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
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
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:

<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th>Clinical Characteristics</th>
<th>Input data characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar racial, ethnic, sex</td>
<td>Similar distribution of disease severity, different disease presentations, comorbidities, etc</td>
<td>Similar representative of relevant imaging modalities/specifications, similar time series, etc</td>
</tr>
<tr>
<td>age characteristics, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• 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!