Methods

Janet A. Tooze, PhD, MPH

June 27, 2017
Methods Section of a paper

- Clearly describe
  - Design of the study
  - Procedures that were performed
- Sufficient detail that an appropriately trained person could replicate your paper
Before you begin

- For each aim
  - Dataset
  - Inclusion/exclusion criteria
  - What variables you will need
    - Where it comes from, how it was collected
    - When
Dataset

- Who owns the database? How can you get access to the database? Do you need permission to use the database? Does the database cost anything to use? Are there rules about storing the database?

- What was the purpose of the study? What are the study hypotheses?

- What methods were used to identify (select) the population under study and gather information from them?

- How was the data collected, entered, and checked for quality control?

- In what program (e.g., MS Access/Epi Info, Excel, SQL, etc.) and in what format is the dataset stored (e.g., text, ASCII, comma-delimited, etc.)?

- How many records/observations/people are in the dataset?

- Were weights used?

- Does it have the variables I need?

Methods section of your proposal

- Similar to paper but with less detail
- Write in future tense
- Similar to a grant approach section
- I am going to focus on writing a methods section for your paper, which you will eventually do, but you do not need to include as much detail for your proposal
- 2-3 pages double-spaced of writing, plus table shells
- Get input from your committee, especially the statistician
Guidelines

- CONSORT: RCT
- STARD: Diagnostic Accuracy
- PRISMA: meta-analysis, review
- STROBE: observational epi
Should include

- Population
- Procedures relevant to your paper
- Outcomes and how they were measured
- Data analysis

For a large cohort that has been previously described, you should reference the design paper

- “Details of the XXX study are described elsewhere (citation)”
- But your paper needs to be understandable without a reader going back to that paper
First Paragraph

• Introduction to the population and design
  • General design of study (RCT, observational, prospective/retrospective)
  • Recruitment
  • What is specific to this paper (we used year 2 as our baseline because it had measure X)
  • Inclusion/exclusion criteria
  • Time frame – years of study
  • Number of visits
  • Include IRB/ethics approval
Second paragraph

• Overview of procedures
  • Number of study visits
  • Give study years (e.g., between September 2002 and March 2003)
  • What was measured when (e.g., at visit 1, participants had height and weight measured)
  • Blinding of assessors if applicable
Next few paragraphs

- Describe measures of interest
  - What was used to measure each outcome or covariate used in analysis
  - If it’s a scale or tool that has been used previously, then cite earlier paper showing it is reliable/valid and discuss how it is interpreted.
  - Not necessary for standard tests like CT
  - Be clear if it was from a chart or a patient, etc.
  - Usually a separate paragraph for each category
Final paragraph

• Statistical methods
  • Should be in the order they will appear in the text, e.g., methods for Table 1, Table 2, etc.
  • Easier to do table shells first
  • If you are fitting models, list all covariates you will adjust for in this section
    • This will be a good list of what you will need to pull from the dataset
  • Include goodness of fit tests (e.g., tests of proportional hazards; testing form of variables)
  • Include significance level (e.g. alpha = 0.05)
  • Include the software you will use (e.g., SAS)
Table Shells

- Each table shell should have a title, category labels, format for results, but no data
- Use “Insert Table” in Word or another table editor
  - Put each row of data in a separate cell
- Tables should stand alone from the text
- Title should be descriptive and include name of study
- Include abbreviations, statistical tests in footnotes
- Table 1 is almost always a description of your study population
- Figures are best for demonstrating trends or showing relationships

Reference: See “Instructions for Table Creation” on http://jama.jamanetwork.com/article.aspx?articleid=202118
# Example Table 1

## TABLE 1 Cohort Characteristics, Children Aged 0 to 15 Years Obtained From the NTDB 2009

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 78,673)</th>
<th>Normotensive (n = 77,077)</th>
<th>Hypotensive (n = 1,596)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, n (%), y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–4</td>
<td>24,819 (31.6)</td>
<td>24,334 (98.0)</td>
<td>485 (2.0)</td>
<td>0.0002</td>
</tr>
<tr>
<td>5–11</td>
<td>28,952 (36.8)</td>
<td>28,420 (98.2)</td>
<td>532 (1.8)</td>
<td></td>
</tr>
<tr>
<td>12–15</td>
<td>24,902 (31.7)</td>
<td>24,323 (97.7)</td>
<td>579 (2.3)</td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.007</td>
</tr>
<tr>
<td>Male</td>
<td>51,368 (65.3)</td>
<td>50,377 (98.1)</td>
<td>991 (1.9)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>27,305 (34.7)</td>
<td>26,700 (97.8)</td>
<td>605 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>White</td>
<td>47,237 (60.0)</td>
<td>46,319 (98.1)</td>
<td>918 (1.9)</td>
<td></td>
</tr>
<tr>
<td>AA/Black</td>
<td>12,125 (15.4)</td>
<td>11,843 (97.7)</td>
<td>282 (2.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>12,840 (16.3)</td>
<td>12,566 (97.9)</td>
<td>274 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>6,471 (8.2)</td>
<td>6,349 (98.1)</td>
<td>122 (1.9)</td>
<td></td>
</tr>
<tr>
<td>Heart rate, median (25th, 75th)**</td>
<td>104 (88, 122)</td>
<td>104 (88, 122)</td>
<td>109 (88, 135)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ISS, median (25th, 75th)†</td>
<td>5 (4, 9)</td>
<td>5 (4, 9)</td>
<td>10 (4, 22)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>GCS score, median (25th, 75th)‡</td>
<td>15 (15, 15)</td>
<td>15 (15, 15)</td>
<td>15 (6, 15)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AIS score (head), median (25th, 75th)§</td>
<td>3 (2, 4)</td>
<td>3 (2, 4)</td>
<td>4 (2, 4)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* p value from $\chi^2$ test (age, sex, race) or Wilcoxon rank-sum test (heart rate, ISS).
** n = 78,074 for heart rate.
† n = 74,415 for ISS.
‡ n = 73,926 for GCS.
§ n = 26,070 for AIS (head).

NTDB, National Trauma Data Bank; n, number; %, percent; sd, standard deviation; AA, African American; ISS, Injury Severity Score; GCS, Glasgow Coma Scale; AIS, Abbreviated Injury Scale.

Injury patterns associated with hypotension in pediatric trauma patients: A national trauma database review.
Gardner, Alison; MD, MS; Diz, Debra; Tooze, Janet; PhD, MPH; Miller, Chadwick; MD, MS; Petty, John

DOI: 10.1097/TA.0000000000000658
# Example Table

## TABLE 3  RR and PAR% of Hypotension by Injury Type and Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>RR (95% CI)</th>
<th>PAR %**</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–4 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolated head injury</td>
<td>2.48 (1.95, 3.16)</td>
<td>30.7</td>
</tr>
<tr>
<td>Hemorrhagic injury</td>
<td>2.67 (2.05, 3.48)</td>
<td>18.2</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>3.21 (1.42, 7.25)</td>
<td>0.9</td>
</tr>
<tr>
<td>Other</td>
<td>1.00</td>
<td>—</td>
</tr>
<tr>
<td>5–11 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolated head injury</td>
<td>1.45 (1.15, 1.83)†</td>
<td>6.9</td>
</tr>
<tr>
<td>Hemorrhagic injury</td>
<td>2.89 (2.37, 3.51)</td>
<td>28.1</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>2.49 (1.43, 4.34)</td>
<td>1.5</td>
</tr>
<tr>
<td>Other</td>
<td>1.00</td>
<td>—</td>
</tr>
<tr>
<td>12–15 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolated head injury</td>
<td>1.54 (1.20, 1.97)†</td>
<td>7.5</td>
</tr>
<tr>
<td>Hemorrhagic injury</td>
<td>3.70 (3.00, 4.55)</td>
<td>40.2</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>1.33 (0.79, 2.23)</td>
<td>0.7</td>
</tr>
<tr>
<td>Other</td>
<td>1.00</td>
<td>—</td>
</tr>
</tbody>
</table>

*National Trauma Data Bank 2009.

**PAR% = population attributable risk percent.

†p < 0.0001 vs. RR for hemorrhagic injury using linear contrast.

Injury patterns associated with hypotension in pediatric trauma patients: A national trauma database review.
Gardner, Alison; MD, MS; Diz, Debra; Tooze, Janet; PhD, MPH; Miller, Chadwick; MD, MS; Petty, John

DOI: 10.1097/TA.0000000000000658
Table 3. Serum 25-Hydroxyvitamin D Status, Physical Performance, and Muscle Strength (Least-Squares Mean (SE)) at Baseline, Health, Aging, and Body Composition Study, 1998–1999a

<table>
<thead>
<tr>
<th>Variable and Model</th>
<th>No. of Participants</th>
<th>Serum 25(OH)D Concentration</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;50 nmol/L</td>
<td>50–75 nmol/L</td>
</tr>
<tr>
<td>SPPB score³ (range, 0–12)</td>
<td>2,603</td>
<td>9.77 (0.05)***</td>
<td>10.02 (0.05)</td>
</tr>
<tr>
<td>Model 1</td>
<td>9.46 (0.11)</td>
<td>9.60 (0.11)</td>
<td>9.60 (0.11)</td>
</tr>
<tr>
<td>Model 2</td>
<td>2.07 (0.02)***</td>
<td>2.17 (0.02)</td>
<td>2.21 (0.02)</td>
</tr>
<tr>
<td>Model 1</td>
<td>1.95 (0.04)*</td>
<td>1.99 (0.04)</td>
<td>2.01 (0.04)</td>
</tr>
<tr>
<td>Model 2</td>
<td>1.08 (0.01)***</td>
<td>1.12 (0.01)*</td>
<td>1.14 (0.01)</td>
</tr>
<tr>
<td>Model 2</td>
<td>1.03 (0.01)***</td>
<td>1.06 (0.01)</td>
<td>1.07 (0.01)</td>
</tr>
<tr>
<td>200-m gait speed, m/second</td>
<td>2,607</td>
<td>1.20 (0.01)***</td>
<td>1.25 (0.01)**</td>
</tr>
<tr>
<td>Model 1</td>
<td>1.14 (0.02)***</td>
<td>1.17 (0.02)*</td>
<td>1.19 (0.02)</td>
</tr>
<tr>
<td>Model 2</td>
<td>13.43 (0.13)***</td>
<td>13.98 (0.13)</td>
<td>14.07 (0.14)</td>
</tr>
<tr>
<td>Knee extensor strength, nm/kg of leg lean mass</td>
<td>2,254</td>
<td>12.83 (0.27)</td>
<td>13.01 (0.27)</td>
</tr>
<tr>
<td>Model 1</td>
<td>28.87 (0.51)*</td>
<td>29.71 (0.50)</td>
<td>29.81 (0.50)</td>
</tr>
<tr>
<td>Model 2</td>
<td>30.73 (0.25)*</td>
<td>31.58 (0.24)</td>
<td>31.50 (0.26)</td>
</tr>
</tbody>
</table>

Abbreviations: Health ABC, Health, Aging, and Body Composition; Health ABC PPB, Health ABC Physical Performance Battery; 25(OH)D, 25-hydroxyvitamin D; SE, standard error; SPPB, Short Physical Performance Battery.

* P < 0.05; ** P < 0.01; *** P < 0.001 (difference from 25(OH)D ≥75 nmol/L when P < 0.05 for the overall model).

25-Hydroxyvitamin D status and change in physical performance and strength in older adults: The Health, Aging, and Body Composition Study.
Denise K. Houston*, Janet A. Tooze, Rebecca H. Neiberg, Dorothy B. Hausman, Mary Ann Johnson, Jane A. Cauley, Doug C. Bauer, Peggy M. Cawthon, M. Kyla Shea, Gary G. Schwartz, Jeff D. Williamson, Frances A. Tylavsky, Marjolein Visser, Eleanor M. Simonsick, Tamara B. Harris, and Stephen B. Kritchevsky for the Health ABC Study
Figure 2. Baseline cognitive function is associated with worse OS among older adults treated for AML (N = 73). Median survival differed using log-rank testing.
Fig. 1. Distribution of 25(OH)D (A) and PTH (B) concentrations by race: the Health ABC Study, 1998–1999. Values differ significantly by race ($P < 0.001$).
Next Time

- July 25th
  - Present Methods Section
  - Final questions
  - Finalize committee
- Lecture
  - Timeline, etc.