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CS 492

How Biased Clinical Research Data Affects Healthcare

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Introduction

Artificial intelligence (AI) is becoming an integral part of modern healthcare, with applications in diagnostics, treatment planning, and patient monitoring. In fact, the technology is expanding so quickly that in 2022, almost 20% of U.S. hospitals integrated some form of AI (Baten & Abdul, 2022). However, AI systems rely on vast datasets, and if these datasets contain biases, the outcomes can be dangerously skewed. A biased AI model can misdiagnose illnesses, delay treatment, or even exacerbate healthcare disparities. In some cases, these biases can be the difference between life and death. Our project explores how biases in healthcare data, particularly racial and gender biases, influence AI decision-making and contribute to systemic inequalities in medical treatment.

To investigate this issue, we are interviewing researchers from SickKids and professors from the University of Waterloo and conducting research. Our goal is to gather expert insights on the impact of biased clinical datasets and explore potential solutions to mitigate these issues. The final project will likely take the form of a website that summarizes our research and interviews. Additionally, we may include an interactive feature (game) where users can engage with real-world case studies and consider how they would respond to the dilemmas and compare their decisions with decisions from AI-driven healthcare. This document, i.e., project update, will outline the research conducted so far, the specific case studies we plan to discuss, and the key questions we will pose during our interviews. Since most of our research has been completed at this stage, the remainder of the term will focus on conducting interviews, developing the website, and potentially implementing the interactive component.

Gender Bias in AI

How Bias Manifests

AI is being used more frequently in the healthcare sector in order to improve the diagnosis of illnesses and to personalize treatments, but gender biases in these systems can lead to unequal and dangerous outcomes.

There are 2 sources of this kind of bias. Firstly, there is the data bias, which is caused by a shortage of women in the training datasets. Datasets often overly represent male patients (Straw & Wu, 2022). For example - in a study for predicting liver disease, of the 583 participants, only 142 were female (Straw & Wu, 2020). The other source is algorithmic bias. That refers to incorrect predictions produced by the AI model that is a direct result of its learning process or design. This kind of bias can result in the model having unequal predictions for different genders (Norori et al, 2021).

Impact on Minority Groups

There was a study involving Parkinson's disease biomarkers, where only 18.6% of the participants were women (Cirillo et al., 2020). The models generated with the data from those participants were significantly less accurate for female patients as opposed to male patients. Another example of this is that many supervised machine learning models for predicting liver disease had a significantly higher false negative rate for women, as it missed 44% of actual liver disease cases for women as opposed to only 23% in men (University College London, 2022). False negatives for liver disease detection can have significant negative impacts on female patients. This shows how biases can be extremely dangerous.

One study showed that AI models to predict COVID-19 severity performed significantly worse when trained on data with one gender and applied to another (Chung et al., 2021). This shows the importance of training AI models with diverse data. Historically, people have been very negligent toward women's health. 80% of the drugs that were withdrawn were withdrawn because they had unforeseen side effects in females (Joshi, 2024). AI technologies come with the risk of reinforcing these existing biases, and that can be extremely dangerous.

Case Studies

Case 1: Transgender Patient's Emergency Misdiagnosed by Algorithmic Bias

Scenario

A transgender man experienced a life-threatening delay in care due to biases in health records and protocols. The 32-year-old patient went to an emergency room in severe abdominal pain. Despite informing staff that he was transgender, the hospital's intake and record system listed him as "male," and clinicians initially assumed his pain was due to something like obesity – failing to consider pregnancy (Compton, 2019). In fact, he was pregnant and in labour complications. The oversight meant that a pregnancy test and urgent obstetric care were delayed. By the time a pregnancy was confirmed and an emergency C-section was ordered, the situation had worsened: tragically, the baby was stillborn (Ring, 2019).

Impact

This case shows how rigid or biased algorithms in electronic health records (EHRs) and triage can harm transgender and non-binary individuals. The system's binary classification and the providers' biases led to a critical misdiagnosis — treating the patient as a non-pregnant male by default. The NEJM report on this incident noted that a patient identified as a female with similar symptoms "would almost surely have been triaged and evaluated more urgently for pregnancy-related problems" (Ring, 2019). Because the patient was recorded as male, standard alerts or decision support for pregnancy was never triggered, and providers' judgment was clouded by gender assumptions. The result was a catastrophic outcome that likely would have been prevented with more inclusive algorithms and training. In essence, the healthcare AI/IT infrastructure did not account for a trans man's reality, illustrating how algorithmic bias and lack of nuance in sex/gender data can lead to incorrect or delayed treatment for transgender patients.

Interview Questions

1. Imagine you're a physician treating a patient with severe abdominal pain and no visible injuries. What diagnoses would immediately come to mind, and what additional information would you ask for?
2. How might your diagnostic thinking change if you were told the patient was a man?
3. What if you were told the patient was a woman?
4. How would learning that the patient is a transgender man affect your clinical reasoning, and what challenges might arise in ensuring they receive appropriate care?

Summarize the case.

5. In your opinion, now knowing that the person was transgender and pregnant, what role did algorithmic bias, system design, or any other factors that you can think of, play in the AI's failure to identify pregnancy risk in this case?
6. What changes would you suggest — to electronic health records, triage systems, provider training, etc. — to prevent similar outcomes for transgender patients in the future?

<u>Case 2: Symptom Checker Underestimates a Woman's Heart Attack</u>

Scenario

An AI-driven symptom-checker app provided vastly different recommendations for a man and a woman with identical health inputs, revealing a dangerous gender bias. In an analysis by an NHS doctor, two patients – one male, one female – both 59-year-old smokers with sudden chest pain and nausea, queried a popular health chatbot. The only difference was the gender selected. The female patient was told her symptoms might be due to depression or a panic attack, with no urgent action needed beyond maybe a GP visit (Trendall, 2024). In stark contrast, the male patient with the same profile was warned that it could be gastritis or even serious heart problems like unstable angina or heart attack – in which case he should seek emergency care or call an ambulance (Trendall, 2024). In other words, the AI did not even consider a cardiac emergency for the woman, whereas it did for the man, solely because of gender. This chatbot (used in the UK's "GP at Hand" service by Babylon Health) was purportedly basing its advice on statistical evidence that women's chest pain is less likely to be heart attack – but in doing so, it risked missing a real heart attack in a female patient (Trendall, 2024).

Impact

A female patient following this AI advice could have delayed going to the ER for a true heart attack, with potentially fatal consequences. Heart disease in women often goes underdiagnosed precisely because symptoms can present differently and biases lead to attributing them to anxiety or other causes. Here the AI essentially mirrored and amplified that bias. The public outcry around this example was significant – observers were "deeply concerned" that the program failed to even raise the possibility of a heart attack in the woman's case (Trendall, 2024). This case highlights how AI triage tools, if not carefully designed, can perpetuate harmful stereotypes (e.g. "women are hysterical, men have real heart attacks"), thus providing suboptimal or dangerous guidance. Babylon Health defended the system as operating as intended, citing medical data differences (Trendall, 2024). However, even if statistically fewer women present with classic heart attacks, many do – and an AI that dismisses women's cardiac symptoms can lead to delayed treatment, poorer outcomes, or even preventable death for female patients. It underscores the need for AI in healthcare to be rigorously tested for gender bias and for algorithms to err on the side of caution with life-threatening possibilities for all patients.

Interview Questions

1. Imagine a 59-year-old patient who presents with sudden chest pain and nausea. Without knowing their gender, what would be your top differential diagnoses, and what would your next steps be?
2. Would you take the problem seriously right away, or would you think that chest pain for a 59-year-old is likely not serious?
3. Now imagine learning the patient is a woman, and you're told that statistically, women are less likely to have a heart attack. Would this influence your decisions? Should it?
4. If the patient was a man, would your sense of urgency change, keeping in mind that statistically, men are more likely to have a heart attack?
5. So overall, would your perspective and seriousness stay the same if they were a 59-year-old with chest pain regardless of their gender?
6. Even if the statistical risk is lower in women, how would you balance data like this with the need to consider life-threatening conditions like heart attacks?

Summarize the case.

7. How should an AI triage system handle gender-based statistical differences? Should it present all serious possibilities regardless of probability, especially in potentially fatal scenarios?
8. Was the AI's response defensible, given it followed statistical trends, or should its priority have been patient safety over data-driven averages? Where's the line between data and ethical care? Do you believe it failed in its duty to provide safe recommendations?

<u>Case 3: Male Breast Cancer Patient Denied Treatment by Gendered Algorithm</u>

Scenario

Raymond Johnson, a 26-year-old man in South Carolina, faced a life-threatening algorithmic bias after being diagnosed with breast cancer. When he applied to a federal Medicaid program for breast cancer treatment, he was denied coverage solely because he is male (Park, 2022). The program (created by the Breast and Cervical Cancer Prevention and Treatment Act) was designed to cover cancer care for patients diagnosed via federal screening programs – but those programs only screened women, so by policy only women qualified for treatment coverage (Park, 2022). In Raymond's case, the insurance algorithm automatically excluded men, rendering him ineligible for the chemotherapy and surgery he urgently needed simply due to his gender (Park, 2022).

Impact

This is a clear example of gender bias embedded in a treatment plan algorithm. Raymond was left to struggle for access to life-saving care because the system failed to consider that men can get breast cancer. Denying benefits based solely on gender meant a potentially deadly delay or enormous out-of-pocket costs for his treatment. Advocacy groups intervened; the ACLU condemned the policy, noting that refusing cancer coverage to a patient “simply because they are men” is a blatant violation of law and basic fairness (Park, 2022). Raymond’s case not only illustrates bias against a male patient with a so-called “women’s disease,” but also led to calls for policy change so that diagnostic and coverage algorithms include all patients who need care (Park, 2022). It underlines how men can also be harmed when medical algorithms or guidelines incorrectly treat certain serious conditions as “female-only,” resulting in suboptimal or delayed care for male patients.

Interview Questions

1. When a young patient (let’s say 25 years old) presents with a lump in their chest, what key factors guide your differential diagnosis and decision to recommend further testing?
2. How might your diagnostic approach change based on if the patient is female? What would your decision lean more towards in terms of diagnosis?
3. If they were male, would you consider the same things as women's chest pain or would your approach be quite different for male chest pain?
4. Breast cancer is rare in men, less than 1% of all breast cancers occur in men, should that rarity affect your decision to test for it? How do you balance the risk of over-testing versus missing a critical diagnosis?

Summarize the case.

5. What role do you think societal assumptions — like breast cancer being a “women’s disease” — played in the algorithm’s decision to deny coverage to Raymond?
6. What changes would you suggest to healthcare algorithms or policies to prevent gender-based denial of coverage in similar cases? How can we ensure equal access to treatment for all?
7. Should healthcare algorithms prioritize statistical likelihoods and trends or be designed to account for rare but serious conditions — especially when lives are at stake? How should they strike that balance?

Racial Bias in AI

<u>How Bias Manifests</u>

Racial bias in medical AI occurs when algorithms aren't equally effective spanning different racial or ethnic groups. That often comes from the inequality in the data that is used to train the models or in the presumptions that were incorporated into the clinical algorithms. For instance, patients suffering from skin diseases and AI diagnostic tools for dermatology have demonstrated poor accuracy towards individuals who have darker skin due to the predominantly lighter skinned image datasets used to train the models (Nicholls, 2022). That type of diagnostic bias entails AI that was not designed with black or brown patients in mind and would fail to recognize or in worse cases, misdiagnose them.

Biased Algorithms

Racial bias discrimination can also be seen in recommendations regarding medical treatment as well as the classification of risk factors and categories. A well-known example is an algorithm that was created in hospitals to flag patients who may be eligible for care management and monitoring (Manke, 2019). A particular study done in 2019 showed that the software would consistently favor white patients over more ill black patients because it utilized the proxy of healthcare spending as a substitute for health needs.

Historically Black patients did not have equal access to care therefore, in the eyes of the algorithm, the Black patients incurred less medical spending leading the algorithm to not appreciate black patients costing more due to having lower access to medical assistance. An algorithm that was used to aid an assessment of kidney disease also incorporated a correction with bias concerning race in which the function was assumed to be better than it was in coloured people. As a result, many black patients were inappropriately delayed for specialty referrals or consideration for transplant operations. The need for these patients was higher but the assumption made it more difficult for those who were in need leading to discrimination. Structural racism that is embedded in a data set because of poor integration through healthcare systems artificially create inequities that allow the power of these systems to implement deeper discriminatory boundaries.

Biased Medical Devices

Racial biases don't just exist in automated software; they also extend to AI-based medical devices and sensors. For example, light-based pulse oximeters (devices that estimate blood oxygen levels) have been shown to overestimate oxygen saturation in patients who have darker skin (Department of Epidemiology & Biostatistics, UCSF, 2022). Research from the COVID-19 pandemic showed that pulse oximeters were three times more likely to not detect dangerously low oxygen levels in black patients when compared to white patients. The reason for this bias lies in how light absorption differs across people with varying skin tones (Allen, 2024). Another case is the blood oxygen level monitoring function in commercial smartwatches and fitness trackers: marketed wearable pulse oximeters were found to be much less precise in estimating the oxygen saturation level in darker skin. In the listed algorithms, tools and devices, prejudice may result in minority patients being overdiagnosed or receiving the wrong treatment recommendations.

Impact on Minority Groups

Black, Hispanic, and Indigenous communities tend to be impacted by the AI healthcare bias the most. These communities have had to deal with systemic inequalities and discrimination not just in education and employment, but healthcare, which includes access to services, representation in clinical studies, and discrimination (Penn Medicine, 2024). AI systems that carry forward biases from historical data risk worsening these disparities. Take, for instance, the biased risk algorithm described earlier that resulted in Black patients not receiving enough preventive care. With regards to kidney disease, the racial bias adjustment in kidney function score calculations resulted in Black patients being added to the transplant waiting list much slower than white patients who were equally qualified. This meant that Black patients were forced to wait years to receive transplants, while it is well known that Black Americans with end-stage kidney disease dramatically outnumber whites in their need for these organ donations.

The way technology suffers from bias against certain groups of people truly stood out in the case of the minority of patients during the COVID-19 pandemic. The use of pulse oximeters on patients with darker skin resulted in tragically poor treatment for patients severely suffering from COVID-19. One study estimated that such errors could have caused an average delay of 4.5 hours in Black patients receiving COVID treatment (Allen, 2024). The overestimation of blood oxygen levels which were used as a key metric to decide hospitalization and therapy were over before Black and other non-white patients life-saving oxygen or medications. The treatment given after these prolonged periods was insufficient and did not help avoid increased mortality rates in affected communities.

Discriminatory technology can deteriorate healthcare trust among marginalized communities. It’s no secret that medicine has a history of being racist- from the Tuskegee syphilis experiment to current inequalities- and the application of AI technology that systematically ignores Black or Indigenous people serves to make them more cynical. Indigenous populations and other minority groups need to worry that algorithms based on mostly white or urban populations will not capture their distinctive health characteristics and subsequently get diagnosed or treated as if they do not exist. In other words, the existing prejudice AI systems tend to have will likely widen the gap and worsen the care that minorities receive by delaying treatment, providing inaccurate diagnoses, and ignoring advanced care options.

Case Studies

<u>Case 4: Anthony Randall and Kidney Transplant Algorithm Bias</u>

Anthony Randall is a Black man from Los Angeles who was on dialysis, waiting for a kidney transplant for over five years (TheGrio, 2023). What he did not know is that an algorithm from the transplant system incorporated a race-based “modifier” that made Black patients’ kidney scores seem better than they were. This modifier caused Randall’s kidney disease to be less severe than it truly was, leading to his placement on the national transplant waiting list being significantly delayed. In mid-2023, he filed a case against his hospital (Cedars Sinai Medical Center) and the United Network for Organ Sharing alleging that he was unfairly deprived of a fair chance to get the transplant because of the racially biased formula. It was no secret that the algorithm had a bias.

The board of the transplant system understood the modifier was resulting in Black patients' illnesses being severely underestimated. By early 2023, all hospitals were directed to stop the usage of race adjustment and Black patients' waiting times were to be changed to reflect the postponement. Randall claims that had these changes come sooner; he could have already had the kidney that he desperately needs. His case highlights how the goal of the clinical algorithm was good, but the execution was not due to the insertion of race which caused Black patients to not receive quality care in a timely manner.

Interview Questions

1. Imagine you're a healthcare provider evaluating a patient with kidney disease for transplant eligibility. What clinical factors would you typically consider when assessing disease severity and readiness for transplant?
2. Have you heard of race-based modifiers in kidney function scoring (such as eGFR)? What do you think was the original intention behind including race in those calculations?

Summarize the case.

3. Knowing now that this modifier made Black patients appear healthier than they were — delaying transplant eligibility — how do you think this affected patients like Anthony Randall?
4. Should hospitals or national organizations be held accountable when algorithms known to be biased continue to be used? What obligations do they have once they become aware of harm?
5. In Randall's case, the board eventually mandated the removal of race adjustments, but it came years after the issue was known. Do you think that delay was acceptable? What should have been done differently?
6. How can health systems design clinical algorithms that avoid reinforcing historical or systemic inequities — especially those tied to race?
7. What steps, if any, should be taken to make things right for patients who were harmed by biased algorithms — such as adjusting wait times, issuing apologies, or offering compensation?

<u>Case 5: Dr. Noha Aboelata and Pulse Oximeter Bias During COVID-19</u>

During the pandemic, race-related biases in medical technology confronted Dr. Noha Aboelata, a family physician and the Chief Executive Officer of Roots Community Health Center based in Oakland. In late 2020, one of her patients was an elderly African American gentleman who suffered from chronic lung illness (Department of Epidemiology & Biostatistics, UCSF, 2022). One of the checks done previously, the pulse oxygenation check, revealed that his oxygen saturation levels were high. Even though the device showed a relatively normal oxygen level, Dr. Aboelata's clinical instinct indicated the patient was much more distressed. She conducted an arterial blood gas test which confirmed her worst fears, the oxygen content in the patient's blood was too low and he needed oxygen.

Sometime later, she came across an article in the New England Journal of Medicine that confirmed her hunch; the oximeters were unable to register low oxygen levels in dark-skinned patients as compared to white patients. She and her colleagues were outraged by a device that was supposed to help their patients but was grossly inaccurate for the Black population. Finally, her clinic participated in a class-action lawsuit against easier manufacturers and sellers of pulse oximeters for more detailed warnings and up-to-date devices. She did not stand idle while demanding the FDA take pulse oximeter discrimination towards races very seriously.

Interview Questions

1. Imagine you're treating a patient with chronic lung disease during a respiratory pandemic. If a pulse oximeter shows normal oxygen saturation, but the patient appears visibly distressed, what would you do next?
2. How much would you completely rely on tools like pulse oximeters in clinical decision-making? Do you think you would ever question or double-check the accuracy of a medical device?

Summarize the case.

3. In this case, Dr. Aboelata's clinical judgment overruled the device's reading. What does this say about the limitations of relying too heavily on technology without understanding its biases?
4. Pulse oximeters were found to overestimate oxygen levels in patients with darker skin. Why do you think this design flaw persisted for so long, despite the risk it posed to patients of colour?
5. Do you believe the FDA and manufacturers have done enough to address this issue? What more should regulatory bodies be doing to ensure devices are accurate across diverse populations?
6. How should future healthcare providers be trained to detect and challenge device-based bias in patient care?
7. For communities that have been historically underserved or harmed by biased tools, how can the medical system begin to rebuild trust and ensure safer, more equitable care?

<u>Case 6: Alex Morales and Smartwatch Blood-Oxygen Reading Bias</u>

Alex Morales, a New York resident, brought attention to a case of possible racial bias in the consumer health device, Apple Watch (Stempel, 2023). Morales, who has a darker complexion, bought an Apple Watch with the expectation that its blood oxygen sensor would accurately log his oxygen levels for fitness and health purposes. To his surprise, he later found out that the device's oximeter may not work well with people from his demographic.

In late 2022, Morales initiated a class action lawsuit against Apple for allegedly containing a blood oxygen app that was racially discriminatory and did not function as promised for non-white customers. Supported in part by complaints of other studies claiming that more advanced pulse oximetry devices are "massively" less useful on people with darker skin, Morales asserted that Apple owed the public an explanation. After all, paying smartphone users assumed that the device would be equal for all users, which is not the case. While the judge dismissed the case in 2023, it did start an important discussion regarding Apple products. Their case showed the world that there are, in fact, indirect biases in medical-grade equipment. This shows us that Alex Morales and the rest of the community are still subjected to discrimination based on race even in the technology they choose to use. Moreover, it demonstrates the keen eye for responsibility the tech industry has in these situations.

Interview Questions

1. If you purchase a health-monitoring device like a smartwatch, what level of accuracy and reliability would you expect — especially when it comes to tracking critical health metrics like blood oxygen levels?
2. How would you feel if you discovered that your device didn't work as accurately for people with your skin tone or demographic?

Summarize the case.

3. Do you think companies like Apple have an obligation to disclose limitations in their health sensors, especially if those limitations affect certain racial or skin tone groups?
4. Why do you think skin tone bias in oximeters and wearable health devices hasn't received widespread attention until recently? What might be some of the barriers to addressing it?
5. The court dismissed Morales's case, but do you think tech companies should still be held accountable in other ways? What kind of responsibility should they carry when their products are shown to underperform for marginalized users?
6. Should consumer tech devices with health features (like smartwatches) be subject to the same regulatory scrutiny as medical devices? Why or why not?
7. How can the tech industry ensure that innovations in health and wellness tools are tested fairly across diverse populations? Who should be involved in that process?
8. What does this case reveal about the intersection between technology, race, and access to accurate health information in the digital age? How can companies rebuild or maintain trust with users who may feel excluded or misled by biased product performance?

Overall Final Reflecting Questions

1. Have you ever encountered or learned about implicit bias in clinical settings? How do you think it affects healthcare decisions?
2. How can we ensure that AI systems in healthcare reflect the diversity and complexity of human identity, including transgender and non-binary experiences?
3. If you were designing this AI tool, how would you balance giving statistically accurate information with not downplaying rare but deadly possibilities?
4. What kind of training or human oversight should go into building and testing these AI symptom checkers to avoid embedded gender bias?
5. What do you think it feels like to be a patient denied care not because of medical necessity, but due to how an algorithm classifies you? How can future healthcare professionals be trained to recognize and challenge biases like these in medical systems or software?
6. If you were on a team creating a new clinical algorithm, what safeguards would you recommend to ensure it doesn't harm any demographic group, even unintentionally?
7. Is there any questions you have for me, or anything else you would like to say about any related topics, maybe things you found interesting?

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