Legal Policies, Regulations and Ethics in Healthcare

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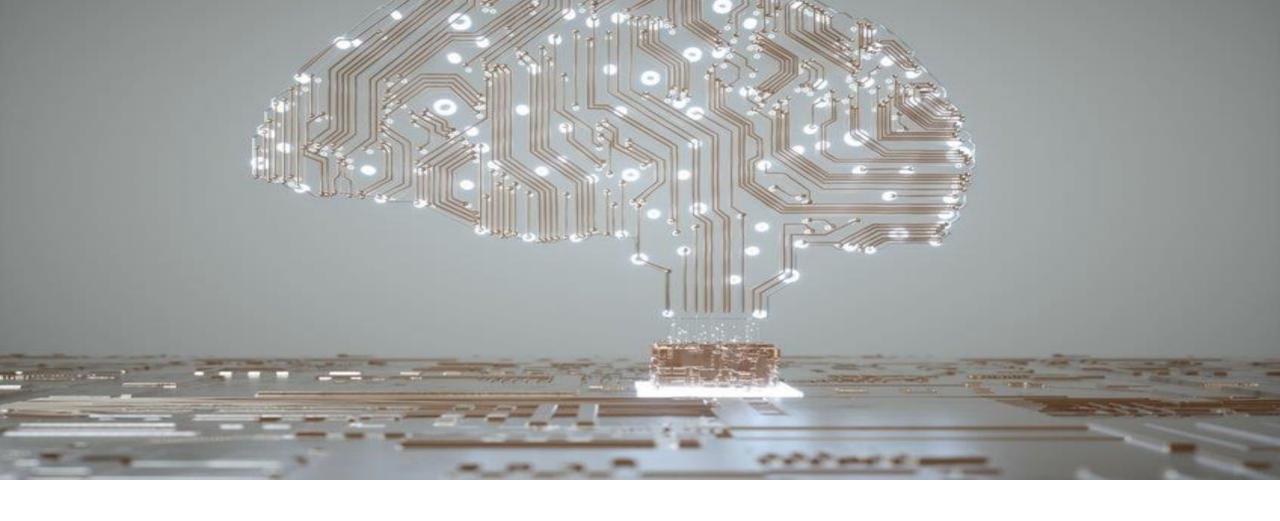
Tuesday, 27th February 2024



Outline

- Artificial Intelligence in Healthcare
- Ethical Al and it's implications in healthcare
- Ethical issues for AI in healthcare
- Summary of legal regulations and policies for AI in healthcare
- Conclusion





Artificial Intelligence (AI) describes a program or system that can effectively address real-world problems in a human-like way.





The goal is to use AI systems to sustainably benefit society across different industries.

economics healthcare education transportation finance





What is Artificial Intelligence in Medicine?

Artificial intelligence in medicine is the use of machine learning models to help process medical data and give medical professionals important insights, improving health outcomes and patient experiences.



Machine Learning

Machine learning (ML) is a subset of artificial intelligence (AI), that is all about getting an AI to accomplish tasks without being given specific instructions.



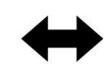
Machine Learning Pipeline

Data is collected from individuals

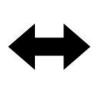
Data is used to educate AI system

Al system makes informed decisions

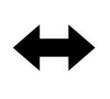














Individuals

Data

Supervised learning Unsupervised learning Reinforcement learning

Outcome





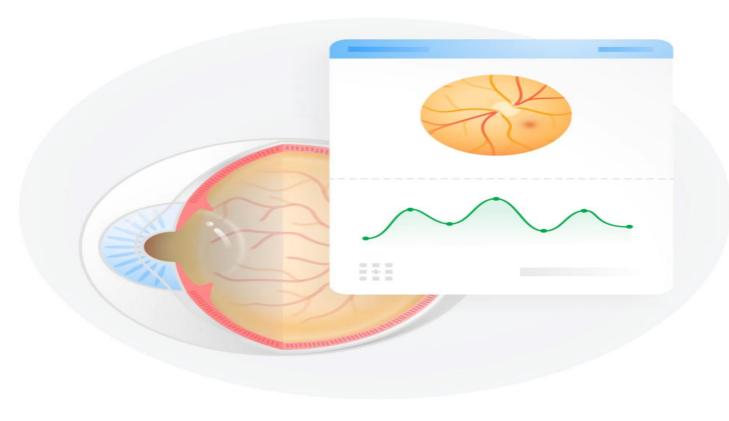


Detection of signs of disease in external photographs of the eyes via deep learning

Boris Babenko^{1,7}, Akinori Mitani ^{⑤ 1,2,7}, Ilana Traynis³, Naho Kitade¹, Preeti Singh¹, April Y. Maa^{4,5}, Jorge Cuadros⁶, Greg S. Corrado¹, Lily Peng¹, Dale R. Webster ^{⑥ 1}, Avinash Varadarajan¹, Naama Hammel ^{⑥ 1 □} and Yun Liu ^{⑥ 1 □}

Babenko, B., Mitani, A., Traynis, I., Kitade, N., Singh, P., Maa, A. Y., ... & Liu, Y. (2022). Detection of signs of disease in external photographs of the eyes via deep learning. *Nature biomedical engineering*, *6*(12), 1370-1383.





Article Published: 23 December 2019

Detection of anaemia from retinal fundus images via deep learning

Akinori Mitani [™], Abigail Huang, Subhashini Venugopalan, Greg S. Corrado, Lily Peng, Dale R. Webster,

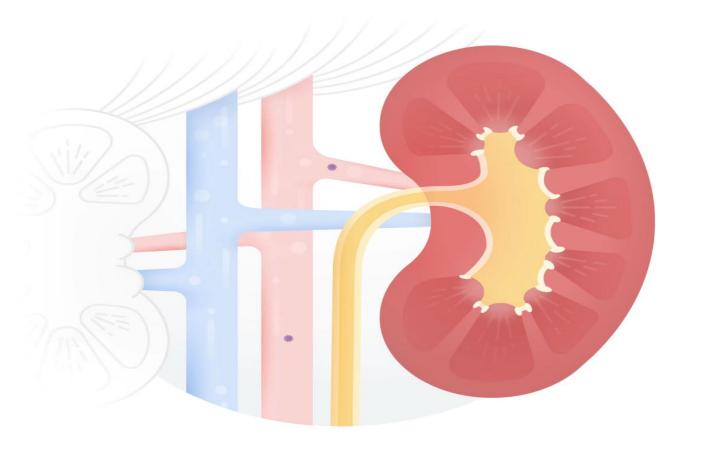
Naama Hammel, Yun Liu & Avinash V. Varadarajan

Nature Biomedical Engineering 4, 18–27 (2020) Cite this article

4925 Accesses | 111 Citations | 96 Altmetric | Metrics

Mitani, A., Huang, A., Venugopalan, S., Corrado, G. S., Peng, L., Webster, D. R., ... & Varadarajan, A. V. (2020). Detection of anaemia from retinal fundus images via deep learning. *Nature Biomedical Engineering*, *4*(1), 18-27.





A clinically applicable approach to continuous prediction of future acute kidney injury

Nenad Tomašev

, Xavier Glorot, Jack W. Rae, Michal Zielinski, Harry Askham, Andre Saraiva, Anne

Mottram, Clemens Meyer, Suman Ravuri, Ivan Protsyuk, Alistair Connell, Cían O. Hughes, Alan

Karthikesalingam, Julien Cornebise, Hugh Montgomery, Geraint Rees, Chris Laing, Clifton R. Baker, Kelly

Peterson, Ruth Reeves, Demis Hassabis, Dominic King, Mustafa Suleyman, Trevor Back, ... Shakir

Mohamed

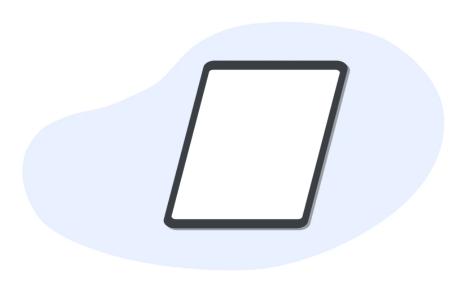
+ Show authors

Nature 572, 116–119 (2019) | Cite this article

47k Accesses | 554 Citations | 1555 Altmetric | Metrics

Tomašev, N., Glorot, X., Rae, J. W., Zielinski, M., Askham, H., Saraiva, A., ... & Mohamed, S. (2019). A clinically applicable approach to continuous prediction of future acute kidney injury. *Nature*, *572*(7767), 116-119.







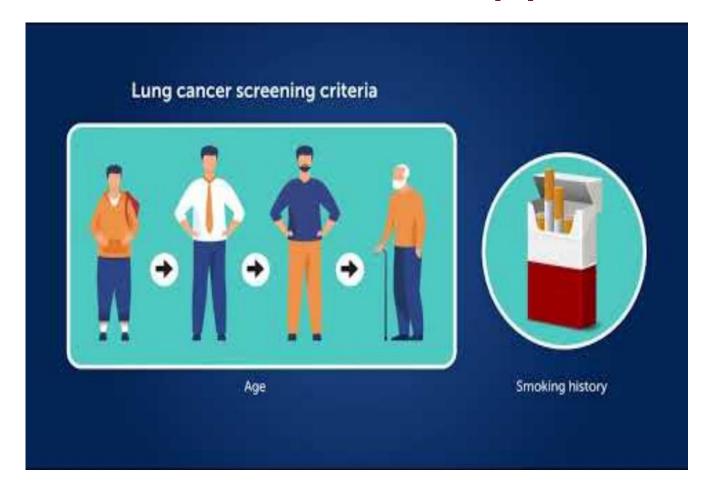
Original Investigation | Dermatology

Development and Assessment of an Artificial Intelligence-Based Tool for Skin Condition Diagnosis by Primary Care Physicians and Nurse Practitioners in Teledermatology Practices

Ayush Jain, MS; David Way, ME; Vishakha Gupta, MS; Yi Gao, PhD; Guilherme de Oliveira Marinho, BS; Jay Hartford, MS; Rory Sayres, PhD; Kimberly Kanada, MD; Clara Eng, PhD; Kunal Nagpal, MS; Karen B. DeSalvo, MD, MPH, MSc; Greg S. Corrado, PhD; Lily Peng, MD, PhD; Dale R. Webster, PhD; R. Carter Dunn, MS, MBA; David Coz, MS; Susan J. Huang, MD; Yun Liu, PhD; Peggy Bui, MD, MBA; Yuan Liu, PhD

Jain, A., Way, D., Gupta, V., Gao, Y., de Oliveira Marinho, G., Hartford, J., ... & Liu, Y. (2021). Development and assessment of an artificial intelligence—based tool for skin condition diagnosis by primary care physicians and nurse practitioners in teledermatology practices. *JAMA network open*, 4(4), e217249-e217249.







Mikhael, P. G., Wohlwend, J., Yala, A., Karstens, L., Xiang, J., Takigami, A. K., ... & Barzilay, R. (2023). Sybil: A validated deep learning model to predict future lung cancer risk from a single low-dose chest computed tomography. *Journal of Clinical Oncology*, *41*(12), 2191-2200.



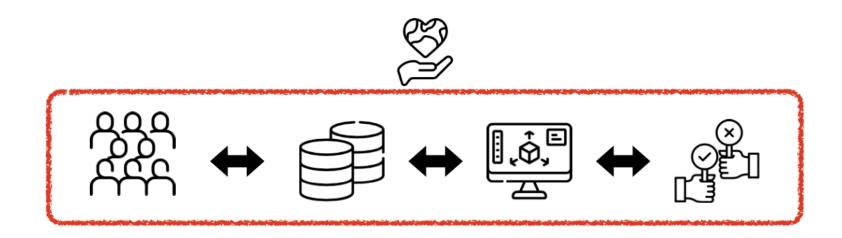
Outline

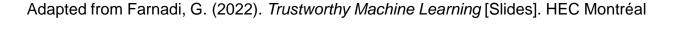
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Ethics and Al

Al ethics is a set of guidelines that advise on the design and outcomes of artificial intelligence.







Overarching Ethical Principles



Transparency – Al should be interpretable for users.



Justice and Fairness – Al should avoid unwanted bias and discrimination.



Non-maleficence – Al should never cause harm.



Responsibility – Al should make reliable decisions that are accountable.



Privacy – The data obtained by AI should be secure and protected.



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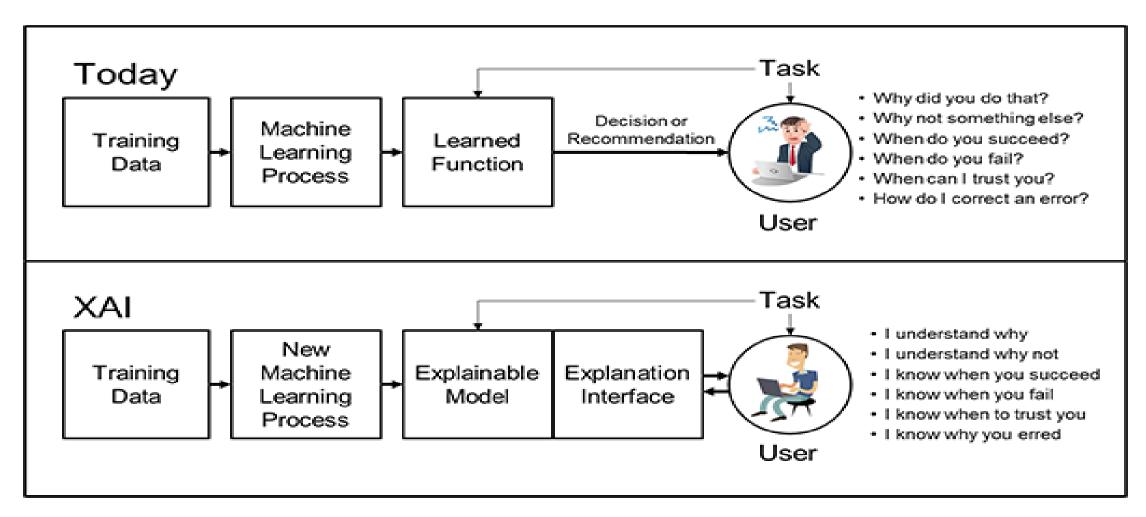
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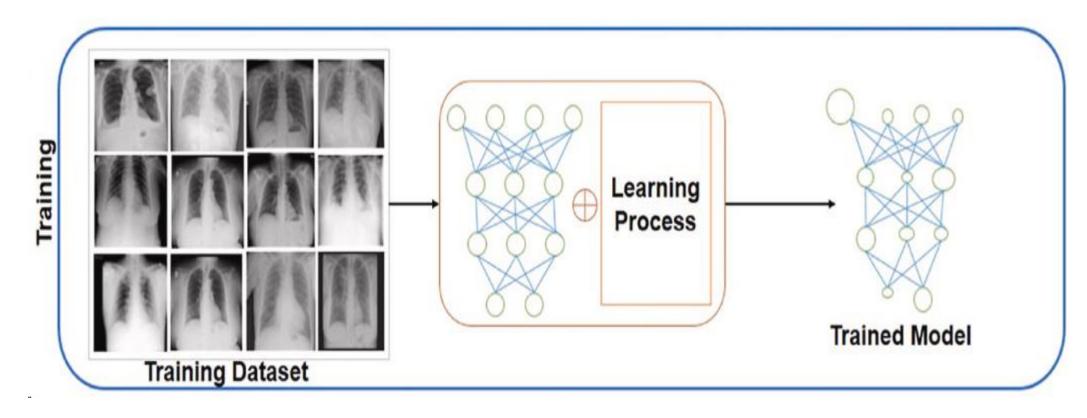
Transparency/Explainability



Source: https://www.darpa.mil/program/explainable-artificial-intelligence



Transparency/Explainability in Healthcare

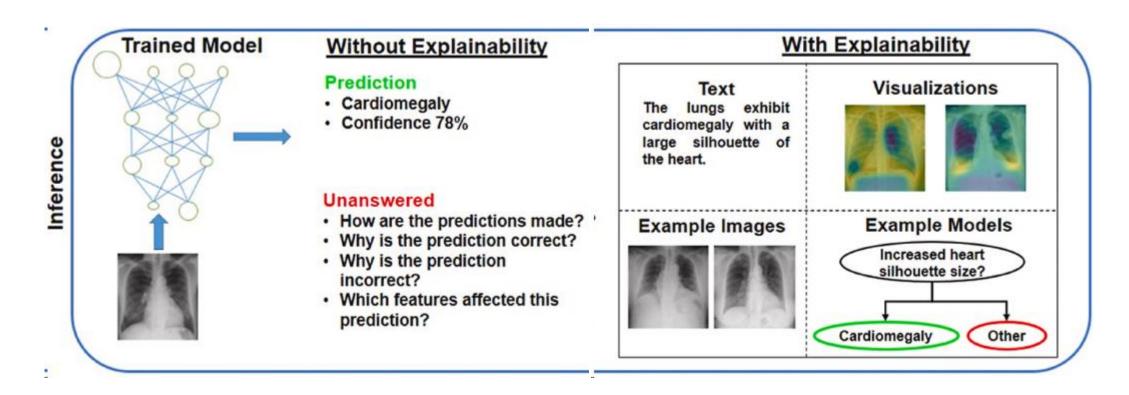


Goal: Diagnosing medical conditions such as pneumonia, COVID-19, asthma

Nazir, S., Dickson, D. M., & Akram, M. U. (2023). Survey of explainable artificial intelligence techniques for biomedical imaging with deep neural networks. *Computers in Biology and Medicine*, 106668.



Transparency/Explainability in Healthcare



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Nazir, S., Dickson, D. M., & Akram, M. U. (2023). Survey of explainable artificial intelligence techniques for biomedical imaging with deep neural networks. *Computers in Biology and Medicine*, 106668.



Benefits of Transparency/Explainability

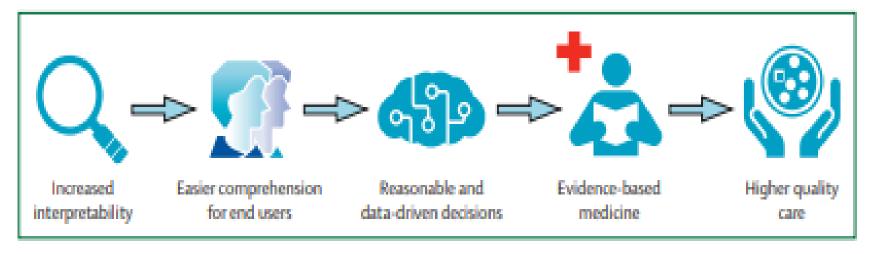


Figure: How does explainable artificial intelligence drive better medical care?



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Justice and Fairness





Justice and Fairness

- Justice is concerned with treating people fairly
 - It can refer to:
 - Outcomes such as gender equality
 - Processes such as having possibility to challenge decisions



Justice and Fairness

- Fairness refers to the attempts at correcting algorithmic bias
- Correcting bias requires:
 - Identifying type of bias
 - Mitigate those biases

Biases are subjective, therefore there is no single agreed-upon measure of fairness



Addressing Fairness in Machine Learning



bias

Data is unbalanced
Historical discrimination
Encodes protected attributes

Data scientists do not build the models Unfair outcome Black-box models No user feedback



Algorithmic Biases

Data Bias

Algorithms are trained using biased data. (*Pre-processing*)

Examples:

- Selection bias
- Sampling bias
- Reporting bias
- Participation bias
- Non-response bias
- Coverage bias

Interpretation Bias

Human assumptions perpetuate a skewed interpretation of results. (Post-processing)

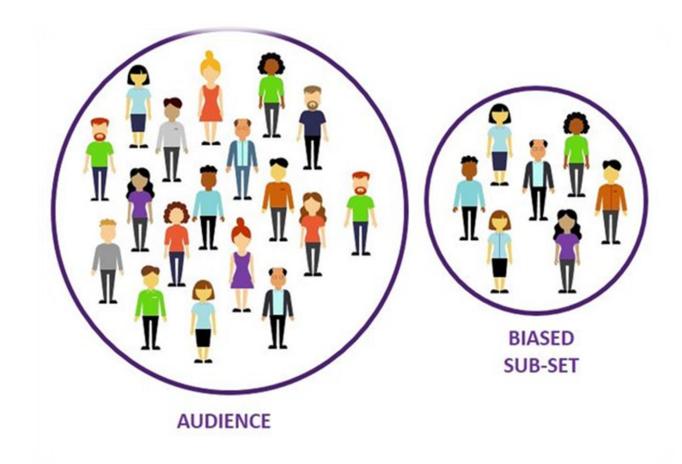
Examples:

- Automation bias
- Overgeneralization
- Confirmation bias
- Experimenter's bias
- Group attribution bias
- Implicit bias
- Correlation fallacy



Data Bias- Selection Bias

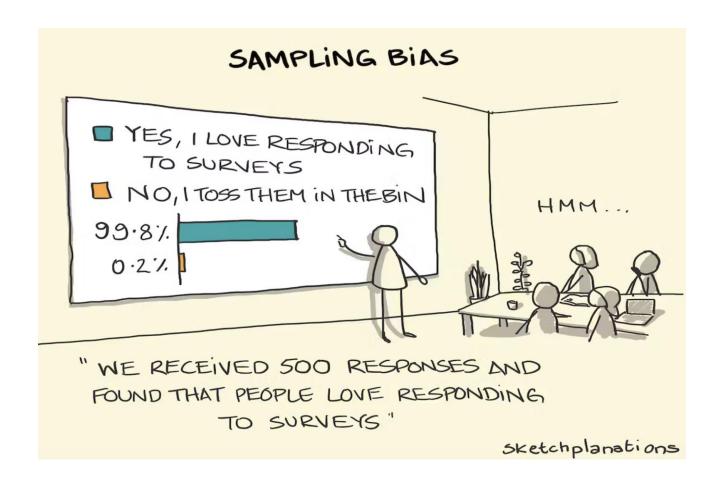
Selection Bias – Data selections don't reflect randomization





Data Bias- Sampling Bias

Sampling Bias – Data instances are more frequently sampled



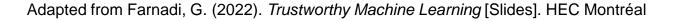


Interpretation Bias- Overgeneralization

Overgeneralization –

Making more general conclusions from limited testing data

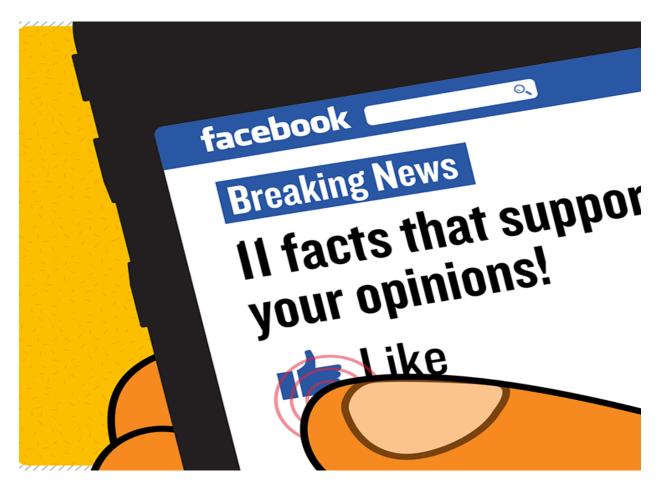






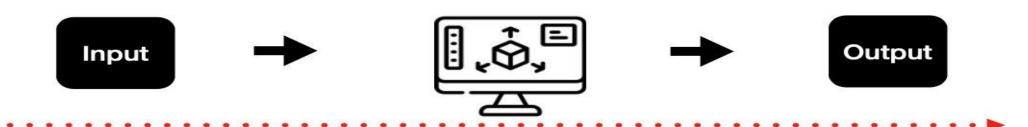
Interpretation Bias- Confirmation Bias

Confirmation Bias – The tendency to search for, interpret, favor, recall information in a way that confirms pre-existing beliefs





Addressing Fairness in Machine Learning



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Historical discrimination
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Data scientists do not build the models

Unfair outcome Black-box models No user feedback

Pre-processing

Discrimination Discovery Sampling/weighting Representation learning

In-processing

Learning/Inference subject to constraints
Ranking
Constrained Optimization

Post-processing

Thresholding
Causal discovery
Explainable Al
Verification



Bias Detection, Mitigation and Prevention

1

Step 1: Inventory Algorithms 2

Step 2: Screen for Bias

3

Step 3: Retrain Biased Algorithms 4

Step 4: Set Up Structures to Prevent Future Bias



Step 1: Inventory Algorithms

Step 1A

Talk to stakeholders about how and when algorithms are used. Create a list of algorithms within your organization.

Step 1B

Choose a 'steward'. This person will be responsible for keeping the inventory updated.

Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.

Algorithm name	Specialty	Original intended use
Braden Scale	Hospital medicine	predict risk of developing pressure sores or ulcers
Schmid Fall Score	Hospital medicine	predict fall risk in hospital inpatients
STRATIFY Score	Geriatrics	predict fall risk in hospital inpatients ages 65 and older
Nursing Delirium Screen Score (Nu-DESC)	Hospital medicine	early diagnosis of delirium in hospital inpatients
AWOL Score	Hospital medicine	assess risk for developing delirium upon hospital admission
Little Schmidy Fall Scale	Pediatrics	assess the risk of falls in pediatric hospital inpatients

Step 2: Screen for Bias

Step 2A

Articulate the ideal target
(what the algorithm should
be predicting) vs. the actual
target (what it is actually
predicting)

Consider whether there is a mismatch that can cause bias.

Example: Screening for Label Choice Bias

Algorithm	Ideal Target	Actual Target	Risk of Bias
Care Management Prioritization: Identifying patients for additional services	Health needs, benefit from high-risk care management programs	Total costs of care	High. Less money is spent on Black patients who have the same level of need

Two patients with the same level of need might have different costs if one receives less care.

This disconnect could cause bias in patients being identified for additional services.

Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.



Step 2: Screen for Bias

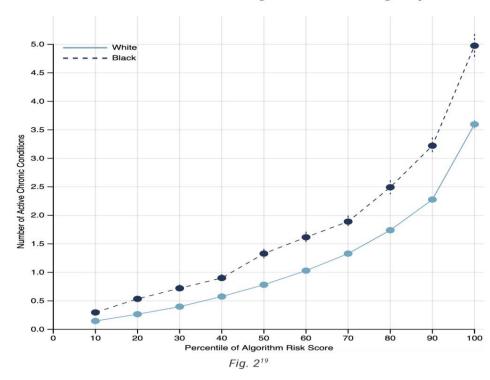
Step 2B

Choose comparison groups and perform check of how well the algorithm predicts its actual target.

Then, investigate how label choice might create bias in how well the algorithm predicts its ideal target.

Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.

Difference between Ideal Target and Actual Target by Race



In this case, less money is spent on Black patients compared to White patients with same level of need.

Black patients may not be selected for additional services due to cost differences despite their same level of need.



Step 3: Retrain Biased Algorithms

Step 3A

Try retraining the model on a label closer to the ideal target.

Assess possible mitigations to label choice by comparing results between different labels.

Example: Screening for Label Choice Bias

Algorithm	Ideal Target	Actual Target	Risk of Bias
Care Management Prioritization: Identifying patients for additional services	Health needs, benefit from high-risk care management programs	Total costs of care	High. Less money is spent on Black patients who have the same level of need

In this example, the current label of cost of care appears to cause bias.

Number of chronic conditions may be a more appropriate label to use.

Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.



Step 3: Retrain Biased Algorithms

Step 3B

Consider alternative options, if necessary. If data is the problem, consider collecting new data.

Example:

Suppose you are interested in helping diabetic patients control their blood sugar by giving them access to dietary and exercise programs. A common approach is to take the entire population of patients and train an algorithm to predict which will have a high hemoglobin A1c value. However, we are implicitly assuming those without a value in the system are low. Patients who lack access to their doctor may also be high.

Sending out at-home kits could help eliminate sampling bias for patients in underserving communities.

Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.



Step 4: Setup Structures for Prevention

Step 4A

Conduct recurring audits to ensure rigorous documentation of current and future models.

- 1. Establish protocols for bias mitigation
- 2. Assign a permanent team to oversee bias mitigation efforts.
- 3. Consider working with a thirdparty to ensure accountability and offer guidance.
- 4. Stay informed about changes in the field.



Adapted from Obermeyer et al. (2021). Algorithmic Bias Playbook.



Transparency – Al should be interpretable for users.

Overarching Ethical Principles



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Non-maleficence – Al should never cause harm.



Responsibility – Al should make reliable decisions that are accountable.



Privacy – The data obtained by AI should be secure and protected.



Non-maleficence

- Non-maleficence principle emphasizes the importance of not causing harm and minimize potential negative consequences of AI.
- Al algorithms in healthcare must be carefully designed, validated and evaluated for accurate and reliable results.
- All users need to properly educated about the application and it's potential benefits and consequences.
- With the real patient data, privacy and confidentiality of sensitive data must be warranted.

Busch, F., Adams, L. C., & Bressem, K. K. (2023). Biomedical Ethical Aspects Towards the Implementation of Artificial Intelligence in Medical Education. *Medical Science Educator*, 1-6.



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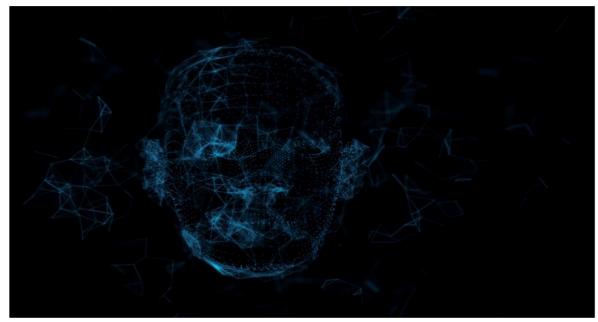
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Responsibility

Responsibility is defined as being able to ascertain whether an AI system is behaving as expected, which is necessary for blame-worthiness

Error-prone facial recognition leads to another wrongful arrest



About the Author

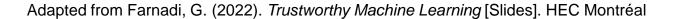
By Ryan Daws | August 7, 2023 Categories: Applications, Artificial Intelligence, Ethics & Society, Face Recognition, Privacy, Surveillance,

Social media algorithms are still failing to counter misleading content



About the Author

Categories: Ethics & Society, Machine Learning, Meta (Facebook)





Responsibility









DECISION MAKERS



SYSTEM DEPLOYERS







END USERS



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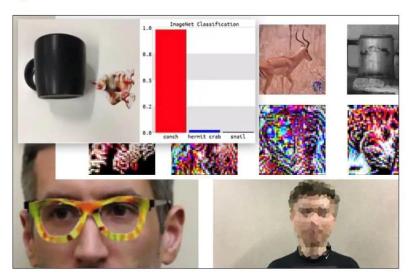
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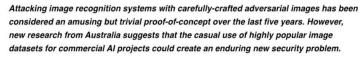
Security and Privacy

CYBERSECURITY

Why Adversarial Image Attacks Are No Joke







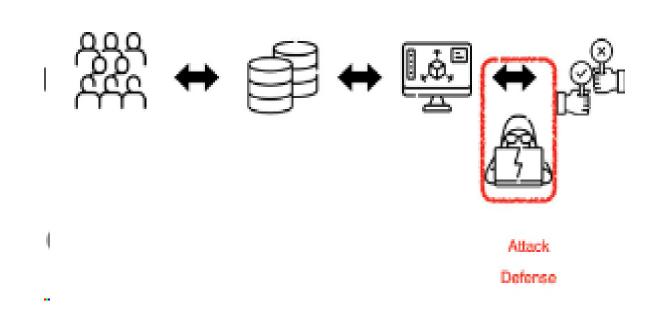


Physical adversarial example from CVPR 2018 paper





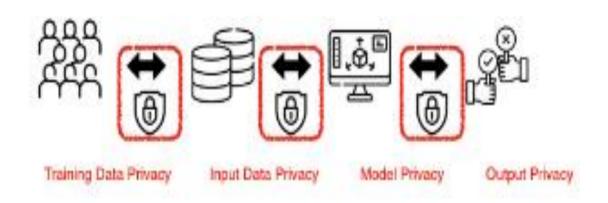
Security



Security is the practice of protecting systems, networks, and programs from digital attacks



Privacy



Data privacy is a central issue to training and testing AI models, especially ones that train and infer on sensitive data



Privacy-preserving Techniques







DIFFERENTIAL PRIVACY



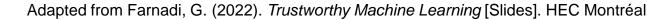
HOMOMORPHIC ENCRYPTION



SECURE MULTI-PARTY COMPUTATION



FEDERATED LEARNING





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Ethical Issues for AI in Healthcare

Major Principles

- 1. Justice and Fairness
- 2. Freedom and autonomy
- 3. Privacy
- 4. Transparency
- 5. Safety
- 6. Trust
- 7. Beneficence
- 8. Responsibility
- 9. Solidarity



Justice and Fairness

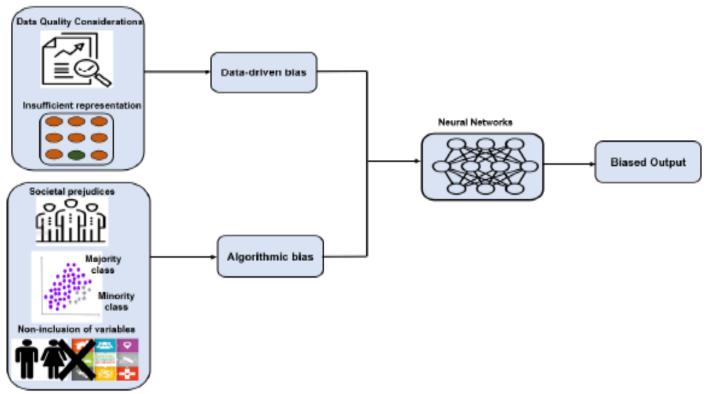


Figure 1: Different sources of bias in ML algorithms

Data-driven bias: data not

reflecting the true distribution of population including-

- enough samples for a specific ethnicity/race
- data quality considerations

Algorithmic Bias: Data reflecting

- societal prejudices
- power imbalances
- class imbalance
- non-inclusion of some variables such as age, sex
- socioeconomic status
- social determinants of health factors (SDOH)



Justice and Fairness

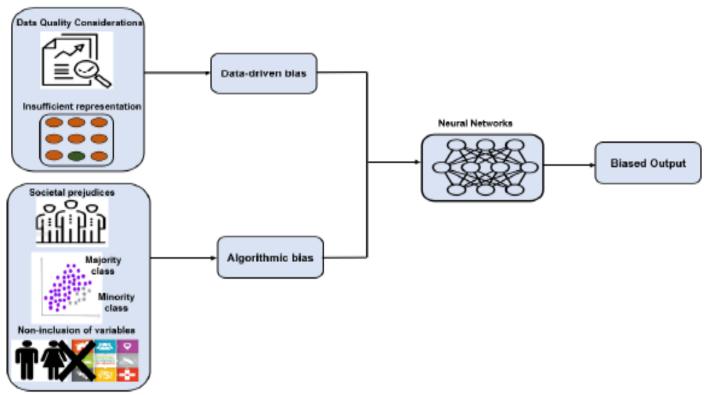


Figure 1: Different sources of bias in ML algorithms

Other biases:

- Sampling bias
 - Result in over or under treatment of certain ethnic groups
- Gender bias
 - Models predominantly trained on male/female data



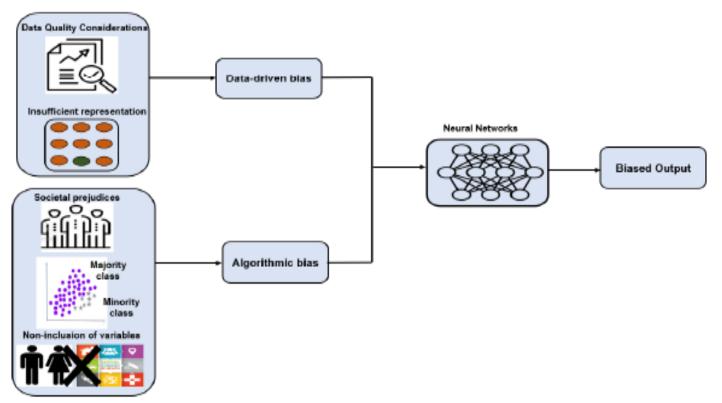


Figure 1: Different sources of bias in ML algorithms

Algorithmic perspective:

- Purify the algorithms of Al-based decision support tools by :
 - Understanding the difference between the training data and input data
- Manage fairness constraints

Data perspective:

- Input data collection and analysis are conducted in a mindful, objective and diverse manner
- Cooperation of stakeholders



Freedom and Autonomy



Control: Management of data involved in Al system

 Ability of individuals to control their data used by different stakeholders

Respecting Human Autonomy: Respect for patient autonomy

Respecting patient's choice

Informed Consent: General consent to treatment, procedure or participation in research





- Regulations and code of conduct to maintain rights of users to control their data
- Discuss patient autonomy in the context of trust
- Communicate with vulnerable groups carefully before consent is obtained



Privacy



Data Privacy: Control over the individual's health information

- The use of sensitive personal health information without patient awareness
- The misuse of sensitive information

Confidentiality: Responsibility of maintaining the privacy of anyone entrusted the data





Data Privacy

- Establish strict rules about data acquisition, data flow management, anonymization etc.
- Store and transfer data securely within regulatory requirements
- Restrict identifiable health data during data sharing
- Data analysis follows code of ethics, laws and regulations



Transparency



Transparency: Understanding an AI system's decision making process

Black box nature of Al algorithms

Explainability: Explaining and interpreting the relationship between input data and outcomes





- Enable AI solutions to be transparent and explainable to patients in terms of AI algorithms and decisions
- Elaborate the data collected from patients
- Embed transparency in data analysis
- Inform stakeholders



Safety



Patient Safety: Unnecessary or potential harm caused by AI tools or unsafe AI in healthcare

Black box nature of Al algorithms

Cybersecurity: Capability to take precautions to avoid undesired results and mitigate existential risks





- Develop AI systems with clinicians and data scientists
- Review AI tools through legally selected regulatory committees before using
- Update regulations, code of conduct, and standards continuously
- Ensure robustness of AI systems with attacks



Trust



Trust: Central part of relationship between human care providers and patients. It depends on various aspects:

- Data usage
- Data-driven technology
- Data confidentiality





- Inform patients about when and how the data is shared
- Improve data privacy and confidentiality
- Educate healthcare professionals on AI concepts



Beneficence



Beneficence: Act with the best interest of others

- In healthcare it refers to the act of a healthcare professional who provides benefits for:
 - Care-recipients
 - Lowering risk
 - Preventing health problems





- Improve the communication of beneficence by:
 - Exhibiting caring behavior
 - Informing patients about their best interests
- Encourage AI developers to design and enhance beneficence by:
 - Personalizing Al-powered solutions



Responsibility



Responsibility: Being responsible for the decisions made by AI systems when applied to healthcare





- Define clear guidelines while making decisions about ethics and legal liability of AI outputs
- Share the document with all stakeholders



Solidarity



Solidarity: Dealing with the issue of justice and equality with Al-powered solutions in healthcare

Inequality of care distributed in society





- Solidarity based models when applying AI solutions in society
- Improving the health of disabled and vulnerable population while designing AI solutions
- Community based solutions



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Legal Regulations and Policies for AI in Healthcare

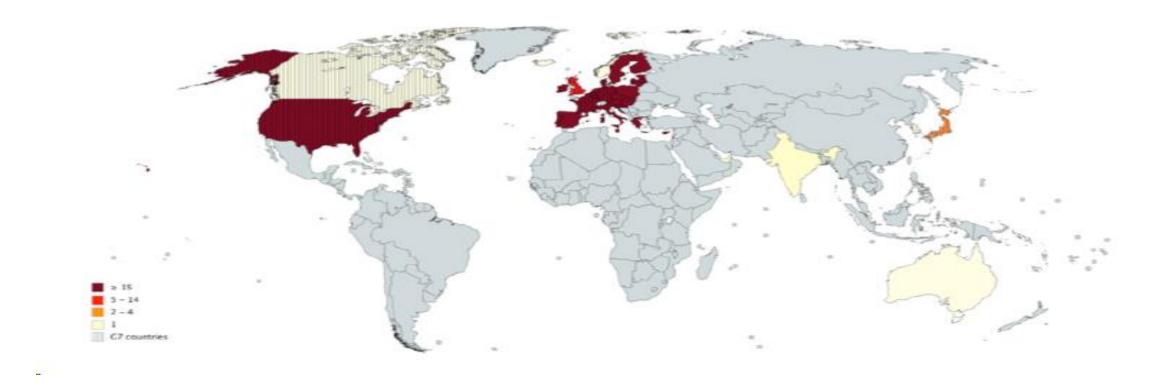
Ethical guidelines vary from country to country and across different industries.







Legal Regulations and Policies for AI in Healthcare



Geographic distribution of issuers of ethical AI guidelines by number of documents released.



EU Al Act: First regulation on Al

- In April 2021, the European commission proposed the first EU regulatory framework for AI
- All systems are classified according to the risk they pose to users
 - Unacceptable risk: systems considered a threat to people and will be banned
 - Cognitive behavioral manipulation of people
 - classifying people based on behavior, socio-economic status or personal characteristics
 - Real-time and remote biometric identification systems, such as facial recognition



EU Al Act: First regulation on Al

- High risk: systems that negatively affect safety or fundamental rights
 - Al systems that are used in products falling under the EU's product safety legislation. This includes toys, aviation, cars, medical devices and lifts.
- General purpose and generative AI: generative AI like ChatGPT, would have to comply with transparency requirements:
 - Disclosing that the content was generated by AI
 - Designing the model to prevent it from generating illegal content
 - Publishing summaries of copyrighted data used for training
- Limited risk: systems should comply with minimal transparency requirements



White House Executive order on Safe, Secure, and Trustworthy Al

- In Oct 2023, an executive order was issued by White House for safe, secure and trustworthy AI.
- New standards for AI safety and security
 - Developers of powerful AI systems need to share their safety test results and other critical information with US government
 - Develop standards, tools, and tests to help ensure that AI systems are safe, secure, and trustworthy
 - Protect against the risks of using AI to engineer dangerous biological materials
 - Protection from AI-enabled fraud



whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/

White House Executive order on Safe, Secure, and Trustworthy Al

- Establish cybersecurity programs
- Protect Americans' privacy by:
 - Prioritizing federal support for accelerating development and use of privacypreserving techniques
 - Evaluate how agencies collect and use commercially available information
- Advancing equity and Civil rights
 - Provide clear guidelines to keep AI algorithms from being used to exacerbate discrimination
 - Ensure fairness throughout the criminal justice system
- Ensuring responsible and effective government use of AI



whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/

WHO guidelines on Ethics and governance of AI in healthcare

- Key ethical principles for use of AI in healthcare:
 - Protecting human autonomy: Humans should remain in control of health-care systems and medical decisions.
 - Promoting human well-being and safety and the public interest: Al technologies should not harm people.
 - Ensuring transparency, explainability and intelligibility: Al technologies should be understandable to developers, medical professionals, patients, users and regulators.



WHO guidelines on Ethics and governance of AI in healthcare

- Fostering responsibility and accountability
- Ensuring inclusiveness and equity
- Promoting AI that is responsive and sustainable



Conclusion

- Ethical principles are crucial for the development and deployment of safe, secure and trustworthy AI.
- All applications in healthcare has to follow the guidelines for effective use of these technologies.
- Research is required to build and implement these technologies and it's safe use in healthcare



Questions?

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