Health Care Artificial Intelligence Foundation

CALIFORNIA TELEHEALTH RESOURCE CENTER

Part of OCHIN

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ABOUT CTRC

The California Telehealth Resource Center (CTRC) offers no-cost, unbiased training, educational resources, and technical assistance to help California providers and patients get the most from telehealth. As the federally designated telehealth resource center for the region, we offer unbiased tools and services based upon proven telehealth practices. We create lasting change and improvement by focusing on implementation, sustainability, reimbursement and policy, integration, workflows, and patient/provider adoption.

As part of the National Consortium of Telehealth Resource Centers and the OCHIN family of companies, CTRC assists thousands of providers and patients annually. We have extensive experience supporting the health care safety net, rural and urban providers, and patients and families throughout California who would otherwise be unable to access quality health care due to geographic isolation, language/cultural barriers, lack of insurance, disability, homelessness, and more.

Health Care AI Toolkit: An Introduction

"By augmenting human performance, AI has the potential to markedly improve productivity, efficiency, workflow, accuracy and speed, both for [physicians] and for patients … What I'm most excited about is using the future to bring back the past: to restore the care in healthcare."

-Eric Topol, MD, Director and Founder of Scripps Translational Institute

The rapid increase in advanced artificial intelligence (AI) systems and applications in healthcare has occurred seemingly overnight. Clinicians, operational staff, and provider leadership may not be aware that they are utilizing an AI system, may not know what questions to ask, nor know what policies, procedures, processes, and professional training should be in place to ensure that such systems drive improved health outcomes and reduce chronic diseases, reduce the burden on their teams, improve chronic disease rates, and increase overall sustainability.

This is an introductory guide to support these efforts.

AI systems can be applied to clinical care, operations, research and public health and may involve different AI **systems**, **methods**, **functions**, **levels of autonomy**, and **conditions of deployment**. As a result, the risk profile of the system may be varied. Your staff training and AI policies and procedures should be built to account for the varied risk profiles and the questions you ask of vendors/developers will also vary as a result.

Across California, healthcare providers have many questions concerning healthcare AI. This guide will help you navigate these questions while providing foundational information.

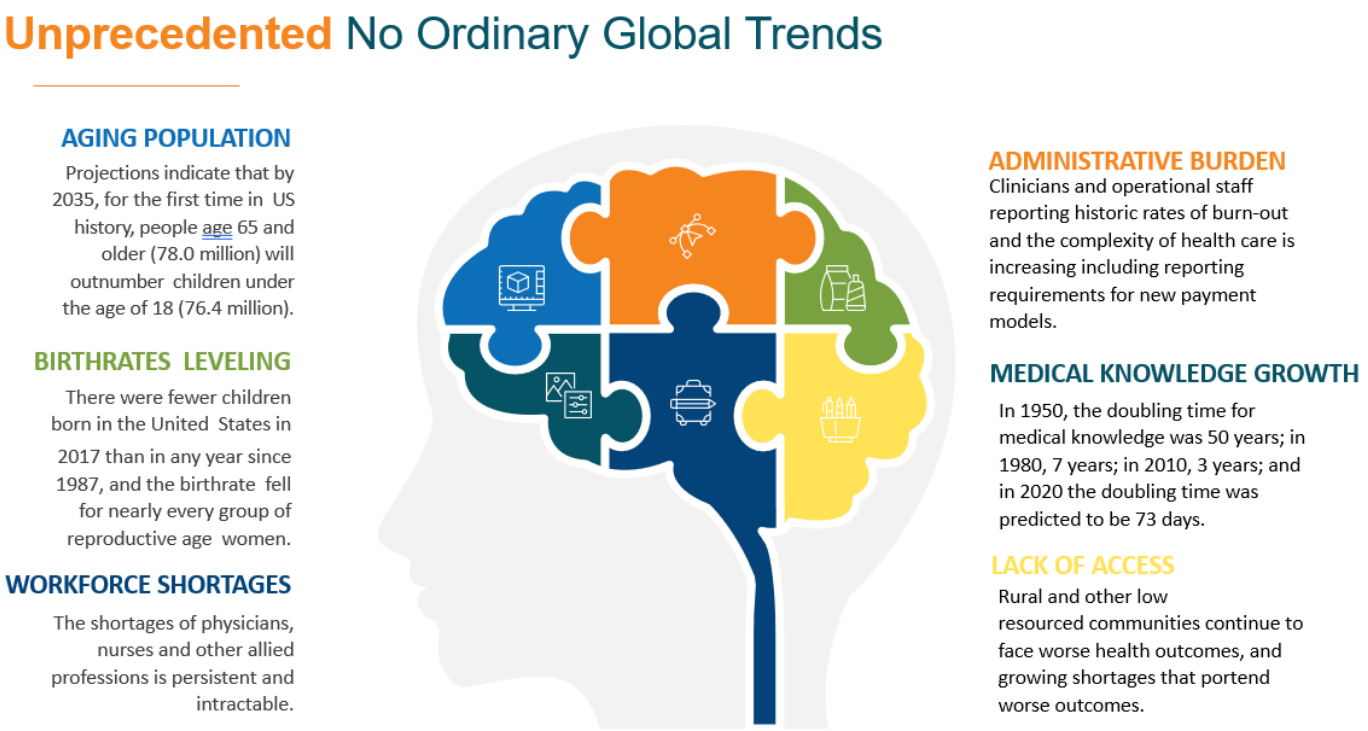
Our goal is to simplify, streamline, and provide clear explanations.

As a result, we will outline in this foundational chapter:

- What is the **imperative** to adopt AI systems in healthcare?
- What is AI?
- Are there different **levels of autonomy** of AI in healthcare?
- What are the **different applications** of AI in healthcare?
- What are the **benefits and areas of risk**?
- What **responsibility** do you and your **team** have to ensure AI systems comply with federal and California laws and are safe and function as intended?
- What responsibility does **your vendor** have?

You are taxed for time and are likely to ask: **why utilize AI tools given the complexity, potential harm, and need for engagement and training across staff and patients?**

The reality is that you may already be utilizing a number of these systems including, for example, when using remote physiological monitoring or embedded in other health IT tools like facial ID logins, spam filters, predictive text, and voice assistants. In many instances, AI scribes are becoming standard as they help to alleviate administrative burden and clinician burnout.



Even if you are not using AI tools and systems, there are significant global, national, and regional trends that are **unprecedented and require innovation to address these challenges including AI to support sustainability and drive high quality care while reducing costs**.

Workforce shortages of healthcare professionals will remain intractable with an aging population across California and the nation while birthrates are leveling off and, in some places, declining.

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The complexity of healthcare has increased exponentially for several reasons, including:

- Advances in medical knowledge have exceeded the capacity of humans to process and adopt in a timely way.
- The amount of data from a wide array of sources, including patient generated data, exceeds the capacity to organize, validate, secure, synthesize, and ascribe meaning.
- Regulatory requirements at the federal and state level as well as hundreds of varied and different policies of health care programs and health insurers impose increasing administrative burdens.

Finally, patients in rural and other underserved communities continue to experience adverse health outcomes and high chronic disease rates, which are all exacerbated by the intractable health care clinician shortages. **AI tools and systems can drive scalable solutions.**

> "[AI] may well make care more efficient [and] more accurate. But realizing this promise requires being aware of the potential for bias and guarding against it. It means regularly monitoring both the output of algorithms and the downstream consequences … Most fundamentally, it means **recognizing that humans, not machines, are still responsible for caring for patients. It is our duty to ensure that we're using AI as another tool at our disposal — not the other way around."**
>
> -Dhruv Khullar, MD, Physician, New York Presbyterian Hospital

What does AI mean? Predictive analytics? Generative AI? General AI? Narrow AI?

Like the term "telehealth," there are many meanings and definitions for AI that vary based on state or federal agency, health insurer, vendor, and other health care stakeholder. In 2024, California enacted a new law establishing a standard definition of AI (**AB 2885**). It borrows from the definition contained in a since-repealed presidential executive order (**Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence**) and a definition developed by the international **Organization for Economic Co-Operation and Development (OECD)** which is used by European countries. However, it is important to understand that there is not a single agreed upon definition of AI across the U.S. federal government, states, and industry standards setting bodies.

In California, the legal definition of AI is:

> **"Artificial intelligence" means an engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments**.
>
> **California AB 2885 Artificial Intelligence**

Other key definitions included in California law include:

Automated decision system: A computational process derived from machine learning, statistical modeling, data analytics, or artificial intelligence that issues simplified output, including a score, classification, or recommendation, that is **used to assist or replace human discretionary decision-making and materially impacts natural persons**.

High-risk automated decision system: An automated decision system that is used to assist or replace human discretionary **decisions that have a legal or similarly significant effect**, including decisions that materially impact access to, or approval for, housing or accommodations, education, employment, credit, health care, and criminal justice.

New Laws Passed in 2024 Concerning AI in California

California had an active 2023-2024 legislative session around AI. Along with the new law establishing definitions related to AI (AB 2885), Governor Newsom signed 18 AI bills into law, several of which will impact health care directly or indirectly.

Health Care AI Laws

Provider Notification When Using AI to Communicate with Patients. One law (AB 3030) requires health providers to disclose when they use generative AI to communicate with patients about clinical information

Health Insurer Limited Use of AI. A new law (SB 1120) prohibits health insurers from using AI to deny healthcare claims without human review. Only licensed health care professionals can make the final medical necessity determination.

Privacy

Two laws will **increase AI and privacy for individuals** by clarifying that that protected* "personal information" includes:

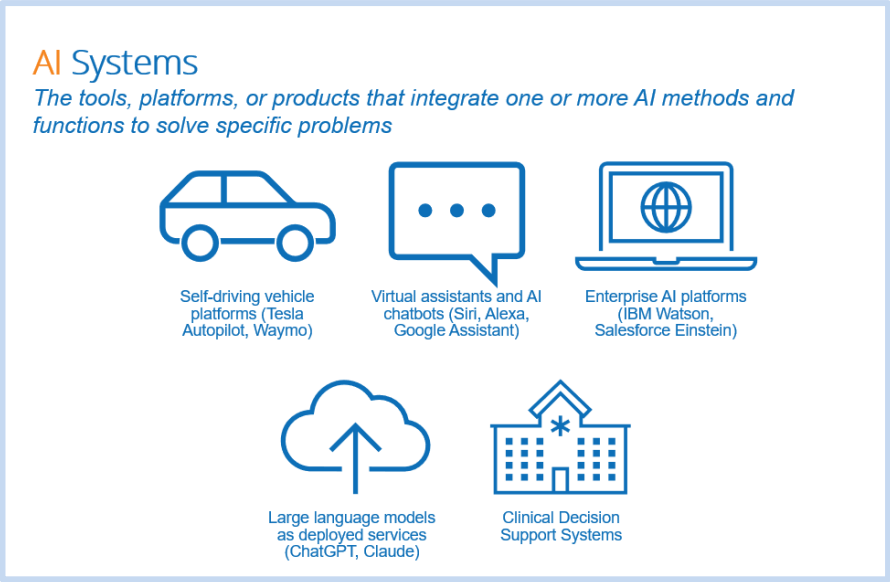
- **Artificial Intelligence systems** capable of outputting personal information (AB 1008)
- A consumer's **neural data**, which may be stored or used by AI (SB 1223)

- **These laws do not apply to Protected Health Information regulated under HIPAA*

Transparency

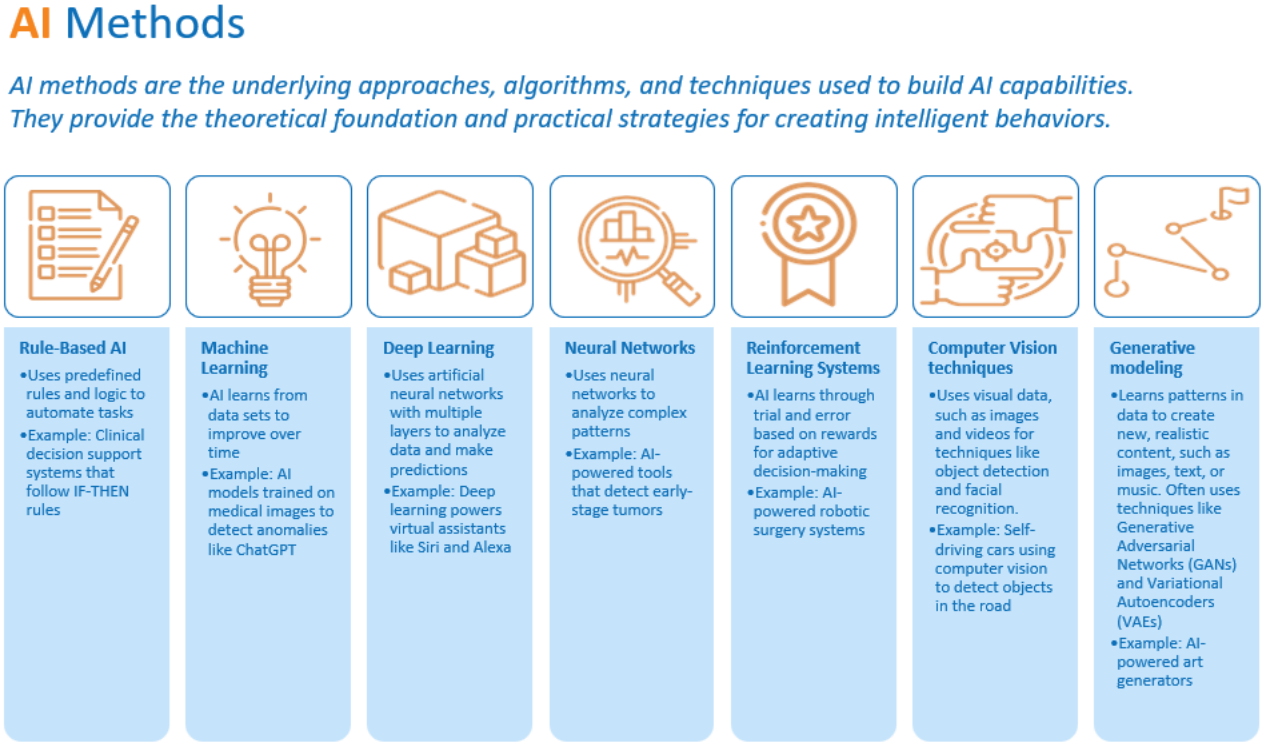
- Two laws will **improve transparency in AI tools** used by the public by requiring companies that develop AI tools to:
  - Publicly disclose information about the **data they used to train the AI tool** (AB 2013)
  - Provide free **AI detection tools** to allow users to detect whether content is AI-generate (specific to large AI deployers) (SB 942)

AI **systems** are the **tools, platforms, or products** that utilize one or more AI methods and functions to solve specific problems. For example, self-driving vehicles, chatbots, language models, and clinical decision support systems.



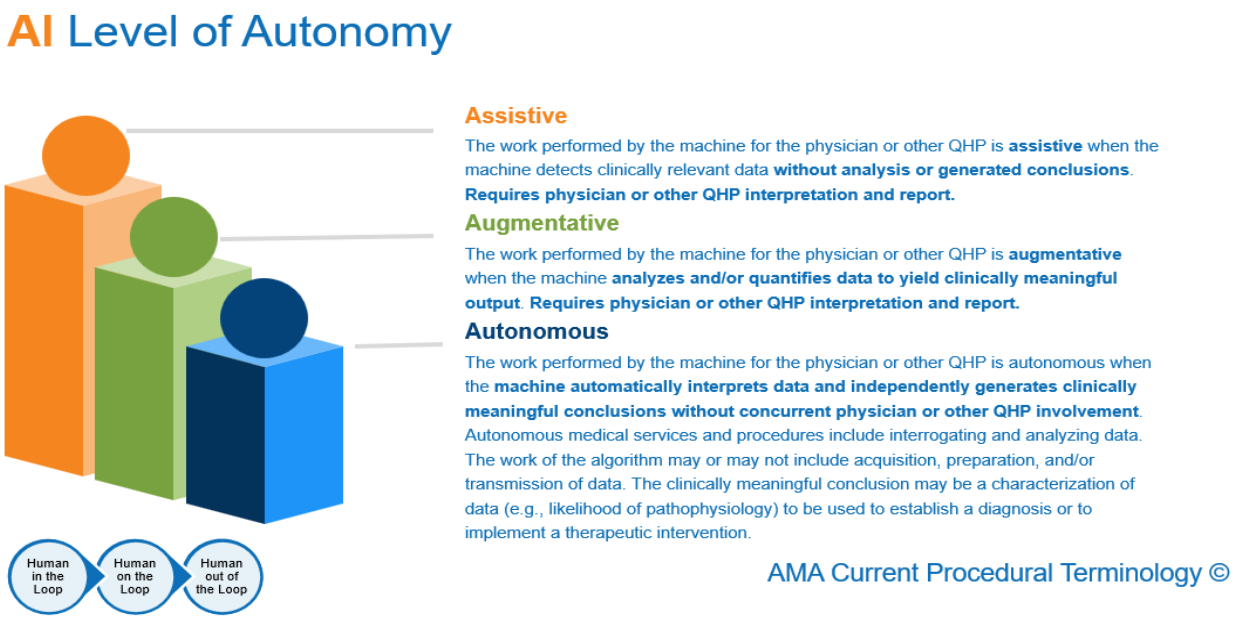
Meanwhile, AI **methods** are the underlying **approaches, algorithms, and techniques used to build AI tools**. For example, some AI systems are **rules based**, meaning there is a human in the loop along with the ability to identify the rationale and reason for the output, resulting in higher transparency.

Example: **Machine learning** systems have two algorithms—one that is a **"learner" algorithm** which gathers information for the **"output" algorithm**. If the system does not have a **human is in the loop**, the learner algorithm can change the output algorithm without a clear explanation. Because of the higher risk, developers often **"lock" the learner** so that the output algorithm can be tested for safety, efficacy, and any unintended consequences.



In addition to the systems and methods, different AI models have varied levels of **autonomy** once deployed into clinical and operational settings.

The AMA's CPT Editorial Panel has identified **levels of autonomy** for systems deployed in the clinical setting, including whether a system **assistive**, **augmentative** or **autonomous**. (This classification could apply to other settings including operational and research.) The CPT Editorial Panel stratified **autonomous** systems into three different categories (**human in the loop**, **human on the loop**, and **human out of the loop**) to describe whether clinicians are expected to be in the loop when the system is deployed. See below.



Example: Physicians Make Decisions Act. One of the 2024 laws listed above (**SB 1120**) deals with level of autonomy and human in the loop. It ensures that health insurers do not use AI systems to deny health care claims without a licensed health care professional in the loop. Specifically, it ensures that **only human, licensed health care professionals make the determination about whether a health insurance claim was medically necessary.**

"For AI to add the most value and for patients and physicians to embrace it, it needs to support, not supplant, the patient-physician relationship … AI will be most effective when it enhances physicians' ability to focus their full attention on the patient by shifting the physicians' responsibilities away from transactional tasks toward personalized care that lies at the heart of human healing."

– Steven Lin, MD, Vice Chief for Technology Innovation in Stanford University's Division of Primary Care and Population Health

Clinical and Operational

There are significant benefits to the broad array of AI systems in healthcare including both operational and clinical. These can be used to reduce clinician burnout, ease workforce shortages, engage with patients, and improve health outcomes.

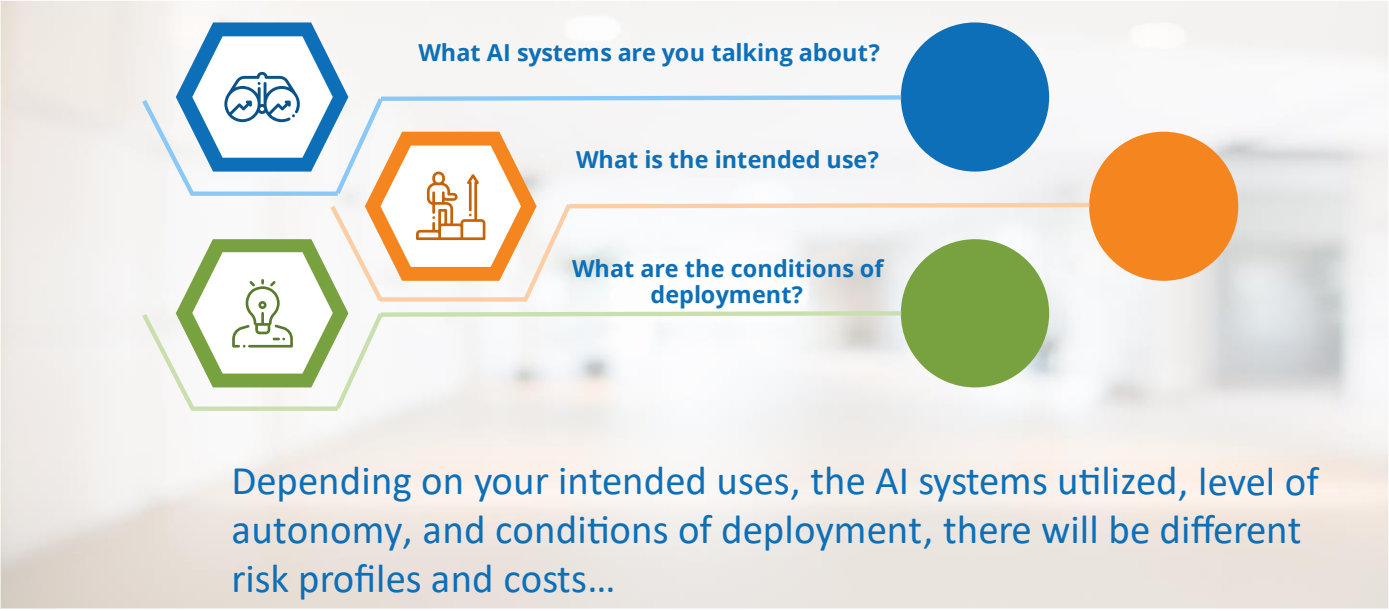
However, when considering uses of AI in healthcare, providers must pay close attention to the **level of risk** associated with the AI **systems, methods and level of autonomy.**

Key questions:

- Do you understand *why* the AI system is arriving at the outcome/recommendation it is providing?

- What *level of autonomy* does the system have to implement its output/recommendation? Is human decision-making or action required before it is implemented?

APPLICATIONS Research, Operations, Clinical



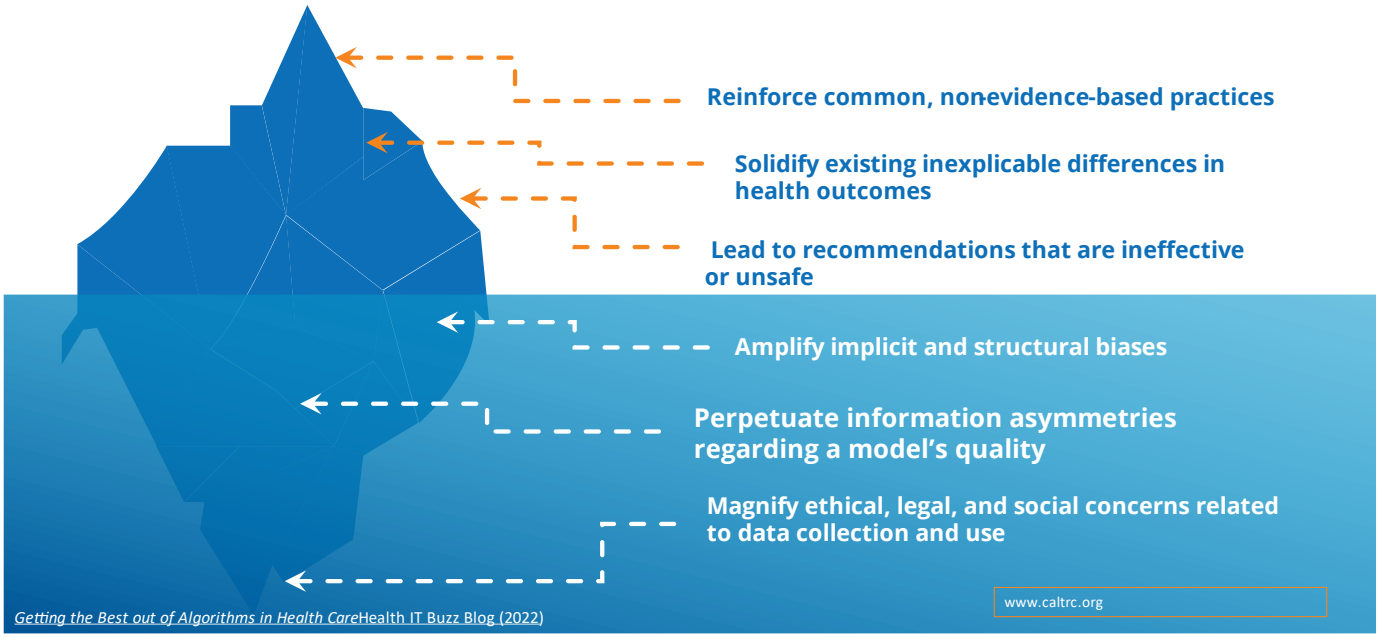
As you consider different AI systems and how these are intended to be used in your healthcare setting, it is important to ask several key questions:

- What *type* of AI systems are we considering?
- What is the *intended use* of the AI system?
- What are the *conditions of deployment*?

This last question regarding **conditions of deployment** is critical in all settings, but particularly important when comparing AI systems that were developed in high resourced settings to settings with lower resources due to lack of investment, lower reimbursement rates, and/or higher clinically and socially complex patient populations.

An AI system that was designed for and functions properly in a high resource setting may break down or have unintended consequences when deployed in a lower resource setting. **Providers in rural and low resourced communities should carefully evaluate what resources, staffing, and processes are needed to ensure the AI systems are deployed as intended and tested.**

RISKS Without Governance, Validation, and Oversight



There can be significant risks associated with AI systems. Because AI systems can automate some activities and can scale quickly, the order of magnitude of harm is significantly higher than human-only created errors. Before deploying AI systems, it is important that you have appropriate **governance policies**, procedures, and practices in place.

Key considerations include how the AI systems were **tested** and **validated**. Further, beyond implementation, it is important that there is process, training, and procedures to **evaluate the performance of the system over time**.

The MIT **AI Risk Repository** is a free, comprehensive database of over 1600 categorized AI risks categorized using seven domains (pictured left) that can help health care providers conduct internal risk assessments and develop risk mitigation strategies.

1. Discrimination & Toxicity
2. Privacy & Security
3. Misinformation
4. Malicious Actors & Misuse
5. Human-computer interaction
6. Socioeconomic & Environmental Harms
7. AI System Safety, Failures, and Limitations

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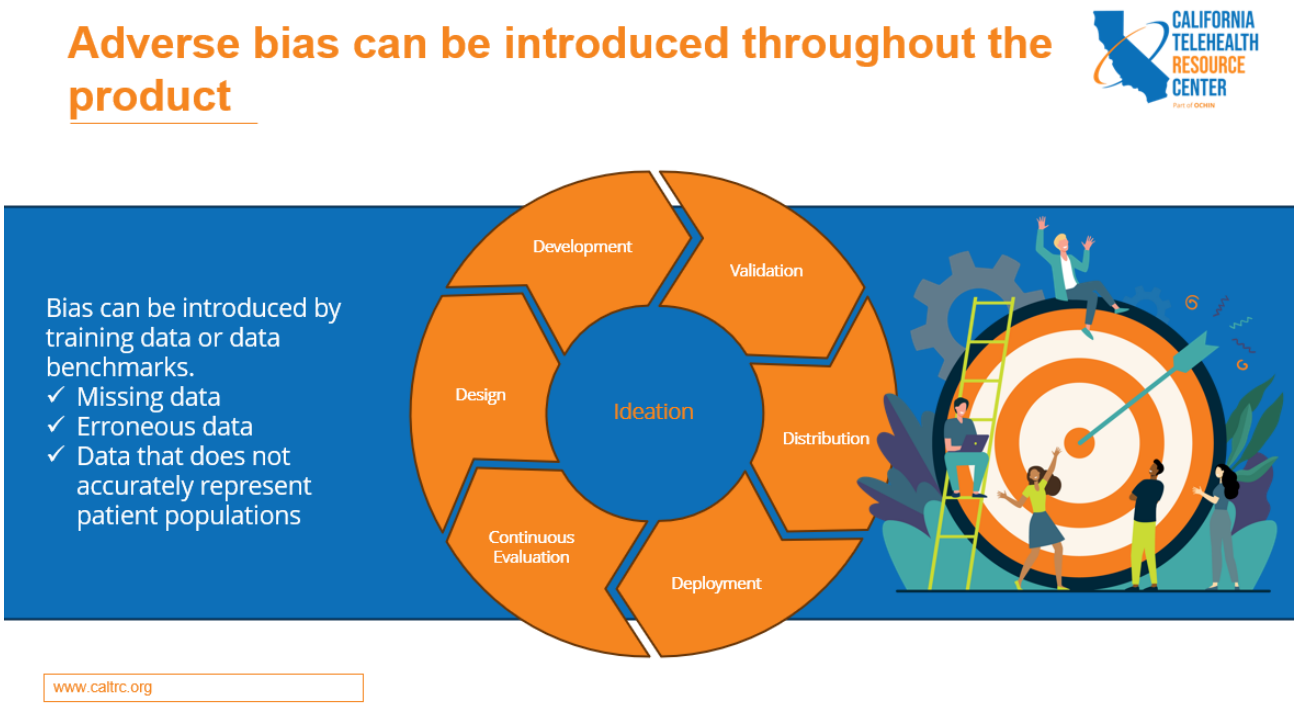


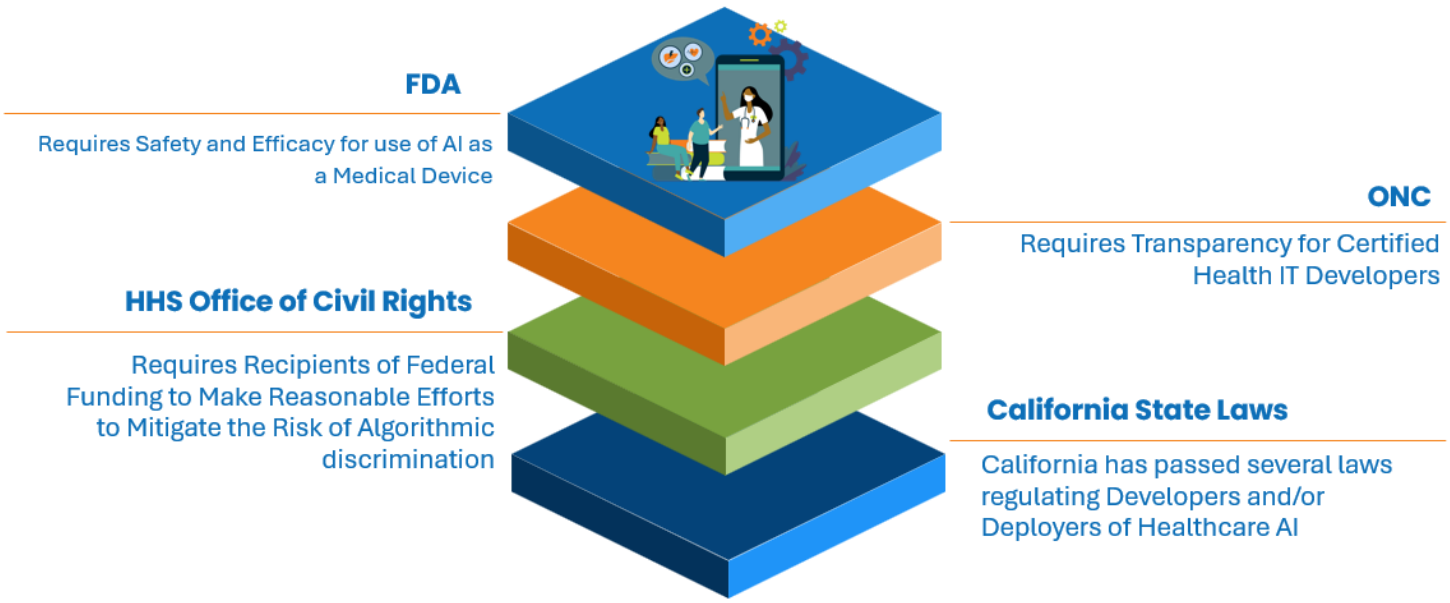
The risk most often discussed is **algorithmic bias** in the training data of AI systems. AI systems can only be as accurate as the data used to train and validate them. This can be compounded where gaps in data are difficult to detect, including missing or erroneous data that reflect current structural misrepresentation. These risks can be introduced through the **life cycle of the AI**, beginning with ideation all the way through deployment and evaluation over the life of the AI system.

Example: Faulty Training Data. An algorithm developed by Optum used healthcare costs as a proxy for health needs. Since some demographics of patients historically had less access to healthcare and therefore incurred lower costs, the model underestimated their needs and incorrectly gave them a lower priority for care.

Some ways to reduce bias include:

- increasing transparency in the data used to train and validate AI systems
- testing models both before and after deployment, and
- using synthetic datasets that include accurate representation of the patient population.

Example: Training Data Transparency. AB 2013 of 2024 (listed above) aims to increase AI training data transparency by requiring AI developers to publicly disclose information about the data they used to train the AI tool.



FDA: Software as a Medical Device.

- The FDA is responsible of evaluating the safety and efficacy of software and health IT devices that meet the definition of "medical device," including AI tools.
- The FDA has a number of levels of review, including clearance, approval, and de novo authorization.
- Autonomous AI medical device systems have the highest level of regulatory review and requirements.

ASTP/ONC

- The Assistance Secretary for Technology Policy (ASTP) Office of the National Coordinator for Health Information (ONC) has requirements for health IT vendors that seek certification.

HHS OCR

- The U.S. Department of Health and Human Services' Office of Civil Rights (HHS OCR) oversees any entity that receives HHS federal funding, including health care providers.
- In May 2024, OCR issued a final rule (Nondiscrimination in Health Programs and Activities) that prohibits discrimination in the use of algorithms in health care.