Supporting Health AI for Impact

Christopher A. Longhurst, MD, MS   **@CALonghurst**
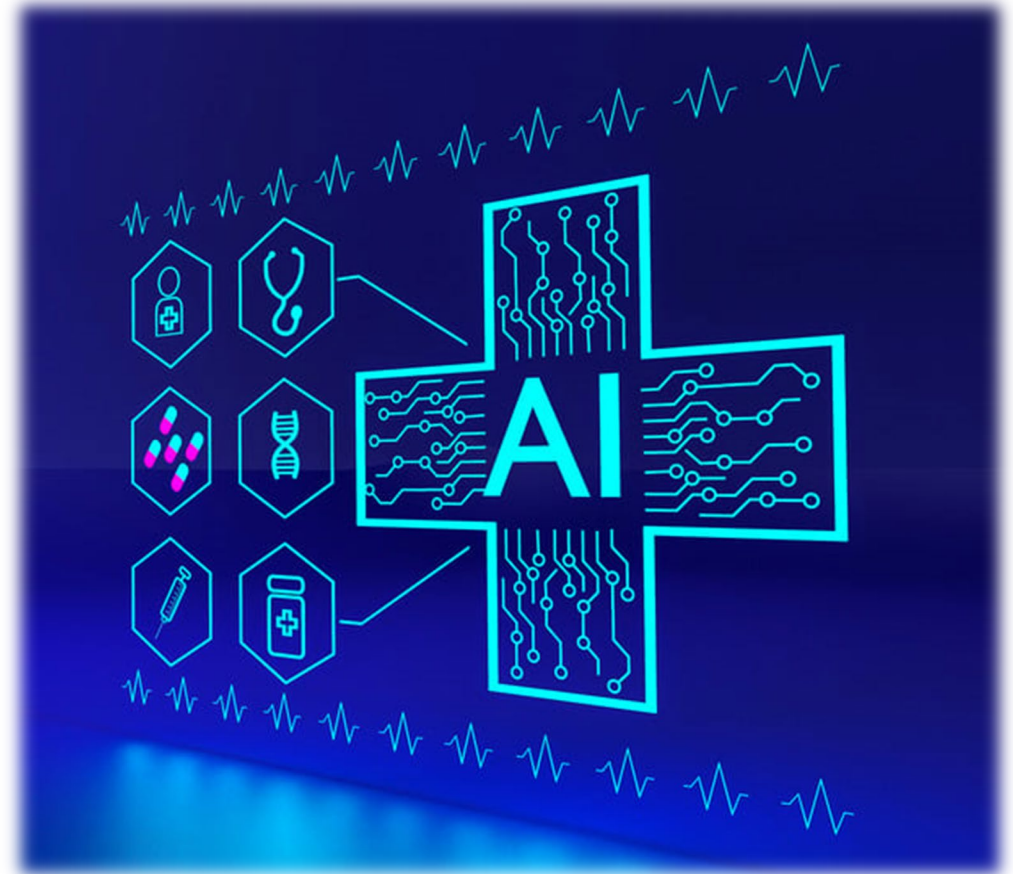
Chief Clinical & Innovation Officer, UC San Diego Health

Executive Director, Jacobs Center for Health Innovation

Professor and Associate Dean, UC San Diego School of Medicine

UC San Diego Health

Compelling Need for Shared Responsibility of AI Oversight

- The **FDA** should be empowered with:

  1. Increased authority to **require transparent outcomes data** about products

  2. Increased authority for **post-marketing surveillance**

- **Healthcare delivery organizations** should be subject to a CMS requirement for local testing and monitoring to ensure that AI oversight is a shared responsibility of developers and users

UC San Diego Health

Nature Digital Medicine, January 2023

npj | digital medicine

COMMENT   **OPEN**   can AI help?

Bending the p

David C. Classen [1] ✉, Christo

This paper reviews the curr[...]e (AI) techniques to patient safety.
This paper defines patient s[...]care, including diagnostic errors,
misdiagnosis, adverse even[...]ses of AI in patient safety and the
relative adoption of these t[...]the limitations of these AI systems
and the challenges with eva[...]oping a proactive agenda for AI in
healthcare that includes ma[...]

npj Digital Medicine (2023)6[...]

Table 2. Top use cases for the application of AI to specific clinical problems in patient safety.

1. Actionable real time patient safety electronic clinical quality measures
2. Surgical complication prediction
3. Pressure ulcer prediction
4. Hypoglycemia prediction
5. Sepsis prediction
6. Suicide prediction
7. Diabetic eye AI screening
8. Breast imaging cancer screening
9. Chest x-ray imaging AI diagnosis
10. Skin melanoma AI diagnosis
11. Chest x-ray imaging AI cancer screening
12. Patient self-managed electronic safety dashboards

Check for updates

UC San Diego Health

March 28, 2020 – AI in Diagnostic Radiology
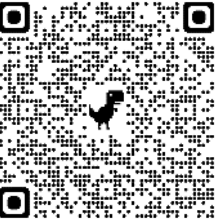
Artificial Intelligence Enables Rapid COVID-19 Lung Imaging Analysis at UC San Diego Health

With support from Amazon Web Services, health care providers are using AI in a clinical research study aimed at speeding the detection of pneumonia, a condition associated with severe COVID-19

April 07, 2020 | Heather Buschman, PhD

For most patients who have died of COVID-19, the pandemic disease caused by a novel coronavirus, the ultimate cause of death was pneumonia, a condition in which inflammation and fluid buildup make it difficult to breathe. Severe pneumonia often requires lengthy hospital stays in intensive care units and assistance breathing with ventilators — medical devices now in high demand in some cities grappling with a surge of COVID-19 cases.

To quickly detect pneumonia — and therefore better distinguish between COVID-19 patients likely to need more supportive care in the hospital and those who could be followed closely at home — UC San Diego Health radiologists and other physicians are now using artificial intelligence (AI) to augment lung imaging analysis in a clinical research study enabled by Amazon Web Services (AWS).

The new AI capability has so far provided UC San Diego Health physicians with unique insights into more than 2,000 images. In one case, a patient in the Emergency Department

UC San Diego uses AWS cloud to deploy homegrown AI algorithms for COVID-19

The health system's algorithms can detect early pneumonia on medical imaging with the precision of a subspecialist radiologist.

By Bill Siwicki | June 24, 2020 | 11:57 AM
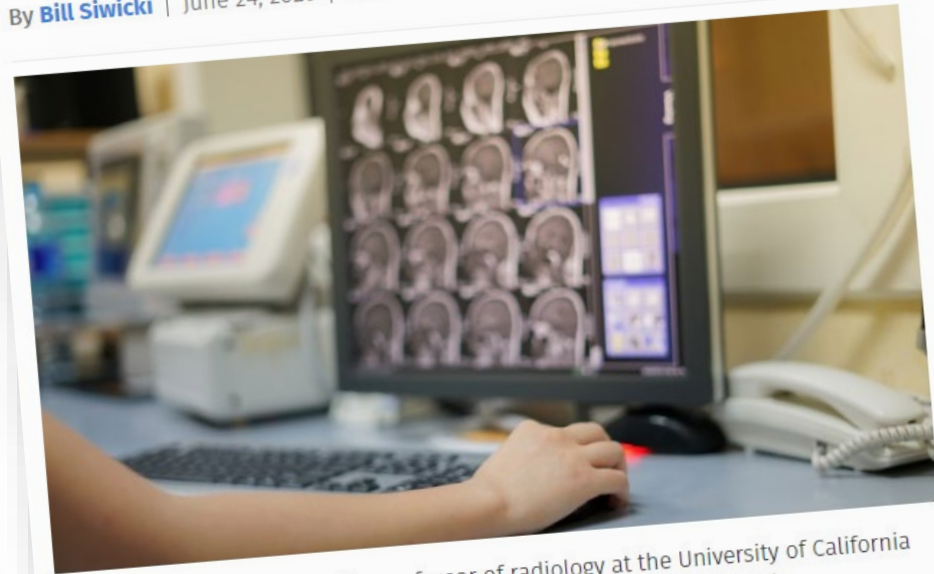
Dr. Albert Hsiao is an associate professor of radiology at the University of California San Diego School of Medicine and a radiologist at UC San Diego Health.
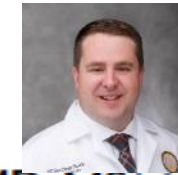
UC San Diego Health

JACEP OPEN
JOURNAL OF THE AMERICAN COLLEGE OF EMERGENCY PHYSICIANS OPEN

WILEY

BRIEF RESEARCH REPORT

Infectious Disease

Deployment of artificial intelligence for radiographic diagnosis of COVID-19 pneumonia in the emergency department

Christian Dameff, MD
Emergency Medicine

Morgan Carlile MD[1] | Brian Hurt MD, MS[2] | Albert Hsiao MD, PhD[2] |
Michael Hogarth MD[3] | Christopher A. Longhurst MD, MS[3] | Christian Dameff MD, MS[1,3]

"Of the 5,125 total visits and 1,960 chest radiographs obtained in the ED during the study period, 1,855 were analyzed by the algorithm. Among these, emergency physicians were surveyed for their experiences on 202. Overall, **86% either somewhat agreed that the intervention workflow. 20% of respondents reporte impacted clinical decision making**."

In its blueprint for an AI Bill of Rights, the Biden administration outlined that AI "**testing conditions should mirror as closely as possible the conditions in which the AI will be deployed**." The administration has also recommended that **AI should be monitored for adverse outcomes on an ongoing basis rather than a single, off-site evaluation.**

Christian Dameff, MD, MS, UC San Diego
Health Department of Emergency Medicine,
200 W Arbor Drive MC #8676, San Diego, CA
92103, USA.
Email: cdameff@health.ucsd.edu

San Diego Health
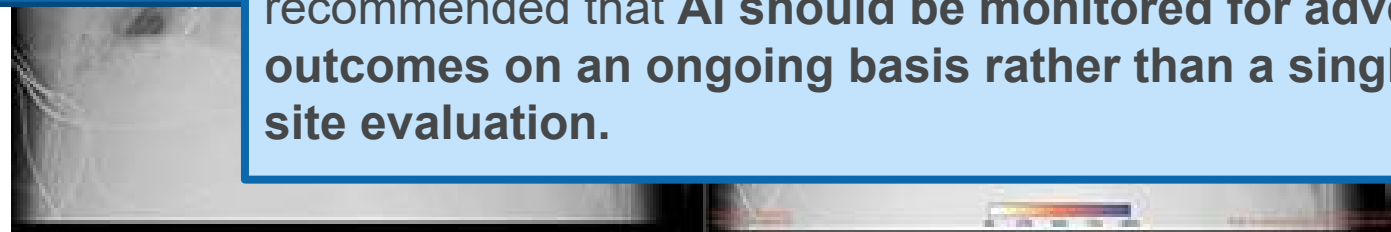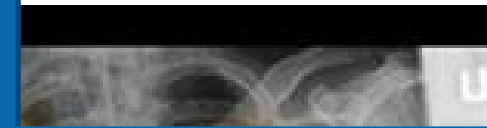
Public Health Preparedness, March 2023

Artificial Intelligence Functionalities During the COVID-19 Pandemic

Milad Ahmadi Marzaleh PhD[1], Mahmoudreza Peyravi PhD[1], Shahrokh Mousavi MD[2], Fatemeh Sarpourian PhD[3], Milad Seyedi BSC[4] and Naseh Shalyari PhD[1]

[1]Department of Health in Disasters and Emergencies, Health Human Resources Research Center, School of Health Management and Information Sciences, Shiraz University of Medical Sciences, Shiraz, Iran; [2]Student Research Committee, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran; [3]Student Research Committee, Department of Health Information Technology, School of Health Management and Information Sciences, Shiraz University of Medical Sciences, Shiraz, Iran and [4]Department of Computer Engineering, Sanandaj Branch, Islamic Azad University, Sanandaj, Iran

Abstract

Background: The coronavirus disease 2019 (COVID-19) pandemic has led us to use virtual solutions and emerging technologies such as artificial intelligence (AI). Recent studies have clearly demonstrated the role of AI in health care and medical practice; however, a comprehensive review can identify potential yet not fulfilled functionalities of such technologies in pandemics. Therefore, this scoping review study aims at assessing AI functionalities in the COVID-19 pandemic in 2022.

Methods: A systematic search was carried out in PubMed, Cochran Library, Scopus, Science Direct, ProQuest, and Web of Science from 2019 to May 9, 2022. Researchers selected the articles according to the search keywords. Finally, the articles mentioning the functionalities of AI in the COVID-19 pandemic were evaluated. Two investigators performed this process.

Results: Initial search resulted in 9123 articles. After reviewing the title, abstract, and full text of these articles, and applying the inclusion and exclusion criteria, 4 articles were selectd for the final analysis. All 4 were cross-sectional studies. Two studies (50%) were performed in the United States, 1 (25%) in Israel, and 1 (25%) in Saudi Arabia. They covered the functionalities of AI in the prediction, detection, and diagnosis of COVID-19.
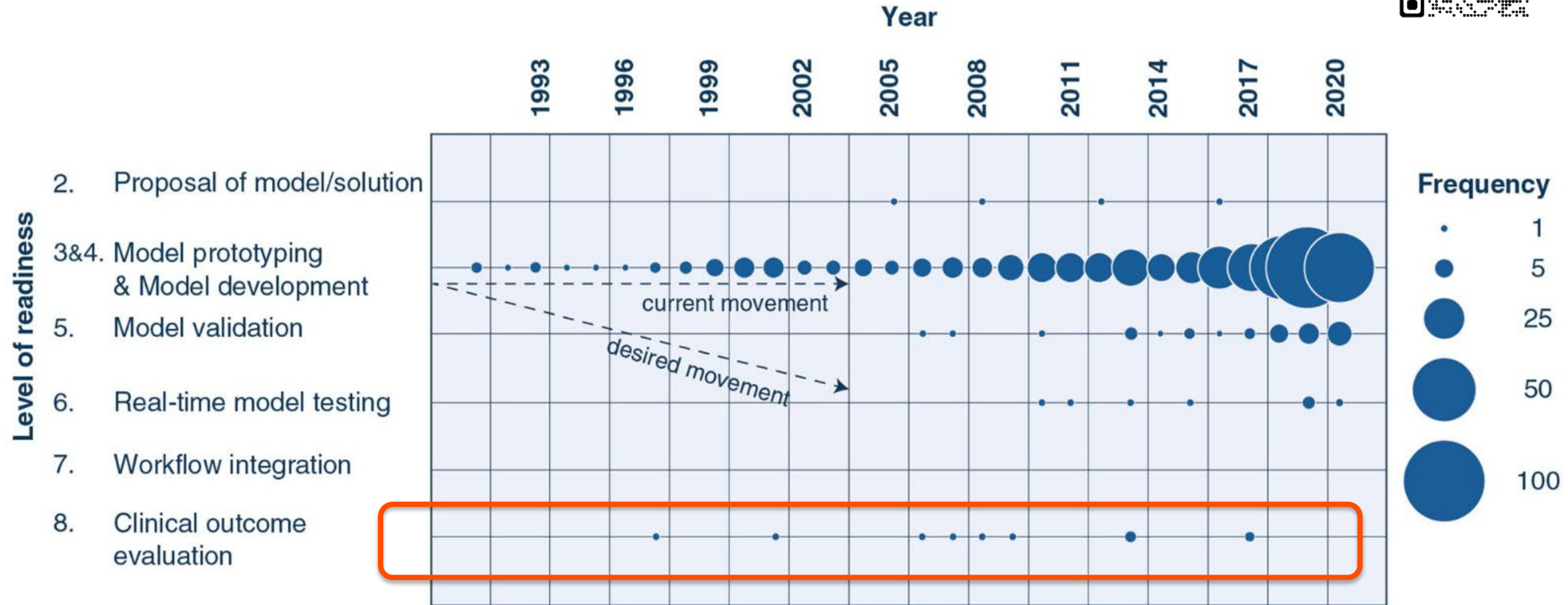
Over **9000** articles…
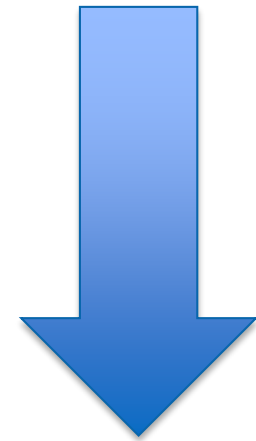
…just **4** studies w/ clinical outcomes!!

UC San Diego Health

We need more clinical outcome evaluation for AI

UC San Diego Health

npj | digital medicine

www.nature.com/npjdigitalmed

COMMENT   **OPEN**

Bending the p[...]can AI help?

David C. Classen [1][✉], Christo[...]

This paper reviews the curre[...]e (AI) techniques to patient safety.
This paper defines patient s[...]care, including diagnostic errors,
misdiagnosis, adverse event[...]ses of AI in patient safety and the
relative adoption of these t[...]the limitations of these AI systems
and the challenges with eva[...]oping a proactive agenda for AI in
healthcare that includes ma[...]

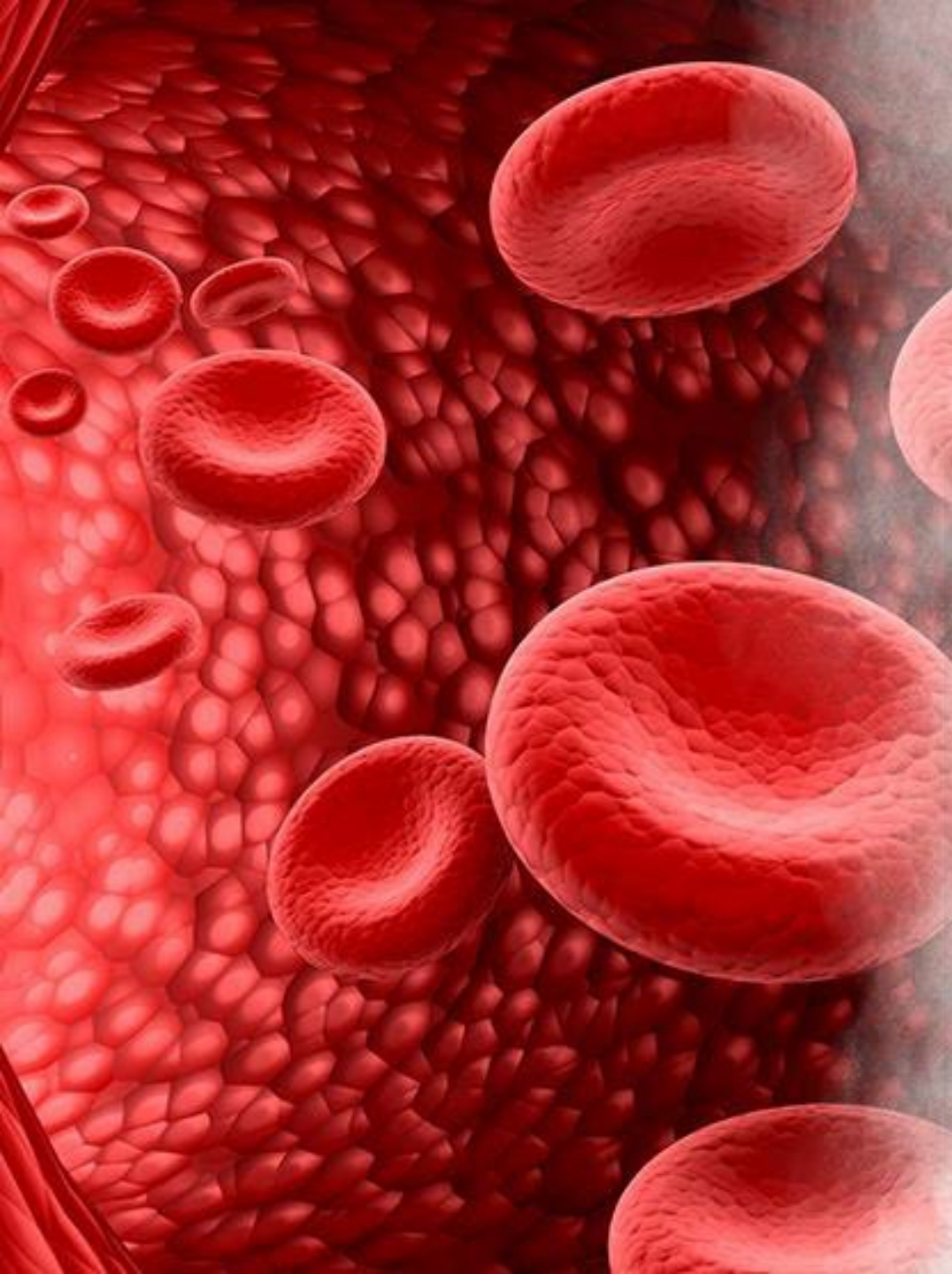*npj Digital Medicine* (2023)6[...]

Check for updates

Table 2. Top use cases for the application of AI to specific clinical problems in patient safety.

1. Actionable real time patient safety electronic clinical quality measures
2. Surgical complication prediction
3. Pressure ulcer prediction
4. Hypoglycemia prediction
5. Sepsis prediction ⬅
6. Suicide prediction
7. Diabetic eye AI screening
8. Breast imaging cancer screening
9. Chest x-ray imaging AI diagnosis
10. Skin melanoma AI diagnosis
11. Chest x-ray imaging AI cancer screening
12. Patient self-managed electronic safety dashboards

UC San Diego Health

EACH YEAR, ABOUT 1.7 MILLION ADULTS IN AMERICA DEVELOP SEPSIS. AT LEAST 350,000 DIE DURING THEIR HOSPITALIZATION OR ARE DISCHARGED TO HOSPICE.

GET AHEAD OF SEPSIS
KNOW THE RISKS. SPOT THE SIGNS. ACT FAST.

Learn more at cdc.gov/sepsis

Nature Digital Medicine (2024)

Impact of a deep learning sepsis prediction model on quality of care and survival

Aaron Boussina [1,4], Supreeth P. Shashikumar [1,4], Atul Malhotra [1], Robert L. Owens [1], Robert El-Kareh [1,2], Christopher A. Longhurst [1,2], Kimberly Quintero [2], Allison Donahue [3], Theodore C. Chan [3], Shamim Nemati [1,3,5] and Gabriel Wardi [1,3,5 ✉]

Sepsis remains a major cause of mortality and morbidity worldwide. Algorithms that assist with the early recognition of sepsis may improve outcomes, but relatively few studies have examined their impact on real-world patient outcomes. Our objective was to assess the impact of a deep-learning model (COMPOSER) for the early prediction of sepsis on patient outcomes. We completed a before-and-after quasi-experimental study at two distinct Emergency Departments (EDs) within the UC San Diego Health System. We included 6217 adult septic patients from 1/1/2021 through 4/30/2023. The exposure tested was a nurse-facing Best Practice Advisory (BPA) triggered by COMPOSER. In-hospital mortality, sepsis bundle compliance, 72-h change in sequential organ failure assessment (SOFA) score following sepsis onset, ICU-free days, and the number of ICU encounters were evaluated in the pre-intervention period (705 days) and the post-intervention period (145 days). The causal impact analysis was performed using a Bayesian structural time-series approach with confounder adjustments to assess the significance of the exposure at the 95% confidence level. The deployment of COMPOSER was significantly associated with a 1.9% absolute reduction (17% relative

The deployment of COMPOSER was significantly associated with a 17% relative decrease in in-hospital sepsis mortality (95% CI, 0.3%–3.5%) and a 10% relative increase in sepsis bundle compliance.

UC San Diego Health

Nature Digital Medicine (2024)
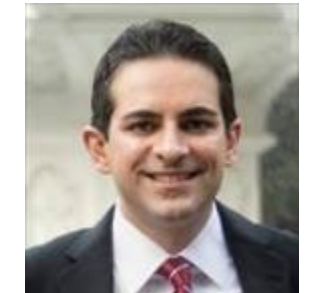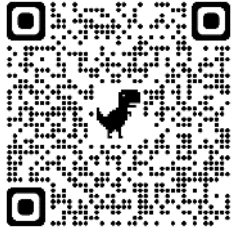
Integrating artificial intelligence into healthcare systems: more than just the algorithm

Check for updates

Boussina et al. recently evaluated a deep learning sepsis prediction model (COMPOSER) in a prospective before-and-after quasi-experimental study within two emergency departments at UC San Diego Health, tracking outcomes before and after deployment. Over the five-month implementation period, they reported a 17% relative reduction in in-hospital sepsis mortality and a 10% relative increase in sepsis bundle compliance.

This editorial discusses the importance of shifting the focus towards evaluating clinically relevant outcomes, such as mortality reduction or quality-of-life

This reality is a sobering reminder that translating... associated with a 17% relative reduction in in-

sepsis detection has catalyzed the development of several predictive algorithms across various clinical settings, including the emergency department (ED), inpatient ward, and intensive

described by Sendak et al.[11]. A nurse-facing Best Practice Advisory (BPA) (i.e., a reminder/warning) presenting the COMPOSER sepsis risk score alongside top predictive features was

AI researchers should **shift the focus from measuring just algorithm performance metrics such as accuracy to meaningful outcomes.** As a healthcare and AI community, we have a responsibility to deliver on these clinically relevant metrics, and **funding agencies and journals alike should be encouraged to prioritize such studies.**"

UC San Diego Health

11

PRENOSIS

Home   Solutions ⌄   Evidence   News   Team
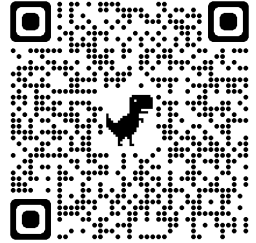
Device Classification Under Section 513(f)(2)(De Novo)

FDA Home ▸ Medical Devices ▸ Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search   Back to Search Results

Device Classification Name	Software Device To Aid In The Prediction Or Diagnosis Of Sepsis
De Novo Number	DEN230036
Device Name	Sepsis ImmunoScore
Requester	Prenosis, Inc. 3440 S Dearborn Street Suite 222s Chicago, IL 60616
Contact	Bobby Reddy
Regulation Number	880.6316
Classification Product Code	SAK
Date Received	05/05/2023
Decision Date	04/02/2024
Decision	Granted (DENG)
Classification Advisory Committee	General Hospital
Review Advisory Committee	Gastroenterology/Urology
Classification Order	Classification Order
FDA Review	Decision Summary
Type	Direct

Prenosis Announces... o
Marketing A... epsis
ImmunoSco... Artificial
Intelligence... ictive Tool
For Early Se...

APRIL 3, 2024 | IN PRESS RELEASE

The Sepsis ImmunoScore^TM is the first-ever AI Sepsis Diagnostic granted marketing authorization by the FDA.

12

UC San Diego Health

AI IN MEDICINE

VIEWPOINT

Regulate Artificial Intelligence in Health Care by Prioritizing Patient Outcomes

John W. Ayers, PhD, MA
Qualcomm Institute, University of California San Diego, La Jolla; and Altman Clinical Translational Research Institute, University of California San Diego, La Jolla.

Nimit Desai, BS
Qualcomm Institute, University of California San Diego, La Jolla; and School of Medicine, University of California San Diego, La Jolla.

Davey M. Smith, MD, MAS
Altman Clinical Translational Research Institute, University of California San Diego, La Jolla; and Division of Infectious Diseases and Global Public Health,

Artificial intelligence (AI) holds great promise to enhance the quality of health care.[1] Despite the aim of health care regulations to ensure high-quality care, there are few regulations governing the use of AI in health care. This dearth will soon change because a White House executive order instructed the Department of Health and Human Ser~~vices to develop new AI-specific regulatory~~ strategies ~~~~ ity for AI in ~~~~ we agree a~~~~ themselves ~~~~ der did not ~~~~ latory refo~~~~

Complicat~~~~

Traditionally, regulators observe health care systems and treat problems as "teachable moments" to make rules that mitigate the likelihood of similar problems happening again. These regulations typically mandate compliance with specific procedures. We refer to these as "process-centric" regulations because they manipulate

instance, it calls for AI-powered algorithms with more than 10 billion parameters to potentially register their codebase with federal agencies, perform a battery of to-be-determined regulator-selected tests, and report codebase modifications for review. Concurrently, the executive order does not appropriately address ~~decades of Food and Drug Administration regu~~

early with antibiotics when these medications are most effective, but despite a growing marketplace, these systems have not been required to produce such evidence. A third-party evaluation of the most widely adopted system, the Epic Sepsis Model, found that among 2552 hospitalized patients who developed sepsis, only 7% who did not already receive early treatment were identified by the

"We propose a regulatory strategy for AI that is outcome-centric by requiring companies to demonstrate that AI tools produce clinically important differences in patient outcomes before being brought to market."

AI Principles at UC San Diego Health

Artificial Intelligence

Our Statement

1. We believe that AI can enhance human health and well-being, and we are committed to developing and deploying AI solutions that are ethical, responsible, and beneficial for patients and society.
2. We respect the dignity, autonomy, and privacy of each patient, and we design and evaluate our AI systems with their needs, preferences, and feedback in mind.
3. We uphold the highest standards of scientific rigor, transparency, and accountability in our AI research and practice, and we adhere to the ethical codes and regulations of our profession and institution.
4. We foster a culture of collaboration, excellence, and innovation among our AI researchers, practitioners, partners, and stakeholders, and we seek to share our knowledge and expertise with the broader community.
5. We embrace the diversity of our patients, staff, and collaborators, and we strive to create an inclusive and supportive environment that values different perspectives, backgrounds, and experiences.

Effectiveness, Responsibility, and Accountability

AI products should be successful for their intended use, beneficial, valid, accurate, and reliable and those who develop and apply tools with responsibility and accountability

Ethics and Inclusiveness

AI products should strive to achieve health equity and fairness by design and operation

Human Factors

AI product design, development, and implementation should involve and prioritize the needs of the diverse population it serves

Promoting Human Well-Being, Safety, Privacy, and Common Good

AI products should protect human well-being, privacy, sustainability, and the environment

Transparency

AI products should be explainable, trustworthy, intelligible, and accountable

Protecting Human Autonomy and Dignity

AI products should empower individuals it serves

DECEMBER 14, 2023

Delivering on the Promise of AI to Improve Health Outcomes

🏛 ▸ BRIEFING ROOM ▸ BLOG

Lael Brainard, National Economic Advisor
Neera Tanden, Domestic Policy Advisor
Arati Prabhakar, Director of the Office of Science and Technology Policy

As President Biden has said, artificial intelligence (AI) holds tremendous promise and potential peril. In few domains is this truer than healthcare. The President has made clear, including by signing a landmark Executive Order on October 30, that the entire Biden-Harris Administration is committed to placing the highest urgency on governing the development and use of AI safely and responsibly to drive improved health outcomes for Americans while safeguarding their security and privacy.

AI Principles in Action – April 2023

HEALTH TECH

HIMSS23: Epic taps Microsoft to integrate generative AI into EHRs with Stanford, UC San Diego as early adopters

By Heather Landi · Apr 17, 2023 11:00am

Microsoft · Epic · generative AI · electronic health records (EHRs)

...with the patient at the

Generated Draft Reply   Pioneering Feature

Hello Barbara,

Your CBC with Auto Diff result from 3/7/2023 is within the normal range and does not indicate any cause for concern. Your provider will contact you if any further action is needed. Your results are available for viewing in MyChart, under the "Test Results" tab.

If you have any further questions or concerns, please do not hesitate to contact us.

Best regards,

❓ Learn more   Start with Draft   Start Blank Reply

Did you find the draft reply helpful?

👍 This was helpful   👎 This was not helpful

Dear ▬▬▬

Thank you for your message and for taking an active role in your health. It's great to hear that you're considering the Hepatitis A vaccine. Twinrix is indeed a combination vaccine that covers both Hepatitis A and B. However, since you've already had the Hepatitis B vaccine, you may not need the combination.

I see you have an upcoming appointment and I recommend reviewing at that appointment. It is a 2 shot series so you can do the 1st shot at the appt if you would like. |

Take care,
Marlene May Millen, MD

Part of this message was generated automatically and was reviewed and edited by Marlene May Millen, MD.

UC San Diego Health

AB 3030: Health care services: artificial intelligence.

Session Year: 2023-2024   **House:** Assembly

Current Status: PASSED ✓ (2024-09-28: Chaptered by Secretary of State - Chapter 848, Statutes of 2024.)
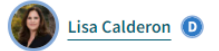
Introduced — First Committee Review — First Chamber — Second Committee Review — Second Chamber — Enacted

Summary | Bill Text | Status | Votes | Supporters & Opponents | Analysis
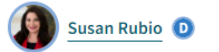
Version: Chaptered (9/28/2024)

Existing law provides for the licensure and regulation of health facilities and clinics by the State Department of Public Health. Existing law, the Medical Practice Act, establishes the Medical Board of California for the licensing, regulation, and discipline of physicians and surgeons. Existing law, the Osteopathic Act, enacted by an initiative measure, establishes the Osteopathic Medical Board of California for the licensing and regulation of osteopathic physicians and surgeons.

This bill would require a health facility, clinic, physicians office, or office of a group practice that uses generative artificial intelligence to generate written or verbal patient communications pertaining to patient clinical information, as defined, to ensure that those communications include both (1) a disclaimer that indicates to the patient that a communication was generated by generative artificial intelligence, as specified, and (2) clear instructions describing how a patient may contact a human health care provider, employee, or other appropriate person. The bill would exempt from this requirement a communication read and reviewed by a human licensed or certified health care provider. Under the bill, a violation of these provisions by a physician would be subject to the jurisdiction of the Medical Board of California or Osteopathic Medical Board of California, as appropriate.

Bill Author

Lisa Calderon (D)

Bill Co-Author(s):

Susan Rubio (D)

Blood Pressure   131 / 113

Pulse   77

The New York Times

That Message From Your Doctor? It May Have Been Drafted by A.I.

Overwhelmed by queries, physicians are turning to artificial intelligence to correspond with patients. Many have no clue that the replies are software-generated.

Where do we go from here?

NEJM AI

PERSPECTIVE

A Call for Artificial Intelligence Implementation Science Centers to Evaluate Clinical Effectiveness

Christopher A. Longhurst, M.D., M.S.,[1] Karandeep Singh, M.D., M.M.Sc.,[1] Aneesh Chopra, M.P.P.,[2] Ashish Atreja, M.D., M.P.H.,[3] and John S. Brownstein, Ph.D.[4,5]

Abstract

Artificial intelligence (AI) holds significant promise for revolutionizing health care by enhancing diagnosis, treatment, and patients' safety. However, the current disparity between the abundance of AI research and the scarcity of evidence on real-world impact underscores the urgent need for comprehensive clinical effectiveness evaluations. These evaluations must go beyond model validation to explore the real-world effectiveness of AI models in clinical settings, especially because so few have gone on to show any meaningful impact. The importance of local context in AI model validation and impact assessment cannot be overstated. We call for increased recognition of implementation science principles and their adoption through development of a network of health care delivery organizations to focus on the clinical effectiveness of AI models in real-world settings to help achieve the shared goal of safer, more effective, and equitable care for all patients.

> "Health delivery organizations must play a critical role in this real-world validation, and mitigation of health inequities will require that public health systems serving diverse populations be well-represented."

AI IN MEDICINE

VIEWPOINT

The Compelling Need for Shared Responsibility of AI Oversight
Lessons From Health IT Certification

Raj M. Ratwani, PhD
MedStar Health
National Center for
Human Factors
in Healthcare,
MedStar Health,
Washington, DC.

David Classen, MD, MS
Division of
Epidemiology,
University of Utah
School of Medicine,
Salt Lake City.

Christopher
Longhurst, MD
Departments of
Medicine and
Pediatrics, University of
California, San Diego.

As artificial intelligence (AI) tools become more consistently used in health care, federal agencies, health care facilities, medical societies, and other stakeholders are grappling with how to ensure they do not introduce unintended patient harm. One suggested approach is the development of national AI algorithm assurance laboratories that could test and certify that AI algorithms meet certain requirements, such as use of diverse datasets, in the development process.[1] Others have suggested that meaningful clinical outcomes in real-world settings should be demonstrated prior to regulatory approval.[2] Regardless of approach, a well-designed one could improve safety, promote patient and health care professional confidence in AI use, and incentivize developers and users to focus on these important issues. Developing a testing and certification approach that is effective, rigorous, and rapid and that is a shared responsibility of both developers and users is necessary

...which AI tools will be used, this function need performed by local AI governance and oversig could be required as part of the Centers for Med

> "The combination of algorithm assurance testing and certification, along with a CMS requirement to require local testing and monitoring, will ensure that AI oversight is a shared responsibility of developers, users, and other stakeholders."

JAMA

UC San Diego Health

Compelling Need for Shared Responsibility of AI Oversight

- The **FDA** should be empowered with:

  1. Increased authority to **require transparent outcomes data** about products

  2. Increased authority for **post-marketing surveillance**

- **Healthcare delivery organizations** should be subject to a CMS requirement for local testing and monitoring to ensure that AI oversight is a shared responsibility of developers and users
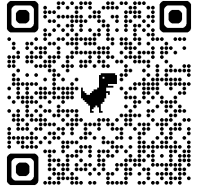
STAT+ | HEALTH TECH

FDA commissioner: Health systems have to 'step up' on AI regulation or will 'end up holding the bag'

Developers can't fully guarantee an AI model's performance, Califf said

Alissa Ambrose/STAT

By Brittany Trang   Sept. 11, 2024
Health Tech Reporter

WELLESLEY, Mass. — Amid heated discussions on how artificial intelligence should be regulated and who should be involved in health care AI governance, the U.S. Food and Drug Administration commissioner said that health systems need to take a leading role.

UC San Diego Health

Thank you!

clonghurst@health.ucsd.edu

@calonghurst