	AUROC	AUPRC	PPV at 20% sensitivity (with 3hr snooze)	PPV at 50% sensitivity (with 3hr snooze)
Retrospective test set	0.816	0.483	0.769	0.612
Temporal validation	0.862	0.386	0.851	0.611

Silent Trial Design



Identifying Label Leakage During a Silent Trial

- Silent trial results
  - Model ran on 1,475 unique encounters over 2 months
  - Model generated 30 alarms per day >> 2 alarms per day expected
  - Model fired alarm on almost all patients in ED within first hour of arrival

Identifying Label Leakage During a Silent Trial

- Label leakage due to layer normalization in LSTM
  - In retrospective training data:
    - set maximum encounter length to 168 hours
    - truncated sepsis encounters at time of sepsis
  - Shorter encounter → more padding of encounter hours with 0s → smaller mean after layer normalization
  - Longer encounter → less padding of encounter hours with 0s → larger mean after layer normalization
  - In retrospective data, model learned to associate early hours of encounter with sepsis

Identifying Label Leakage During a Silent Trial

- Retrained LSTM without layer normalization using the same hyperparameters

	AUROC	AUPRC
Retrospective test set (with layer normalization)	0.816	0.483
Temporal validation (with layer normalization)	0.862	0.386
Retrospective test set (without layer normalization)	**0.782**	**0.01**

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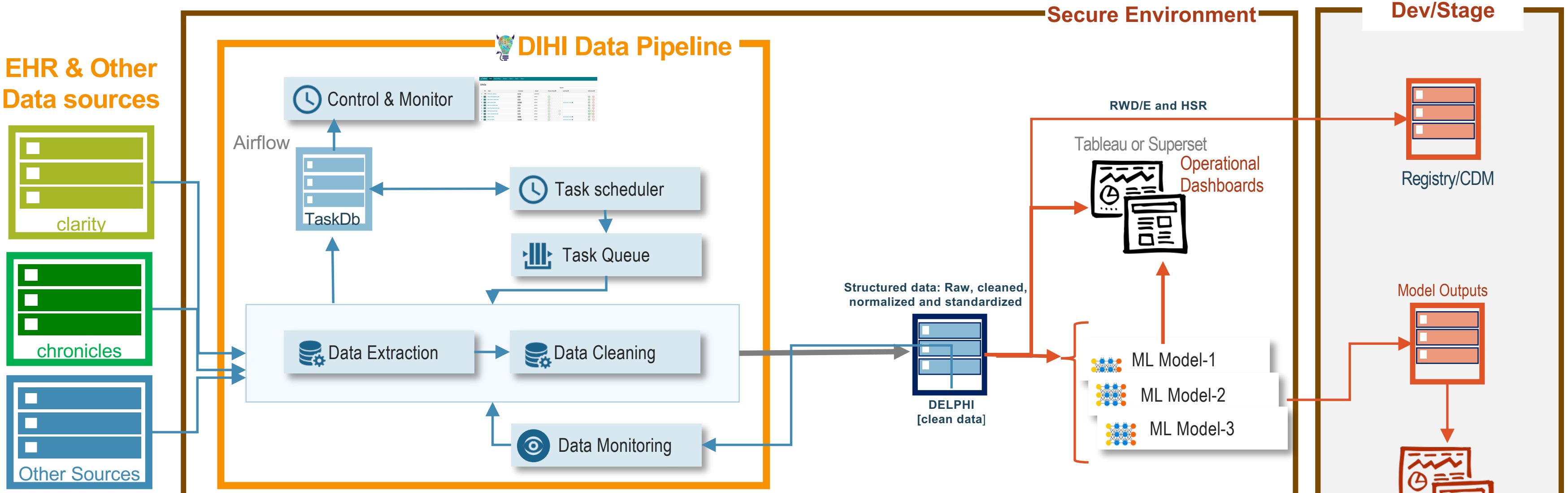
Build Modular Infrastructure to Support Many Projects

Flexible Data Pipeline Technology Infrastructure



- Docker + Kubernetes
- Airflow
- RabbitMQ
- Ansible
- Gitlab

- Data normalization standardization
- CCS class grouping
- ICD9 - ICT10 crosswalks
- Comorbidity groupings
- Lab grouping
- Meds therapeutic class
- Provider grouping

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Model Labels

Model Facts

Model name: Deep Sepsis **Locale:** Duke University Hospital

Approval Date: 09/22/2019 **Last Update:** 09/24/2019. **Version:** 1.0

Summary

This model uses EHR input data collected from a patient's current inpatient encounter to estimate the probability that the patient will meet sepsis criteria within the next 4 hours. It was developed in 2016-2019 by the Duke Institute for Health Innovation. The model was licensed to Cohere Med in July 2019.

Mechanism

- **Outcome** ……sepsis within the next 4 hours, see (1) for sepsis criteria
- **Output** ……0% - 100% probability of sepsis occurring in the next 4 hours
- **Patient population** ……all adult patients >18 y.o. presenting to DUH ED and admitted
- **Time of prediction** ……every hour of a patient's encounter
- **Input data source**……electronic health record (EHR)
- **Input data type** ……demographics, analytes, vitals, medication administrations
- **Training data location and time-period** ……DUH, 10/2014 – 12/2015
- **Model type**…… Recurrent Neural Network

Validation and performance

	Prevalence	AUC	PPV @ Sensitivity of 60%	Sensitivity @ PPV of 20%
Local Retrospective	18.9%	0.88	0.14	0.50
Local Temporal	6.4%	0.94	0.20	0.66
Local Prospective	TBD	TBD	TBD	TBD
External	TBD	TBD	TBD	TBD

Uses and directions

- **Operational use case(s):** Every hour, data is pulled from the EHR to calculate risk of sepsis for every patient at the DUH ED. A rapid response team nurse reviews every high-risk patient with a physician in the ED to confirm whether or not to initiate treatment for sepsis.
- **General use:** This model is intended to be used to by clinicians to identify patients for further assessment for sepsis. The model is not a diagnostic for sepsis and is not meant to guide or drive clinical care. This model is intended to complement other pieces of patient information related to sepsis as well as a physical evaluation to determine the need for sepsis treatment.
- **Examples of appropriate decisions to support:** Patient X has a high risk of sepsis according to the model. A rapid response team nurse discusses the patient with the ED physician caring for the patient and they agree the patient does not require treatment for sepsis.
- **Before using this model:** Test the model retrospectively and prospectively on local data to confirm generalizability of the model to the local setting.
- **Safety and efficacy evaluation:** Analysis of data from clinical trial (NCT03655626) underway. Preliminary data shows rapid response team, nurse-driven workflow was effective at improving sepsis treatment bundle compliance.

Comment | Open access | Published: 23 March 2020

Presenting machine learning model information to clinical end users with model facts labels

Mark P. Sendak, Michael Gao, Nathan Brajer & Suresh Balu

npj Digital Medicine 3, Article number: 41 (2020) | Cite this article

Warnings

- **General warnings:** This model was not trained or evaluated on patients receiving care in the ICU. Do not use this model in the ICU setting without further evaluation. This model was trained to identify the first episode of sepsis during an inpatient encounter. During long inpatient stays with multiple sepsis episodes, model accuracy needs to be further evaluated. The model is not interpretable and does not provide rationale for high risk scores. Clinical end users are expected to place model output in context with other clinical information to make final determination of diagnosis.
- **Examples of inappropriate decisions to support:** This model may not be accurate outside of the target population, primarily adults in the non-ICU setting. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment for sepsis.
- **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

Other information:

- **Outcome Definition:** https://doi.org/10.1101/648907
- **Related model:** http://doi.org/10.1001/jama.2016.0288
- **Model development & validation:** arxiv.org/abs/1708.05894
- **Model implementation:** jmir.org/preprint/15182
- **Clinical trial:** clinicaltrials.gov/ct2/show/NCT03655626
- **Clinical impact evaluation:** TBD
- **For inquiries and additional information:** please email mark.sendak@duke.edu

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AI System Monitoring at DIHI

Effective monitoring of AI/ML solutions also requires multidisciplinary combination of technical and human capabilities, including expertise in engineering, data analysis, AI/ML, and clinical domain knowledge employed during the solution development phase.

Model Monitoring

- Data quality monitoring
  - Input data accurate, complete, and up-to-date
  - Entity/grouper monitoring
  - Continuous monitoring
- Performance comparison
  - auroc, auprc wrt. training
  - Analysis cadence: M/Q/Y
- Output drift monitoring
  - Data distribution
  - Category distribution

Solution Monitoring

- Outcome monitoring
  - Project specific measures
  - Bi-annual for most solutions
- Workflow changes
  - Observation / documentation
- Usage monitoring
  - UI tools/dashboard usage
  - Secondary data analysis
- User feedback
  - Survey for model & solution usability and refinements

Operations Monitoring

- Alerting & notification
  - Flexible rules-based engine for alerting
  - Used in clinical workflow
  - Email/page/spok/sms etc.
- Technical monitoring
  - Model run times, failures etc.
  - Service level monitoring
- Regulatory & Policy
  - Compliance monitoring for regulation & Duke policies
  - Ethical and legal standards

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Sepsis Watch Post-Integration Lifecycle Management

	Monitoring & Evaluation	Update	Operational Management
Event based	• Debug issues that arise (e.g., data endpoint unexpectedly goes down)	• **Customize the UI for different user groups** • Train new versions of the model for new clinical settings	• Update user access • **Update reporting functionalities to support clinician management**
Recurring	• Monitor technical elements of the model and source data in pipeline • Monitor changes that affects work environment and use of model	• **Regularly scheduled maintenance (e.g., update groupers every 6 months)**	• **Conduct bi-annual end user training to ensure baseline knowledge of AI system**
Semi-Recurring	• **Audit the solution for impact on clinical and operational outcomes and impact on work environment**	• Improve the UI (e.g., add comment feature, automatically check boxes) • Scale to different use cases	• Convene governance committee monthly • Secure ongoing funding for AI system use
One-off	• Create channels for end users to report issues and provide user support services	• Create process and criteria to scope responses to user requests	• Determine ownership of model (e.g., clinical lead, technical lead)

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Engage with our community of practice!

AMA AMERICAN MEDICAL ASSOCIATION

ONC* Office of the National Coordinator for Health Information Technology

*Participating as a federal observer

Breakout Activity

Remainder of (Table Number) / 4 = X

X = 0
(Table 4, 8, 12, ...)

X = 1
(Table 1, 5, 9, ...)

X = 2
(Table 2, 6, 10, ...)

X = 3
(Table 3, 7, 11, ...)

Procurement → Development & Adaptation → Clinical Integration → Lifecycle Management

Remainder of (Table Number) / 4 = X

X = 0	X = 1	X = 2	X = 3
Procurement	Development & Adaptation	Clinical Integration	Lifecycle Management
1 Identify and prioritize a problem	3 Develop measures of outcomes and success of the AI product	6 Execute change management, workflow integration, and scaling strategy	7 Monitor and maintain the AI product
2 Evaluate AI as a viable component of the solution	4 Design a new optimal workflow to facilitate integration		8 Update or decommission the AI product
	5 Evaluate pre-integration safety and effectiveness of the AI product		

Discussion Questions

- How does your own organization carry out this part of the AI product lifecycle?
- What are common pitfalls you have seen organizations make as they carry out this part of the AI product lifecycle?
- What are the most effective ways you have seen organizations carry out this part of the AI product lifecycle?

Between now and 12 PM, discuss these questions with colleagues at your table and prepare a 45 second report-out to share a best practice with the group

Report Out

Duke Institute for Health Innovation

health ai partnership

Thank you

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