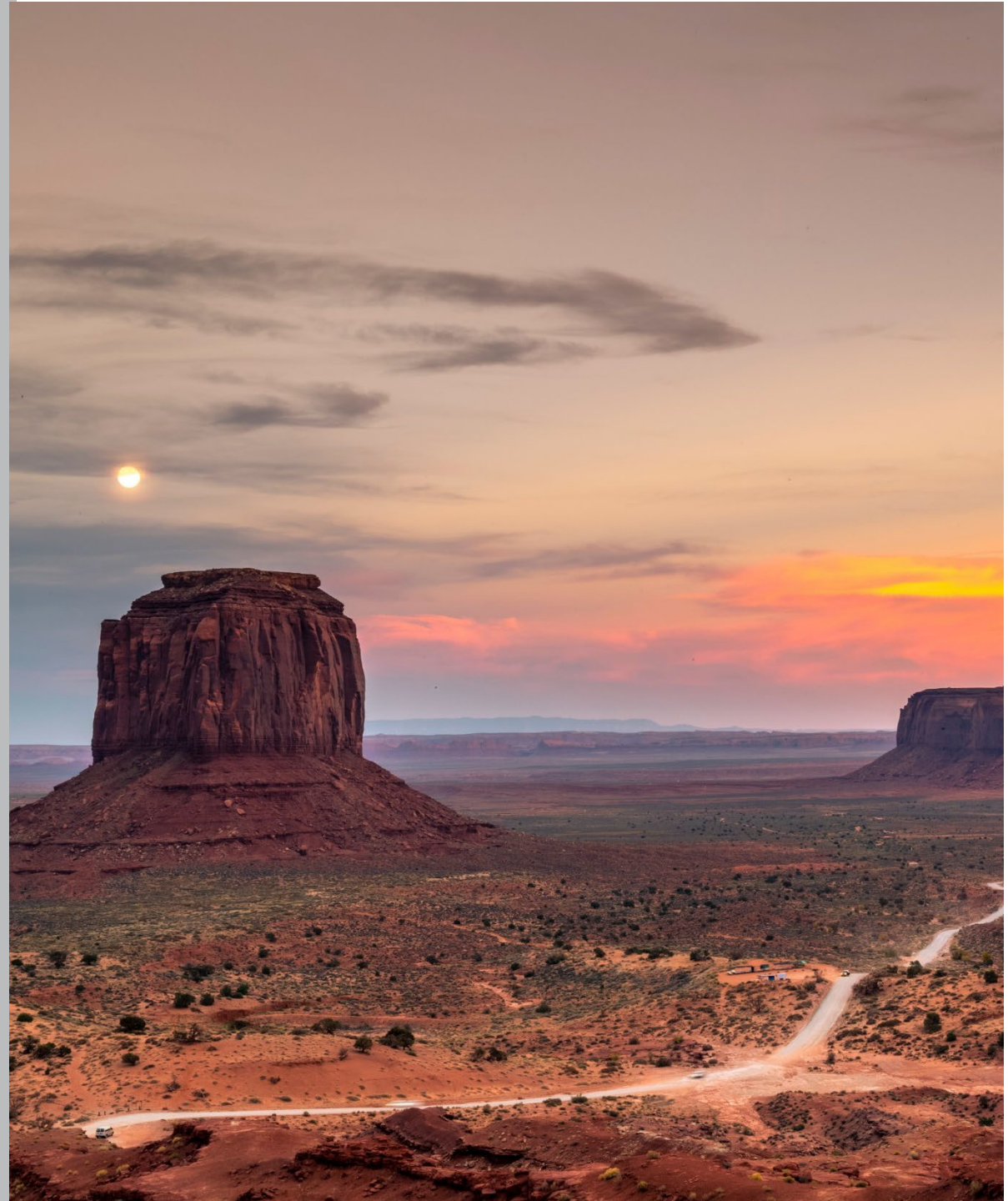
HL7 International

37th Annual Plenary & Working Group Meeting

Phoenix, Arizona

Monday, September 11, 2023



Monday

Welcome

Charles Jaffe, MD, PhD

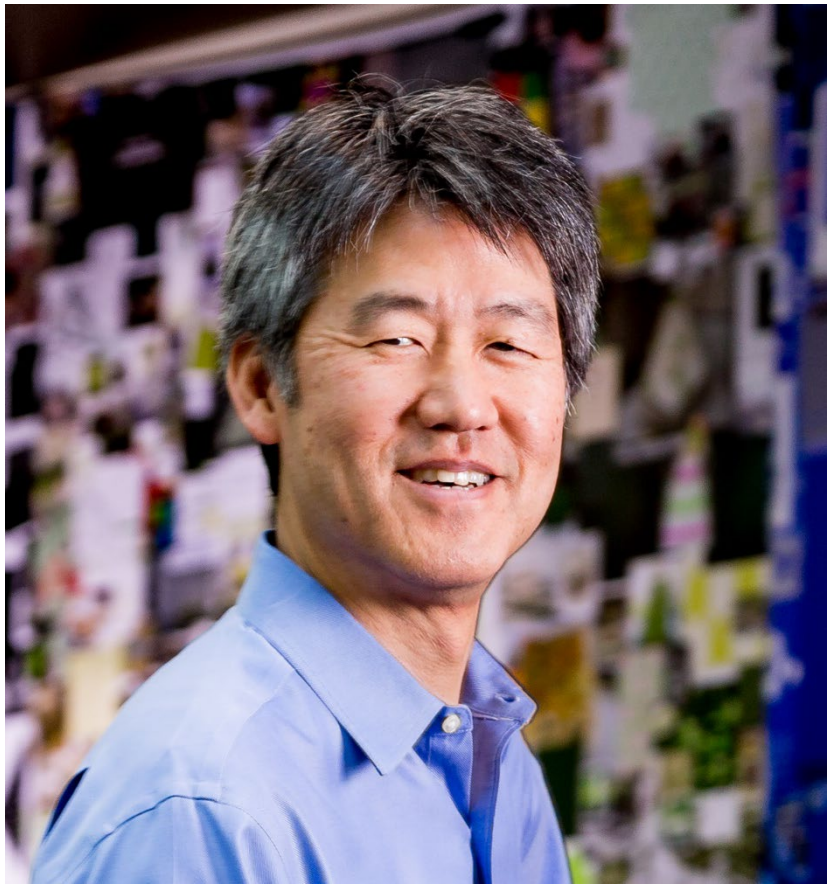
Chief Executive Officer

HL7 International

KEYNOTE PRESENTATIONS

AI IN HEALTHCARE: OPPORTUNITIES & CHALLENGES

Monday



Keynote Session 1

Peter Lee, PhD

Corporate Vice President, Research & Incubations, Microsoft

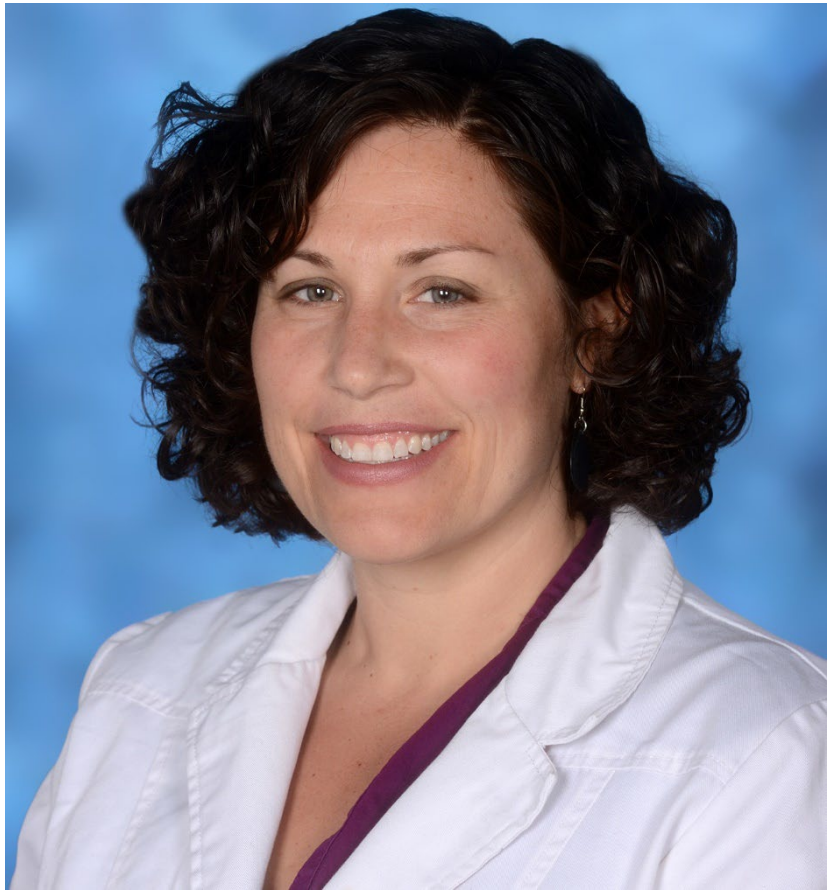
Monday

Keynote Session 2

John Halamka, MD, MS

President,
Mayo Clinic Platform

Monday



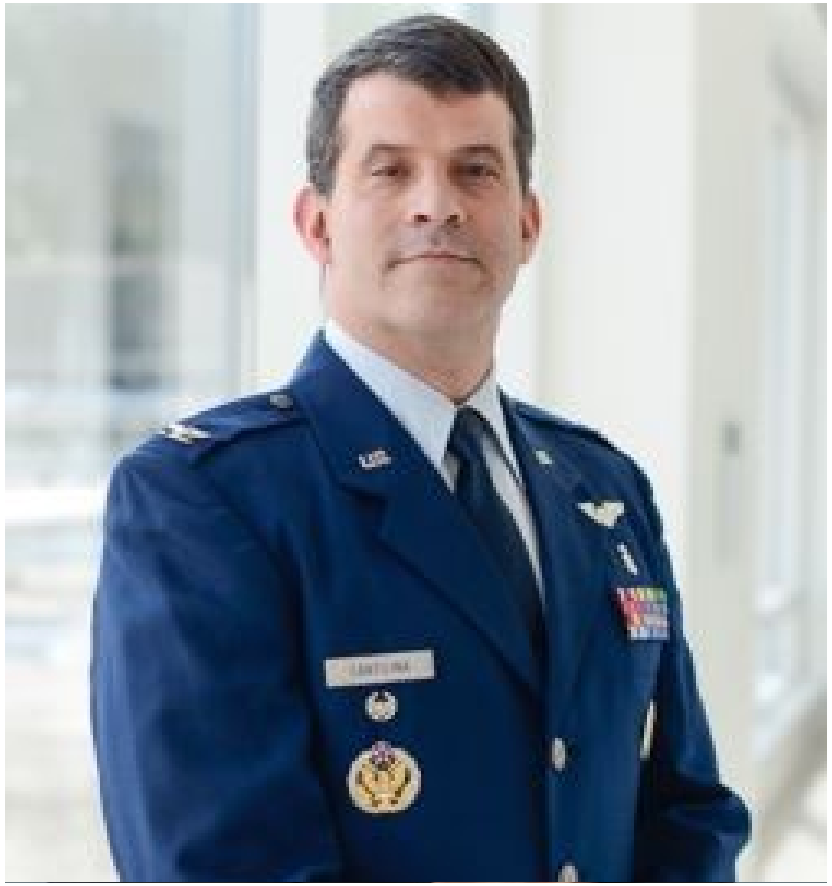
Panel: Government Perspective

North America

Moderator: Julia Skapik, MD

Chair-Elect, HL7 International
Medical Director for Informatics, National Association of Community Health Centers (NACHC)

Monday

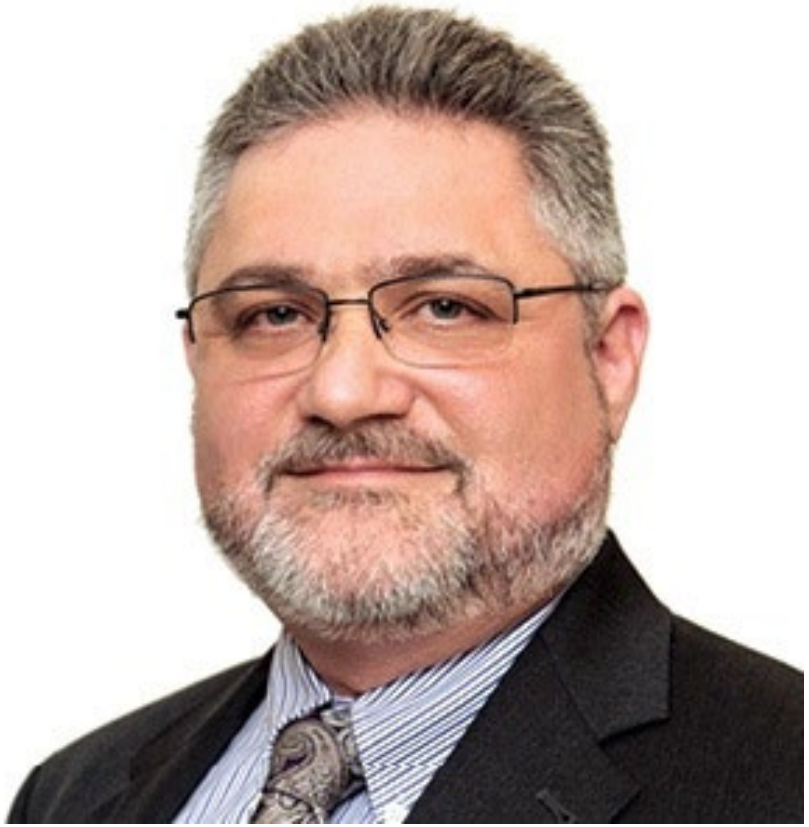


Panel: Government Perspective

Panelist: Colonel Thomas Cantilina, MD

Chief Health Informatics Officer, Department of Defense

Monday



Panel: Government Perspective

Panelist: Jose Galvez, MD

Deputy Director of the Office of Strategic Programs, FDA

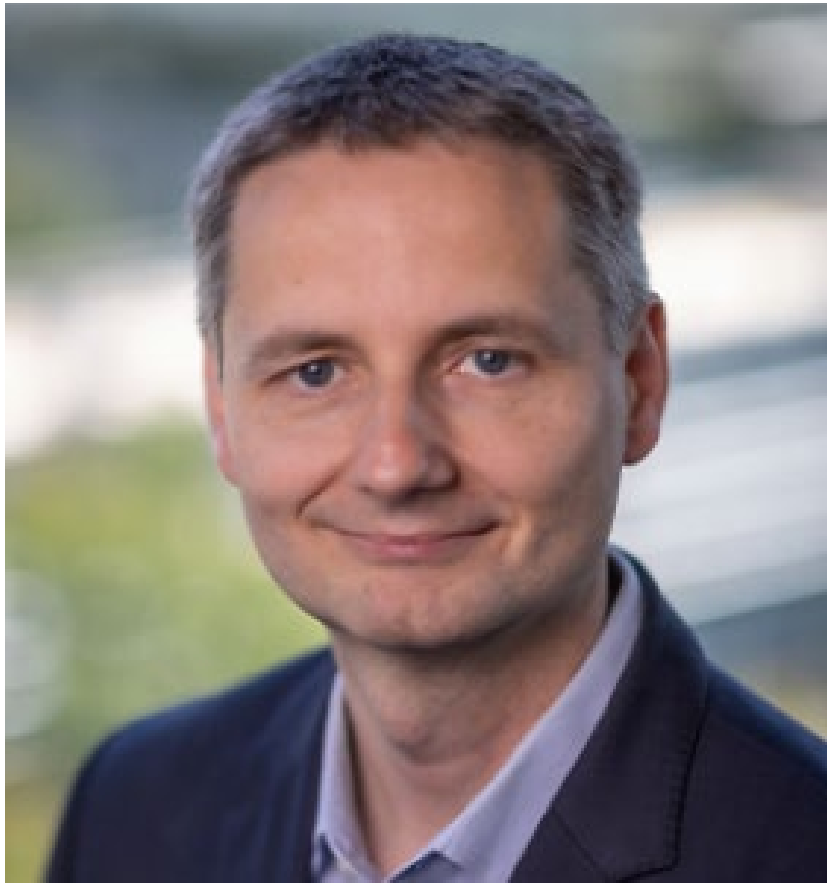
Monday

Panel: Government Perspective

Panelist: Steve Posnack, MS, MHS

Deputy National Coordinator for Health Information Technology, ONC

Monday

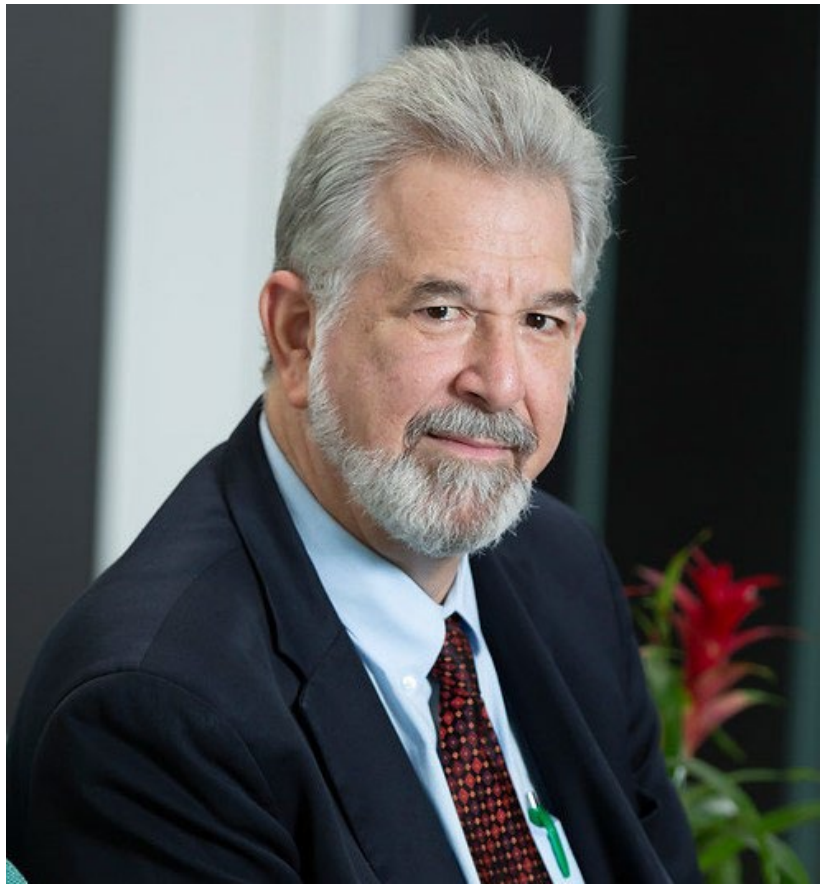


Keynote Session 4

Michael Pencina, PhD

Vice Dean for Data Science; Chief Data Scientist, Duke University School of Medicine

Monday



Keynote Session 5

Kenneth Goodman, PhD, FACMI, FACE

Director, Ethics Programs

Director for Ethics & Health Policy, University of Miami

Ethics, AI Standards, and Responsibility

HL7 37th Annual Plenary
Phoenix, Arizona
September 11, 2023

Kenneth W. Goodman, PhD, FACMI, FACE
Professor of Medicine and Philosophy
Director, University of Miami Miller School of Medicine Institute for Bioethics and Health Policy and
UM Institute for Data Science and Computing Program in Data Ethics + Society,
kgoodman@med.miami.edu

UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

“More and more the tendency is towards the use of mechanical aids to diagnosis; nevertheless, the five senses of the doctor do still, and must always, play the preponderating part in the examination of the sick patient. Careful observation can never be replaced by the tests of the laboratory. The good physician now or in the future will never be a diagnostic robot.”

– Scottish surgeon Sir William Arbuthnot-Lane (Lane, 1936)

The AI story so far

- Bias
- Safety
- Transparency
- Explainability
- Accountability
- Responsibility
- Governance

Standards as ethics

- convenience, economy
- reliability, efficiency
- safety
- profit maximization
- values protection, promotion
- quality
- interoperability

Standards for ethics

- Values protection, promotion
- Cf. privacy and security (HL7: Privacy, Access and Security Services)
- Appropriate uses
- Appropriate users

The Hard Problem

- The Parfait System: no bias, no confabulation, explainable to the satisfaction of all, designed by committed and responsible coders, manufactured by corporations dedicated to the common good …
- Affordable, reliable, easy to use
- Consistently more accurate than human experts

It gets worse…

- Diagnostic systems get it right more frequently than humans
- Prognostic systems get it right more frequently than humans (cf. “computational futility metric”)
- Patients and family members use them all the time (cf. online cancer nomograms)

Hurray … or uh-oh?

- The data and information scraped from electronic health records, registries, etc. and used to train the Parfait System thus guides practice – and eventually replaces the data and information used to train future systems
- Future systems are thus trained on data and information derived from practice shaped or guided by computers
- Which data and information is used to train new systems
- Progress, or the systematic replacement of a store of human-acquired knowledge by machine intelligence?

In the meantime…

- “Better than humans” is usually a good thing. Humans + tools are better than humans without tools,
- …which tend to be imperfect (sometimes because of humans).
- The more we look the more we find uncertainty if not error.

Parfait? Not yet

The problem with humans…

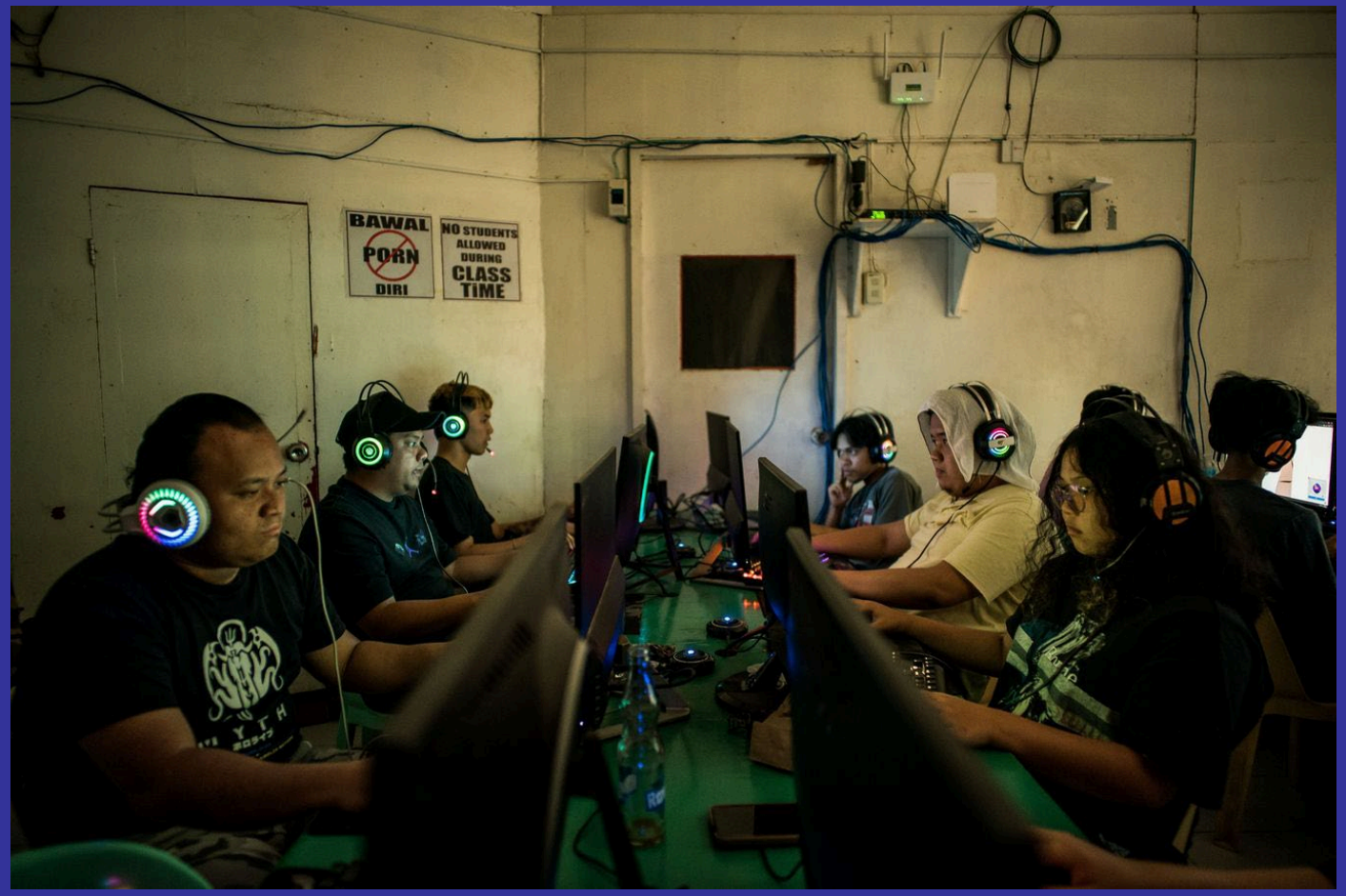
- “Scraping the internet” metaphor is more accurate than supposed: when scraping, you only get the surface.
- Uncertainty in biostatistics; missingness
- Meta-correlation – extremely well-documented correlation – still does not establish causation.
- Cf. early prognostic scoring systems.

(We’re used to error, inaccuracy)

- His prognosis is poo.
- Mr X was seen by himself in the hospital room today.
- I saw but didn't see the order placed. Thank you.
- I asked that her house Mr. H doing prior to come to the hospital.
- His current PPS 505% is more related to …
- Seen by Neurology, unable to do MRI due to penile metal prosthesis. Still minimally arousable.
- He initially presented by EMS, who report they found him on the side of the road stating he wished to diet.
- … is an 82 y.o. male admitted on 1/2/3 with a primary diagnosis of No primary diagnosis.

Other human problems

- Greed
- Selfishness
- Inattention
- Laziness
- Cruelty



Internet cafes in the Philippines are now frequented by workers who sort and label data for artificial intelligence models.

(Martin San Diego for The Washington Post).

https://s2.washingtonpost.com/camp-rw/?trackId=61284be9ae7e8a0d5066f8af&s=64ed6ea1fc110e7018436c03&linknum=5&linktot=61&linknum=5&linktot=61

Miller's "Standard Model"

- Humans are educated and licensed to practice medicine and nursing.
- Humans are better at using tools than allowing themselves to be used by tools (except when well incentivized).
- The computer (should) no more replace human cognitive practice and capacity than, say, the stethoscope.

“Progressive Caution”

- We are dependent on computers
- …which are imperfect.
- It can be blameworthy *not* to use a tool that improves patient care
- … which tension is difficult to resolve.
- “Progressive Caution” (1998) is the idea that wise and compassionate progress can ethically optimize adoption of computational aids in healthcare.

The Hard Problem, redux

- Skill degradation
- What if the loss of human cognitive engagement leads to better outcomes?
- Forever
- What if our EHRs and data sets are wholly supplanted by data and information generated by ever-diminished human decisions?
- Does it matter? Why?

And if they are so good…

- For whom – which populations – will they be available?
- Cf. human-subjects research in low-income countries.
- We have a poor track record sharing useful technologies including, most recently, vaccines.
- Which business plans take this into account?

What if large-language models, for instance, are superior to human agents and more reliably hew to standards than humans?

Standards for ethics, redux

- Appropriate uses, users
- Appropriate role of humans
- Education (not “training”)
- Consider health-ethics-and-informatics swat teams (HEISTs).
- Ongoing, independent review, analysis

Ethics and standards: A hypothesis

- Value-driven standards support ethically optimized products, processes, and actions
- They should be public, transparent, and driven by transparent processes
- This is in many respects an empirical challenge… the opportunity is that we might be able to demonstrate the practical utility of ethics standards and so foster trust and confidence – as HL7 has done for decades.

Thank you.

Monday

HL7 AI Standards - Laying the Foundation

Gary Dickinson, FHL7
EHR WG Co-Chair, Co-Facilitator of AI Focus Team

Monday

HL7 AI Standards - Laying the Foundation

Mark Janczewski, MD, MPH, FAAFP, FAMIA

EHR WG Co-Chair, Co-Lead of AI Data Lifecycle Project

HL7 AI Standards – Laying the Foundation

EHR WG Project – AI Data Lifecycle

Gary Dickinson FHL7

Mark Janczewski MD MPH

HL7 37th Annual Plenary and Work Group Meeting

11 September 2023

Phoenix, Arizona USA

HL7® International

Background

- The HL7 EHR WG has a well-established learning project focused on Reducing Clinician Burden
- Key Objectives are to:
  - Understand the substance, extent and impact of clinician burden
  - Recognize root causes
  - Identify success stories
  - Support novel and disruptively innovative advances that will allow healthcare IT to reduce burden and improve care quality by better supporting clinical workflow

Considering AI...
Where We Started

- Starting in January 2022, we began to receive presentations/reports on AI – with emphasis not so much on artificial, but rather on assistive or augmented, intelligence
  - US NIH, US VA, Mayo Platform, Harvard/MIT, Beth Israel Deaconess, Philips, Akélex, Availity, Cognotekt, Book Zurman
- We began to seriously consider the *potential of AI to reduce burden* – recognizing that AI has applications/benefits beyond this objective
- We then established an AI Focus Team to evaluate the optimum role for HL7 in AI standards development
- With expert input from many sources, we identified *21 AI Topics/Areas of Focus*
- With further review, we prioritized the list and identified *AI Data Lifecycle* as our initial priority and project

Candidates 1-11

AI Topics/Areas of Focus

Item	Topic/Area of Focus
1	Contribute SDO expertise at standards development or providing a framework for such. Use SDO consensus process to review and approve AI artifacts/standards.
2	Establish "Contexts" within which AI Algorithms are developed and ultimately applied in health and healthcare. a) ISO 13119 – Clinical knowledge resources - Metadata b) Patient/Provider/Action Contexts c) Problem Context
3	Create a label for every algorithm — analogous to a nutrition label, or a drug label — describing the data used to develop an algorithm, its usefulness and limitations, its measured performance, and its suitability for a given population.
4	Test and monitor the performance of algorithm-guided care within the settings in which it is deployed in an ongoing way.
5	Create best practices for establishing the usefulness, reliability, and fairness of AI algorithms that bring together different organizations to develop and test AI on data sets drawn from diverse and representative groups of patients.
6	Create a standard way for government, academia, and industry to monitor the behavior of AI algorithms over time.
7	Understand clinical context and goals of each algorithm and know what attributes — quality, safety, outcomes, cost, speed, and the like — are being optimized.
8	Learn how local variations in lifestyle, physiology, socioeconomic factors, and access to health care affect both the construction and fielding of AI systems and the risk of bias.
9	Assess the risk that AI might be used, intentionally or not, to maintain the status quo and reinforce, rather than eliminate, discriminatory policies.
10	Develop approaches for appropriate clinical use of AI in combination with human expertise, experience, and judgment, and discourage overreliance on, or unreflective trust of, algorithmic recommendations.
11	AI Data Lifecycle: AI algorithms depend on data quality and context. Consider how to bolster accountability, data quality, context and provenance at each step in the data lifecycle (capture, share, use). Develop Provenance Resource Profile (FHIR for AI)

Candidates 12-21
AI Topics/Areas of Focus

12	Develop standards for auditing AI
13	Develop standards for CDS software to identify AI tools potentially applicable to a patient problem, combine data about the applicable tools (including but not limited to metadata in ISO 13119) with data about the patient/problem, and generate options (i.e. alternative tools) with details about the pros and cons of each option specific to the patient (see paragraph I.A.4 of the "Problem Context" memo in Item 2c above).
14A	Publication guidance for medical literature including precise markup optimized for extraction of knowledge constructs to support machine learning
14B	Translation of knowledge fragments into structured patterns, assuring validation and fidelity, and enabling input mapping to support the AI user interface and Natural Language Processing
15	Everyday patient care record, rigorously formatted – extracted for diagnosis, treatment, decisions, use for clinical trials
16	Data standards for data brokers
17	Create / enhance standards for capturing results from AI, which are linked back to the AI source
18	Create / enhance standards to translate AI results into existing medical domains while ensuring that they are correctly flagged as coming from AI and linked back to the source AI
19	Use HL7 FHIR resources/data structures for AI data strata
20	Develop a mimimum viable standard for AI ethics specific to healthcare. This might incorporate the idea of making data FAIR and establishing a standard for developing AI ready datasets. (#10 seems to touch on Ethics and therefore it may be possible to address both)
21	Develop standardized approach towards the development of AI ready data sets, including research design, data generation, data processing
	Project Underway
	Deferred to Other Organizations
	Potential Concurrent Track or Subsequent Phase of Current Project
	For Future Consideration

AI Project 11 - AI Data Lifecycle

What Do We Aim to Achieve?

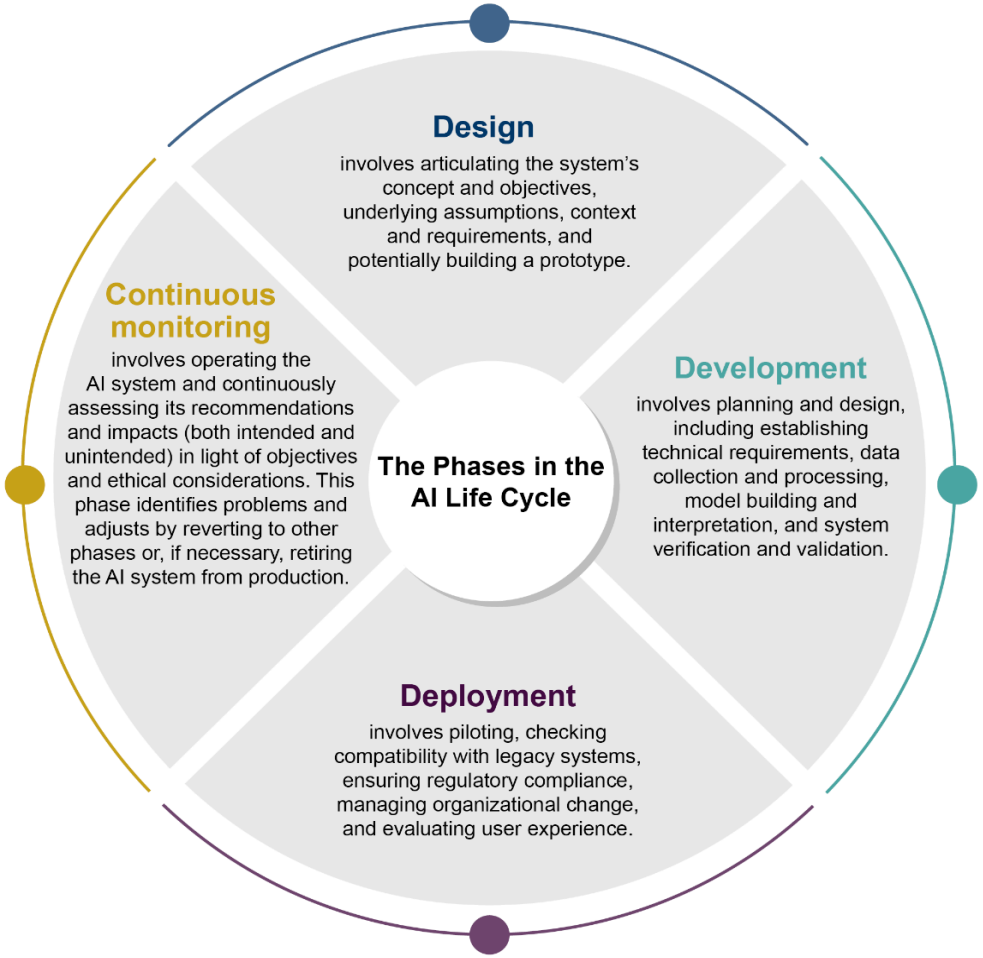
- Explainable AI
- Black Box gives way to Clarity
  - Trustworthy, Accountable, Fit for Purpose
  - Transparent and Fully Traceable – from Machine Learning to Algorithm Derivation to Live Operation
- AI Conclusions/Recommendations are Substantiable
  - Evidence-based
  - Measurable as to Data Accuracy and Quality
- Ethically Sound
- Initially Focused on Training and Developing Machine Learning (AI/ML) Models
  - NOT Generative AI leveraging Large Language Models

AI Project 11 - AI Data Lifecycle Framework

- Incorporates AI Use Case Examples
- Utilizes Trigger Events and Audit Trails (capturing key Provenance and Metadata elements)
- Patterned after FHIR R5 Record Lifecycle Event Implementation Guide
- Uses US General Accounting Office (GAO) Framework for an AI Project Lifecycle, with Distinct Phases:
  - → Design Phase
  - → Development Phase – including Machine Learning/Training and Algorithm Creation
  - → Deployment Phase – including Testing
  - → Production Phase – Live Operation with Continuous Monitoring

Project 11 – AI Data Lifecycle

GAO AI Accountability Framework – Phases 1-4



US General Accountability Office (GAO) – *"Artificial Intelligence An Accountability Framework for Federal Agencies and Other Entities"* (2021) – Guidance for the AI Project Life Cycle, including AI for healthcare, which involves several critical phases, each requiring specific standards to ensure consistent high-quality implementation.

Project 11 – AI Data Lifecycle
Timeline

- Project Underway early 2023
- Project Proposal (Title and Description)
  - 22 Mar 2023: Approved
- Project Scope Statement (PSS)
  - 23 May 2023: Approved by HL7 EHR WG
  - 30 June 2023: Passed Consensus Review
  - 17 July 2023: Approved by Technical Steering Committee (TSC)
- 1st Deliverable: Laying the Foundation – White Paper
  - Draft in development
  - **Ballot Cycle: 2024JAN**

- Over 50 Individuals have Volunteered

Project 11 – AI Data Lifecycle – Initial Deliverable

White Paper

- So far, about 50 pages long
- Table of Contents (High-Level)
  - Introduction (Forward, Caveats, Scope)
  - Use Cases and Case Studies
  - Background (Definitions, Challenges Associated with the Use of AI in Healthcare, Benefits of AI Standardization
  - Discussion
  - Recommendations / Guidance
- Currently in Review and Draft Development

AI Focus Team and P11 Project – AI Data Lifecycle
Participants and Contributors

Many Thanks to:

- AkéLex
- Availity/Diameter Health
- Beth Israel Deaconess/Lahey Health
- Book Zurman
- Booz Allen Hamilton
- Centers for Medicare and Medicaid Services
- Cognotekt (Germany)
- Computer Network Architects
- EHR Standards Consulting
- Harvard University/Massachusetts Institute of Technology
- ISO TC215/Task Force 5 on AI
- JP Systems
- Mitre
- Mayo Platform
- Oak Ridge National Laboratories
- Philips
- Prosumer Health
- Stanford University
- University of Nebraska
- US Department of Defense
- US Food and Drug Administration
- US National Institutes of Health
- US General Accountability Office
- US National Institute of Standards and Technology
- US Office of National Coordinator
- US Veterans Administration
- Wolters-Kluwer
- Yale University
- and Many Other Individuals

→ Key Instigators

AI Focus Team and P11 Project – AI Data Lifecycle

Upcoming Sessions

- This WGM: Tuesday Q4 – hosted by the EHR WG
- Recurring Meetings
  - AI Focus Team: 4th Tuesday each month, 1600-1700 US ET
  - AI Project 11: Every second Monday, 1100-1200 US ET
  - Reducing Clinician Burden: 2nd and 4th Mondays each month, 1200-1300 US ET

- **Your Participation is Welcome!**
  - See POCs on next slide if you wish to be included on email distribution lists
  - To receive meeting announcements, links and materials

Points of Contact

- AI Focus Team
  - Gary Dickinson FHL7, EHR Standards Consulting
    gary.dickinson@ehr-standards.com
  - Steve Datena MD, AkéLex
    steve.datena@akelex.com
- Project 11 – AI Data Lifecycle
  - Rhonna Clark, US Department of Veterans Affairs – Project Lead
    rhonna.clark@va.gov
  - Ioana Singureanu, US Department of Veterans Affairs – Project Advisor
    ioana.singureanu@va.gov
  - Mark Janczewski MD MPH, Medical Networks LLC – Project Facilitator
    mark.janczewski@gmail.com

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Have a great day!

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