

Creating an AI-Enabled, Academic Learning Health System: *Now it's Personal*

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Texas AI Symposium - 2025 Houston, TX May 15, 2025



MEDICAL CENTER

Al Discovery & Vigilance to Accelerate Innovation & Clinical Excellence

ADVANCE

Let's start with a case...

Dec 11, 2017: 5:30am...





October, 2017: To the ER...

- Acute Paroxysms
 - Severe Headache
 - Profuse Sweating
 - Palor
 - Palpitations
 - Panic/Anxiety
 - Flank Pain
 - Nausea
 - Tachycaria
 - Severe Hypertensive
- Years of symptoms
- Discharged as atypical migraine...



Spells continue... what is this?!

- Back home to Indy
- 4 more "spells"
- Neurologist "occipital neuralgia"
- Back to work -> another spell
- In my office, realized what this must be...
- Called MD to get tested...



Diagnosis: Results while at AMIA 2017

- Metanephrines >30x normal!
 - Diagnosis confirmed:
 - <u>Pheochromocytoma</u>
- Next steps...
 - Needed CT abdomen
 - Had to push
 - Needed treatment
 - Rushed Endo visit
 - Started Rx
 - Needed experienced surgeon
 - Had to search
 - Ramping up Rx
 - I accelerated by 1-2 months



Recovery and Lessons/Realizations

- Upon awakening:
 - Grateful! Lucky!
 - Realization:
 - I could have died
 - Others have
 - I didn't because of who I am
 - Not right! Not necessary!
- Many ways that my <u>diagnosis</u>, <u>care</u>, & future <u>care of others</u> like me could have been improved through informatics
- We must learn and do better!



Lesson #1: Diagnostic Error Abounds! We can must do better!



Alternative: "When you hear hoofbeats, expect horses, but <u>consider</u> zebras"

pyright 2012 by WNCAD Alliance.

Diagnostic DSS – still limited at point-of-care

BMJ QUALITY SAFETY

Information technology applications to reduce diagnostic errors

The incidence of diagnostic errors

Cognitive debiasing to reduce diagnostic errors

qualitysafety.bmj.com



BMJ



Internist-1/QMR

MYCIN







About 3,410,000 results (0.43 seconds)

Pheochromocytoma: high blood pressure, headaches, and anxiety ...

https://www.endocrineweb.com/conditions/.../pheochromocytoma-tumor-central-adre... May 27, 2014 - The classic symptoms of pheochromocytomas (or pheos) are those attributable to excess adrenaline production. Often these patients will have recurring episodes of sweating, **headache**, and a feeling of high anxiety. ... Excess sweating (generalized) Racing heart (**tachycardia** and palpitations)

People also ask	
Can you have tachycardia and hypertension?	\vee
What is the most common symptom of pheochromocytoma?	\sim
Can high blood pressure cause headaches and eye pain?	\sim
Can you feel high blood pressure in your head?	\vee

Feedback

Severe Paroxysmal Hypertension (Pseudopheochromocytoma ...

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/484999 -

by SJ Mann - 1999 - Cited by 106 - Related articles

Severe, symptomatic paroxysmal **hypertension** always generates suspicion of a ... such as **headache**, chest pain, dizziness, nausea, palpitations, flushing, and ... pressure, unilateral flushing, dizziness, weakness, **tachycardia**, and polyuria.

Lesson #2: We don't have a LHS today

Lesson/Realization #2a: Actually, we do have one common way of learning, as a system...



The Learning Health System (LHS) - Definitions

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of certified stake	rule beens at "5 o'clock" with the establishment of a multi-	trated on the right side of Figure 2. Interrupted cycles occur when
	holder learning community. Guided by the community, the cycle	entirely different, specialized professional groups within an organiza-
ecure mob proce	eds with collection of data to capture what is happening now	tion execute each component of the cycle. As shown in the figure, a
eporting o (perfo	ormance to data), analysis of these data to generate evidence of	group specializing in P2D might be focused exclusively on program
Dhama's gos	improvement might be effected (data to knowledge), integration	evaluation or quality assessment; a group specializing in D2K might be
it from an I	cally generated evidence with relevant evidence gathered by	focused on health services research; a group specializing the K2P
Office of the N ment	s, and intervention based on that evidence to engender improve- (knowledge to performance). From there, the cycle repeats in a	might be exclusively focused on change implementation. The mem- bers of each of these relatively homogeneous groups will have similar
ion Technolog series	s of iterations over which data-driven improvement can occur.	educational backgrounds and professional cultures, but the back-
Corresponding T	There is nothing fundamentally new about cyclic improvement	grounds and cultures of each group may differ greatly from each
proce	esses. This concept traces back to the seminal work of Deming	other.
and t	the subsequent widespread use of PDSA cycles in health care	Interrupted cycles necessitate challenging handoffs between
impro	ovement.7 The differentiators of the LHS-three in number, in my	these different groups. Less than perfect communication between the
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mediu © 202	an open access article under the terms of the Creative Commons Attribution	n-NonCommercial License, which permits use, distribution and reproduction in any

Η

"Learning health systems (LHS) are healthcare systems in which knowledge generation processes are embedded in daily practice to produce continual improvement in care."

Source: Olsen L, Aisner D, McGinnis JM. The learning healthcare system: workshop summary. Natl Academy Pr; 2007





Traditional path from generation of evidence to its application

Research-Practice Paradigm – EBM+EGM

- Clinical care activities <u>not</u> entirely distinct from research activities
- Must consider EGM when we practice to advance science and care
- Many EGM activities ongoing & need support to achieve goals
- Advancing EGM is critical to completing the EBM lifecycle
- Multiples enabling factors & stakeholders



We want a learning cycle, but...

- Even a simple form of learning "What did I miss?"
- Absence* of feedback loops for clinicians, the system
- Even when "system" has/can share new evidence
- We haven't *decided* to use system for "learning"



Embi & Payne. Medical Care, 2013

Local Learning Systems...

Goals



"Learn from every patient"

Overcome fragmentation among current units/committees, "silos of excellence"

"Scale & Spread" - systematically monitor, study, scale

Improve care/satisfaction among stakeholders

Improve processes, efficiency, outcomes, costs (value)... In an equitable manner

Accelerate discoveries and translation of evidence

Disseminate discoveries, experiences and best practices

Leverage LHS approaches as key differentiator

				Check for updates
Received: 21 December 202	0 Revised: 30 May	2021 Accepted: 3 June 2021		
DOI: 10.1002/lth2.10281				
EXPERIENCE RE	PORT		Lea	arning Health Systems
The Indiana	a Learning	g Health Syste	m Initiative: E	Early experience
developing	a collabo	rative, regiona	al learning hea	alth system
Titus Schleyer ^{1,2} Christopher Wea Chris Frederick ^{1:} Sarah Zappone ¹	[©] Linda V aver ^{7,8} Mi ² Siu Hui ¹ Michael B	Villiams ^{3,4,5} Jona chele Saysana ^{8,9} ^{,13} Areeba Kara ² Bushey ^{14,15} Rand	athan Gottlieb ⁶ Jose Azar ^{2,10} Jo Laura Ruppert ¹ all Grout ^{1,9,16} P	osh Sadowski ¹¹ eter J. Embi ^{2.12.17}
Center for Biomedical Infor	matics, Regenstrief Instit	ute, Inc, Indianapolis, Indiana, USA		
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Department of Psychiatry,	Indiana Univ	WILLIAM E SMOYER ^{1,2} 'LEA	RN FROM EVERY PATIENT' ST	UDY GROUP [†]
¹⁴ Informatics, Eskenazi Healt	th, Indianapo	Nationalda Children's Hamital Columbus	OU: 9 Department of Redistrice The Obie S	tota University Columbus, OE @ Children's Hensital of the Kine's Daughtered
¹⁷ Administration, Indiana Un	iversity Heal	Norfolk, VA; 4 Department of Biomedical Inf	ormatics, The Ohio State University, Columb	is, DH, USA.
		Correspondence to William E Smoyer at Center for 43205, USA, E-mail: william.smover@nationwidech	r Clinical and Translational Research, W303, The R ildness.org	lesearch Institute at Nationwide Children's Hospital. 700 Children's Drive, Columbus, O
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Titus Schleyer, Center for Bio Informatics Regenstrief Insti	omedical tute Inc. 11	This article is commented on by Stevenson o	bers are listed in the Acknowledgements. n pages 119–120 of this issue.	
W. 10th Street, Indianapolis,	IN 46202, U			
Email: schleyer@regenstrief.c	org	PUBLICATION DATA	AIM The convergence of three m	ajor trends in medicine, namely conversion to electronic
Funding information	web and Out	Published online 22nd August 2016.	health records (EHRs), prioritizat healthcare expenditures, has cre	ion of translational research, and the need to control ated unprecedented interest and opportunities to develop
Grant/Award Number: 1R01	HS027185-	ABBREVIATIONS	systems that improve care while system' requires systematic char	reducing costs. However, operationalizing a 'learning healt ages that have not yet been widely demonstrated in clinical
Cook Medical, Grant/Award Advances in Medicine (AIM)	Number: Th grant: Lilly	EHR Electronic health record LEEP 'Learn From Every Patient'	practice. METHOD We developed, implem	ented, and evaluated a model of EHR-supported care in a
Endowment, Grant/Award N	umber: Phy	LHS Learning health system	cohort of 131 children with cerel	oral palsy that integrated clinical care, quality improvement,
Scientist Initiative; National Advancing Translational Scie	Center for noes, Grant/		RESULTS Children treated in the	LFEP Program for a 12-month period experienced a 43%
Award Number: ULI TR0025	529		admissions, a 30% reduction in a	(p=0.030 vs prior 12mo period), a 27% reduction in inpatien emergency department visits (p=0.001), and a 29% reduction
	isplay a men	u	in urgent care visits (p=0.046). LI healthcare costs of 210% (US\$70	EP Program implementation also resulted in reductions in I14/child) versus a Time control group, and reductions of
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	William E. Smoyer,	Transforming the deliver	y of health care to maximize	Hospital recently developed and implemented a
	MD The Research	simultaneously reducing of	costs, is fundamental to re-	clinical care, and OI and then measured its ability
745	Institute at Nationwide	forming health care. Achiev	ring such a goal requires fun-	multaneously improve clinical care, reduce care cost
	Children's Hospital,	damental changes to healt	h care delivery, through so-	generate new knowledge to improve care. The pilo
	and The Ohio State	people, processes, and tech	nology. ¹ As such efforts con-	eral key features. First, a clinical program and a c
	University, Columbus	tinue to gain momentum	they increasingly demon-	leader committed to systematic care improvement
		strate the importance of w	eaving continuous and sys-	that program were identified. Key stakeholde
	Peter J. Embi, MD, MS	tematic evidence-generat	Ing medicine activities into	cruited to the program included 4 physicians, 1 11 clinical staff members 1 program administrator
	The Ohio State	of systematic care improve	ement by coupling evidence	pital EHR team representatives, 1 enterprise data
	Columbus.	generation with evidence a	pplication to health care that	house team representative, 2 research inform
		embodies and enables the	goals of the learning health	systems team representatives, 2 hospital informati
	MD, PhD, MBA	To date, there have bee	n multiple efforts to establish	Once this team was assembled, the benef

LHSs, oriented primarily around the technical and operabional integration of electronic health records (EHRs) including (1) implementation of standardized care among multiple health care systems (ie, a top down (evidence- and expert opinion-based), (2) systematic aprorach).⁶⁴ While substantial progress has been made

Lesson #3: Data are Critical

• Data relevant to health largely exist beyond traditionally collected healthcare data



In my case: Tachycardia at rest each day



Informatics & 'omics integration

Informatics must provide coherent framework for dealing with multi-scale, population data, including:

- Phenome,
- Genome,
- Exposome
- their interconnections.



LHS Infrastructure: *Learning From Data*

Bridging Health IT and Informatics

(R) Check fo Received: 22 February 2022 Revised: 11 March 2022 Accepted: 12 March 20 DOI: 10.1002/ind/10/109 LEARNING FROM DATA Better together: Integrating biomedical informatics and healthcare IT operations to create a learning health system during the COVID-19 pandemic Philip R.O. Payne¹ | Adam B. Wilcox¹ | Peter J. Embi² | Christopher A. Longhurst Abstract The growing availability of multi-scale biomedical data sources that can be used to Department of Biomedical Informati enable research and improve healthcare delivery has brought about what can be anderbilt University Medical Center ashville, Tennessee, USA described as a healthcare "data age." This new era is defined by the explosive growth n bio-molecular, clinical, and population-level data that can be readily access ment of Riemedical Infe in Diego Health, La Jolla, California, US researchers, clinicians, and decision-makers, and utilized for systems-leve proaches to hypothesis generation and testing as well as operational decision-ma hillo R.O. Payne, Institute for In ing. However, taking full advantage of these unprecedented opportunities present Vashington University School of Medicir 444 Forest Park Ave, Campus Box 8102 8. Louis, MO 63110-2212, USA. an opportunity to revisit the alignment between traditionally academic biomedica informatics (BMI) and operational healthcare information technology (HIT) personne and activities in academic health systems. While the history of the academic field o BMI includes active engagement in the delivery of operational HIT platforms, in many porary settings these efforts have grown distinct. Recent experiences during the COVID-19 pandemic have demonstrated greater coordination of BMI and HIT activities that have allowed organizations to respond to pandemic-related change more effectively, with demonstrable and positive impact as a result. In this position paper, we discuss the challenges and opportunities associated with driving alignmen tween BMI and HIT, as viewed from the perspective of a learning healthcare sys tem. In doing so, we hope to illustrate the benefits of coordination between BMI an HIT in terms of the quality, safety, and outcomes of care provided to patients an strating that these two groups can be "better togeth KEYWORD! 1 | INTRODUCTION dministrators to support data-driven solutions to a broad variety of Biomedical research and healthcare practice is experiencing a new use cases, from drug discovery to point-of-care decision-making to pr "data age," where bio-molecular, clinical, and population-level data are cision approaches to individual and population health.¹⁻¹³ Considering ingly available and suitable for use in support of both hypothesis these opportunities, we believe that it is important to consider t generation and testing as well as operational decision-making. Ideally, ways in which the design and delivery of biomedical informatics (BMI) This is an open access article under the terms of the Creative Commons Attribution ded the original work is properly cited. sished by Wiley Periodicals LLC on behalf of University of Michi © 2022 The Authors, Learning Health Systems of Learn Health Sys. 2022;6:e10309. https://doi.org/10.1002/im2.1030



FIGURE 2 Conceptual model for a "rapid learning" healthcare system in which BMI and HIT work synergistically. In this example, four major stages for the design and implementation of a data-driven intervention strategy are shown, spanning the capabilities of BMI and HIT leaders and practitioners. For each stage, examples of the types of competencies and methods that contribute to each such phase are shown

Payne, PRO, Wilcox A, Embi PJ, Longhurst C. Learning Health Systems. 2022 (Learning from Data Series)

Lesson #4: Creating AI-Enabled LHS is a Socio-Technical Challenge

- Information Technologies only part of the solution
 - Fiscal/Administrative
 - Aligning incentives
 - Cultural/Behavioral
 - Individual/Societal concerns
- Must consider EGM issues at several levels
 - Policy level
 - Systems level
 - Individual level



• A growing area in need of focus: Artificial Intelligence in Health/care...



Al Poised to Transform Healthcare and Academic Medicine







Ongoing Activities in Health Artificial Intelligence

MEDICAL CENTER





Health AI Research & Development

Al Discovery & Vigilance to Accelerate Innovation & Clinical Excellence **MDVANCE**

Focus and Goals of ADVANCE Center



VUMC AI Governance:

Led by Al Technology (AIT) Committee

Tracking and responding to changes in federal and state AI regulation

Writing policies and refining approaches to safe, effective, compliant use, while enabling research/innovation

Managing procurement of "internally-" & "exeternally sourced" AI solutions

Inventory of AI solutions and deployments

Development of Al capabilities for ongoing monitoring of algorithms (Algorithmovigilance)

Al-driven Healthcare

- Growth in AI-driven healthcare
- Ongoing development and application of such tools
- Significant potential for improved care and efficiencies
- Evidence of **unintended negative impacts**
- We need for a "learning system" to:
 - Monitor algorithm-driven healthcare for effects
 - Mechanisms respond/adjust to unintended effects, drift

RESEARCH ARTICLE

ECONOMICS

Dissecting racial bias in an algorithm used to manage the health of populations

Ziad Obermeyer $^{1,2\ast}\!\!,$ Brian Powers $^3\!,$ Christine Vogeli $^4\!,$ Sendhil Mullainathan $^{5\ast}\!\!+\!\!$

The NEW ENGLAND JOURNAL of MEDICINE

MEDICINE AND SOCIETY

Debra Malina, Ph.D., Editor

Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms

Darshali A. Vyas, M.D., Leo G. Eisenstein, M.D., and David S. Jones, M.D., Ph.D.

Biases in Data: Known <u>and</u> Unknown

Caution about generalizability

Unexpected results can be expected

Must monitor to promote trust

Need new systems and approaches

Essential for safe, efficient, effective and equitable care

"Algorithmovigilance"

"The scientific methods and activities relating to the evaluation, monitoring, understanding, and prevention of adverse effects of algorithms in health care."

Akin to pharmacovigilance for monitoring drug effects

Increasingly important as AI/ML-derived algorithms are used

JAMA Network Open...

Invited Commentary | Health Informatics

Algorithmovigilance—Advancing Methods to Analyze and Monitor Artificial Intelligence–Driven Health Care for Effectiveness and Equity Peter J. Embi, MD, MS

In recent years, there has been rapid growth and expansion in the use of machine learning and other artificial intelligence approaches applied to increasingly rich and accessible health data sets to develop algorithms that guide and support health care.¹ As they make their way into practice, such algorithms have the potential to fundamentally transform how health care decisions are made and, therefore, how patients are diagnosed and treated.² While such approaches hold great promise for enabling more precise, accurate, timely, and even fair decision-making when properly developed and applied, there is also growing evidence that systematic biases can lead to unintended and even severe consequences.^{3,4} Mirroring disparities and inequities inherent in our society and health system,⁵ such biases can be inherent in not only the underlying data used to develop algorithms but also how algorithmic interventions are deployed.

Related article

Author affiliations and article information are listed at the end of this article.

Elsewhere in *JAMA Network Open*, Park and colleagues⁶ present findings from a study evaluating different approaches to the debiasing of health care algorithms developed to predict postpartum depression (PPD) among a cohort of pregnant women with Medicaid coverage. The researchers, from IBM Research, leveraged the IBM MarketScan Medicaid Database, a deidentified, individual-level claim records data set with approximately 7 million Medicaid enrollees across multiple states, to derive their algorithms. They started by developing 2 sets of machine learning models trained to predict 2 outcomes: (1) diagnosis or treatment for PPD and (2) postpartum mental health service utilization. Their initial, risk-adjusted generalized linear models for each outcome demonstrated a notable difference in the cohort with binarized race, with White patients having twice the predicted likelihood of being diagnosed with PPD compared with Black patients and a significantly higher likelihood of utilizing mental health services. However, as the authors point out,

Embi PJ. JAMA Network Open. 2021;4(4):e214622.

Algorithmovigilance via learning health system

Continuum of algorithmovigilance approaches to ongoing model monitoring and maintenance

Sustainable deployment of clinical prediction tools—a 360° approach to model maintenance Davis S, Embi PJ, Matheny M. J Am Med Inform Assoc, May 2024

The Vanderbilt Algorithmovigilance Monitoring and Operations System (VAMOS)

- Novel socio-technical system of processes and analytical dashboarding for (near) realtime Health AI monitoring:
 - Organizational governance and oversight
 - Capturing and Reporting Adverse events
 - Team-based monitoring
 - Responding to issues

VAMOS Human Centered Design:

Emergent Design Considerations

Users	Support a broad range of users with differing goals and expertise
Use Cases	Support diverse algorithms and implementation use cases
Meta-Data	Enable access to model facts, criticality and organizational contacts
Analytics	Support analytic functions including performance metric monitoring and drift detection
Flexibility	Provide flexible & customizable temporal displays of algorithm performance and impact
Feedback	Receive and display feedback from algorithm end-users
Notes	Log notes and action items for each algorithm
Reporting	Provide reporting tools geared to multiple audiences
Communication	Support communication about algorithmic management between technical, operational, and clinical teams

Initial Users:

- ✓ AIT VUMC AI Governance Committee
- ✓ VUMC Health IT

VANDERBILT VUNIVERSITY MEDICAL CENTER

Al Discovery & Vigilance to Accelerate Innovation & Clinical Excellence

VAMOS DASHBOARD: MOCKUP

Show: All			\checkmark	Search:		٩	Show Alerts	e Reports			
Model Name	•	State	Criticality	Class	Туре	Notices	PERFORMANCE	PROCESS	OUTCOMES	FAIRNESS	
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Surgical scheduling	Ŧ	Inactive	1	Operations	Patient list		🛕 Accuracy drift	~	~	~	
Post-partum hemorrhage	Ŧ	Maint.	1	Research	Storyboard	Q	~	~	~	Urban/rural issue	
AI-VTE		Active	2	Clinical	Order set	:=	~	~	▲ VTE rate increase	~	
Others											
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🔀 Maintenance State

- 🔀 Inactive State
- 🔀 Research Class
- ☑ Clinical Class
- 🔀 Operational Class
- 🔀 Others ...

- **Feedback from end users**
- :
 Input features
- ⑦ Upcoming planned downtimes
- ☐ Upcoming changes/upgrades

Other anomalies ...

*Patent Pending

VAMOS Application

Vanderbilt Algorithmovigilance Monitoring and Operations System

>

MEDICAL CENTER

Directory

Model Name	State	Criticality	Class	Туре	PERFORMANCE	PROC	CESS	Ουτα	OMES	FAIRN	IESS	Actions	
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Post-partum hem	Maint.	1	Research	Storyboard	~		~		~		•	Expand	

VAMOS Application

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	Owner: Peter Embí Email: peter.embi@ Phone: 615-302-11 1	vumc.org 11	Clinic contact: M Email: Megan.Salwei@ Phone: 615-343-	egan Salwei vumc.org 1528			📽 Contac 📑 Reports	sts for model	Q Explore t ≆ Input fea	he data tures	<u>Iıll</u> Sub-popi ♥ User feed	ulation analysis Iback
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*Patent Pending

Creating a Federated Algorithmovigilance (AV) Network

Next Steps / Opportunities

Expand to other users / use cases & Validate

Invitations for early adopter sites/ VAMOS Collaborative partners

Standards development (technical, data, API, Measures, Responses, etc.)

Enhance Platform, Grow Open-Access efforts, Establish Network

Lesson #5: Informatics can must help

- Support Informatics-enabled LHS for discovery & care
- Effective AI to improve prevention, diagnosis, treatment
- Al to accelerate discovery and translation to practice
- Informatics & AI to overcome health disparities
- Empower people and systems to improve health/care
- Create a <u>virtuous cycle</u> of activities to advance healthcare, quality, research, and public health

Embi, Peter J., Payne, Philip R.O. "Evidence generating medicine: redefining the research-practice relationship to complete the evidence cycle." Medical care 51 (2013): S87-S91.

Lesson #5: We can must help

- Urgency!
 - People are suffering. Needlessly.
- Shouldn't have to be an MD, wellconnected, to get great care
- The system isn't working for too many
- Where we know how to fix it, we <u>must</u> act!
- Where we don't (yet), we must continue to innovate!

Thank You!

Business Card

peterembi

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