



Use Cases for AI Tools to Improve Health Care

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About Health Innovation Alliance

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs.

For 18 years, HIA has been a leader on federal policy related to health care technology and interoperability. HIA staff and members successfully ushered through the original Health Information Portability and Accountability Act, influenced the Health Information Technology for Economic and Clinical Health Act, and drafted, negotiated, and passed the 21st Century Cures Act.



Introduction


Artificial intelligence (AI) models present tremendous opportunities to make the American health care system the best in the world. From increasing novel drug discoveries through AI-created problem solving that has already figured out protein folding – a biological process that has eluded scientists for over 50 years – to cleaning up the processes surrounding care delivery, coverage, and payment, AI can help us break through some of the health care industry's most entrenched problems. Take physician burnout – ninety-three percent of physicians regularly feel burned out, and over half would prefer to quit or at least stop seeing patients.[1] One of the largest contributors to this sentiment is documentation and compliance burden: doctors and their teams spend more time doing paperwork to get paid by insurers or comply with government rules than caring for patients. AI models are helping to address this problem with clinicians reporting a significant reduction in documentation burden after incorporating AI tools.[2]

In 2024, HIA formed a working group of more than 30 different organizations to produce a set of principles for the use of artificial intelligence (AI) in health care and life sciences:

- **Risk-Based Approach:** Regulation of AI in health care should be proportionate to risk
- **Transparency:** Patients, users, and regulators of AI should have access to information about how technology is being used, but not to proprietary information
- **Privacy:** Any use of health information by AI should be compliant with current laws and regulations, including HIPAA
- **Responsibility:** Developers and users of AI programs in health care should adopt and adhere to best practices and processes
- **Fairness:** AI tools should should mitigate bias and be available for all users, not just those who can afford it

[1] <https://www.athenahealth.com/resources/blog/ai-help-clinician-burnout>

[2] <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2830383>




Since the release of HIA’s principles, there has been increased interest in the safety of using AI in health care. To help guide those discussions and to highlight why AI should be regulated according to a context-dependent, risk-based approach, HIA examined currently available AI health care tools and their uses through the lens of the life cycles patients, drugs, and medical devices undergo in our health care system.

The following report serves as a catalog of AI use cases, exploring the different types of AI tools that are and can be used across the healthcare system. HIA strongly believes these cases highlight the need for AI oversight to follow a risk-based model to ensure product innovation and effectiveness while maintaining patient confidentiality.



Overview of Risk Analysis for Health Care



Before exploring the considerations for artificial intelligence specifically, it is necessary to review the current state of risk analysis in health care more broadly.

Evaluating risk is necessary to ensure safety in patient care. Each step and process undertaken must be evaluated separately, ranging from diagnostic procedures performed by a clinician to diagnostic lab tests, pharmaceutical treatments, surgeries, imaging procedures, and more. Health information technology (health IT) solutions are present in many, if not all, of these processes to varying degrees – whether recording and transmitting or processing information.


Risk in the context of health IT solutions contemplates 1) the chance that output of a system will be inaccurate; 2) the likelihood or frequency of potential inaccuracy; and 3) the level of severity of the outcome resulting from an inaccurate output.[3] There are underlying assumptions in any quantification of risk, such as whether all available information was used to arrive at the outcome or output, and how information or sources were weighted to generate the output.

The Food and Drug Administration (FDA) currently evaluates risk for medical products as a part of its mission to assure their safety and effectiveness. More than 1,000 medical devices have been approved by the FDA using their risk-based framework that includes the use of AI.[4] The FDA uses a variety of structures to evaluate the level of risk a particular device carries, whether it uses AI or not. Devices fall under Class I (low to moderate risk), II (moderate to high risk), or III (high risk).[5] Class I devices are generally exempt from premarket notification and approval processes from the FDA as are some Class II devices.

[3] This framework is the result of synthesizing and simplifying existing literature on risk analysis management practices in health IT and health care more broadly. Materials referenced include: [Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables](#), [What is Risk Management in Healthcare?](#), and [Risk Management Event Evaluation and Responsibilities](#).

[4] August 7, 2024 update: The U.S. Food and Drug Administration updated the list of Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. With this update, the FDA has authorized 950 AI/ML-enabled medical devices. Accessed October 23, 2024: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

[5] <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>



If a device is classified as Class III, then it undergoes more rigorous evaluation processes than a Class I or II device, including the full premarket approval process.

Examples of products that fall into the different risk categories are:[6]

- Class I
 - Bandages, manual stethoscopes, oxygen masks, surgical masks, hospital beds
- Class II
 - Syringes, pregnancy tests, transfusion devices, blood pressure readers
- Class III
 - Pacemakers, cardiac stents, ventilators, defibrillators

The FDA currently deals with AI in a few different ways. AI-enabled devices generally fall under Class II or Class III based on the intended use, level of risk, and potential impacts on users. If the device is substantially similar to an existing device, it might undergo a 510(k) clearance (this is common for Class II devices).[7] If the AI-enabled device presents greater risks or provides new functionality, it goes through a pre-market approval process, requiring greater evidence of safety and efficacy.

For modifications to AI-enabled devices that have already been approved for marketing and use, the FDA has established a process called predetermined change control plans (PCCP).[8] [9] A device manufacturer submits a plan regarding how it may change the device over time, rather than submitting a new application every time it is updated. The FDA then reviews and approves the plan before it is carried out. The PCCP must contain an explanation of the proposed modifications and an assessment of how those modifications will impact the use of the device. In general, modifications that introduce some new risk to the use of the device require a separate application, rather than a PCCP. In general, low-risk modifications are acceptable and considered as changes that slightly modify existing risk considerations.


Additionally, some tools fall outside of FDA's purview: electronic health records and certain clinical decision support tools, for example. Electronic health records are regulated by the Assistant Secretary for Technology Policy (ASTP), formerly known as the Office of the National Coordinator for Health Information Technology.

[6] <https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels>

[7] <https://www.qualio.com/blog/fda-medical-device-classes-differences>

[8] <https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles>

[9] <https://www.fda.gov/media/180978/download>



ASTP issued several transparency requirements for AI tools embedded in EHRs that mandate the publication of certain information.[10] Unfortunately, ASTP adopted what they call a “function-based approach” for these transparency requirements, meaning that if an algorithm is in use, then it is subject to the requirements. This is the opposite of a risk-based approach, and HIA believes that AI should be regulated consistently by HHS through a risk-based lens.

In the clinical trials space, the FDA recently issued draft guidance on how pharmaceutical manufacturers can submit AI-generated information to assist the regulatory approval process for drugs and biologics.[11] In their Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products, FDA lays out a risk-based framework whereby credibility and trust can be established for an AI model for a particular context of use.

HIA believes that new technologies, like some AI models, should be considered by the government under the existing regulatory structure. A risk-based approach is the most sensible approach to regulating AI in health care, and that is why it is current practice by the FDA.

When AI is used in health care applications, many factors go into an overall determination of risk. These vary not only by how an AI model itself is constructed, but also what the model is being used for (the use case), how and where the model is being implemented, and who is using the model on whom (or what). The following chart breaks down several categories of risk that commonly arise across health care use cases for medical products along with some factors that can impact the degree of risk. It is important to note that these factors impacting risk exist whether or not AI is being used.


[10] <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>

[11] <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological>

Categories of Risk	Factors Influencing Risk
Patient Harm and Safety Risks	Patient acuity Level of reliance on AI output for decision/action Invasiveness to patient Patient medical history Intended user(s) Provider/implementer training Environmental factors/site of service Ongoing monitoring of the AI system
Data Accuracy – Training and Testing Data	Representativeness of data Insufficient data leading to delays or errors Intended use and level of reliance on AI output for decision/action Model trained and/or tested on outdated or historical patterns, resulting in a gap between simulate scenario vs. experimental validation
Bias and Ethical Concerns	Training and testing of model Level of reliance on AI output for decision/action Level of oversight and remedial processes
Misallocation of Resources and Operations Issues	Intended use of model or output Reliance on output for decision/action Level of oversight
Privacy and Security	Intended use Security systems and processes in place Sensitivity of data in question Likelihood of data misuse in case of disclosure and severity of resulting harm
Technical Issues	Processes for system upgrades and corrections System resiliency and redundancy Level of reliance on AI output for decision/action Understandability of assumptions, intended use, etc. User sophistication Reliability of connected systems
Liability and Compliance Issues	Intended use of data or outputs User sophistication Reliance on data or outputs Process or system for oversight and checks



Discussion on Identifying Use Cases




To map the various use cases in health care where AI can be used, HIA evaluated at the general life cycles of patients and medical products as they move through the health care system.

For example, a patient may use **wearables and remote monitoring tools** that incorporate AI to track aspects of their lifestyle by collecting data in real-time, such as physical activity, sleep, and blood pressure. As patients begin to feel unwell, **virtual health assistants** can provide information on symptoms, mitigation strategies, and even suggest scheduling a visit with a clinician. During the **scheduling** of a doctor's visit, AI tools can book appointments. While at a clinic, **chatbots** can guide patients to their provider, as well as answer queries. To treat patients, providers use **AI-powered medical imaging software, EHR systems, and ambient speech recognition (ASR) tools** to generate suggested diagnoses. Once diagnosed, **clinical decision support (CDS) tools** provide personalized treatment plans. After treatment, patients may use wearables to track their health and use **EHR systems or portals with automated messaging and reminders** for future checkups and to flag potential complications.

HIA applied the same thought model to examine how AI can be used in the stages of the medical product development process, from discovery to post-market surveillance. At the beginning of **drug discovery**, AI-driven research accelerates the identification of potential drug candidates through screening datasets and simulating chemical processes that predict drug safety and efficacy in **preclinical testing**.^[12] During **clinical trials for drugs and medical devices**, AI streamlines patient recruitment, the design of the trial, experimental data, and dosing suggestions, allowing researchers to conduct more accurate **Phase I, II, and III trials**. In Phase I, AI tools assist in recruiting patients to achieve the best possible sample size. In Phases II and III, AI can help assess the drug's efficacy by refining patient profiles within the sample size and increasing the sample size by checking application within a larger population.

[12] <https://pubmed.ncbi.nlm.nih.gov/37514102/>



Once a drug passes trials, AI can track compliance, helping speed up **regulatory approval processing for drug or device launch, as well as assist with ongoing compliance reporting**. Afterward, AI optimizes production through heightened **quality control measures** and **supply chain management** during the **manufacturing** and **distribution** processes. This includes monitoring and identifying equipment that is operating out of tolerance or at risk of failure, conducting quality control and consistency checks, and ensuring distribution is optimized for a product's shelf life. After the drug is introduced, AI supports **pharmacovigilance** by monitoring patient safety data. AI can then take the results of pharmacovigilance into the **post-market surveillance safety and recall** phase to inform and advertise new iterations of the product and future innovations.

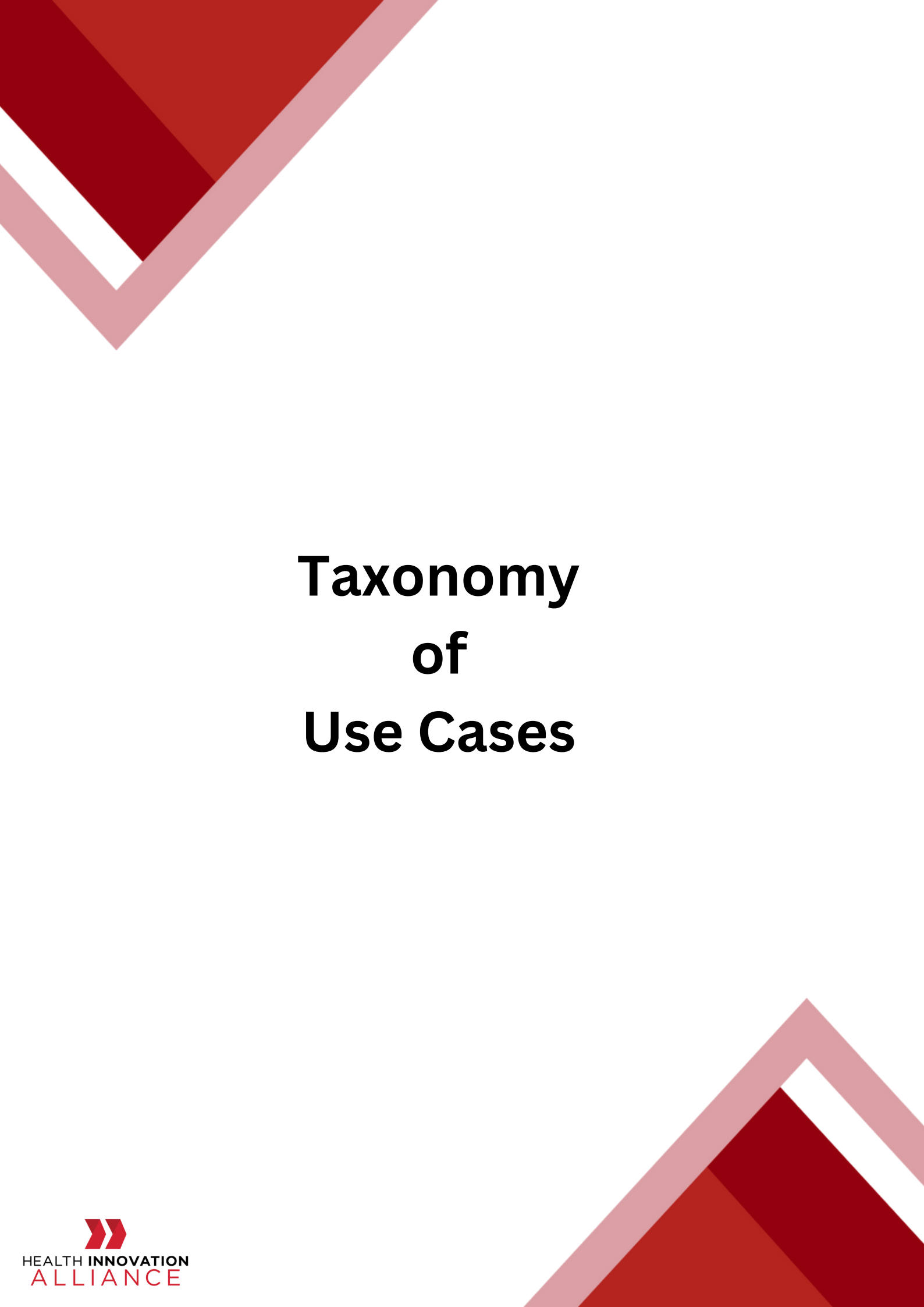
In the provider domain, we applied the life cycle model to identify key AI-driven tools that streamline the operational aspect of health care delivery. Functions like **billing, scheduling, and error/fraud detection** ensure resource management efficiency, reduce administrative burden, and ease the patient experience, especially during transitions.

AI-powered billing can automate the claims process accurately and quickly. These AI tools can analyze claims data, detect anomalies, and identify coding errors before a patient enters the hospital system. This can reduce the likelihood of claim denials and shorten the reimbursement cycle.


AI-powered scheduling can optimize appointment bookings, manage patient flow, and reduce patient wait times. AI-driven platforms may also help schedule appointments based on patient preferences and clinician availability in a way that reduces bottlenecks.

In addition to billing and scheduling, AI models can transform and improve error and fraud detection by scanning claims and transactional data and using machine learning algorithms to detect anomalies or patterns. This may help hospitals and insurers reduce financial losses and maintain compliance with health care regulations by safeguarding against erroneous or improper billing practices.

The taxonomy lays out various AI use cases in health care. Each use case may carry a different level of risk, and that risk level can vary depending on the specific implementation and other factors within the context of use. In most circumstances, a use case will not always be a single risk level across implementations.



Taxonomy of Use Cases



The taxonomy below breaks out the potential use cases for AI in health care. This list is not exhaustive, nor would it be feasible to generate one as AI technology is constantly developing and is increasingly capable of more complex tasks.

HIA offers this list for use by policymakers when considering AI's potential applications, implementations, benefits, and associated risks and risk variation specific to health care. It is important to note that for a given use case, risk may vary depending on what the AI model is applied to – for example, the risks associated with scheduling a primary care visit are not the same as the risks associated with scheduling an emergency open-heart surgery.

In addition, these risks apply to a given application regardless of whether or not AI is being used. In some cases, an AI-enabled application would lower the risk in the context of use compared to a non-AI solution, even if the risk still exists.

Examples of commercially available AI solutions for some use cases below may be found in the appendix.

Patient Life Cycle / Journey

Pre-Diagnosis

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Symptom Research	Patient researches condition using AI-powered search engine or symptom search tool	<p>Faster information to patient</p> <p>Increases patient involvement in care</p> <p>Reduces burden on providers</p>	<p>Misinterpretation of symptoms</p> <p>Patient steered in incorrect direction or to harmful action by model</p> <p>Patient accepts erroneous diagnoses</p> <p>Privacy concerns</p>
Appointment Scheduling	AI finds and books an appointment for patient	<p>Faster and easier patient experience</p> <p>Burden reduction on office staff</p>	<p>Delayed care for emergency/ high-priority visits</p> <p>Discrimination risk</p>
Provider Search	AI tools query provider directory and check insurance participation	<p>Lowers barrier to entry to find provider for patients with limited health/digital literacy</p> <p>Faster and more accurate network participation determination</p>	<p>Incorrect provider information</p> <p>Insurance participation errors</p> <p>Potential for delayed care based on patient reliance on incorrect information</p>
Price Estimator Tool	AI tool estimates price of given services/drugs, in coordination with insurance coverage if applicable	Faster, easier, more accurate cost estimation for patients	<p>Inaccurate price estimates</p> <p>Inaccurate coverage representation</p> <p>Potential for delayed care based on patient reliance on incorrect information</p>
Patient Intake	AI collects and summarizes patient clinical and clinically adjacent information	<p>Reduces clinician burden</p> <p>Reduces patient burden on redundant intake forms</p>	<p>AI leaves out important patient information</p> <p>AI inaccurately summarizes patient record</p> <p>Bias concerns – how AI portrays social determinants of health or health-related social needs information</p>

Patient Life Cycle / Journey

Diagnosis

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Clinical Decision Support (CDS) Tools	AI provides clinicians with treatment options or suggestions based on patient data, including genetic testing/mapping; patient summary generation	<p>Faster and potentially more tailored diagnosis and treatment suggestions</p> <p>Provider burden reduction – time, mental load</p> <p>Accounts for latest research and best practices</p>	<p>Inappropriate suggestions based on incomplete or inaccurate patient history</p> <p>Suggestions conflict with best practice guidelines</p> <p>Tool suggests harmful treatment</p> <p>Provider relying too heavily on AI tool</p>
Diagnostics	AI is used for precision lab testing; real-time medical device data collection, recording, analysis, and interpretation	<p>Faster, more integrated data collecting, recording, reporting</p> <p>More accurate testing</p> <p>Faster results and next steps suggestions, faster treatment to patient</p>	<p>Erroneous test results and downstream effects of said results</p> <p>Inappropriate testing or services based on incorrect recommendations</p>
Vitals Collection	AI-powered medical devices collect vital signs data and input to patient record	<p>Provider burden reduction</p> <p>Faster/easier integration with other technologies</p>	<p>Privacy concerns</p> <p>Erroneous readings or miscalculated values</p>
Medical Imaging Analysis (X-rays, MRIs)	AI algorithms detect abnormalities in imaging data to assist clinicians	<p>More accurate, faster diagnosis</p> <p>Provider burden reduction</p> <p>Detect disease further in advance</p>	<p>Misinterpretation of imaging results</p> <p>Algorithmic bias</p>
Ambient Listening Tools	AI-driven ambient speech recognition (ASR) helps clinicians document patient interaction	<p>Provider burden reduction</p> <p>Better documentation and integration with patient record and other technologies</p>	<p>Privacy risk</p> <p>Transcription inaccuracy</p>

Patient Life Cycle / Journey

Treatment

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Personalized Treatment Plan	AI leverages patient data to create tailored treatment plan, drug recommendation (including contraindicated warnings), including patient's genetic information	Relieves provider burden Better error detection and reduction More comprehensive analysis of whole patient record	Errors in data interpretation lead to inappropriate treatments Errors result in no treatment when treatment would have been appropriate Privacy concern
Virtual Health Assistant	AI provides patients with medication reminders, hospital support	More tailored reminders Increases adherence to medication and keeping appointments	Erroneous communication or no communication when action would have been appropriate Security concern Leading patients to incorrect treatment or care choices
Medication/ Equipment Ordering and Delivery	Optimize prescription, device, or equipment delivery method based on patient data	Mitigate out-of-stock situations More patient-centered care	Incorrect item(s) delivered; deliveries missed Drug diversion Privacy
Medical Procedure Assistance	Surgical technology augmented by AI	More precise than human alone Potentially more up-to-date on best practices	Patient harm Potential for physician reliance on tool Potential for deviation from best practices Malpractice liability
Vitals Monitoring	Monitor vital signs, record data, notify providers of important changes	Faster actionable information Better integration with electronic records	Misallocation of staff resources if a false positive Failure to notify provider in dangerous situation

Patient Life Cycle / Journey

Post-Treatment and Follow-Up Phase

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Remote Monitoring with Wearables	AI analyzes data from wearables to track recovery and detect complications	Check incoming data more frequently than patient or provider Faster notice of warning signs of adverse health events	Data breach Privacy concerns Incorrect readings or assumptions
Patient Follow-up Scheduling	AI streamlines scheduling process based on treatment timelines	Administrative staff burden reduction Optimize treatment timelines for individual patients and facility usage	Scheduling errors Delayed treatment
Recurring Orders	Organize recurring deliveries of medical supplies for patient or practice location	Reduce adverse events for patients Increase patient convenience Increase adherence to treatment regimen	Deliveries too often, not often enough, or not at all Issues when the course of care is changed, or product is not available
Monitoring Treatment Guidelines	Monitoring and notifying providers of changes to best practices, treatment guidelines, etc.	Provider burden reduction Lower chances of adverse events due to outdated best practices	Erroneous information Misrepresentation of guidelines

Patient Life Cycle / Journey

Administrative and Logistics Support; Public Health

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Billing, Coding, and Claims	AI automates billing processes and medical coding, claims submission, adjudication, and review	Administrative burden reduction Increase cost efficiency Faster adjudication of claims	Incorrect billing due to flawed algorithm Security concern
Fraud Detection	AI identifies patterns in claims data to detect fraud	Increased accuracy of fraud detection, resulting in more money saved for payers Increased cost efficiency of fraud detection	False positives Privacy concern
Resource Allocation and Optimization	AI suggests allocation or allocates resources based on projections/reports	Administrative burden reduction More efficient allocation of resources Reduce unnecessary surpluses or shortages	Resource misallocation Shortage/surplus of supplies
Insurance Optimization	Real-time checks and coverage efficiency suggestions	Reduce unnecessary expenditures for patients Increase medication pick-up rate	Incorrect information Care avoidance due to inaccurate information or flawed assumptions
Caregiver Staffing	Allocate medical staff	Increase efficiency of staff allocation, reduce costs	Staffing misallocation due to incorrect data or assumptions Patient harm
Site Allocation	Synthesize schedules and room usage to optimize the use of the site	Increase efficiency Advanced warning of capacity issues	Suboptimum allocation of resources Misplaced providers unable to give timely care Patient harm

Patient Life Cycle / Journey

Administrative and Logistics Support; Public Health Cont.

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Care Team Coordination	Notify providers of new medications, treatments, and diagnoses of patients	<p>Provider burden reduction</p> <p>Improve patient experience</p> <p>Increased visibility for contraindicated medication or treatments, reduces adverse events</p>	Incorrect/misrepresented information
Public Health Surveillance and Prediction	AI systems analyze data patterns to identify potential outbreaks and monitor disease spread	More advanced warning for emerging threats	<p>False positives</p> <p>Privacy concern</p>

Patient Life Cycle / Journey

Data-Management and Security

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
EHR System Tools	AI-enabled EHRs integrate patient data for care coordination; summarize patient information; help automate compliance and documentation	Provider burden reduction Improved patient outcomes and experience	Data breach System inoperability Incorrect data or assumptions lead to inappropriate care or patient harm
Drug Discovery and Development	AI analyzes molecular structures and trial data to develop new drugs	Faster and less expensive discovery of new molecules	Algorithmic bias Lack of validation in clinical environments
Clinical Trial Optimization	AI identifies candidates and predicts outcomes for clinical trials	More diverse clinical trial representation Faster, lower cost clinical trials	Outcomes may not be diverse
Compliance	Compliance with government requirements around cybersecurity, value-based payment, etc.	Lower cost compliance	Financial, civil, and criminal liability Breach of contract

Drug Discovery Life Cycle

Pre-Development

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Target ID and Validation	AI identifies biological targets for drug intervention	Faster, more efficient process Enhanced capability for rapid response to emerging pathogens	False positives/ negatives Excluding diverse populations in a dataset
Additional Indication Research	AI identifies additional uses for existing drugs/molecules	More efficient use of resources – more targeted investment in molecules with promise	Inaccurate predictions create resource waste

Drug Discovery Life Cycle

Development & Clinical Trials

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Drug Design and Optimization	AI uses predictive modeling to generate molecular compounds to identify candidates	Faster, less costly drug development Provides another reference point for people making decisions	Relying on simulations vs. experimental validation Potential to miss side effects
Preclinical Testing	AI models predict drug efficacy as a replacement for animal testing	Provides additional reference points, more data supporting decisions Faster, less costly drug development	Inaccurate predictions lead to side effects Ethical concern about relying on incomplete models
Clinical Trial Design and Optimization	AI predicts trial outcomes	Provides additional reference points, more data supporting decisions Can help mitigate shortcomings of clinical trial participation/design	Potential risk of excluding underrepresented groups Bias in predictive models
Clinical Trials Search Tool	Patient or provider uses AI tool to search clinical trials for given condition(s)	Streamlined clinical trial participation pathway Provider burden reduction Increased clinical trial diversity	Patient pursues a trial they are not eligible to participate in Delayed care based on incorrect data or model assumptions
Funding	AI evaluates historical funding data to recommend an investment timeline	Greater financial predictability More efficient investment in clinical trials	Historical patterns might not predict current trends
Trial Participant Recruitment and Communication	AI identifies trial subjects	Increased diversity in clinical trials Patient benefits from access to medicine in trials	Possible narrow inclusion criteria

Drug Discovery Life Cycle

Development & Clinical Trials Cont.

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Data Validation	AI evaluates clinical trial data to determine effectiveness	Faster, more efficient evaluation	Safety concerns Risk of inappropriately weighing results and demographic trends
FDA Approval Preparation	AI is used to compile information for the FDA approval process	Faster, more efficient data compilation	Errors in documentation, delaying the compliance process

Post-Market

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Logistics for Shipping	AI optimizes the supply chain	Faster, more efficient shipping Lower costs for logistics providers and customers	Possible algorithm issues and errors in handling that can cause delays
Post-Approval Safety Monitoring	AI analyzes patient and clinician data to detect adverse events post-market	Faster identification of events Fewer adverse events as trends are detected faster	Missing rare adverse events Underreporting from incomplete data sources
Post-Market Surveillance	AI monitors databases for signals of drug-related safety issues	Faster identification of events Fewer adverse events as trends are detected faster	False positives/ negatives

Medical Device Development Life Cycle

Pre-Development

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Funding	AI identifies investment timeline	Greater financial predictability Greater predictability in timelines	Outdated market trends may not supply a good timeline for the current landscape

Development & Clinical Trials

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Device Design	AI generates prototypes of medical devices	Lower cost prototyping Faster iteration on prototypes	Chance of faulty designs that do not withstand real-world application
Clinical Trial Efficiency	AI predicts patient outcomes, device failure rates	More efficient iteration process for devices Better identification of potential issues	Biased data sets
Trial Participant Communication	AI provides real-time updates to participants to collect feedback	Better communication with patients; patients more engaged Enhanced feedback loop from trial participants	Communication gaps between AI and human participants
Regulatory Submission	AI compiles data and documentation to ensure regulatory compliance for FDA approval	Faster, more efficient data compilation	Errors in documentation, delaying the compliance process
Data Validation	AI evaluates clinical trial data to determine effectiveness	Better detection of underlying trends in data Additional validation of safety and effectiveness	Safety concerns Risk of inappropriately weighing results and demographic trends

Medical Device Development Life Cycle

Post-Market

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Logistics for Shipping and Deployment	AI optimizes the supply chain to deliver devices	Faster, more efficient shipping Lower costs for logistics providers and customers	Failure in prediction can lead to delays Improper handling may result in damages
Safety Monitoring	AI tracks device usage data and adverse events	Faster identification of events Fewer adverse events as trends are detected faster	False negatives/ positives
Post-Market Surveillance	AI monitors user feedback and performance logs to identify trends in device malfunctions	Faster identification of events Fewer adverse events as trends are detected faster Better and more information for future device modifications	Algorithmic blind spots



Conclusion

The future of health care includes AI. How it is incorporated and used depends on the constraints placed on it and resources allocated to support it by both Congress and the administration. As regulators continue to evaluate the use of AI in health care, they must consider what the technology is being used for and decide how it is being deployed to appropriately consider the potential risk factors inherent to every individual scenario. The federal government must also consider how best to support the development and deployment of AI broadly and in the health care ecosystem, including how to train the workforce to use these new tools. HIA believes that government should work with the private sector to ensure that these tools are available across the health care industry so that AI can realize its full potential to solve some of the industry's most challenging problems.

HIA encourages policymakers and regulators to be thoughtful and forward-looking, rather than reactionary, in their approach to the rules and regulations around AI in health care. A one-size-fits-all approach is not appropriate and risks mitigating any of the potential benefits of the technology now and in the future.

If you have questions about the findings of HIA's use cases, please contact Brett Meeks at bmeeks@health-innovation.org.



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Appendix

Resources

AI model in EHRs

- <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2695078>
- https://aws.amazon.com/solutions/case-studies/anthem/?did=cr_card&trk=cr_card

Efficacy of AI models

- [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(21\)00208-9/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00208-9/fulltext)

AI transforming lab and clinical trials, drug development

- https://www.tandfonline.com/doi/full/10.2144/btn-2021-0077?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org
- <https://pmc.ncbi.nlm.nih.gov/articles/PMC9424628/>
- https://aws.amazon.com/solutions/case-studies/AstraZeneca-case-study/?did=cr_card&trk=cr_card

AI detecting diabetic retinopathy

- [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(20\)30060-1/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30060-1/fulltext)
- <https://jamanetwork.com/journals/jama/fullarticle/2588763>
- [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(20\)30250-8/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30250-8/fulltext)

AI in decision making process

- <https://arxiv.org/abs/1905.02599v2>
- <https://www.nature.com/articles/s43856-022-00214-4>

AI assessment of cardiac function

- <https://www.nature.com/articles/s41586-020-2145-8>
- <https://www.nature.com/articles/s41586-023-05947-3>
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Examples of AI Technologies

Below are examples of real-life products, solutions, and ecosystems that incorporate AI technologies in some capacity, organized by use case. This is by no means an exhaustive list of all products available on the market – rather it is meant to be illustrative of the fact that AI is already being used across the health care system.

- **Treatment Assistance**

- Surgical Robots
 - Da Vinci Surgical System
 - Mazor X Stealth Edition
 - Monarch platform
- Medical Imaging Data
 - X-Rays
 - Zebra Medical Vision's AI1
 - MRIs
 - Philips SmartExam AI
 - Siemens AI-Rad Companion Brain MR
 - CT Scans
 - GE HealthCare's Revolution CT with Deep Learning Image Reconstruction
 - Ultrasound
 - Philips EPIQ Elite with AI-assisted quantification
 - Mammography
 - iCAD ProFound AI
 - Kheiron Medical's Mia
 - Retinal Imaging
 - IDx-DR for diabetic retinopathy detection
 - General
 - AWS HealthImaging
- Diagnosis
 - MYCIN
 - IBM Watson
 - Jvion

- **EHR systems**

- Athenahealth
- McKesson
- Epic
- Cerner
- MEDITECH

Examples of AI Technologies Cont.

- **CDS Tools**
 - ClinicalKey
 - UpToDate
 - Epocrates
 - VisualDx
 - DynaMed and Microdex with Watson
 - Medscape
 - MDCalc
- **Transcription and Automatic Speech Recognition (ASR)**
 - Nuance Dragon Medical One
 - M*Modal Fluency Direct
 - DeepScribe
 - AWS Healthscribe
- **Administration**
 - Billing
 - Waystar
 - Change Healthcare
 - Scheduling
 - Qventus
 - Lumeon
 - Zocdoc
 - Fraud Detection
 - LexisNexis Risk Solutions
 - HMS Healthcare / Gainwell Technologies
 - OptumInsight
- **Pharmaceutical Development**
 - Atomwise
 - Excientia
 - BenevolentAI
- **Clinical Trials**
 - AiCure
 - Unlearn.ai
 - Medidata (Acorn AI)



Examples of AI Technologies Cont.

- **Public Health Research**
 - Disease Outbreak and Prediction
 - BlueDot
 - HealthMap
 - Metabiota
- **Patient Experience**
 - Virtual Health Assistants
 - Ada Health
 - Babylon Health
 - Woebot
 - Remote Patient Monitoring
 - Wearables
 - Apple Watch
 - Fitbit
 - Garmin
 - Whoop Coach



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