Characterization of Underrepresented Populations in Modern Era Radiation Therapy Clinical Trials

Emily H. Bero
Medical College of Wisconsin
Disclosure

• I have no conflicts of interest to disclose.

• E. H. Bero¹, L. Rein², A. Banerjee², M. W. Straza Jr³, C. A. F. Lawton³, C. J. Schultz³, B. A. Erickson³, M. L. Siker³, and W. A. Hall³; ¹Medical College of Wisconsin, Milwaukee, WI, ²Medical College of Wisconsin Department of Biostatistics, Milwaukee, WI, ³Department of Radiation Oncology, Medical College of Wisconsin, Milwaukee, WI
Method

- 122 met inclusion criteria and were compared to 2018 US census for racial composition

<table>
<thead>
<tr>
<th>Number of Trials in Study Subgroups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trials located in the US</td>
</tr>
<tr>
<td>Toxicity mitigation/prevention trial</td>
</tr>
<tr>
<td>Female-specific cancer trial</td>
</tr>
<tr>
<td>Male-specific cancer trial</td>
</tr>
<tr>
<td>Proton therapy trial</td>
</tr>
</tbody>
</table>
Racial Composition of US Census vs. RT Trials

<table>
<thead>
<tr>
<th></th>
<th>2018 US Census</th>
<th>US Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>72.2</td>
<td>84.8</td>
</tr>
<tr>
<td>Black</td>
<td>12.7</td>
<td>11.8</td>
</tr>
<tr>
<td>Asian</td>
<td>5.6</td>
<td>2.9</td>
</tr>
<tr>
<td>Other</td>
<td>9.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

p < 0.001
US Census vs. Gender-specific Cancer Trials

**Female Cancer Trials**

- White: 72.2
- Black: 12.7
- Asian: 5.6
- Other: 0.3

**Male Cancer Trials**

- White: 72.2
- Black: 12.7
- Asian: 1.4
- Other: 9.5

**2018 US Census**

- Female Cancer Trials: 83.3
- Male Cancer Trials: 80.2

*p < 0.001*
US Census vs. Proton Therapy Trials

p < 0.001
Conclusion

• We have demonstrated that every group analyzed had a significant variance in clinical trial race population when compared to the US census composition.

• Black patient participation was below that expected from the US census in every subgroup analyzed, with the exception of the US female-specific cancer trials and US male-specific cancer trials. However, the comparison fails to consider differences in incidence between different racial populations which may account for the higher participation.

• When considering all trials, Asian and other excluded populations had the largest magnitudes of difference from the US census. All differences were statistically significant, and were most pronounced in trials evaluating proton therapy.

• This highlights that not only is there inequitable participation on clinical trials, but specific trials using modalities (such as proton therapy) appear to be differentially susceptible to these inequitable distributions.
Discussion

• While investigating the etiology behind the disparity in enrollment were beyond the scope of the current study, structural racism, systemic bias and related barriers consistently limit inclusion of patients from underrepresented minority groups in clinical trials.

• Findings point to a need for oncologists designing clinical trials and institutions implementing trials to increase inclusion of excluded groups. Efforts to overcome enrollment disparities in radiation therapy trials are important and worthy of continued investigation.