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Bias in the Post-Market Phase

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What do we mean by “Bias” ?

“Bias” is defined in IMDRF’s Machine Learning-enabled Medical Devices: Key Terms and Definitions:

Systematic difference in treatment of certain objects, people, or groups in comparison to others.

Note 1 to entry: Treatment is any kind of action, including perception, observation, representation, prediction or decision. (ISO/IEC TR 24027:2021)

Note**:** The term ‘Bias’ is used **in different ways in different fields.** For example, in data science, bias is often defined with a statistical/mathematical meaning while in law, bias is often used to **mean unfair or unfairly prejudiced/partial**.

ISO/IEC TR 24027 refers to systems having both “wanted” and “unwanted” bias depending on the intended purpose of an AI(-based) system.

Sources of bias include:

- **human cognitive biases** (including automation bias, societal bias, and confirmation bias),
- **data biases** (including statistical bias, data processing bias, and data aggregation bias), and
- **bias introduced by engineering decisions** (e.g., during feature engineering, via algorithm selection, and model bias)

BIBO!

We are familiar with the concept of “Garbage In, Garbage Out (GIGO)” – there is a similar term “Bias In, Bias Out (BIBO)”

Bias is like a magnifying mirror – it reflects (and possibly enhances) bias that already exists in healthcare.

Bias Examples

A system trained to detect breast cancer did not perform as well on African-American women; they weren't fully represented in the training set as the developers did not realize that tissue density varies by race.

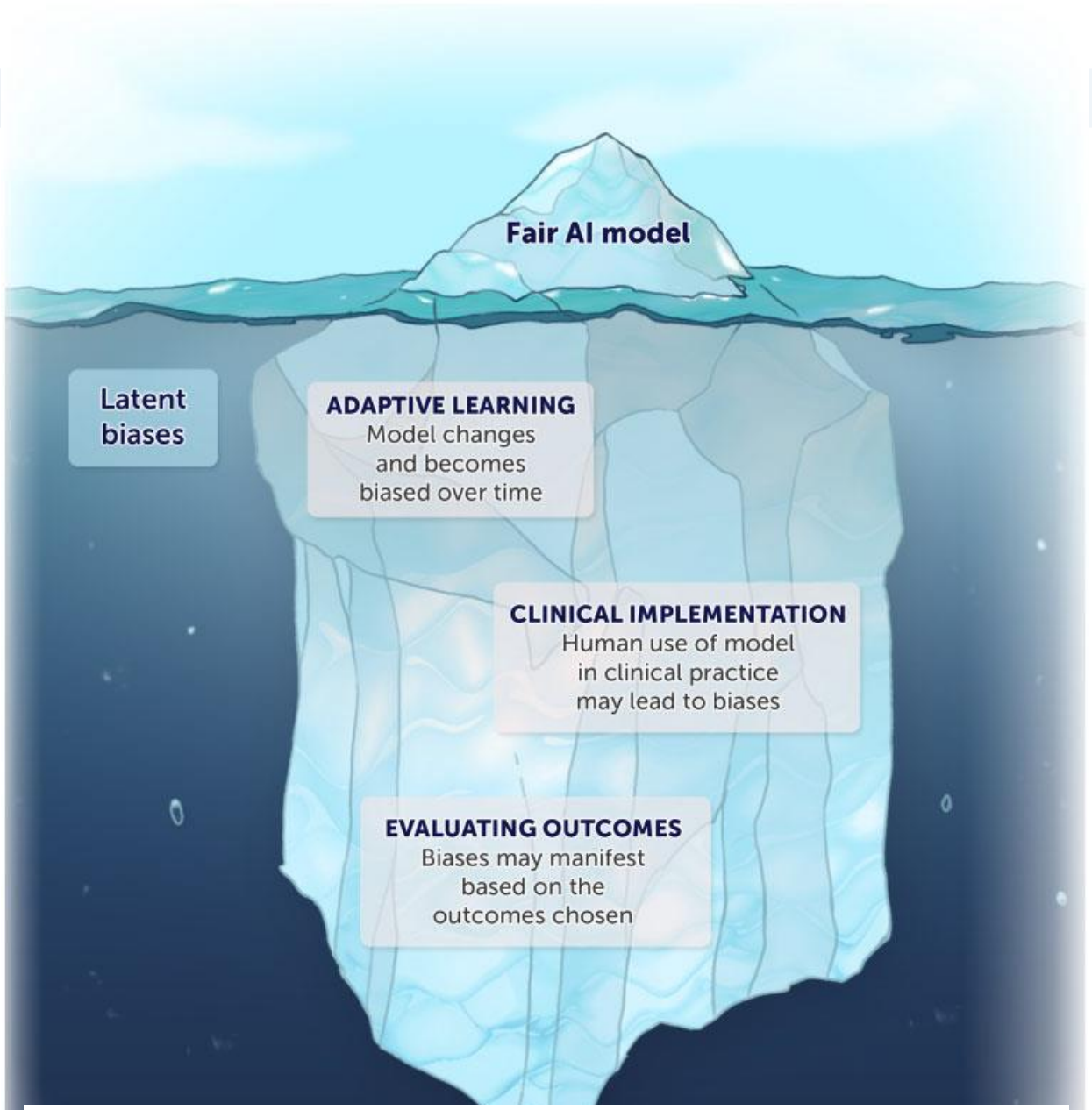
A system intended to detect early onset of a disease used healthcare costs as a proxy measure for how sick a patient is. Unfortunately, some patients are poor and could not afford proper treatment of their disease. The software concluded that people that live in poor neighborhoods were at low-risk because they didn't seek medical care..

Positive Bias: A hospital once approached me and started asking questions about the patient demographics used to train one of our products. They did not want a product that was trained with a large, diverse dataset (e.g. representing patients across the country); they wanted something that was specifically trained for **their** patients (e.g. patients living in a retirement community on the beach..)

A seemingly fair AI model could involve latent biases after clinical implementation.

"Increasing recognition of biases in artificial intelligence (AI) algorithms has motivated the quest to build fair models, free of biases. However, building fair models may be only half the challenge. A seemingly fair model could involve, directly or indirectly, what we call "latent biases." Just as latent errors are generally described as errors "waiting to happen" in complex systems, latent biases are biases waiting to happen."

One of the goals of post-market activities will be to monitor for bias..



Source: "Latent bias and the implementation of artificial intelligence in medicine", Matthew DeCamp and Charlotta Lindvall, Journal of the American Medical Informatics Association, 00(0), 2020, 1–4

Similarities & Differences

There are similar problems in post-market as there are in pre-market. For example, one of the challenges is getting data from small, rural hospitals with limited resources – this is true in the post-market phase as well. The patient demographics for those hospitals is likely different than patients in large city hospitals.

Post-market data isn't always of the same quality as pre-market data, but for the system to effectively learn, we need high quality data & need to be aware of potential bias in that data.

Additional considerations

One of my committees recently released a paper about bias management, and it included a discussion of post-market activities. The recommended data collection process was similar to our current processes; the differences were in the review of the data:

- Identify necessary changes to existing residual impact assessments of bias source/type/sequence combinations (i.e., impact level, likelihood of occurrence, likelihood of impact).
- Identify new bias source/type/sequence combinations.
- Identify new uses or foreseeable misuses of the system that may drive new or changed bias source/type/sequence combinations.
- Identify changes to the stated benefits of the system.
- Identify changes in what may be considered positive, negative, or neutral bias.
- Identify changes in the criteria for determining the acceptability of bias at both a bias source/type/sequence combination level and a system level.
- Identify new bias mitigations for existing bias source/type/sequence combinations.

Additional considerations

That committee is currently working on a paper about ML post-market considerations, and when I mentioned this presentation to them, they wanted to add:

1. Post-market might detect types of bias that were not identified during development.
2. Target demographic can change over time – the patient population may change (drift.)
3. The deployment model for the product and the listening model for post-market information might have bias (e.g. small hospital example)
4. Because we are not collecting ALL data, we might not know about ALL potential biases.

Because of these factors, for learning systems, consideration should be given for what is needed in a rollback plan.

Resources

Bias has gotten a lot of attention and many papers, guidance, and standards have already been created – the IMDRF can leverage the existing work. Example resources include:

- NMPA AI Framework
- ISO/IEC TR 24027:2021 Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
- IEEE P7003 Algorithmic Bias Considerations
- Bias in Artificial Intelligence in Healthcare Deliverables, AFDO/RAPS Healthcare Products AI Global Initiative
- CTA 2116 (draft) The Use of Artificial Intelligence in Health Care: Best Practices and Recommendations for Bias Management

THANK YOU / QUESTIONS

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