Health Care Artificial Intelligence Toolkit

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

"AI will be critical in meeting the care needs of a growing, aging population facing projected physician shortages. However, concerted effort is needed to assure this tech advances the quintuple aim."

National Academy of Medicine Report on AI (Matheny et al., 2019)

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 equity, reduce the burden on their teams, and increase overall sustainability.

This is an introductory guide to support these efforts.

AI systems can be applied to clinical care, operations, and research and may involve different AI systems and methods. As a result, the risk profile of the system may be varied. The governance should be built to account for use across the varied operations of a health care provider and the questions asked of vendors/developers will also vary as a result.

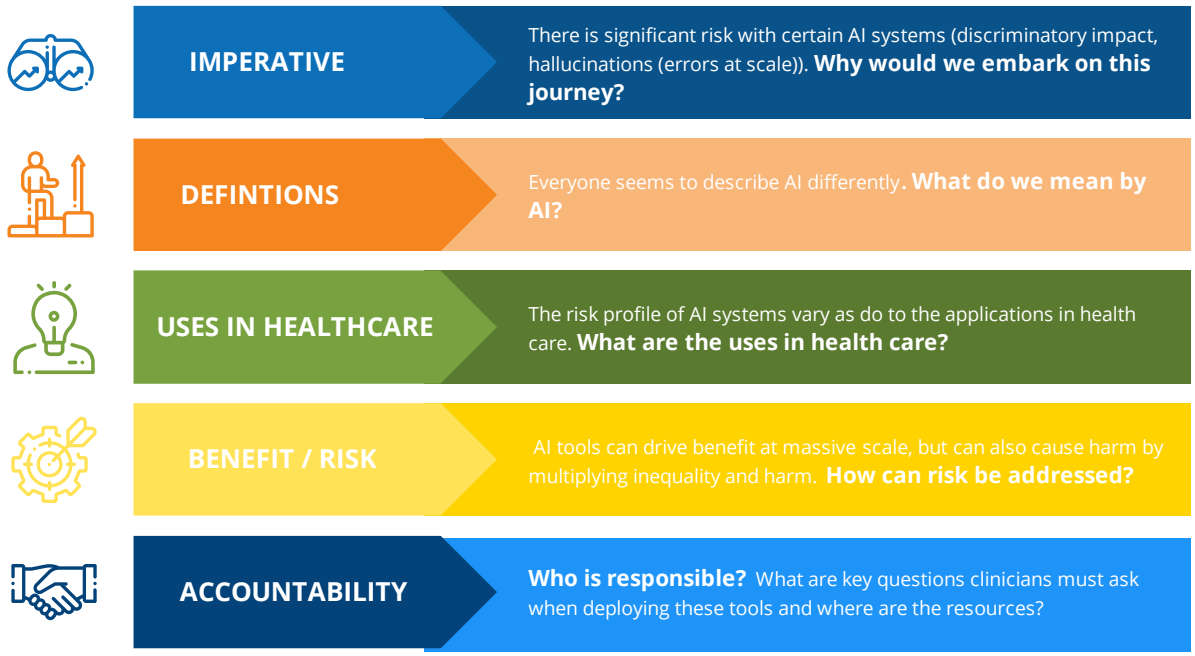
Across California healthcare providers including community health clinics and rural hospitals have many questions concerning healthcare AI. This guide will help you navigate these questions while providing foundational information.

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 convene a team to consider the issues outlined in this guide?
- What is AI as there are many different **definitions of this term** and these systems appear to have different **levels of autonomy**?
- What are the **different applications** of health care in AI?
- What are the **benefits and areas of risk**?
- What **responsibility** does **your team** have to ensure AI systems comply with federal and California laws and are safe, function as intended, and do not discriminate? What responsibility does **your vendor** have?

FOUNDATIONAL Questions



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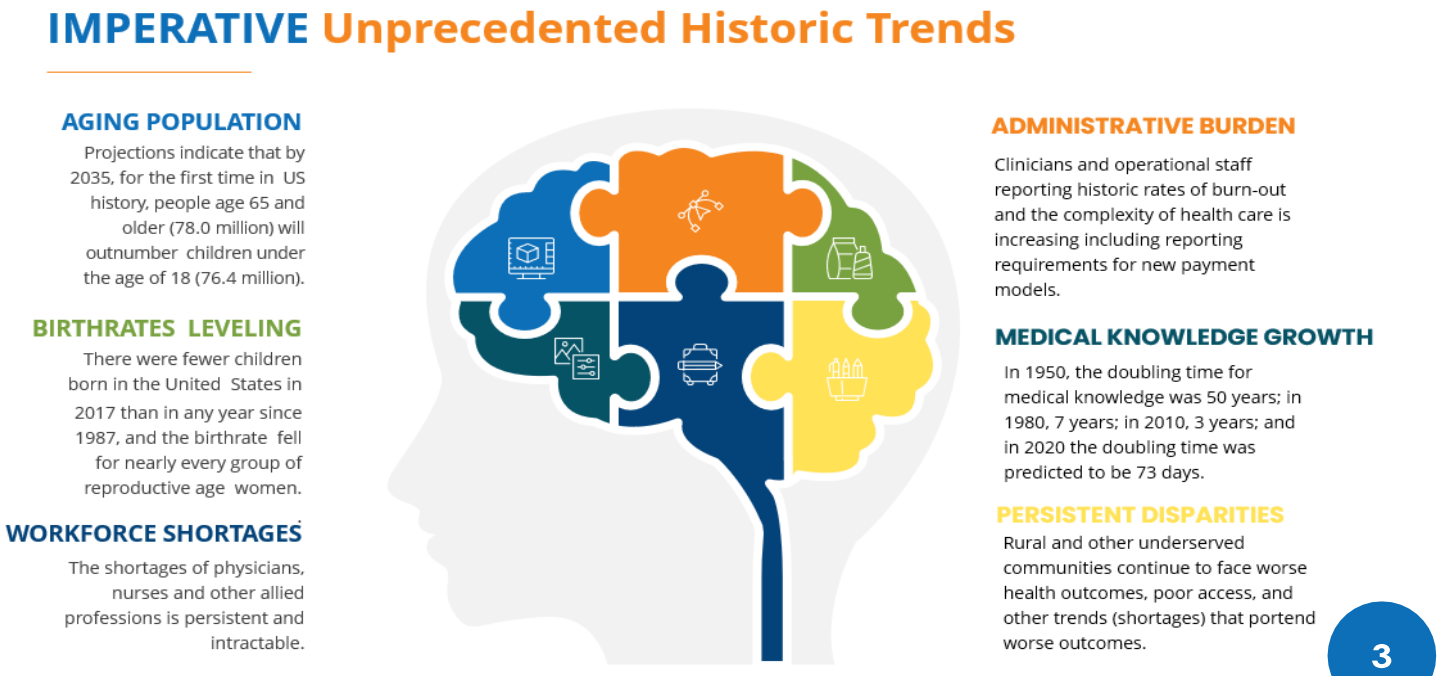
As your team is handling many challenges, the first question you are likely to ask: **why utilize AI tools given the complexity, potential harms, and need for engagement and training across staff and patients**? **The reality is that you may already be utilizing a number of these systems** including, for example, when using remote physiological monitoring or embedded in other health IT tools.

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 equitable care**. 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. 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 timely.
- 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 more and more administrative burdens.

Finally, patients in rural and other underserved communities continue to experience health disparities, lack of access, and persistent structural inequality. This is exacerbated by the intractable health care clinician shortages. **AI tools and systems can drive scalable solutions.**



What is meant by AI? 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. There is not a single definition of AI that enjoys broad consensus. However, the State of California Legislature is considering establishing a definition of AI that must be used by all state agencies. This legislation has not, yet, passed. However, it borrows from the definition issued by the Biden Administration contained in the **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.

The following is the pending California legislation definition:

"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 [as amended]

The White House	The term "artificial intelligence" or "AI" has the meaning set forth in 15 U.S.C. 9401(3): a machine -based system that can, for a **given set of human-defined objectives**, make **predictions**, **recommendations**, or **decisions influencing** real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to **perceive real** and **virtual environments**; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action . Link
HHS Office of the National Coordinator for Health Information Technology Link	
HHS Food and Drug Administration Link	
HHS Office of Civil Rights Link	
Dept of Commerce National Institute of Standards & Technology Link	
50 States and Multiple Definitions of AI CA Link	
OECD	An AI system is a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment. Link

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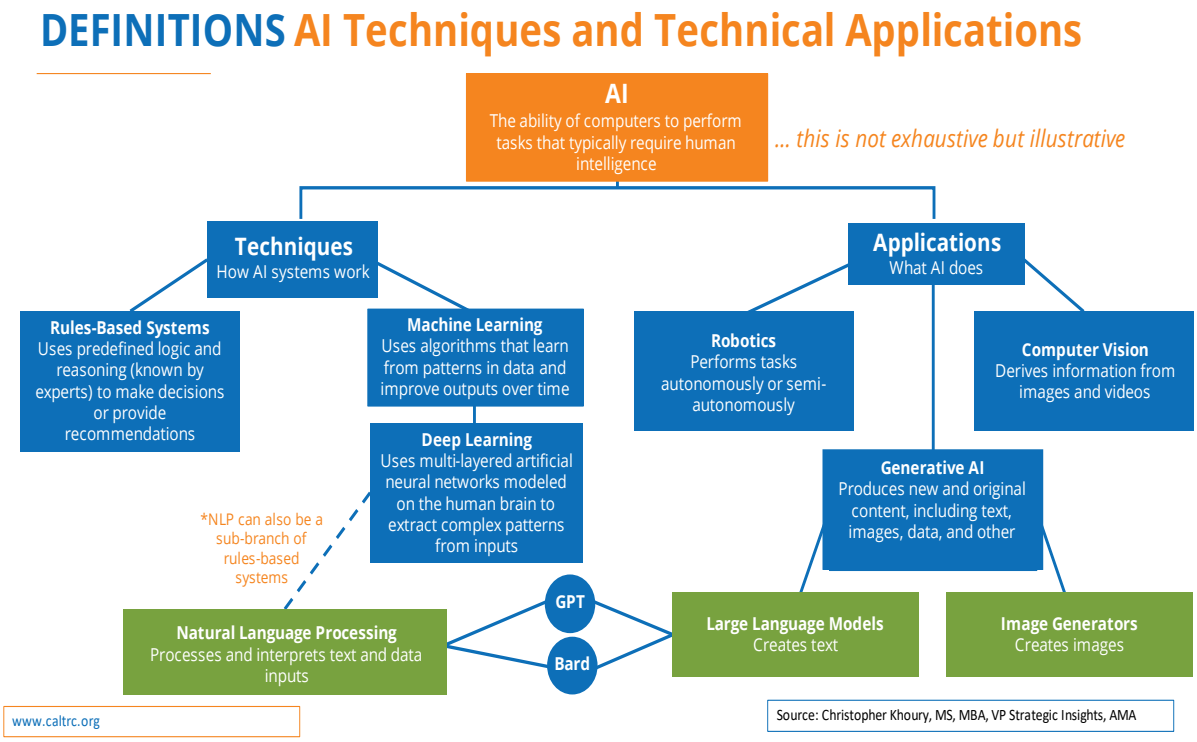
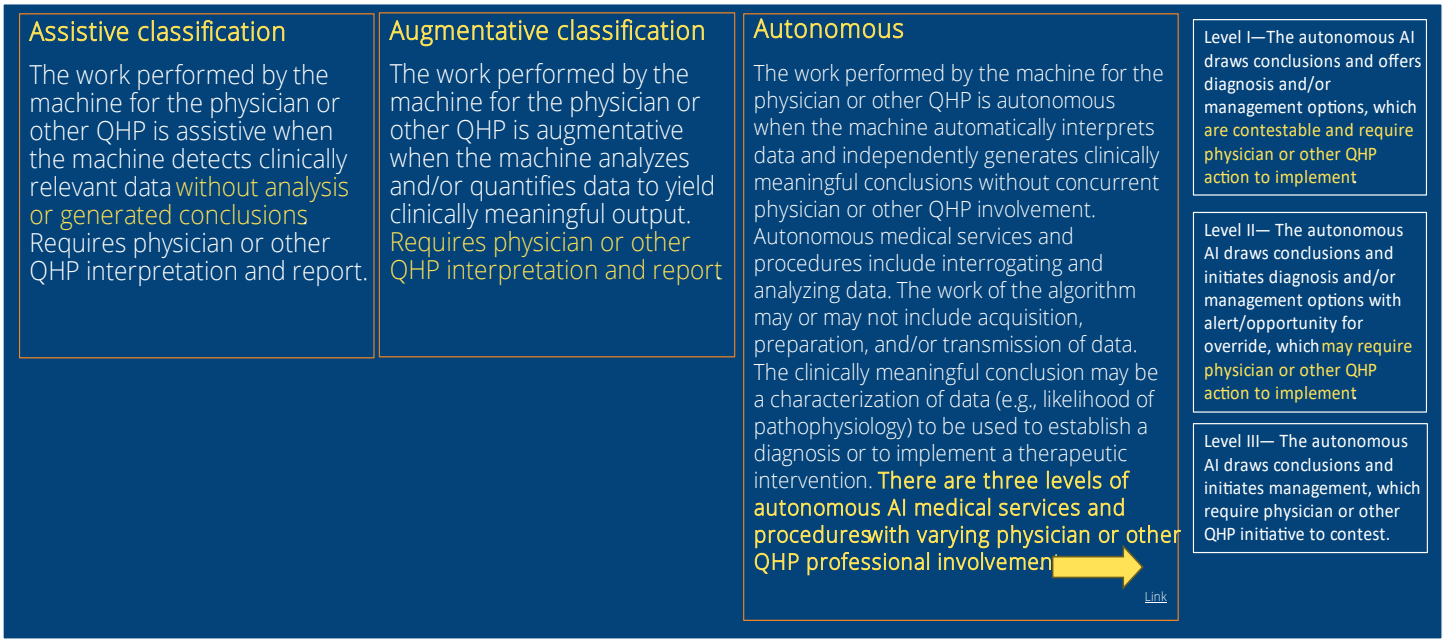
Besides the definitions provided by government agencies, it is important to understand that these **definitions cover different methods and systems that are called AI**.

Not all AI systems and methods have the same level of risk.

- Some AI systems are rules based and have a high level of transparency as a result. Meaning there is a human in the loop and the ability to identify the rationale and reason for the output.
- In contrast, some systems such as machine learning systems have less transparency and higher risk as a result. Machine learning systems have two algorithms—one that is a "learner" algorithm and the other algorithm that is modified by the learner to generate the output ("output" algorithm). If the system is not structured so that a human is in the loop, it may not be evident what pattern or reason the learner algorithm relied on to change the output algorithm. There are techniques to mitigate the risk of these systems through the life cycle including "locking" the learner so that the output algorithm can be tested for safety, efficacy, and equity.
- Below you will see the different types of systems and methods as well as technical applications to different types of data, for example language models or image- based models.



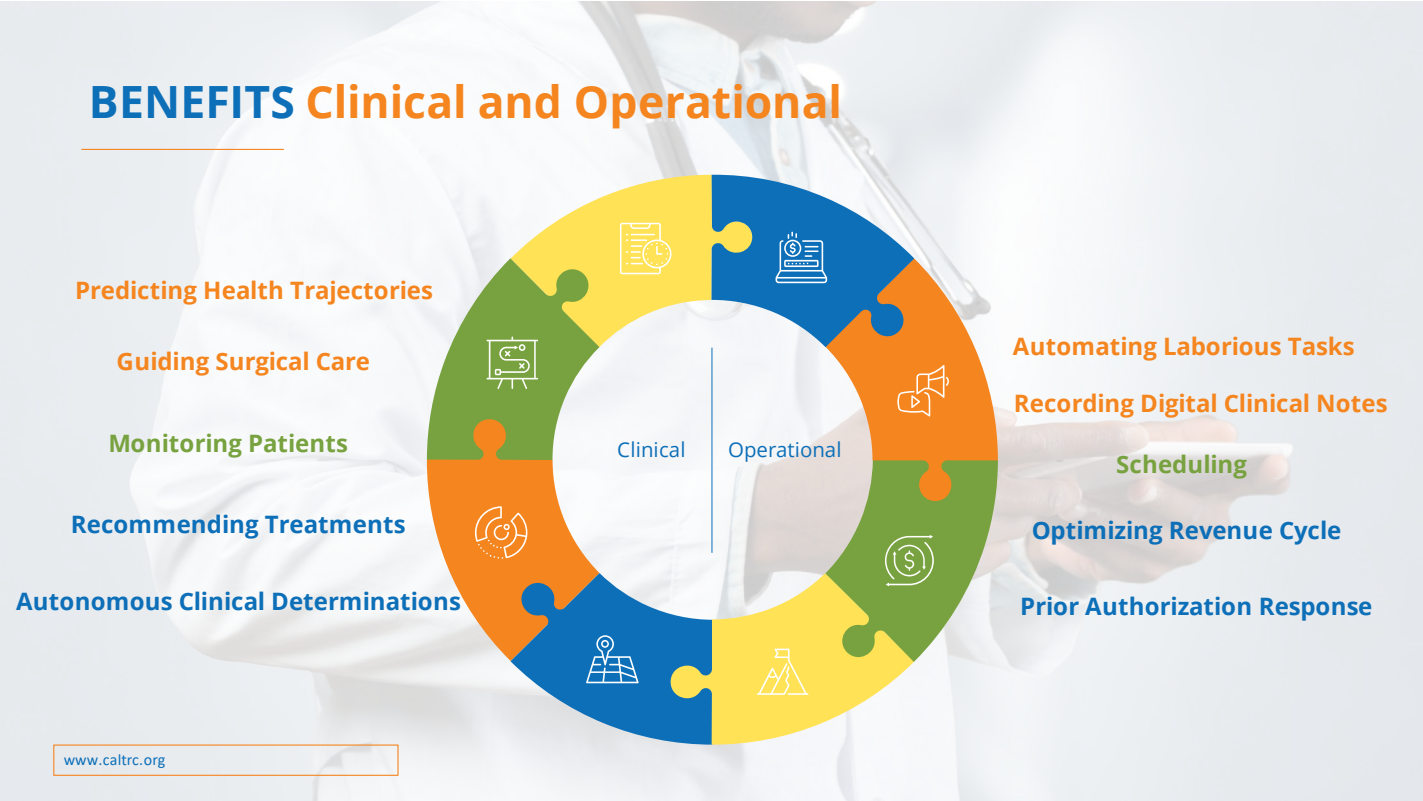
DEFINITIONS Levels of Autonomy



Source: AMA CPT Appendix S: AI taxonomy for medical services & procedures, June 10, 2024 accessed online July 18, 2024

In addition to the type of technique, technical application and level of transparency, 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.) Further, the CPT Editorial Panel further stratified autonomous systems into three different categories of whether clinicians are expected to be in the loop when the systems is deployed. See above.



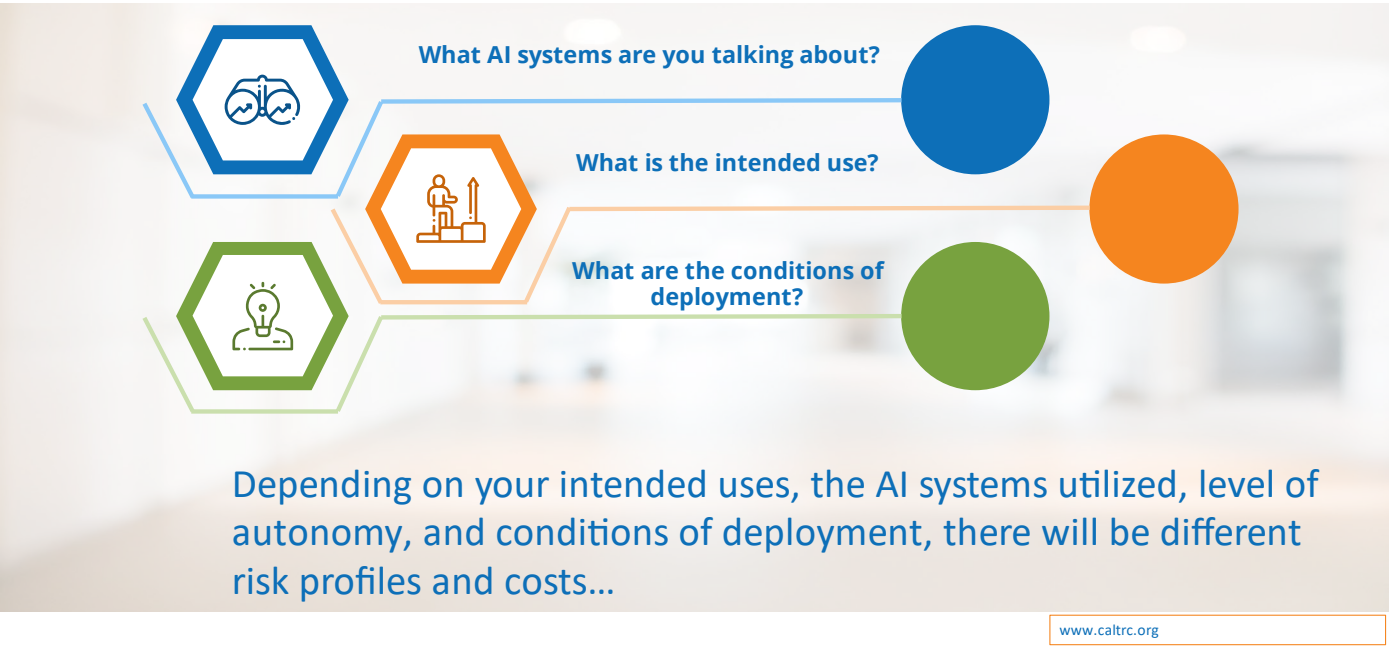
There are significant benefits to the broad array of AI systems in healthcare including both operational and clinical.

When considering uses of AI in healthcare—whether to support operations, clinical care, or even research and public health—considerations should be given to the level of risk associated with the AI techniques/methods and level of autonomy.

- Specifically, 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

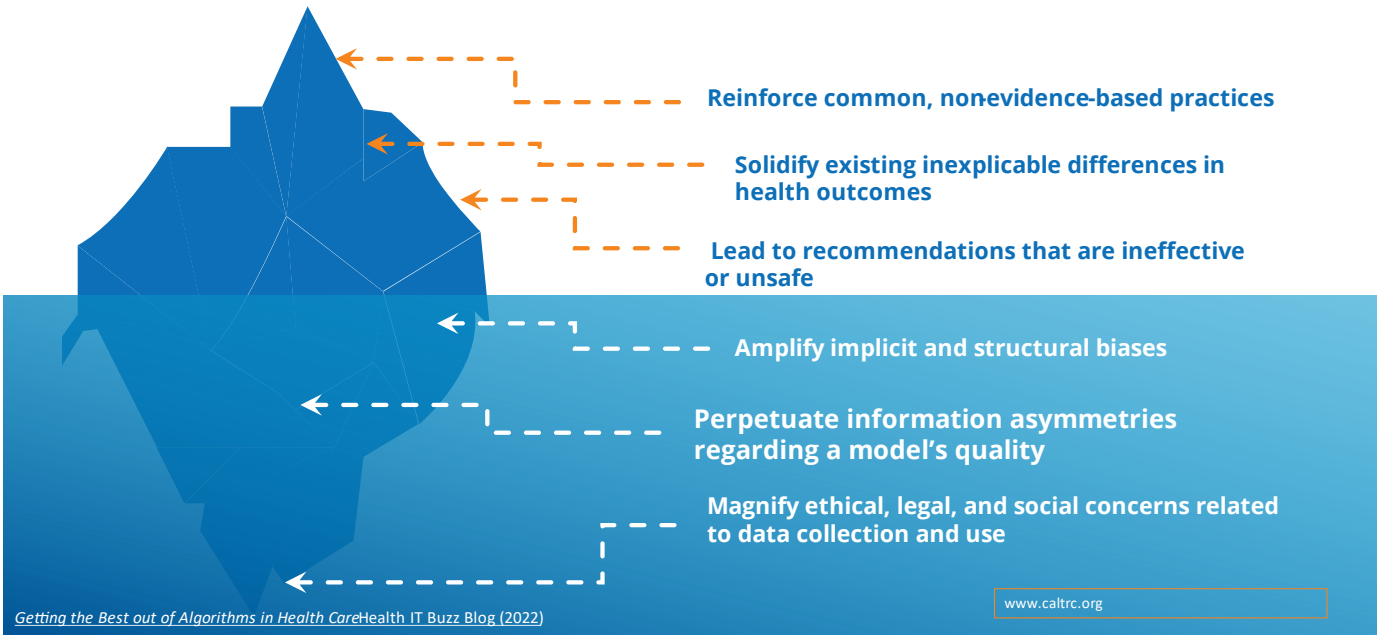


As you consider different AI systems and how these are intended to be used in your healthcare setting, it is important to ask several key questions:

- 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 is critical in all settings, but particularly when an AI system was developed in a high resource setting as compared to a setting that has not received commensurate levels of investment due to lower reimbursement rates and higher clinically and socially complex patient populations, for example.

Rural providers and those in underserved communities should carefully evaluate what resources and staffing are needed to ensure the AI systems are deployed as intended and tested.

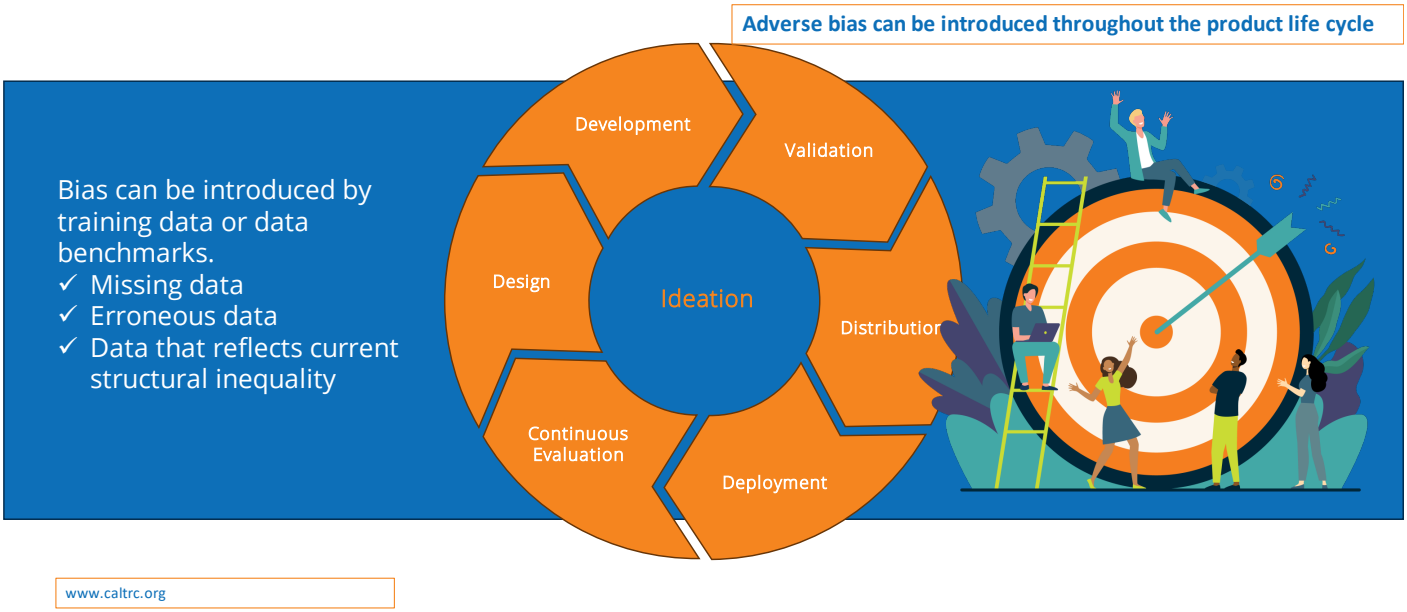


There can be significant risks associated with AI systems. Because AI systems can automate some activities and can scale quickly, the order of magnitude of harm is significantly higher than human-only created errors.

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.

RISKS Addressing Adverse Bias in Product Life Cycle



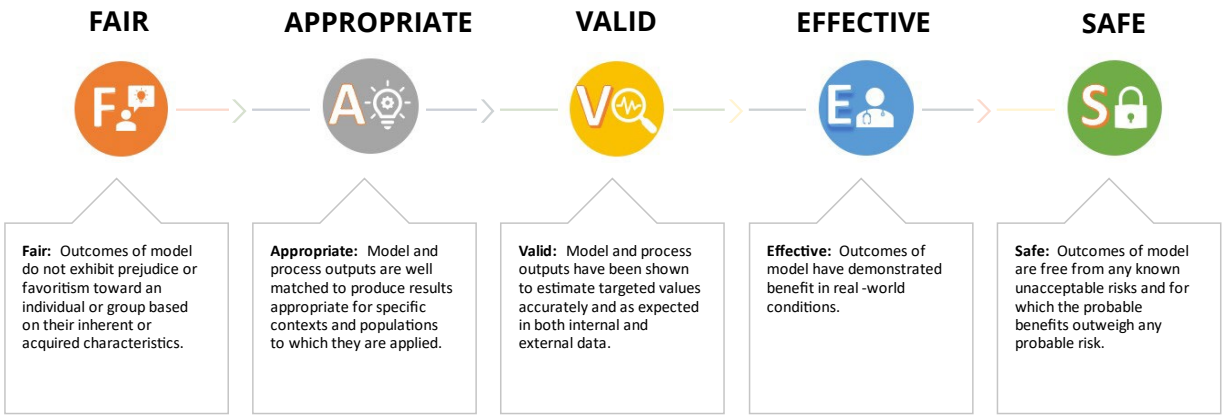
The risk most often discussed: discriminatory bias in the training data of AI systems. This risk can be significant.

This can be compounded where discriminatory bias are difficult to detect. This includes missing or erroneous data or data that reflect current structural inequity.

However, bias can be introduced through the life cycle of the AI beginning with ideation all the way through deployment and operation over the life of the AI system.

It is important to discuss these areas where adverse bias can be introduced in addition to data bias.

ACCOUNTABILITY FAVES Framework



Federal regulators have developed several approaches to **partially** address adverse and discriminatory bias.

Certified Health IT. The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) has developed a framework and parameters that vendors of certified health information technology (HIT) are expected to disclose. However, this is simply equivalent to "truth in labeling." The ONC is not testing and validating the systems to ensure they meet the FAVES parameters. Also, the onus is on health care providers to ask vendors questions related to the FAVES parameters.

FDA Regulated Medical Devices. Only a subset of AI systems are subject to the regulatory oversight of the Food and Drug Administration (FDA). The FDA is also authorized to regulate software and health IT devices that meet the definition of "medical device." The FDA has a number of level of review including clearance, approval, and de novo authorization. These all have different evidentiary requirements. Autonomous AI medical device systems have the highest level of regulatory review and requirements. The FDA evaluates the safety and efficacy of AI systems that are considered medical devices.

In addition to the FDA which regulates medical device developers/sponsors and ONC which has requirements for vendors that seek certification, the U.S. Department of Health and Human Services' Office of Civil Rights (HHS OCR) provides oversight of all persons and entities that receive HHS federal funding including health care providers.

The HHS OCR now requires that recipients of HHS federal funding ensure that a broad array of tools and systems including those considered AI systems with application in health care (both operational, clinical, research, and public health) are not discriminatory. Specifically in May 2024, OCR issued a final rule that prohibits discrimination in the use of algorithms in health care. The rule, which implements a provision of the Patient Protection and Affordable Care Act (ACA), is meant to prevent health care providers and health insurers from using algorithms in a way that discriminates against individuals based on race, color, national origin, sex, age, or disability.

ACCOUNTABILITY **Identification and Mitigation**

Key Questions Addressing OCR Non- Discrimination Obligation

- What health disparities are reported for the present AI application?
- How can the AI tool be designed to be accessible to and improve outcomes for the disadvantaged population?
- What clinical interventions are needed to realize the benefit, and are these accessible?
- How can data collection be supported in underserved communities for tool retraining over time?

Badal, K., Lee, C.M. & Esserman, L.J. Guiding principles for the responsible development of artificial intelligence tools for healthcare. *Commun Med* **3**, 47 (2023). https:// doi.org/10.1038/s43856 -023-00279 -9

Table 2 Questions that can be used when considering each principle in the AI development process.

Principle	Questions
1. Alleviate healthcare disparities	• What health disparities are reported for the present AI application? • How can the AI tool be designed to be accessible to and improve outcomes for the dis population? • What clinical interventions are needed to realize the benefit, and are these accessible? • How can data collection be supported in underserved communities for tool retraining o
2. Report clinically meaningful outcomes	• How is clinical benefit defined in this domain? • What is the present threshold for the clinical benefit of existing tools, and how can the A
	is an overdiagnosis? verdiagnosis, what are the downstream costs to the patient and health plication reduce the number of overdiagnoses compared to existing essing a high-priority healthcare need?
	e cost to the healthcare system in implementation, maintenance, and e cost to the patient who does and does not benefit from this tool? e high healthcare value, and if not, how can it be improved?
	data can be collected or carefully coded for the intended population? ors vary in the intended population? tors be included when developing AI tools?
6. Be easily tailored to the local population	• Can the training features be easily collected in different settings? • Are these features reliable for training across different populations? • Will the AI/ML workflow be made open-access?
7. Promote a learning healthcare system	• How will this AI application be evaluated over time, and at what intervals? • What are acceptable thresholds for performance? • How will the evaluation results contribute to continuous improvement?
8. Facilitate shared decision-making	• Have AI explainability tools been explored and utilized? • Do clinicians and patients find the explainability results helpful?

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GOVERNANCE FOR AI APPLICATIONS IN A COMMUNITY CLINIC OR CRITICAL ACCESS HOSPITAL

Policy Framework

Objective: Establish clear guidelines and principles for the use of AI in healthcare to ensure safety, effectiveness, equity and ethical standards are met.

- AI Ethics Policy: Outline principles related to transparency, fairness, accountability, and patient consent.
- Data Privacy and Security Policy: Define standards for data protection, including access controls, encryption, and patient privacy.
- AI Usage Policy: Specify permissible uses of AI, including diagnostic support, predictive analytics, and administrative automation.
- Risk Management Policy: Establish procedures for identifying, assessing, and mitigating risks associated with AI applications.

Procedures

Objective: Develop standard operating procedures (SOPs) to ensure consistent and safe deployment and management of AI systems.

AI System Deployment Procedure:

- Evaluation: Assess the AI tool for clinical effectiveness, reliability, and alignment with organizational goals.
- Implementation: Detailed steps for integrating AI systems into existing workflows.
- Training: Ensure all relevant personnel are adequately trained in using the AI tools.

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Data Management Procedure:

- Data Collection: Guidelines for collecting high-quality, relevant data while ensuring patient privacy.
- Data Processing: Steps for preprocessing data to be used by AI systems, including cleaning and normalization.
- Data Storage: Secure storage solutions to protect sensitive health information.

Monitoring and Evaluation Procedure:

- Performance Monitoring: Regular monitoring of AI system performance, including accuracy, efficiency, and user satisfaction.
- Issue Reporting: Mechanisms for reporting and addressing any issues or malfunctions.
- Continuous Improvement: Procedures for incorporating feedback and making iterative improvements to AI systems.

Personnel

Objective: Assign clear roles and responsibilities to ensure proper governance and management of AI systems.

AI Governance Committee:

- Composition: Include representatives from clinical staff, IT, legal, and administrative departments.
- Responsibilities: Oversee the implementation of AI policies, review AI system performance, and make decisions on AI usage.

AI Ethics Officer:

- Role: Ensure that AI applications comply with ethical standards and patient consent requirements.
- Duties: Conduct regular ethical reviews and address any ethical concerns related to AI usage.

AI System Administrator:

- Role: Manage the technical aspects of AI systems.
- Duties: Oversee system integration, perform routine maintenance, and ensure data integrity.
- Data Processing (where applicable): Steps for preprocessing data to be used by AI systems, including cleaning and normalization.

Clinical AI Champions:

- Role: Act as liaison between clinical staff and the AI governance committee.
- Duties: Provide feedback on AI tool performance, assist in training, and promote best practices.

Compliance Testing

Objective: Regularly test and verify that AI systems comply with established policies and procedures.

Initial Validation:

- Clinical Validation: Test AI systems for clinical accuracy and relevance before deployment.
- Technical Validation: Ensure the AI system is technically sound and integrates well with existing IT infrastructure.

Ongoing Compliance Testing:

- Routine Audits: Conduct periodic audits to check for compliance with AI usage policies, data privacy, and security standards.
- Performance Reviews: Regularly review AI system performance against predefined metrics (e.g., accuracy, reliability, user satisfaction).
- Security Testing: Perform vulnerability assessments and penetration testing to identify and address security gaps.

Incident Response:

- Incident Management Procedure: Establish clear steps for responding to AI system failures or breaches.
- Root Cause Analysis: Investigate incidents to determine the root cause and implement corrective actions.
- Reporting and Documentation: Maintain detailed records of incidents, responses, and outcomes for accountability and learning.

Regulatory Compliance:

- Compliance Checks: Ensure AI systems meet all relevant regulatory requirements, such as
    - The Health Information Portability and Accountability Act (HIPAA)
    - The U.S. Department of Health & Human Services (HHS) Office of Civil Right's Non-Discrimination prohibition, and other local health data regulations
    - The Food and Drug Administration requirements for medical devices
    - The HHS Office of the National Coordinator for Health Information Technology requirements for certified health IT
    - California Privacy laws and AI laws

Conclusion

Implementing robust governance for AI applications in a community clinic or critical access hospital requires a comprehensive approach that includes clear policies, detailed procedures, well-defined personnel roles, and rigorous compliance testing. By adhering to these components, healthcare providers can ensure that AI tools are used safely, effectively, and ethically, even with limited resources.

KEY STEPS TO ASSESS AND MITIGATE DISCRIMINATORY IMPACTS OF AI SYSTEMS IN HEALTH CARE

Pre-Deployment Assessment

Objective: Identify potential biases and discriminatory impacts before the AI system is deployed.

Understand the Context:

- Community Demographic: Analyze the demographic characteristics of the community served by the clinic or hospital.
- Health Care Disparities: Identify existing health care disparities and inequities within the community.

Algorithmic Fairness Review:

- Bias Identification: Obtain from the developer/vendor and carefully review their disclosures on the AI system's algorithms for potential biases, including training data sources, feature selection, and decision-making processes.
- Fairness Metrics: Ask the developer/vendor what fairness metrics were used such as demographic parity, equal opportunity, and disparate impact to assess potential biases.

Stakeholder Involvement:

- Diverse Input: Engage a diverse group of stakeholders, including patients, healthcare providers, and community representatives, to provide input on potential discriminatory impacts.

Data Review and Preparation:

- Data Quality and Representation: Ensure that the developer/vendor provides you with a report on the training data and discuss whether it is representative of the diverse patient population. Check for any underrepresented groups in the data.
- Data Cleaning: Ask developer/vendor steps taken to remove any biased data points and ensure the data is free from errors that could lead to biased outcomes.

Deployment Phase

Objective: Implement the AI system with safeguards to minimize discriminatory impact and continuously monitor its performance.

Pilot Testing:

- Similar Deployments: Ask developer/vendor for information on deployment in similar settings and ask for recommendations from providers that have already implemented systems.
- Controlled Environment: Deploy the AI system in a controlled environment or as a pilot program to monitor its initial performance and impact.
- Performance Evaluation: Measure the AI system's performance across different demographic groups to identify any disparities in outcomes.

Monitoring and Feedback Mechanisms:

- Monitoring: Implement monitoring tools to regularly assess the AI system's performance and its impact on different patient groups. The frequency of the assessment should be based on the level of risk. Clinical applications typically provide the highest levels of risk. Accordingly, these should be monitored more frequently.
- Feedback Loops: Establish feedback mechanisms for healthcare providers and patients to report any concerns or perceived biases in the AI system's recommendations or decisions.

Post-Deployment Assessment

Objective: Continuously evaluate the AI system to ensure it does not perpetuate or exacerbate disparities and take corrective actions when necessary.

Regular Audits:

- Bias Audits: Conduct regular audits to assess the AI system for any emerging biases or discriminatory impacts.
- Outcome Analysis: Compare clinical and operational outcomes across different demographic groups to identify any disparities.

Impact Mitigation Strategies:

- Human Oversight: Ensure that healthcare providers review and validate AI recommendations, especially in cases where decisions have significant impacts on patient care.
- Autonomous AI System Accountability: If an AI system does not have a human in the loop, ensure that developer/vendor has assumed liability and has mechanisms to monitor.

Transparency and Accountability:

- Documentation: Maintain detailed documentation of the AI system's deployment, and evaluation processes, including any actions taken to address biases.
- Reporting: Regularly report on the AI system's performance and any identified biases or corrective actions to stakeholders, including patients, staff, and regulatory bodies.

Continuous Improvement

Objective: Establish a culture of continuous improvement to adapt to changing demographics, medical practices, and emerging technologies.

Ongoing Training:

- Staff Training: Provide ongoing training for staff on the ethical use of AI, recognizing and addressing biases, and ensuring equitable care.
- Community Engagement: Engage with the community to understand their evolving needs and concerns regarding AI in healthcare.

Conclusion

Deploying an AI system in a healthcare setting, particularly in community health clinics or rural hospitals, requires a comprehensive approach to assess and mitigate any discriminatory impact. By following these key steps—pre-deployment assessment, careful deployment, continuous post-deployment evaluation, and ongoing improvement—healthcare providers can ensure that AI systems contribute to equitable and high-quality care for all patients.

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AI TOOL VENDOR EVALUATION CHECKLIST FOR COMMUNITY HEALTH CLINICS AND CRITICAL ACCESS HOSPITALS

Questions to Ask AI Tool Vendors

Intended Use and Features of Tool

- What specific clinical or operational problems does the AI tool address?
- What are the key features and capabilities of the AI tool?

Track Record

- What is your company's history and expertise in developing AI tools for healthcare?
- Can you provide case studies or references from similar healthcare settings to our patient population and settings where your AI tools have been successfully implemented? How was success defined?

Assessing Fit for Your Practice and Potential for Adverse Bias

- What data sources were used to train the AI model?
- How do you ensure that the training data is representative of my patient population?
- How often is the AI model updated or retrained with new data?
- What measures have been taken to identify and mitigate biases in the AI tool?
- How do you ensure that the AI tool does not disproportionately adversely impact any specific demographic group?
- Can you provide evidence or documentation of bias testing and results?
- What metrics are used to evaluate the effectiveness of the AI tool?
- Can you provide detailed documentation on the AI tool's development, testing, and performance?
- How transparent are you about the AI tool's decision-making processes and algorithms?

Ethical Considerations

- What ethical guidelines and principles do you follow in the development and deployment of your AI tools?
- How do you ensure patient consent and privacy when using the AI tool?

Training and Workforce Support

- What training programs and materials do you provide for our staff?

Implementation and Technical Support

- How is the AI tool integrated into existing workflows and EHR systems?
- What is the process for integrating the AI tool into our existing systems?
- What are the technical requirements for successful implementation?
- How do you handle data interoperability with our EHR system?
- How do you handle software updates and system upgrades?
- What ongoing support and maintenance services are included?
- How do you monitor the performance of the AI tool post-deployment?
- How do you handle incidents or malfunctions of the AI tool?

Compliance, Privacy, and Security

- How do you ensure that the AI tool complies with relevant healthcare regulations (e.g., HIPAA, California Privacy laws)?
- Have you obtained the necessary certifications and/or approvals for the AI tool?
- What security measures are in place to protect patient data?
- How is data encrypted and stored?
- How do you handle data breaches and security incidents?

Costs and Sustainability

- What is the total cost of ownership, including licensing, implementation, and ongoing maintenance?
- What is the expected return on investment (ROI) from using the AI tool?
- Are there any additional costs for future updates or add-ons?

Liability and Accountability

- What is your policy on accountability for errors or negative outcomes resulting from the AI tool?
- What liability coverage do you provide in case of AI tool failure or inaccuracies?

Conclusion

This checklist provides a set of questions for community health clinics and critical access hospitals to ask AI tool developers/vendors. By thoroughly evaluating the responses, healthcare providers can make informed decisions about acquiring and implementing AI tools that align with their clinical and operational needs while ensuring ethical, fair, and secure use.

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