Introduction

- Diagnostic tools often operate with imperfect sensitivity and specificity.
- Thus, two consecutive test results are sometimes required to confirm diagnoses.
- Most studies which require two tests to confirm diagnoses censor data incorrectly, potentially biasing results.

Objective of the Study

Investigate the bias of different censoring strategies for disease events.

Methods

- Use R to simulate and analyze existing data for uncertain events such as HCV infection.
- Compare bias in incidence rates estimated for this data via different censoring strategies.
- Investigate errors underlying bias.

Results

<table>
<thead>
<tr>
<th></th>
<th>100% sensitivity and specificity</th>
<th>90% sensitivity and specificity</th>
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</thead>
<tbody>
<tr>
<td>True</td>
<td>I.e I I I</td>
<td>I.e I I I</td>
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<tr>
<td>6 mos. 5</td>
<td>3.0 5.1 5.0</td>
<td>3.0 5.3 13.5</td>
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<tr>
<td>12 mos. 5</td>
<td>3.0 5.0 5.0</td>
<td>3.3 5.3 13.5</td>
</tr>
<tr>
<td>6 mos. 10</td>
<td>6.0 10.1 10.0</td>
<td>6.5 10.7 27.0</td>
</tr>
<tr>
<td>12 mos. 10</td>
<td>6.2 10.1 10.1</td>
<td>6.1 9.8 18.1</td>
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</table>

- One-test diagnostic analysis demonstrates significant upward bias at suboptimal sens./spec.
- Two-test diagnostic analysis with correct censoring yields only slight bias at suboptimal sens./spec.
- Incorrect censoring with two-test analysis produces downward bias in unidirectional and bidirectional simulations.
- Visit rate significantly affects bias in bidirectional simulations.

Discussion

- In the two-test analysis of simulated data, incorrectly censoring at the ultimate event contributed to significant downward bias in incidence estimates.
- This downward bias is apparent in real HCV primary infection data and further persists in simulated bidirectional data.

Questions

- How much bias is observed across censoring methods for diverse data types, such as body temperature data?
- Is the two-test diagnostic standard appropriate for bidirectional data when sens./spec are suboptimal?

Conclusion

When two tests are used for diagnosis, the popular but incorrect data censoring method is likely to yield significantly biased results.

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