



## Background

**Background:** AI is playing an increasingly important role in our lives and the healthcare field is no stranger to this technological revolution. Within healthcare, many uses of AI exist such as: image analysis for diabetic retinopathy<sup>1</sup>, natural language processing (NLP) of electronic health records (EHRs)<sup>2</sup>, analysis of sensory data by wearable devices<sup>3</sup>, etc. With a growing list of products being actively implemented and used to aid clinicians, a number of regulatory and ethical considerations exist that must be addressed and further explored. The identified challenge areas that are explored in this project can be found in **Table 1**.

**Purpose:** Explore current research that is being conducted within the AI-healthcare policy space and how various organizations, universities, governmental agencies, and non-profits are exploring the issues facing AI in healthcare. We aim to produce an up-to-date database including research publications surrounding the identified challenges, as well as the authors/organizations conducting and funding this research.

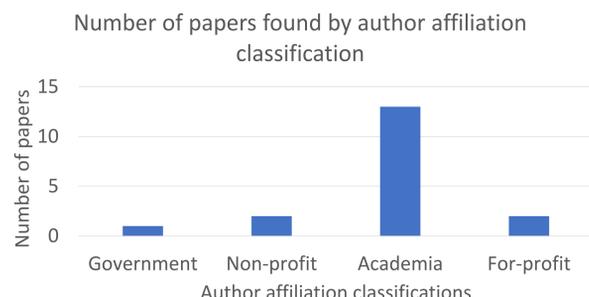
**Table 1:** Identified challenges facing AI in healthcare<sup>4</sup>

Challenge Areas	Description
<b>1 Liability of AI</b>	In the case that liability of a decision or mistake must be assigned, which entity is assigned liability when aided by artificial intelligence? What sort of liability is AI subject to/responsible for?
<b>2 Explainability/Interpretability of AI</b>	Considering typical AI algorithms use a complicated mathematical and statistical foundation, is there a need to understand the rationale/logic underlying an AI's output?
<b>3 AI Regulation and Evaluation</b>	Prior to and following implementation (see problem 7), what steps must be taken to ensure safe and effective use of AI within healthcare settings?
<b>3a Pre-Market</b>	Prior to implementation, what regulatory processes must AI undergo to validate its future efficacy and safety?
<b>3b Post-Market</b>	Following implementation, what systems must be developed to ensure prolonged model use and allow for consistency in model performance?
<b>4 Coverage and Payment of AI</b>	Within our current healthcare system, what type of coverage plan would AI fall under and how can patients be reimbursed for the use of AI?
<b>5 Model bias in AI</b>	From a regulatory perspective, what steps can be taken to avoid the introduction of model bias and model degradation?
<b>6 AI Privacy</b>	What implications does AI use have for health information privacy and how can we ensure security of sensitive information in the face of complex algorithms?
<b>7 Implementation/Scaling of AI</b>	What steps must be taken to allow for full integration of AI into clinical settings? How can AI be scaled once implemented? How about translation to different systems?

## Methods

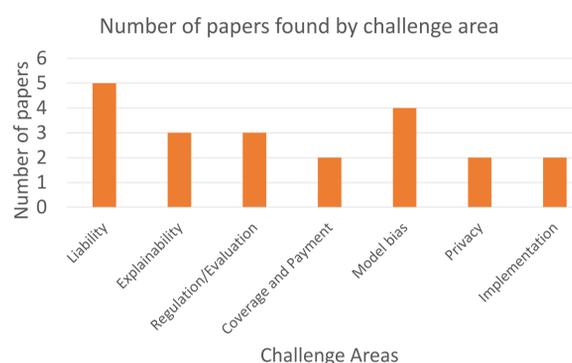
- Initially developed the challenge areas (**Table 1**) and found key search terms that may aid in initially finding resources.
- Catalogued publications and articles found specifically targeting identified challenge areas.
- Identified resources through general search engines such as Google, Google scholar, PubMed, etc – did not utilize proprietary research databases.
- Unique search operators and key words found through our preliminary search were used to develop search terms. Example search terms include:
  - Legal Outcome + Clinical Practice + (Artificial Intelligence OR Machine Learning) + (Healthcare OR "Health care") + Liability*
  - FDA + (PMA OR 510) + (Artificial Intelligence OR Machine Learning) + (Healthcare OR "Health care")*
  - Surveillance + (Post market OR "Post-market") + (Artificial Intelligence OR Machine Learning) + (Healthcare OR "Health care")*

## Results



**Figure 1.** A majority of resources found via developed search terms are derived from academia, however a number of entities outside of academic institutions are also doing work in this space.

**Figure 2.** Through our finite review, articles have been catalogued in all identified challenge areas. We found a large number of resources addressing liability and model bias specifically.



**Table 2:** Organizations found conducting research in identified challenge areas

Challenge Areas	Major Entities
<b>1 Liability of AI</b>	<ul style="list-style-type: none"> <li>PHG Foundation (Foundation for Genomics and Population Health)<sup>5</sup></li> <li>American Medical Association<sup>6</sup></li> <li>Stanford Law School<sup>7</sup></li> <li>Glenn Cohen Lab<sup>8</sup></li> <li>Nicholson Price Lab<sup>9</sup></li> </ul>
<b>2 Explainability/Interpretability of AI</b>	<ul style="list-style-type: none"> <li>Google Health<sup>10</sup></li> <li>KenSci Inc.<sup>12</sup></li> <li>Cornell University<sup>11</sup></li> </ul>
<b>3 AI Regulation and Evaluation</b>	<ul style="list-style-type: none"> <li>Harvard Law School<sup>13</sup></li> <li>Glenn Cohen Lab<sup>14</sup></li> </ul>
<b>4 Coverage and Payment of AI</b>	No major entity studying this field
<b>5 Model bias in AI</b>	<ul style="list-style-type: none"> <li>University of California, San Francisco<sup>15</sup></li> <li>University of California, Berkeley<sup>16</sup></li> <li>National Institute of Minority Health and Health Disparities<sup>17</sup></li> </ul>
<b>6 AI Privacy</b>	<ul style="list-style-type: none"> <li>Research Triangle International<sup>18</sup></li> </ul>
<b>7 Implementation/Scaling of AI</b>	<ul style="list-style-type: none"> <li>Duke University<sup>19</sup></li> </ul>

**Table 3:** Organizations found funding AI research in healthcare

Funding Organizations	Project Description
<b>1 Schmidt Foundation</b>	<ul style="list-style-type: none"> <li>Created a philanthropic initiative known as "Schmidt Futures"                             <ul style="list-style-type: none"> <li>Has sponsored a national academies study which will explore the potential for AI to control scientific workflows.</li> </ul> </li> </ul>
<b>2 Wallenberg Foundation</b>	<ul style="list-style-type: none"> <li>Created initiative known as the "Initiative for Humanistic and Social Scientific Research in AI and Autonomous Systems" (WASP-HS).                             <ul style="list-style-type: none"> <li>WASP-HS vision is "to realize excellent research and develop competence on the consequences and challenges of artificial intelligence and autonomous systems for humanities and society."</li> </ul> </li> </ul>
<b>3 Pew Research Center</b>	<ul style="list-style-type: none"> <li>Created the Pew Internet and American Life Project.                             <ul style="list-style-type: none"> <li>Covers the growing role of AI in our everyday lives in not only healthcare but farming, construction, etc.</li> </ul> </li> </ul>
<b>4 Agency for Healthcare Research and Quality</b>	<ul style="list-style-type: none"> <li>Supporting AI-based healthcare research in various ways. One of the products they support is eTriage, an ED triaging algorithm from John Hopkins University.</li> </ul>
<b>5 Rockefeller Foundation</b>	<ul style="list-style-type: none"> <li>The Precision Public Health Initiative aims to leverage data and analytic tools to accelerate progress on the world's greatest public health challenges. This initiative aims to use AI to improve public health in the developing world.</li> </ul>

## Conclusions

- A majority of catalogued papers address AI liability and AI model bias challenge areas. Areas of least research are addressing AI payment and coverage, as well as AI implementation into clinical environments.
  - Potential rationale:**
    - Machine Learning-based AI is still a novelty and is in the "pilot phase" of development – few publications addressing large-scale implementation.
    - Papers generally address the role of AI in healthcare, but fail to describe the nuances and details of large-scale implementation.
    - AI Liability and model bias are challenge areas that fall outside of healthcare and into law and public policy – more organizations exploring these areas.
- Additional challenge area was identified: Understanding the interaction between human and algorithm<sup>10</sup>.
  - Currently have a very limited understanding of the effect's algorithms have on humans in clinical practice.
  - Developing methods to better understand the long- and short-term effects of AI-human interactions over time can allow for developers to account for expected factors such as alert fatigue.
- Future work** should focus on
  - Understanding AI's role in the context of payment and coverage.
  - AI implementation and understanding what steps should be taken to allow for scaling and translation of AI in health systems<sup>3</sup>.
  - Exploring the interaction between AI and humans in a clinical setting and how this long-term interaction affects human behavior.

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