Background

- Tobacco harm reduction (THR) is the substitution of less risky nicotine products for cigarettes.
- Epidemiologic evidence clearly shows that non-smoked sources of nicotine (smokeless tobacco and pharmaceutical nicotine) have approximately 1% of the health risk of cigarette.
- Despite the dramatic potential risk reduction of THR, many clinicians and public health practitioners oppose THR efforts.
- Opponents overstate the risks from smokeless tobacco, which is currently the most promising reduced harm substitute, sometimes by perverting epidemiologic research.

We have previously identified the epidemiologic "methods" used by politically-driven THR opponents:

- Not acknowledging potential residual confounding;
- Inconsistent exposure, outcome, and covariate definitions;
- Nonsensical meta-analyses;
- Misinterpreting descriptive epidemiology that clearly shows the success of THR in Sweden; and

Engaging in publication bias in situ (PBIS) (intentionally blasing results from a study; e.g., running many different models and reporting only the one that produces the preferred results).

Ethical obligations of researchers and journals.

- Researchers should report their findings honestly, signifying respecting for scientific truth and the right of their readers to interpret results rather than feed authors' preferred conclusions.
- This may require reporting results that contradict favored hypotheses or might call into question some conclusions from other results.

Journals are currently incapable of ensuring adequate methodology, but can endeavor to reduce PBIS particularly when it is called to their attention.

We reviewed a series of articles based on a large cohort of Swedish construction workers and exposure to snus (the type of smokeless tobacco common in Sweden) to illustrate the apparent failure to conduct and publish epidemiologic research according to the above observations about ethics.

Following the publication of Zendehdel (2008), we identified signs of PBIS in this series of articles which shared population/data and exposure of interest, and looked at a variety of endpoints.

In particular, it appears that each study used its own data-driven model, presumably to increase the magnitude of reported associations.

Results and discussion

Table 1 compares the sample size and variables used in 8 analyses of the Swedish construction workers cohort that included snus use as an emphasized independent variable.

The authors were undoubtedly aware of the methods used in prior studies due to overlapping authorship, etc. (And yet, laterly, the last articles did not usually cite the former ones.)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Time (yr)</th>
<th>Sex use</th>
<th>Age at stabilized and analyzed</th>
<th>BMI</th>
<th>Smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zendehdel 2008</td>
<td>50</td>
<td>Never, non-smoker</td>
<td>Admitted age</td>
<td>Yes or no</td>
<td>Current, previous, or never</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adjusted age for age as time scale</td>
<td></td>
<td>Product, cigarette-only, pipe only, cigar only</td>
</tr>
<tr>
<td>Lyer 2007</td>
<td>&gt;79</td>
<td>Never, previous, or current</td>
<td>Initial age</td>
<td>Yes, no, or current</td>
<td>Amount used (g/day)</td>
</tr>
<tr>
<td>Odemirs 2007</td>
<td>&lt;200</td>
<td>Occasional snuff use vs tobacco users (TNU)</td>
<td>Age (continuous)</td>
<td>Yes, not, or current</td>
<td>Length of time (years)</td>
</tr>
<tr>
<td>Zendehdel 2005</td>
<td>50</td>
<td>Never, previous, or current</td>
<td>Initial age</td>
<td>Yes, no, or current</td>
<td>Years since snuff use cessation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adjusted age for age as time scale</td>
<td></td>
<td>Years since smoking cessation: TNU, &lt;10, &gt;=10</td>
</tr>
<tr>
<td>Zendehdel 2005</td>
<td>50</td>
<td>Ever, never (including regular snuff use and casual snuff use)</td>
<td>Initial age</td>
<td>Yes, no, or current</td>
<td>Years since smoking cessation: TNU, &lt;10, &gt;=10</td>
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<td></td>
<td></td>
<td></td>
<td>Adjusted age for age as time scale</td>
<td></td>
<td>Years since snuff use cessation</td>
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<tr>
<td>Zhang 2007</td>
<td>&lt;30</td>
<td>Occasional snuff use vs TNU</td>
<td>Initial age</td>
<td>Yes, no, or current</td>
<td>Years since smoking cessation: TNU, &lt;10, &gt;=10</td>
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</tbody>
</table>

Results and discussion - continued

Conflicting eligibility criteria

Different eligibility criteria were used, without justification, leading to vastly different sample sizes.

The main difference was whether males enrolled from 1971-75 were included.

Some articles excluded these participants due to “ambiguities in the coding of smoking status in the questionnaires used during 1971-75” (from a study published in 2008). This is a bias, for this case it is a more first-party effect described by the American Cancer Society in their report on the Swedish Cohort.

Conclusions

- Taking advantage of the weaknesses of epidemiology to advance a worldly agenda not only huts scientific integrity, but makes epidemiology a junk science.
- PBIS skews perceptions of study results, and so misleads anyone who is genuinely interested in determining true health risks.
- PBIS is not taken seriously by most epidemiology/public health journals.
- A simple way to reduce PBIS is reporting, as a sensitivity analysis, results calculated based on related statistical models that were previously published. This can show whether a result is largely driven by the choice of model. Doing this is particularly easy when the same authors created the previous models using the same data.
- However, the most robust solution to PBIS is to end the practice of publishing based on secret data using half-described methods.
- Novel forums are needed to discuss variations in study methodology when the journal that published the original article is not receptive to such concerns.

References


