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Engineering the extraordinary

Unintentional Bias and AI-Enabled Medical Devices

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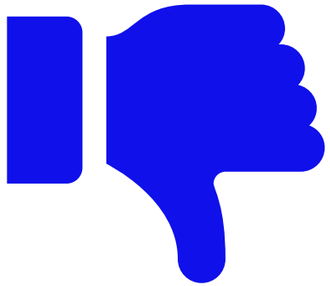
Unwarranted vs. Warranted Bias

Bias can be harmful….

- For example
  - Systems that inadvertently perpetuate historical discrimination in health
  - Tools that are inadvertently designed to work well in male patients, but are labeled for use in all adults



But sometimes bias is intended and helpful….

- For example:
  - Tools optimized (and labeled) for specific populations
  - Systems optimized for performance only at specific healthcare sites

Bias is not new….

- Bias has long been a potential medical device consideration for many types of products
  - For example, datasets used to develop *in vitro* diagnostic products also *could* introduce unwarranted bias into performance

- In mitigating bias, we should consider and employ well establish tools, such as risk management principles

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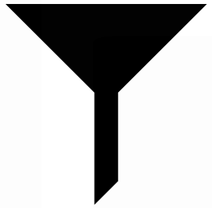
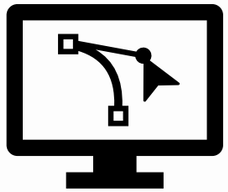
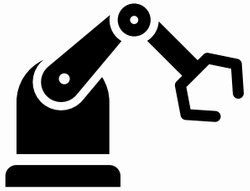
Unwarranted bias and lifecycle

- Unwarranted bias could be introduced during different stages of the product lifecycle
- Thus, each phase should be considered in planning for avoidance of bias
- Extent of efforts undertaken to characterize and minimize bias should be calibrated to risk associated with the particular bias

Data Collection	Data Annotation & Curation	Model Construction	Algorithm Training	Algorithm Testing and Validation	AI Deployment
					

Mitigation of Unwarranted Bias
Requires Understanding of the Intended Use Population and Expected Use

- Use of datasets for development and performance evaluation that are not appropriately representative of the intended use population and conditions of use can result in unwarranted bias
- Determination of “appropriateness” requires consideration of variables that *could* be expected to impact algorithm performance
- For example:

Patient Demographics	Clinical Characteristics	Input data characteristics
Similar racial, ethnic, sex, age characteristics, etc.	Similar distribution of disease severity, different disease presentations, comorbidities, etc	Similar representative of relevant imaging modalities/specifications, similar time series, etc

- BUT variables are only relevant for avoidance of unwarranted bias if there is an association between the characteristic and the data being analyzed
  - For example, if there is no association between age and the presentation of a target clinical condition or data being analyzed, then consideration of age may have no impact on avoiding unwarranted data
- Important to define the relevant variables and plan for consideration throughout the development and performance evaluation phases

Thank you!

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