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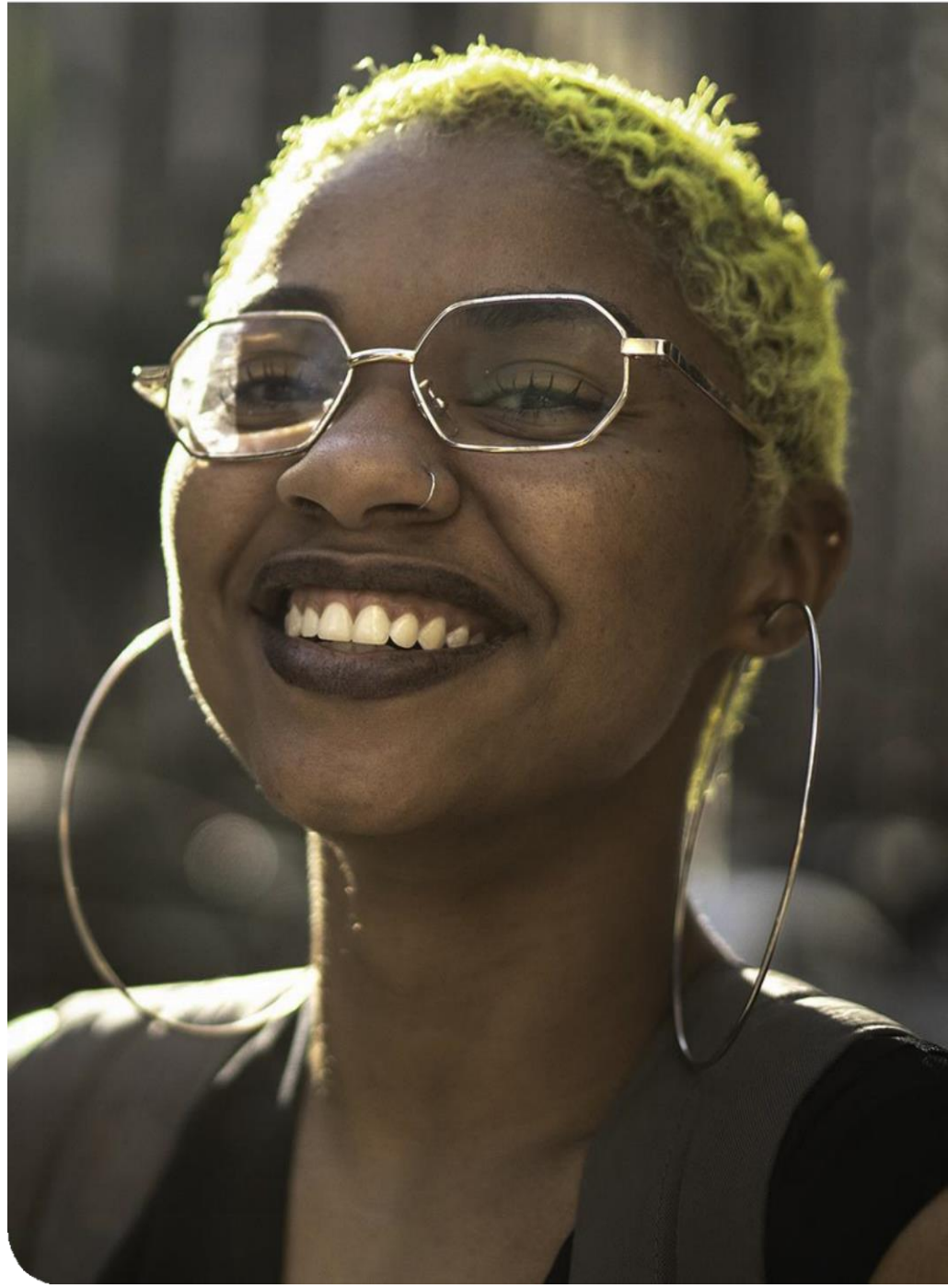
Using Artificial Intelligence to Improve Safety: Risks and Opportunities



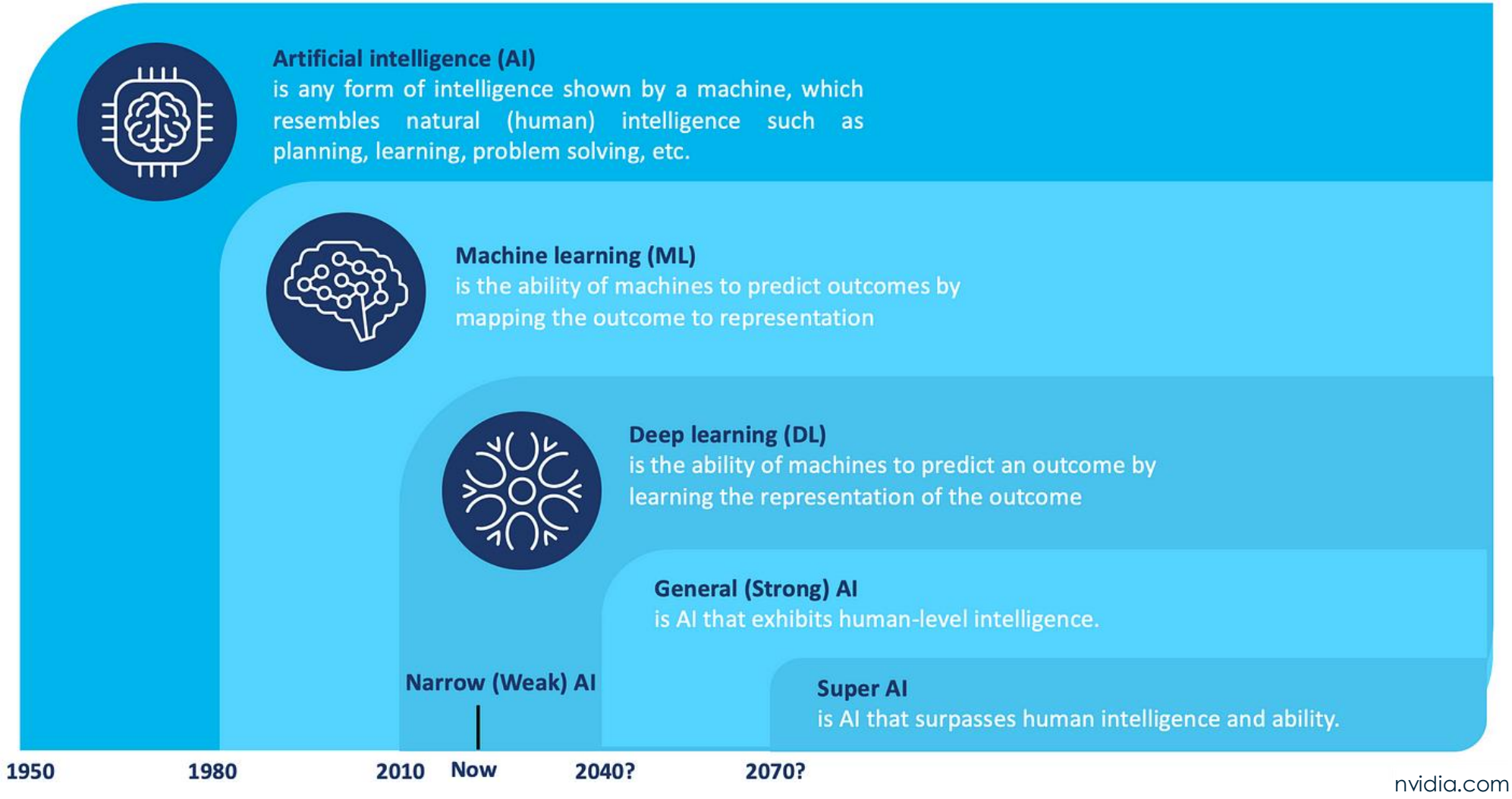
Prepared by

Tejal Gandhi, MD, MPH, CPPS
Chief Safety & Transformation Officer

Caveats

- I have a long history in patient safety research and operations
- I have studied and implemented a wide range of clinical decision support tools in EHRs
- I am constantly learning, as all of you are, about AI and generative AI
- I am not an expert in AI algorithms!

AI is not new



nvidia.com

What is AI?

- A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.

The Artificial Intelligence Spectrum

Slide courtesy of Dr. Raj Ratwani

AI in healthcare

1 in 4 dollars invested in healthcare going toward companies leveraging AI

- Silicon Valley Bank report

38%

Currently use AI

42%

Plan to use AI

definitivehc.com

AI in healthcare

57%
Process or workflow improvement

27%
Computer-aided image detection for disease states

25%
Care guideline consultation/ suggestive care options

definitivehc.com

The safe, secure, and trustworthy development and use of artificial intelligence

PRESIDENT BIDEN ISSUES EXECUTIVE ORDER (EO)

- **Directs federal agencies to create standards and regulations for the use and oversight of AI across sectors like energy, infrastructure, criminal justice, healthcare, housing, education, and labor, with a focus on protecting civil rights and liberties.**
- **Guiding principles are reflected across several sections:**
  - Ensuring the safety and security of AI technology
  - Promoting innovation and competition
  - Supporting workers
  - Advancing equity and civil rights
  - Protecting consumers, patients, passengers, and students
  - Protecting privacy
  - Advancing federal government use of AI
  - Strengthening American leadership abroad

Federal agencies to watch

- **National Institute of Standards and Technology (NIST)** within the Department of Commerce: tasked with developing guidelines and best practices for AI safety and security
- **The Department of Health and Human Services (HHS)**: responsible for new strategy and safety programs for AI in healthcare programs
- **Office of Management and Budget (OMB)** coordinates interagency activity and use of AI in government

"Harnessing AI for good and realizing its myriad benefits requires mitigating its substantial risks. This endeavor demands a society-wide effort that includes government, the private sector, academia, and civil society."

Core Principles of Trustworthy AI

- Valid
- Beneficial & Effective
- Testable
- Reliable & Robust
- Usable

CHAI™ Coalition for Health AI

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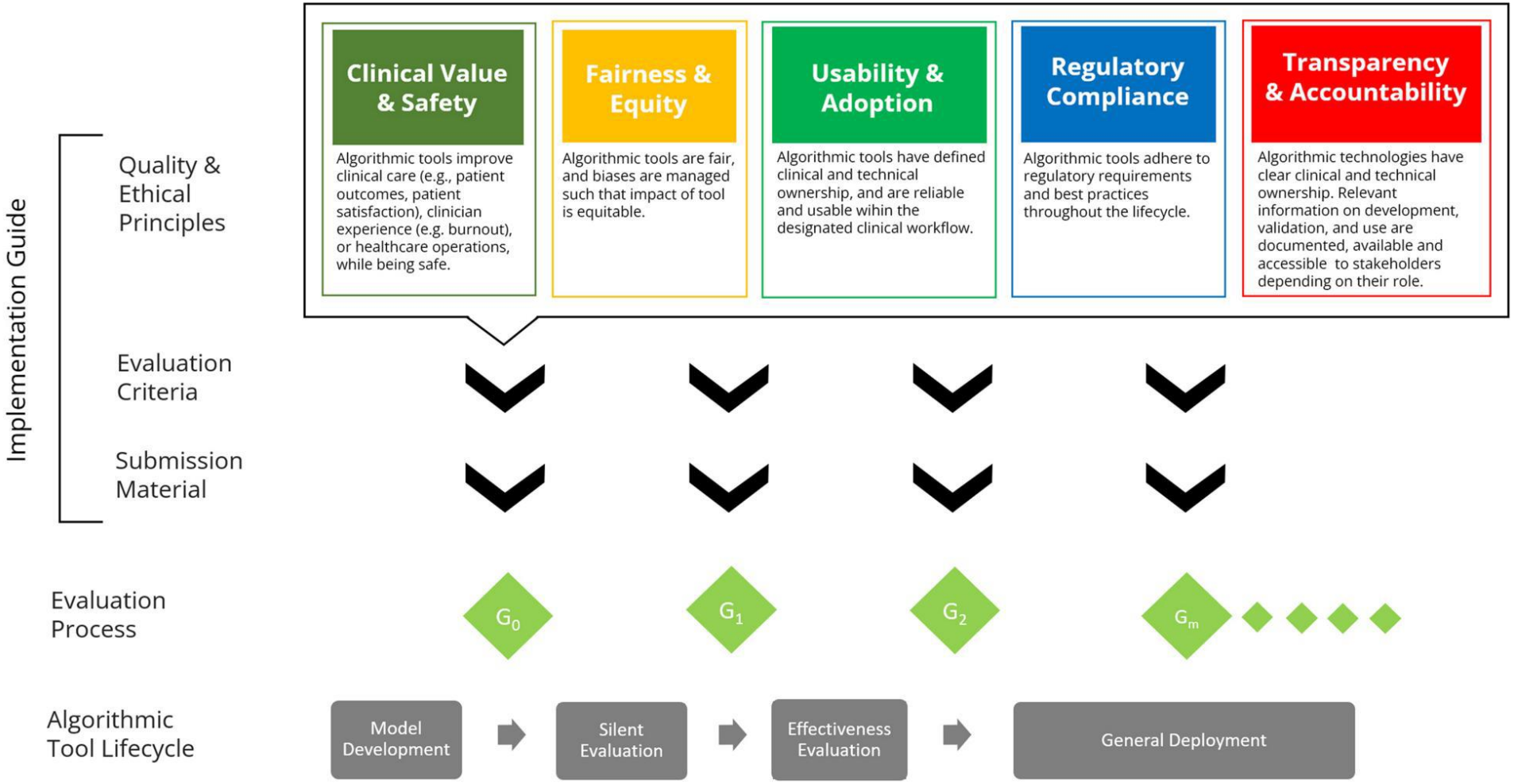
Questions to ask:

- Is the technology designed to be safe?
- Is the technology being used safely?
- Is the technology implemented safely?

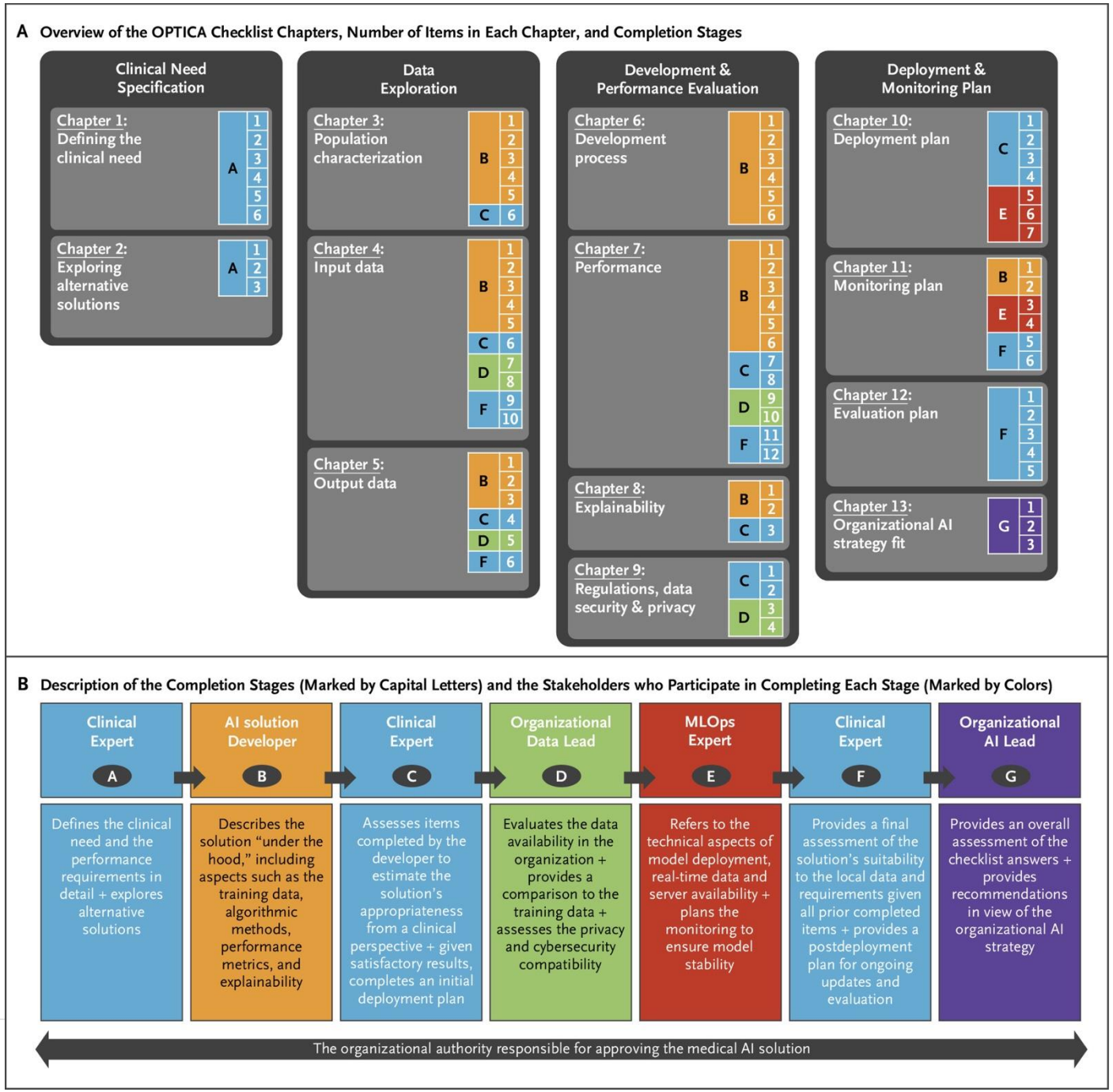
Oversight Criteria



Duke University Health System; Economou-Zavlanos N. JAMIA brief communication 2023

Evaluation of AI Solutions in Health Care Organizations — The OPTICA Tool

Dagan et al. NEJM AI 2024



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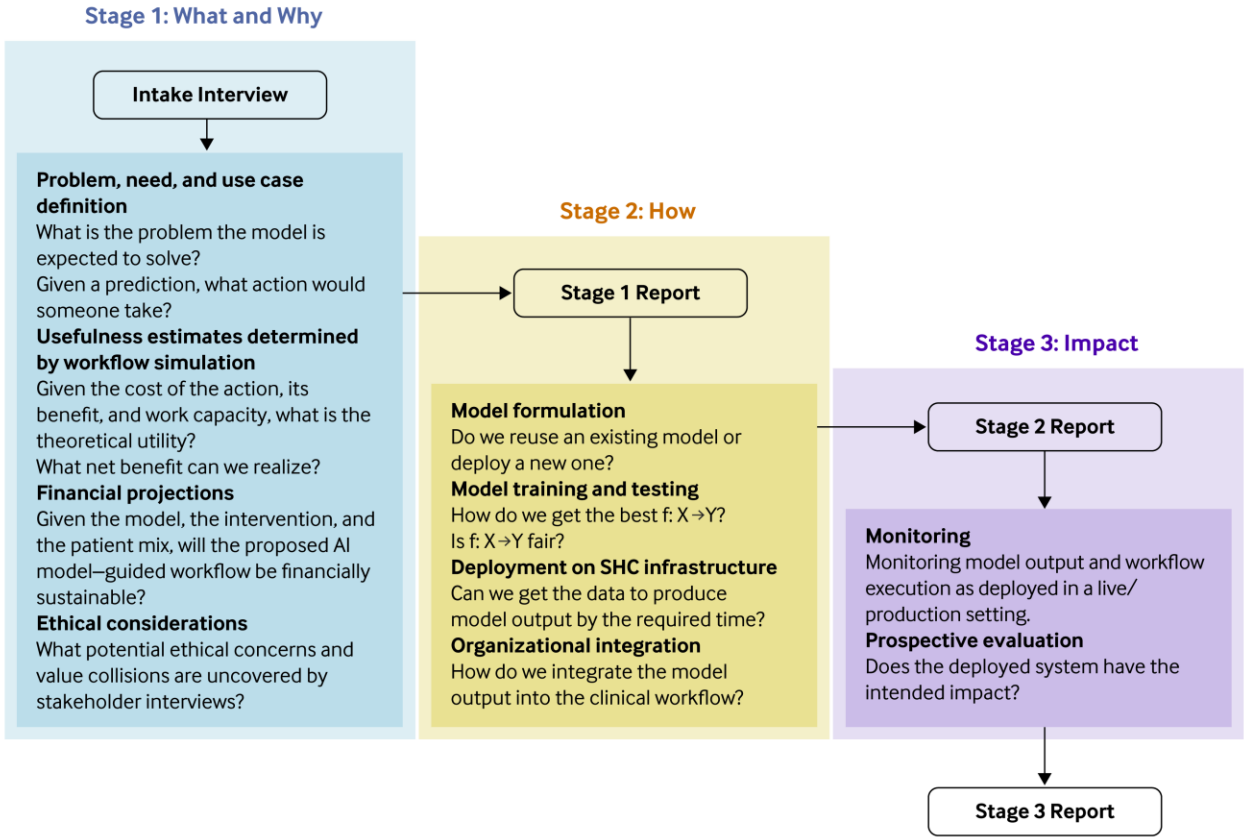
Standing on FURM Ground: A Framework forEvaluating Fair, Useful, and Reliable AI Models in Health Care Systems

Callahan et al. NEJM Catalyst 2024

FIGURE 1

The Fair, Useful, and Reliable AI Model Assessment Process

Each Fair, Useful, and Reliable AI Model (FURM) assessment consists of three stages: evaluating the what and why behind a particular AI use case; how a given AI model will be formulated, evaluated, and integrated into a given health care system workflow; and the impact of the proposed implementation. Each of these three stages has multiple components (as shown in the boxes), each addressing a different aspect of the use case. After each of the three stages, a report is prepared, which recommends whether or not to proceed.

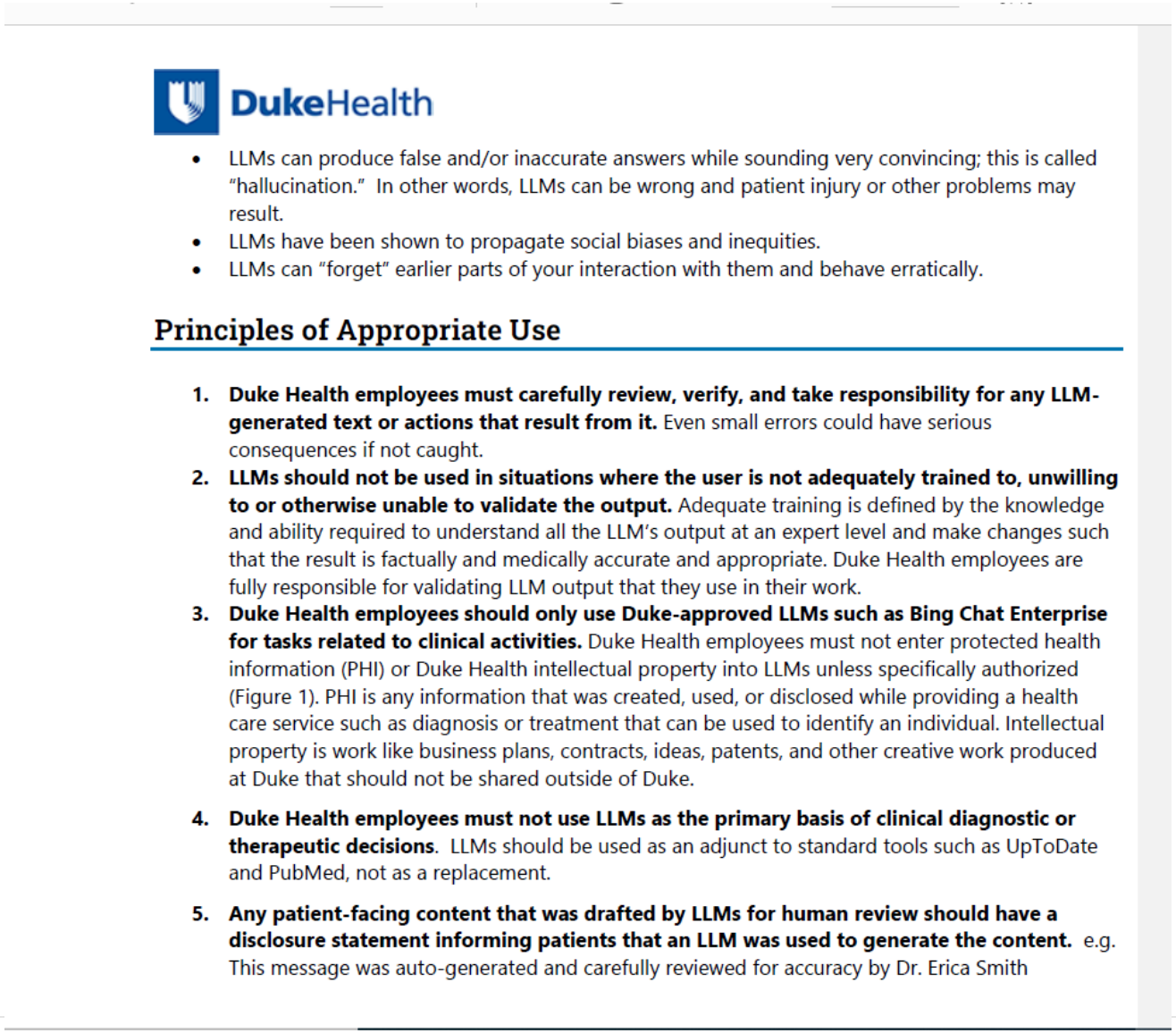


AI = artificial intelligence, SHC = Stanford Health Care.

Note: f: X → Y denotes a function that maps some values of X to some values of Y.

Source: The authors

Safe Use



DukeHealth

- LLMs can produce false and/or inaccurate answers while sounding very convincing; this is called "hallucination." In other words, LLMs can be wrong and patient injury or other problems may result.
- LLMs have been shown to propagate social biases and inequities.
- LLMs can "forget" earlier parts of your interaction with them and behave erratically.

Principles of Appropriate Use

1. **Duke Health employees must carefully review, verify, and take responsibility for any LLM-generated text or actions that result from it.** Even small errors could have serious consequences if not caught.
2. **LLMs should not be used in situations where the user is not adequately trained to, unwilling to or otherwise unable to validate the output.** Adequate training is defined by the knowledge and ability required to understand all the LLM's output at an expert level and make changes such that the result is factually and medically accurate and appropriate. Duke Health employees are fully responsible for validating LLM output that they use in their work.
3. **Duke Health employees should only use Duke-approved LLMs such as Bing Chat Enterprise for tasks related to clinical activities.** Duke Health employees must not enter protected health information (PHI) or Duke Health intellectual property into LLMs unless specifically authorized (Figure 1). PHI is any information that was created, used, or disclosed while providing a health care service such as diagnosis or treatment that can be used to identify an individual. Intellectual property is work like business plans, contracts, ideas, patents, and other creative work produced at Duke that should not be shared outside of Duke.
4. **Duke Health employees must not use LLMs as the primary basis of clinical diagnostic or therapeutic decisions**. LLMs should be used as an adjunct to standard tools such as UpToDate and PubMed, not as a replacement.
5. **Any patient-facing content that was drafted by LLMs for human review should have a disclosure statement informing patients that an LLM was used to generate the content.** e.g. This message was auto-generated and carefully reviewed for accuracy by Dr. Erica Smith

Courtesy of Dr. Eric Poon

Questions to ask:

- Is the technology designed to be safe?
- Is the technology being used safely?
- Is the technology implemented safely?
- Can the technology improve patient safety?

AI & Its Role in Patient Safety: Specific Safety Issues

npj | Digital Medicine

www.nature.com/npjdigitalmed

REVIEW ARTICLE OPEN

Check for updates

The potential of artificial intelligence to improve patient safety: a scoping review

David W. Bates[1,2,3✉], David Levine[1,2], Ania Syrowatka[1,2], Masha Kuznetsova[4], Kelly Jean Thomas Craig[5], Angela Rui[1], Gretchen Purcell Jackson[5,6] and Kyu Rhee[5]

Majority of use cases are prediction models- ADEs, sepsis, falls, pressure injuries, surgical complications, decompensation; key to tie into workflow and action

Table 3. Evaluation of the potential of artificial intelligence to improve patient safety in the eight harm domains.

Patient safety domain	Likelihood of impact
Healthcare-associated infections	AI may have a moderate impact on the reduction of HAIs given that current evidence-based practices are already effective when applied well.
Adverse drug events	AI can play a major role in ADE prevention. As more patients at risk of ADEs are accurately identified before a medication is administered or prescribed, a greater proportion of these events will become preventable. However, a key challenge lies in the lack of integrated high-quality datasets in which ADEs have been accurately captured. A variety of automated approaches have been effective at identifying patients likely to have experienced an ADE, but typically clinician adjudication is still required. ML could also help identify patients who may benefit from additional testing for specific single nucleotide polymorphisms to guide optimal drug therapy. These methods may also help to identify signals from the remainder of the genome beyond single nucleotide polymorphisms which may have prognostic impact.
Venous thromboembolism	We believe that AI will have a moderate effect on the reduction of VTE, as current evidence-based preventive strategies are already effective. AI solutions could provide further insights by identifying patients who could benefit from diagnostic testing for inherited thrombotic disorders to inform management of their condition.
Surgical complications	AI can be expected to have a moderate impact on the prediction and prevention of surgical complications both in the operating room and during recovery. Most complications felt to be preventable today are related to delayed diagnoses or intervention, technical issues, and infections. Given the overlap with other harm domains, focusing on advances in these other areas will likely also improve surgical safety.
Pressure ulcers	Pressure ulcers represent an attractive target with moderate to high potential for AI to prevent harm. Novel data sources such as motion and fluid sensors are now available, and large numbers of traditional clinical variables can be combined with the sensing data to predict who is at risk to guide evidence-based prevention.
Falls	AI is anticipated to have a moderate impact on fall prevention, given that this area has already received substantial attention and current risk mitigation strategies are effective. As with pressure ulcers, clinical data combined with sensing data can be used to predict when falls may occur, and which ones are likely to be associated with the most harm.
Decompensation	Leveraging novel data sources and AI has high potential to improve the prediction of decompensation to guide preventive strategies as well as early intervention to mitigate the impacts including premature death, given that current approaches are not effective. Given the serious nature of these events, preventing decompensation is a particularly attractive target. ML can deeply analyze data, beyond the standard values of heart rate or heart rate variability and will be critical to improving detection of decompensation and subsequent intervention.
Diagnostic errors	Diagnostic error is the most complex of the eight harm domains with vast opportunities for improvement using novel data sources and AI. ML could help to reduce the frequency of diagnostic errors by leveraging pattern recognition, bias minimization, and infinite capacity, areas where diagnosticians often falter. Although this area has garnered a lot of attention, many outstanding challenges remain, and current solutions only address a small fraction of what is possible. Most crucial to constructing valuable ML algorithms that help to reduce diagnostic error is the availability of large databases that accurately report errors.

ADE adverse drug event, *AI* artificial intelligence, *HAI* healthcare-associated infection, *ML* machine learning, *VTE* venous thromboembolism.

AI & Its Role in Patient Safety: Decreasing Cognitive Burden

JAMIA Open, 2023, **6(3)**, ooad079
https://doi.org/10.1093/jamiaopen/ooad079
Perspective

Perspective

How can artificial intelligence decrease cognitive and work burden for front line practitioners?

Tejal K. Gandhi, MD, MPH[1,*], David Classen, MD, MS[2], Christine A. Sinsky, MD[3], David C. Rhew, MD[4], Nikki Vande Garde, BSN[5], Andrew Roberts, PhD[6], Frank Federico, RPh[7]

- Data gathering
- Data synthesis
- Documentation
- Taking appropriate action
- Structure asynchronous activities, outcomes and activities

Table 1. Clinical and cognitive processes potentially impacted by AI.

Function	Description	Example
Data gathering.	AI-based tools such as natural language processing (NLP), large language models, and image recognition can help clinicians comb through large volumes of information sources and discrete or unstructured data to help locate, identify, and surface the most relevant pieces of information, as well as missing information, to reduce cognitive and work burden on clinicians.	*Data gathering*: Using NLP, clinicians can more efficiently search genomic and clinical trial databases, medical literature, and other sources of information to rapidly identify recommended treatments specific to cancer patients. *Data gathering and synthesis*: Solutions identify and compile both structured and unstructured EHR data and present that information to the provider to identify potential missing diagnoses, diagnoses that lack specificity, and documented diagnoses that lack clinical evidence. Presenting this information directly to providers within their workflow eliminates the need to address manual queries hours, days, or weeks later; thus, reducing the cognitive burden on the provider.
Data synthesis. rapidly collect, organize, manage, and making sense of the datasets from clinical assessments, physiologic observations, and documentation.	AI may be used to help support a new clinical workflow (eg, command center; rapid response team) or to improve an existing one (eg, prioritize existing care management outreach based on risk)	*Data gathering and synthesis*: The future of healthcare includes the use of wearable devices and remote monitoring which will present clinicians with an overwhelming amount of information to sift through to make a clinical decision. AI can help filter through data, identifying critical data points or information that may indicate a change in a patient's condition or sudden deterioration. AI can also suggest treatments based on scientific evidence, as well as offer customization based on the patient's condition, ability to adhere to treatment, and personal desires.
Documentation.	AI may be used to create or enter a summary of or provide specific details regarding a patient encounter into an EHR or other system of record using technology. AI can help simplify the billing documentation process, and generative AI can help reduce documentation burden.	*Documentation*: Ambient clinical intelligence (ACI) allows patients and clinicians to engage in conversation without the clinician needing to focus his/her time on a keyboard or screen. When used in ACI, AI helps identify the speaker, uses NLP to convert the voice conversation into text, maps the medical terms and phrases to standardized nomenclatures, and organizes the conversation into a properly formatted clinical note, that can then be reviewed by the clinician for accuracy and relevance. Once finalized, the note is integrated into the EHR. Voice can also be leveraged to navigate and act within the EHR.
Taking appropriate action.	AI can provide decision support, prediction tools, targeted outreach, and guidance in response to signals or deploy an "intelligent" command center to help manage populations	*Data gathering, synthesis and taking action*: In 2018, Ochsner Health System (New Orleans, LA) leveraged a pilot program to redesign care models at several campuses to include virtual nursing.[14,15] With trained clinicians working from remote command centers or virtual bunkers, there is opportunity to leverage AI to remove interruptions for nurses and physicians at the patient's bedside, and to centralize AI and ML model monitoring and management while allowing associated interventions to continue to be carried out at the bedside. *Taking action*: Clinical decision support, particularly related to medication prescribing, has been plagued with issues related to over-alerting, contributing to cognitive burden. In a recent study, researchers at one academic medical center found that ML techniques could enable intelligent filtering of medication alerts and reduce alert volume by 54%.[16]
Structure asynchronous activities, outcomes and activities.	The care team's clinical and operational activities, including patient rounds and communication, are unstructured and asynchronous. AI can help manage coordination and synthesis of the information for updates and the next best course of action.	*Data gathering, synthesis and taking action*: A computer assisted management program for antibiotics and other anti-infective agents showed improved patient and antibiotic outcomes.[17]

From: **Using Artificial Intelligence to Improve Primary Care for Patients and Clinicians**

JAMA Intern Med. Published online February 12, 2024. doi:10.1001/jamainternmed.2023.7965

Table. Potential Use Cases for AI in Primary Care

Use case	Examples of AI role
Inbox management	• Prioritize patient messages • Generate draft responses • Edit physician messages to optimize communication, including for literacy appropriateness
Clinician documentation	With transcription software: • Draft progress notes in real time during visits • Draft prior authorization, disability, and durable medical equipment requests • Draft a list of billing codes for visits
Between-visit panel management	• Accurately identify patients in need of cancer screening using unstructured and structured EHR data to determine exclusions • Identify patients with incomplete cancer screening (such as missed appointments), automate communication with patients, and provide scheduling and/or staff notification • Generate tailored messages to patients related to needed between-visit care needs
Individualized decision support	• Identify relevant information in structured and unstructured EHR data to prioritize differential diagnoses for new symptoms • Recommend medication options for chronic conditions, considering prior medication prescriptions, allergies, and intolerances noted in structured and unstructured EHR data

Abbreviations: AI, artificial intelligence; EHR, electronic health record.

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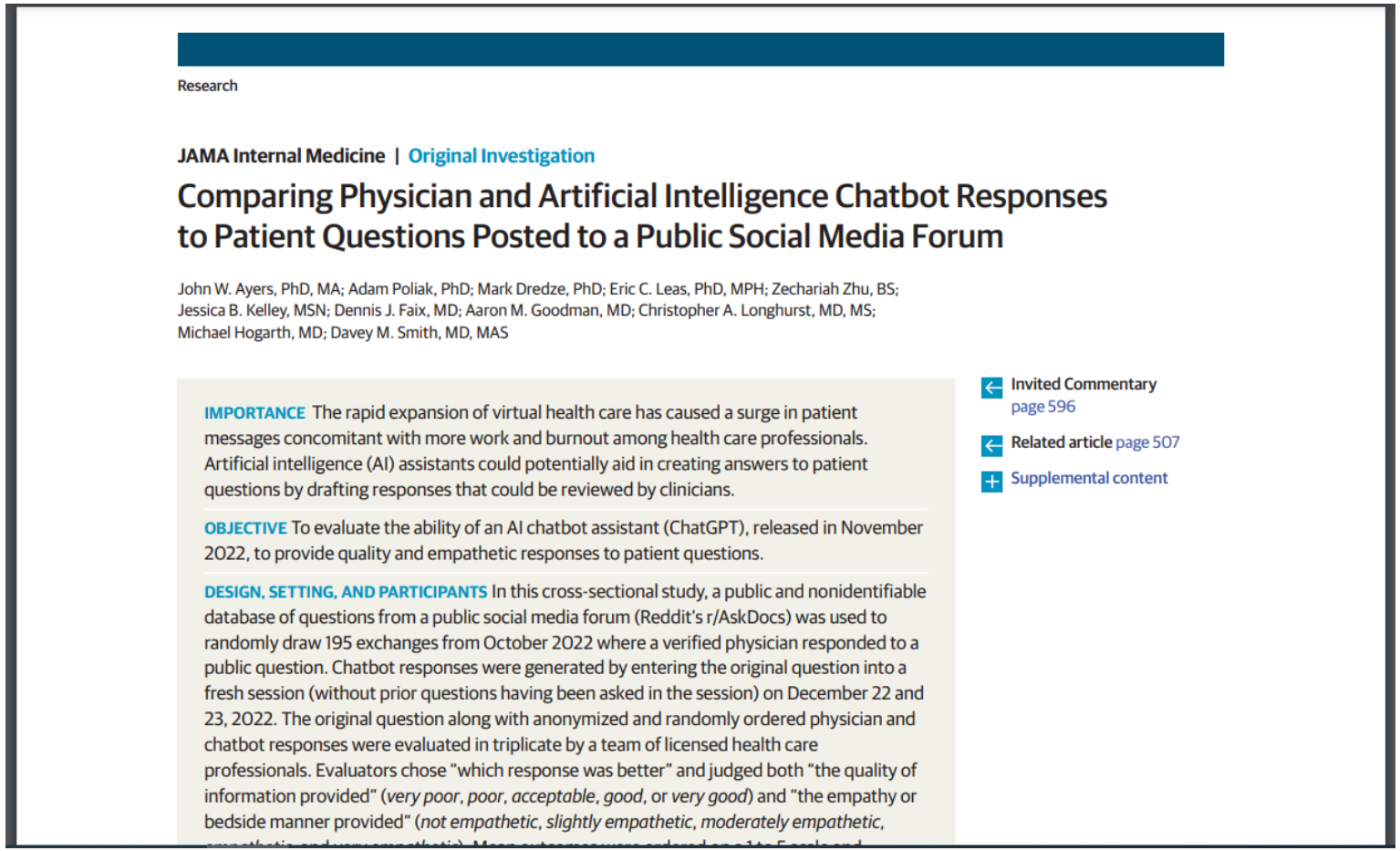
Patient Communication



Research

JAMA Internal Medicine | Original Investigation

Comparing Physician and Artificial Intelligence Chatbot Responses to Patient Questions Posted to a Public Social Media Forum

John W. Ayers, PhD, MA; Adam Poliak, PhD; Mark Dredze, PhD; Eric C. Leas, PhD, MPH; Zechariah Zhu, BS; Jessica B. Kelley, MSN; Dennis J. Faix, MD; Aaron M. Goodman, MD; Christopher A. Longhurst, MD, MS; Michael Hogarth, MD; Davey M. Smith, MD, MAS

IMPORTANCE The rapid expansion of virtual health care has caused a surge in patient messages concomitant with more work and burnout among health care professionals. Artificial intelligence (AI) assistants could potentially aid in creating answers to patient questions by drafting responses that could be reviewed by clinicians.

OBJECTIVE To evaluate the ability of an AI chatbot assistant (ChatGPT), released in November 2022, to provide quality and empathetic responses to patient questions.

DESIGN, SETTING, AND PARTICIPANTS In this cross-sectional study, a public and nonidentifiable database of questions from a public social media forum (Reddit's r/AskDocs) was used to randomly draw 195 exchanges from October 2022 where a verified physician responded to a public question. Chatbot responses were generated by entering the original question into a fresh session (without prior questions having been asked in the session) on December 22 and 23, 2022. The original question along with anonymized and randomly ordered physician and chatbot responses were evaluated in triplicate by a team of licensed health care professionals. Evaluators chose "which response was better" and judged both "the quality of information provided" (*very poor*, *poor*, *acceptable*, *good*, or *very good*) and "the empathy or bedside manner provided" (*not empathetic*, *slightly empathetic*, *moderately empathetic*,

Invited Commentary page 596

Related article page 507

Supplemental content

Chatbot had longer responses or higher quality and empathy compared to doctors

From: **Using Artificial Intelligence to Improve Primary Care for Patients and Clinicians**

JAMA Intern Med. Published online February 12, 2024. doi:10.1001/jamainternmed.2023.7965

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NEJM Catalyst | Innovations in Care Delivery

COMMENTARY

Ambient Artificial Intelligence Scribes to Alleviate the Burden of Clinical Documentation

Aaron A. Tierney, PhD, Gregg Gayre, MD, Brian Hoberman, MD, MBA, Britt Mattern, MBA, Manuel Ballesca, MD, Patricia Kipnis, PhD, Vincent Liu, MD, MS, Kristine Lee, MD

Vol. 5 No. 3 | March 2024

DOI: 10.1056/CAT.23.0404

Clinical documentation in the electronic health record (EHR) has become increasingly burdensome for physicians and is a major driver of clinician burnout and dissatisfaction. Time dedicated to clerical activities and data entry during patient encounters also negatively affects the patient-physician relationship by hampering effective and empathetic communication and care. Ambient artificial intelligence (AI) scribes, which

Significantly larger decrease in time spent in the EHR outside 7 a.m. to 7 p.m. among users starting to use the ambient AI scribe than among those who did not use the tool

From: **Using Artificial Intelligence to Improve Primary Care for Patients and Clinicians**

JAMA Intern Med. Published online February 12, 2024. doi:10.1001/jamainternmed.2023.7965

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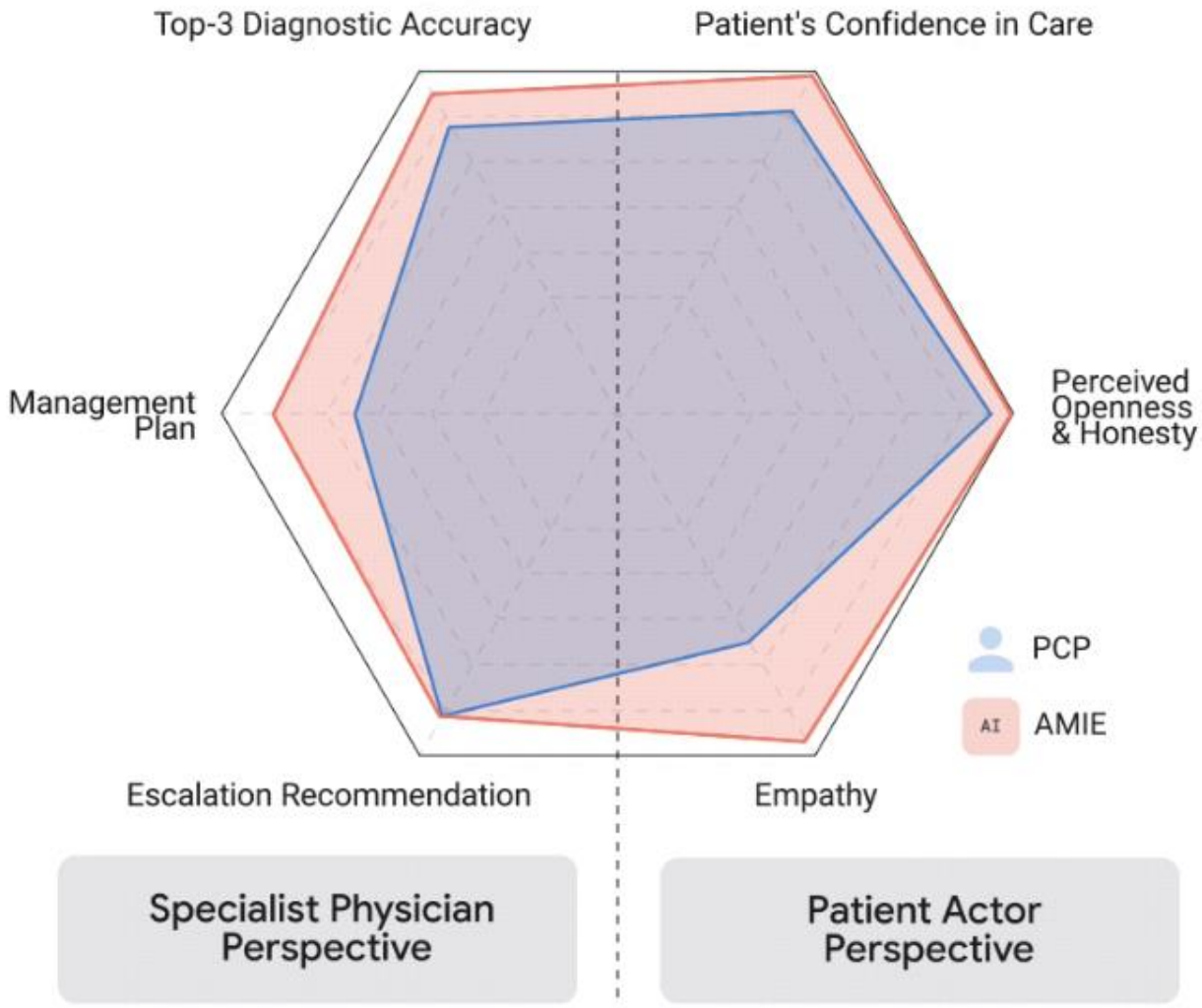
Abbreviations: AI, artificial intelligence; EHR, electronic health record.

Use cases for Safety: Bread and Butter vs. Shiny Object

1. **Automate low priority tasks and decrease administrative burden and cognitive load -> more time to focus on delivering safe care**
2. **Diagnosis**
   - Follow-up of test results and referrals/complaints without follow-up
   - Imaging
   - Synthesizing information in the workflow
3. **Medication Decision Support/Med Reconciliation**
   - Smarter decision support using more robust algorithms
   - Identifying discrepancies
4. **Predicting harm/proactive**
   - Early deterioration/early detection/risk prediction (finding high risk situations through a range of data sources)
5. **Measuring harm**
   - Triggers
   - Safety event reporting/PSOs
     - Easing burden of reporting by leveraging text to minimize data entry
     - Analyzing to find important trends and helping prioritize
6. **Patient engagement**
   - Identifying safety themes in patient comments
   - Communication tools

Diagnostic Dialogue Evaluation



Source: Research.Google

What to worry about

Problem	Example
Design	• Black box • Bias in data/bad data • Perpetuating inaccurate information in the EHR (falsehood mimicry) • Hallucinations/complete the narrative errors • Sycophancy bias • Variability (LLMs are probabilistic) • Other unintended consequences
Implementation/Use of Findings	• Patients using AI generated medical advice and experiencing harm • Bias in how used • Generalizability • Drift in how used • Decay in algorithm accuracy • Inequitable access/widening gaps • Depersonalized care/patient concerns
Cognition Distraction De-skilling/automation bias/induced belief revision Re-skilling	• Too much attention to computer monitors and smart-phones, and not • enough to patients and colleagues • AI does not say patient is deteriorating- do we ignore clinical intuition? • What new teaching and competencies do clinicians need?

Bias/Equity Considerations

Algorithms can perpetuate existing bias in the data

- biased data in= biased data out

Algorithms can potentially reduce existing bias if designed well

- language/access/bias removal

Access/cost of AI can lead to inequities

De-skilling and Re-skilling

- **Deskilling/Automation bias/Alert fatigue**
  - Rely too much on the algorithm/decision support
  - Lose clinical judgment and/or skills
  - Has been a concern for years
    - E.g. Drug interactions, barcode technology
    - E.g. Cookbook medicine
- **Reskilling**
  - How do we teach about what the algorithms can and cannot do?
  - How do we highlight areas where the algorithm may be less certain?
  - How do we teach clinicians how to effectively oversee?
    - E.g. review of clinical notes- are we reducing or adding to workload?
  - How do we talk to patients about it?

Designing AI to Promote Clinician Vigilance

Visual Cues

Highlight AI output that is more uncertain and potentially faulty.

Clinical-Level Measures

The basis for a system to assess whether a clinician is exhibiting automation bias.

Avoid Throughput Expectations

AI-generated practice efficiencies should not be converted into throughout expectations.

Deliberate Shocks

Program AI to introduce faulty outputs to stimulate vigilance.

Paradigm Shift

Design AI to exercise vigilance over clinicians (e.g., AI only shows if different from clinician choice).

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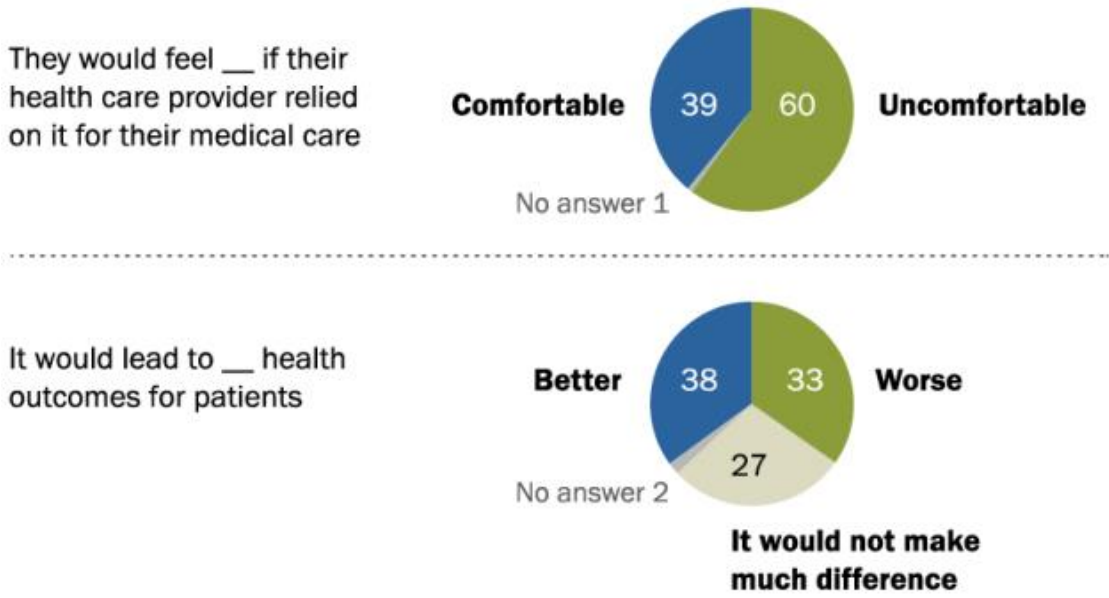
Adler-Milstein J, Redelmeier DA, Wachter RM. The Limits of Clinician Vigilance as an AI Safety Bulwark. *JAMA.* Published online March 14, 2024. doi:10.1001/jama.2024.3620

What Do Patients Think About AI

- **Security/privacy**
- **Consent?**
- **Depersonalized care vs Increased empathy?**
- **Increased access to care (chatbots)**
- **Reduce bias**
- **Reduce errors**
- **Transparency**
  - Do we have to say when using AI? Do we say when using other tools (e.g. UpTo Date)?
- **What are best ways to educate patients?**

Fewer than half in U.S. expect artificial intelligence in health and medicine to improve patient outcomes

% of U.S. adults who say that thinking about the use of artificial intelligence in health and medicine to do things like diagnose disease and recommend treatments ...

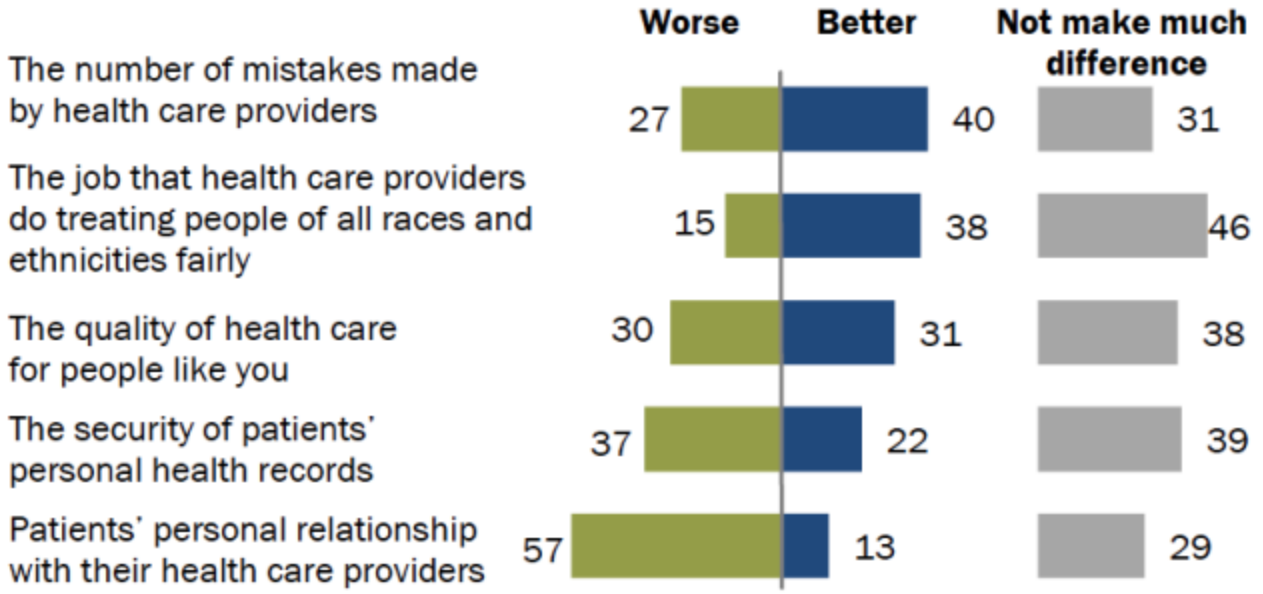


Source: Survey conducted Dec. 12-18, 2022.
"60% of Americans Would Be Uncomfortable With Provider Relying on AI in Their Own Health Care"

PEW RESEARCH CENTER

Americans tilt positive on AI's ability to reduce medical errors; greater concern around data security, patient-provider relationships

% of U.S. adults who say the use of artificial intelligence in health and medicine to do things like diagnose diseases and recommend treatments would make each of the following ...



Note: Respondents who did not give an answer are not shown.
Source: Survey conducted Dec. 12-18, 2022.
"60% of Americans Would Be Uncomfortable With Provider Relying on AI in Their Own Health Care"

PEW RESEARCH CENTER

How Can AI Improve Patient Safety (per Chat GPT)

1. **Early Detection and Diagnosis**: AI-powered algorithms can analyze large volumes of patient data, including medical records, imaging scans, and genetic information, to detect patterns indicative of potential health risks or diseases at an early stage. This can lead to quicker diagnosis and intervention, reducing the likelihood of medical errors and improving patient outcomes.

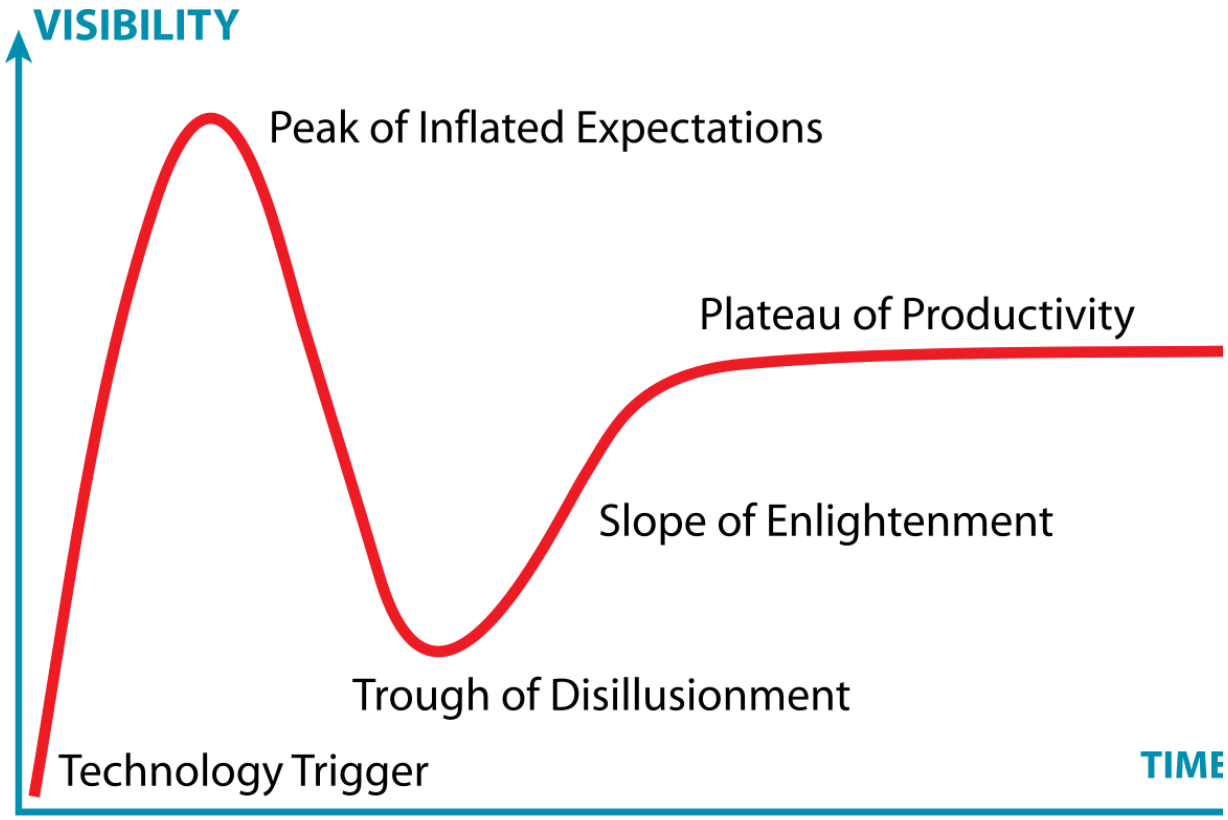
2. **Predictive Analytics**: AI can utilize predictive modeling techniques to forecast adverse events, such as hospital-acquired infections or medication errors, by analyzing patient data and identifying risk factors. Healthcare providers can then implement proactive measures to mitigate these risks, thereby enhancing patient safety and preventing avoidable harm.

3. **Personalized Treatment Plans**: AI algorithms can analyze patient characteristics, including genetic factors, medical history, and treatment responses, to tailor personalized treatment plans that optimize efficacy while minimizing adverse effects. By considering individual patient variability, AI-driven decision support systems can help reduce the likelihood of adverse drug reactions or treatment complications, thereby improving patient safety.

4. **Real-time Monitoring and Alerts**: AI-powered monitoring systems can continuously analyze patient data, such as vital signs, medication adherence, and physiological parameters, in real-time. These systems can automatically detect deviations from normal ranges and issue alerts to healthcare providers, enabling timely intervention and preventing adverse events such as sepsis or cardiac arrest.

5. **Workflow Optimization**: AI can streamline healthcare workflows by automating routine tasks, optimizing resource allocation, and prioritizing patient care activities. By reducing administrative burden and minimizing human error, AI technologies free up healthcare professionals to focus on delivering high-quality care, ultimately enhancing patient safety across the care continuum.

Gartner Technology Hype Cycle



How to go forward

1. **Go forward**
   - Don't hold AI to impossible standards – get wiser about how to use it.
   - Transparency about algorithms
   - Governance/oversight rapidly evolving
2. **Don't be afraid**
   - It is mainly going to do the easy and boring stuff
   - Solve the common problems that have been challenging
   - Clinicians have "superpowers" of critical thinking and relationship building
3. **Think of AI as a new team member**
   - Thoughtful, intelligent, able to do some things very well, and others not-so- well
4. **Understand/proactively assess and monitor safety implications on many levels**

"When will we feel unsafe if we are not using AI?"

Thank you

Tejal.Gandhi@pressganey.com

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