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Who is in this study, anyway? Guidelines for a useful Table 1

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Abstract

Objective: Epidemiologic and clinical research papers often describe the study sample in the first table. If well-executed, this "Table 1" can illuminate potential threats to internal and external validity. However, little guidance exists on best practices for designing a Table 1, especially for complex study designs and analyses. We aimed to summarize and extend the literature related to reporting descriptive statistics.

Study design and setting: In consultation with existing guidelines, we synthesized and developed reporting recommendations driven by study design and focused on transparency related to potential threats to internal and external validity.

Results: We describe a basic structure for Table 1, and discuss simple modifications in terms of columns, rows, and cells to enhance a reader's ability to judge both internal and external validity. We further highlight several analytic complexities common in epidemiologic research (missing data, sample weights, clustered data, and interaction), and describe possible variations to Table 1 to maintain and add clarity about study validity in light of these issues. We discuss considerations and tradeoffs in Table 1 related to breadth and comprehensiveness versus parsimony and reader-friendliness.

Conclusion: We anticipate that our work will guide authors considering layouts for Table 1, with attention to the reader's perspective.

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1. INTRODUCTION

"Who is in this study?" is the first question many readers of clinical and epidemiologic studies ask. Readers care about who is in a study because it helps them understand and evaluate the study's findings: to assess applicability to other patients or populations (i.e. external validity), and risk of bias (i.e. internal validity).[1,2] As a result, papers often include a table that describes the study sample; this is commonly the first table in a paper. This "Table 1," as it is colloquially called, can be designed to shed light on potential threats to both internal and external validity of study findings.

Table 1 can provide insights on threats to internal validity in the traditional epidemiologic framework: a) confounding (i.e. differences in other causes of the outcome between exposed and unexposed), b) selection bias (e.g. differential cohort attrition or control selection), and c) measurement error.[3] The primary threats to external validity about which Table 1 can be informative are differences in effect modifiers or other causes of the outcome between the source population and target population; information on these is often insufficient.[4]

As the study designs and analytic approaches used in modern research have grown in variability and complexity, it has become more challenging to create a Table 1 that serves to inform readers about issues related to study validity. Although brief guidance exists on best practices for reporting descriptive data on study samples,[1,2,5,6] these guidelines generally do not address many analytic issues.

To address this gap, we outline considerations in creating a Table 1 that aids readers in judging internal and external validity. In consultation with the limited existing guidelines, we lay out a minimally sufficient Table 1 structure driven by study design, and discuss examples of specific analytic issues for which Table 1 could be modified. Throughout, we focus on validity of studies estimating causal effects, although some considerations may also be relevant for studies with descriptive or predictive goals. To distill and concretize some of the issues discussed, we include an overview figure (Figure 1), and two annotated example tables adapted from published studies,[7,8] including a case-control study (Figure 2), and a cohort study with a specific analytic complexity, missing data (Figure 3).

2. BASIC STRUCTURE OF TABLE 1

The simplest Table 1 is a single column of descriptive statistics for the total study sample, with rows containing key study variables (minimally, all variables included in the final main analysis). Inside each cell, descriptive statistics are typically given as n (%) for categorical variables and mean (standard deviation) or median (25^{th}-75^{th} percentile or minimum-maximum) for continuous variables.[1,2] The total column can be useful for assessing external validity, as the reader can examine the characteristics of the whole sample. However,

expansions to this basic structure, driven by study design, can provide substantially more insight regarding threats to both internal and external validity (Figure 1) and are more common.

2.1 Considering columns

Table 1 frequently includes columns showing distributions of key variables within sample strata to maximize transparency for assessing internal validity. For example, the primary exposure is a common stratification variable for cohort studies, randomized controlled trials (RCTs), and cross-sectional studies, complementing subsequent tables focused on associations with the outcome. Stratifying by exposure allows assessment of potential confounding,[1,2] which may be apparent as an uneven distribution of other causes of the outcome between exposed and unexposed. (When the exposure of interest is continuous, stratification is less straightforward; median or other splits may be used.) In contrast, in case-control studies, stratifying by disease (case vs. control) status is most common; a total column is no longer appropriate as the controls represent the source population (Figure 2, Point 1).[2] While stratification by disease status may allow for some assessment of selection bias (e.g. showing whether cases would have reasonably arisen from that source population), it does not allow assessment of confounding because cases and controls are expected to have different distributions of causes of the outcome (some of which are confounders).[2] To assess the potential for confounding in a case-control study, the control column can be further stratified by exposure; this allows readers to compare distributions of potential confounders between exposed and unexposed controls, revealing possible confounding resulting from correlations in the source population (Figure 2, Point 2).[2]

Authors may also add columns to Table 1 to inform readers about external validity. When a study has one or more target populations in mind and data are available for these target populations, including a column showing the distribution of the study variables in each target population allows the reader to make a direct comparison between the study and target populations.[6]

The appropriateness of including a column containing inferential statistics (e.g. p-values) is a topic of some controversy. Statistical testing of distributions of variables (e.g. between exposed and unexposed) is common and even occasionally required by journals;[1,6,9,10] although this is a tempting way to assess confounding, it is not best practice. Statistical significance is often misunderstood: non-significance of a p-value does not indicate that no difference in the distribution of a variable exists, and significance does not mean that the difference is meaningful or that the difference indicates presence of confounding.[10–13] As a result, confounder assessment should not be based on p-values (Figure 2, Point 3; Figure 3, Point 4).[1,2] Rather, authors should consider whether the relationship between the exposure and hypothesized confounders is as expected according to the causal theory, and consider whether the magnitude of an observed difference for a potential confounder represents a meaningful difference.[1,9,10] Similarly, when considering external validity, statistical tests are not a helpful way to assess meaningful differences between source and target populations.

2.2 Considering rows

Reader ability to assess internal validity can also be improved with careful consideration of the rows in Table 1. For all types of study designs, in addition to the key study variables included in the final analyses, it may be helpful to include other potential confounders evaluated (Figure 3, Point 7) and selection variables (e.g., variables used in sampling, variables that may influence study participation or loss to follow up). Inclusion of these variables may inform or pre-empt concerns about residual confounding or selection bias by variables not included in the final analysis. For example, in case-control studies, including rows for variables where differences might indicate the presence of selection biases in enrollment (e.g. distance from home to hospital in a hospital-based case-control study) may be useful (Figure 2, Point 6).

Adding rows can also help readers assess external validity. Even if a target population column is not included as described above, adding rows that show distributions of major baseline demographics,[14] including important potential effect modifiers will be useful to a reader in assessing the likelihood of meaningful differences in the effects of interest between the source population and a given target population.[15,16] Even if effect modification is not explicitly modeled, showing distributions of possible effect modifiers is still useful for assessing threats to external validity (Figure 2, Point 8).

For studies involving time-to-event analyses, authors should include a summary of person-time, including total and mean or median per person,[2,5] as well as a summary of reasons for censoring, stratified by exposure status. The reasons for censoring can inform assessment about internal validity; if reasons for censoring differ between exposed and unexposed, the censoring may be informative, a threat to internal validity. The average person-time can be informative about external validity, as effects of exposures/interventions may differ over different lengths of observation.

When variables are analyzed differently from how they were collected (e.g. a continuous variable is categorized or a categorical variable is collapsed), there are tradeoffs in terms of which version of the variable to show. In general, we suggest including the variable as analyzed in the main analysis to ease navigation between tables. However, other choices may also be appropriate. For example, choices about categorizing continuous variables may introduce measurement error or residual confounding compared to the continuous variable; showing both the analyzed categorical variable and the original variable as measured allows categorization decisions, and any bias introduced by them, to be more transparent to the reader (Figure 2, Point 4; Figure 3, Point 6). In addition, showing only a coarsely categorized variable might also limit the reader’s ability to align categories with an outside data source using different cut points to assess external validity.

2.3 Considering cells

For table readability and easy comparison across columns, the contents of the cells should focus on reducing visual clutter. Some options include showing only percentages for categorical variables, with the N in the column header, or rounding percentages to whole

numbers (e.g. 73.1% to 73%, Figure 2, Point 5); more precision should be shown only if it improves a reader's understanding and is based on a large number of observations.

Cell content decisions can also affect clarity regarding internal and external validity, especially for continuous variables, where authors must decide whether to present mean and standard deviation or percentile-based descriptive data. Although the mean and standard deviation approach is common,[1,2] showing a summary including minimum, lower quartile, median, upper quartile, and maximum can be more informative when variables are not normally distributed, or are differently distributed within strata (Figure 2, Point 7). More information about distributions can help readers assess a) whether measurement error could have occurred in data collection, compromising internal validity (e.g. if the distribution of blood pressure measurements is lower than expected), b) whether influential data points could have undue leverage on the reported effect estimate (also potentially compromising internal validity) and c) how the distribution in the sample may compare to a target population, informing the external validity of the results.

A final consideration within cells relates to indicating the absence of a value, which may be due to non-applicability, a measurement that was not completed for all observations (see next section on missing data), or the suppression of values within small strata to preserve confidentiality. The use of shading or a character (e.g., period or dash) rather than a blank cell communicates that the omission is intentional, and may be accompanied with clarifying text in the table footnote.

3. ANALYSIS-SPECIFIC CONSIDERATIONS

3.1 I have missing data

Missing data are a common problem in studies, and may arise from non-response, loss to follow-up/censoring, or other reasons. Patterns such as "missing completely at random," "missing at random," or "not missing at random" are commonly used to describe missing data in the literature.[17] Missing data is primarily a concern because observations without data on all analytic variables cannot be included in the analysis, and only observations with complete data will be "selected" into the final analytic sample. This selection may or may not cause bias depending on the relationships between the missing data (i.e. selection), exposure, outcome, and other variables in the analysis;[18–20] threats to validity due to missing data selection processes are best examined through the lens and language of selection bias.[18,19,21] (One exception is that missing outcome data in those who were censored in time-to-event analyses does not preclude inclusion in the sample; nonetheless, selection can occur because only non-censored person-time with complete data on other analytic variables can be included.)

Table 1 can help show the potential (or lack thereof) for missing data to cause selection bias, complementing participant flow diagrams suggested by guidelines.[1,2] Flow diagrams typically focus on the proportion and reasons (e.g. loss to follow up) for missing data, rather than their potential to bias results. In contrast, columns in Table 1 showing observations with and without missing data (often called partial and complete cases, respectively) allow the reader to assess whether measured variables are associated with missingness/selection

(Figure 3, Point 1). Among these measured variables, including a row to show whether the outcome is associated with selection is particularly important; selection based on disease biases risk measures (Figure 3, Point 5).[19] These modifications to Table 1, in combination with the hypothesized causal structure, can allow a reader to evaluate whether selection is associated with variables that could bias results. However, selection associated with unmeasured variables remains a possibility, for which the reasons for missing data, if known, are informative.

Because several analytic options (e.g. complete case or multiple imputation) exist for handling missing data,[1,2,17,22] showing complete and partial cases in Table 1 can also help an author clarify the motivation for the analytic approach used. For example, if Table 1 shows no differences between complete and partial cases except for the distribution of the exposure, a complete case analysis will likely be unbiased.[19] However, when selection is associated with the outcome, a complete case analysis will be biased and is therefore inappropriate.[18,19] Complete case analyses may also be biased when selection is associated with other variables, depending on the causal structure hypothesized.[18,19] In these cases, authors must consider multiple imputation, inverse probability weighting, or other approaches that are more robust. Importantly, the rationale for the missing data approach taken in a research paper, along with sensitivity analyses, are recommended or required by some journals.[23–25]

Once a final analytic sample has been chosen to minimize concerns about selection bias due to missing data, Table 1 can be further expanded to show other threats to internal and external validity as previously described. The best way to do this is to include data on the final analytic sample (e.g. complete case or one imputed dataset[17]), in accordance with the basic structure outlined above (Figure 3, Point 3).

3.2 My study used sample weights

Many studies, especially surveys designed to produce estimates for a specific population, use sample weights. Sampling weights correct for over- or under-sampling of specific population strata, and after sampling weights have been applied the study sample represents the source population. Therefore, it is not possible to judge the internal validity of a weighted analysis if the weighted distributions are not presented in Table 1; only after weighting is it possible to tell if potential confounder is associated with the exposure in the data as it will be analyzed. To this end, showing unweighted proportions hinders a reader's ability to judge the presence of confounding in the source population. It may also be helpful to report the number of subjects, minimum and maximum weights, and distribution of weights in Table 1 to allow for assessment of the potential for any observations to have undue influence on the results, potentially affecting internal validity. One approach is to show unweighted N's and weighted proportions. Fortunately, the external validity of studies utilizing sample weights is also shown most clearly using weighted percentages because the weighted sample reflects the source population to which the results apply; when shown in Table 1 this is more easily compared to a target population.

3.3 I have clustered data

Studies involving clustered data, such as multilevel studies or studies with repeated measures, are increasingly common and present a unique set of challenges, especially related to external validity. In these studies, there are two source populations: one at the cluster level, and one at the individual observation level. Descriptive statistics should be provided for each population (i.e. for the clusters themselves in addition to the observations). This aids in assessing external validity because the reader can determine if the clusters themselves are similar to a target population of clusters on cluster-level variables that affect the outcome. In the event that the sampling fraction of observations is uneven within clusters, a row that describes the number of observations per cluster and sampling fraction per cluster may help readers better understand the sample. Of note, clustering plays different roles in studies involving social or other network analyses versus studies with repeated measures or hierarchical sampling, and best practices therefore differ. In network analyses, a figure displaying network topology, potentially including network summary statistics, may complement an individual-level Table 1.

3.4 I am interested in interaction or effect modification

When interaction, effect modification, or stratified results more generally are of primary interest, Table 1 should show more detail on the strata. For example, for studies of gender differences or racial disparities, it is more informative to present Table 1 within additional strata of gender or race, respectively, rather than across the entire sample. Further, because confounding can occur for the effect of either the exposure or the stratification variable, it is preferred to show distributions of all variables according to strata of both the exposure and the modifier (e.g. 4 columns for dichotomous exposure and stratification variable). Finally, because the overall causal effect is a weighted average of the stratum-specific effects, to allow assessment of external validity, there is value in using Table 1 or a corresponding results paragraph to show the distributions of the exposure and modifier in the total sample.

4. DISCUSSION

Despite the ubiquity of a “Table 1” describing the study sample, there is limited guidance on how to maximize its utility for readers. Drawing on our experience and on existing guidelines,[1,2,5,6] we have described a basic structure and potential variations to help Table 1 to inform assessments of both internal and external validity. We included two example tables to concretize several of the points we raised.

A common thread across many of our recommendations is consistency between Table 1 and how the data were analyzed in the main analysis. For example, showing complete cases or imputed data reveals how missing data were handled. Likewise, showing weighted estimates in Table 1 makes the use of weighting throughout more salient. In addition to improving transparency about internal and external validity as discussed above, a Table 1 that is consistent with the analytic approach in the main analysis makes it easy on the reader to understand the main analysis, and can therefore improve a reader’s understanding of the study more broadly.

In the real-world context in which epidemiologists work (e.g. an analysis of a complex survey sample in which some data are missing), our guidance for Table 1 may result in conflicting priorities. In such complex situations, the best approach to provide insight into one threat to validity may not as prominently address others; we especially anticipate that selection of columns will be challenging. For example, inclusion of columns for the final analytic sample and the original study sample to show potential selection bias may compete for space with columns stratified by exposure, which better show confounding. Including all the variations that we discussed to maximize assessment of both internal and external validity would lead to a very large and bulky Table 1 and is likely infeasible. Thus, authors will need to prioritize the data they show in any given manuscript.

We recommend attention to a reader's perspective. Generally speaking, it is easier for a reader to compare columns when there are fewer of them and cell contents are simpler. We suggest authors focus on the key issues for their study, driven by their study question and main results. For example, if internal validity is of the highest importance, modifications to Table 1 that show issues of confounding may take precedence over those that show external validity. However, if the goal of the study is to recommend policy for a specific target population, showing the external validity of the study to the target population may be crucial. As authors weigh these questions, they may also find it useful to consult more general resources on making tables user-friendly (e.g.[26–28]). Although journals often dictate style, key principles for readability and ease of comparison across columns and rows include minimizing unnecessary ink (e.g. lines between all rows/columns, or extensive decimals), using judicious shading to accentuate columns or rows in large tables, and aligning data according to decimal location.

Fortunately, many journals now offer the opportunity to include online supplementary materials. Inclusion of additional descriptive data is one excellent use of this space. Authors may include more detailed and exhaustive data, or even alternative Table 1's that show different stratifications of sample data or describe additional target populations. This offers a way to preserve parsimony of an in-text Table 1 while still providing the reader with thorough descriptive data to aid in their assessment of internal and external validity.

5. CONCLUSION

Despite its role in inferential transparency, there is limited guidance about constructing a "Table 1." In this article, we identified a basic structure to allow assessment of study validity, and highlighted options for modifications based on specific analytic issues. As study designs and analyses become more complex, thoughtful consideration is needed to develop a Table 1 that optimizes clarity about study internal and external validity. We believe the recommendations in this paper represent a step in this direction, and we anticipate they will lead to better clarity about study validity and therefore more convincing reporting of study findings. However, we welcome and encourage further discussion in the literature about how to achieve this goal.

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WHAT IS NEW?

1. A well-executed “Table 1” (i.e. sample descriptives table) can illuminate potential threats to internal and external validity, but limited guidance exists on best practices for creating Table 1, especially for complex study designs and analyses.
2. We draw on the existing sparse literature and extend it to make suggestions on best practices for presenting descriptive data.
3. We find that descriptive data, even for complex analyses, can be of greater use to readers assessing study validity than it typically is, currently. Our paper suggests ways to accomplish this.
4. We anticipate our results will particularly improve transparency in communicating threats to internal and external validity.

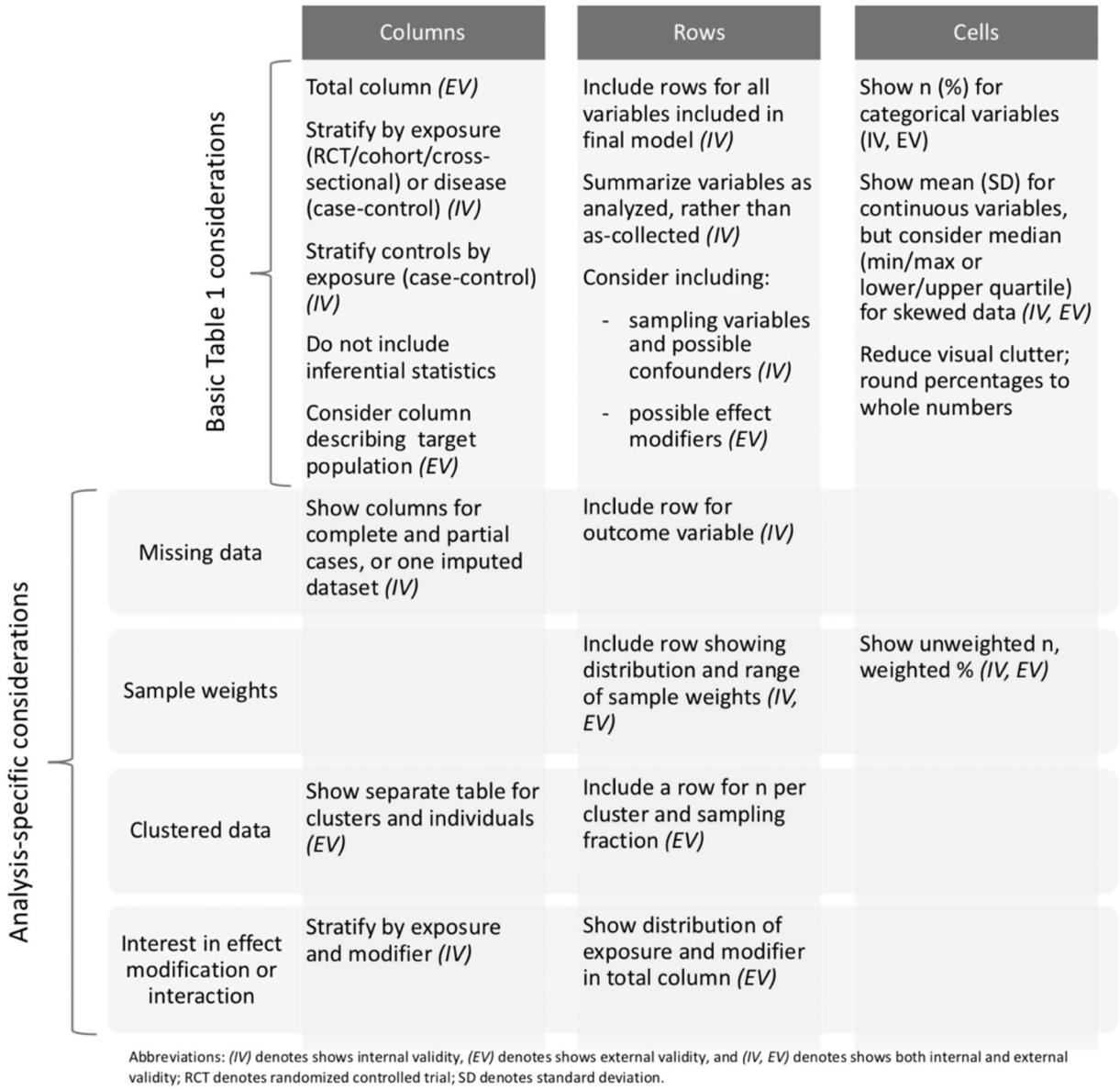

Figure 1.

Basic Table 1 structure and analysis-specific considerations affecting columns, rows, and cells.

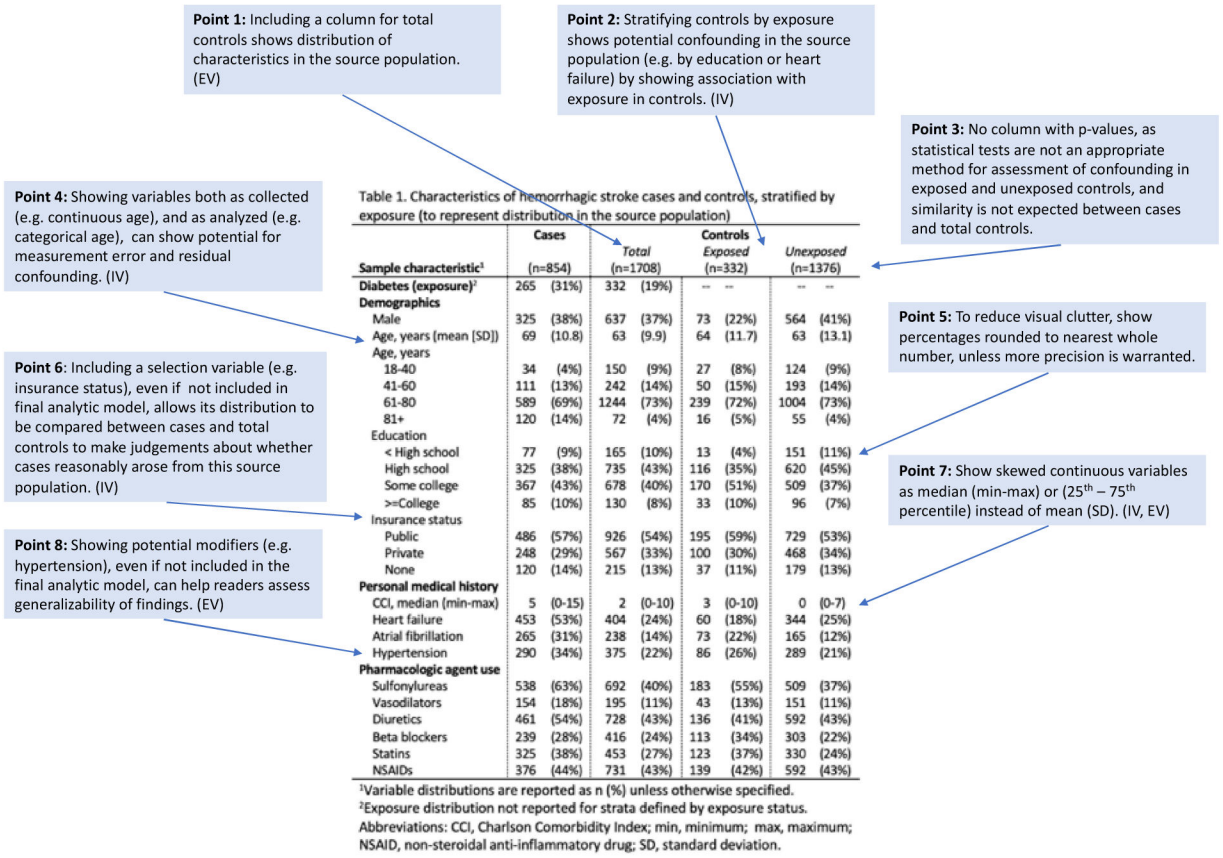

Table 1. Characteristics of hemorrhagic stroke cases and controls, stratified by exposure (to represent distribution in the source population)

	Cases	Controls		
		Total	*Exposed*	*Unexposed*
Sample characteristic[1]	(n=854)	(n=1708)	(n=332)	(n=1376)
Diabetes (exposure)[2]	265 (31%)	332 (19%)	-- --	-- --
Demographics				
Male	325 (38%)	637 (37%)	73 (22%)	564 (41%)
Age, years (mean [SD])	69 (10.8)	63 (9.9)	64 (11.7)	63 (13.1)
Age, years				
18-40	34 (4%)	150 (9%)	27 (8%)	124 (9%)
41-60	111 (13%)	242 (14%)	50 (15%)	193 (14%)
61-80	589 (69%)	1244 (73%)	239 (72%)	1004 (73%)
81+	120 (14%)	72 (4%)	16 (5%)	55 (4%)
Education				
< High school	77 (9%)	165 (10%)	13 (4%)	151 (11%)
High school	325 (38%)	735 (43%)	116 (35%)	620 (45%)
Some college	367 (43%)	678 (40%)	170 (51%)	509 (37%)
>=College	85 (10%)	130 (8%)	33 (10%)	96 (7%)
Insurance status				
Public	486 (57%)	926 (54%)	195 (59%)	729 (53%)
Private	248 (29%)	567 (33%)	100 (30%)	468 (34%)
None	120 (14%)	215 (13%)	37 (11%)	179 (13%)
Personal medical history				
CCI, median (min-max)	5 (0-15)	2 (0-10)	3 (0-10)	0 (0-7)
Heart failure	453 (53%)	404 (24%)	60 (18%)	344 (25%)
Atrial fibrillation	265 (31%)	238 (14%)	73 (22%)	165 (12%)
Hypertension	290 (34%)	375 (22%)	86 (26%)	289 (21%)
Pharmacologic agent use				
Sulfonylureas	538 (63%)	692 (40%)	183 (55%)	509 (37%)
Vasodilators	154 (18%)	195 (11%)	43 (13%)	151 (11%)
Diuretics	461 (54%)	728 (43%)	136 (41%)	592 (43%)
Beta blockers	239 (28%)	416 (24%)	113 (34%)	303 (22%)
Statins	325 (38%)	453 (27%)	123 (37%)	330 (24%)
NSAIDs	376 (44%)	731 (43%)	139 (42%)	592 (43%)

[1]Variable distributions are reported as n (%) unless otherwise specified.
[2]Exposure distribution not reported for strata defined by exposure status.
Abbreviations: CCI, Charlson Comorbidity Index; min, minimum; max, maximum; NSAID, non-steroidal anti-inflammatory drug; SD, standard deviation.

Figure 2.
Example construction of Table 1 for a hypothetical case-control study.

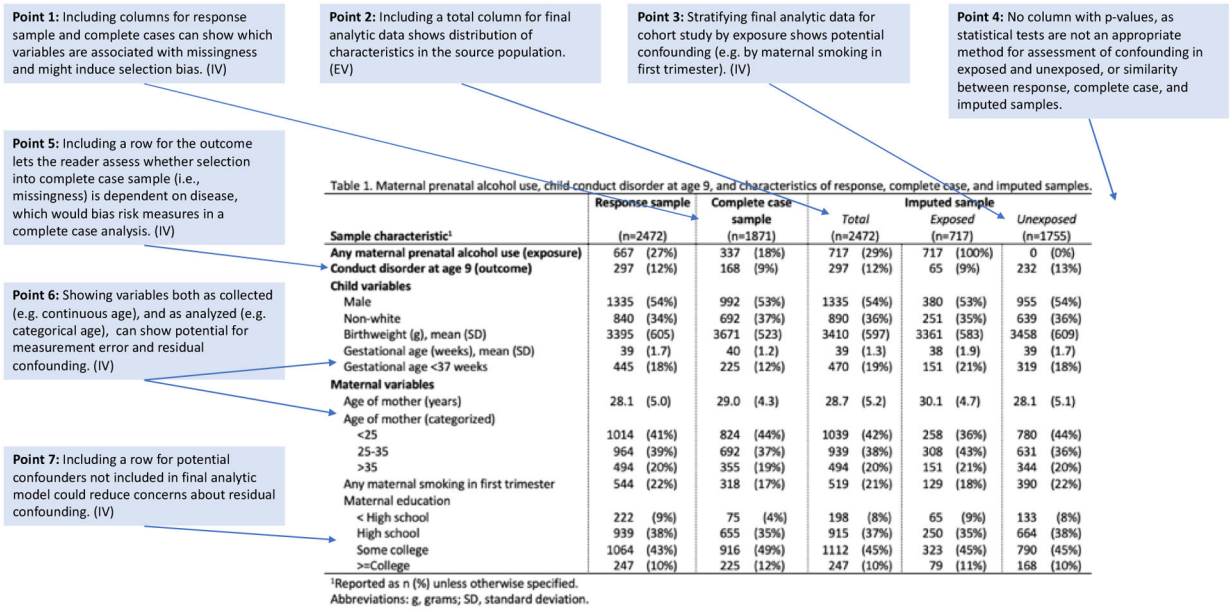

Table 1. Maternal prenatal alcohol use, child conduct disorder at age 9, and characteristics of response, complete case, and imputed samples.

	Response sample	Complete case sample	Imputed sample		
			Total	*Exposed*	*Unexposed*
Sample characteristic[1]	(n=2472)	(n=1871)	(n=2472)	(n=717)	(n=1755)
Any maternal prenatal alcohol use (exposure)	667 (27%)	337 (18%)	717 (29%)	717 (100%)	0 (0%)
Conduct disorder at age 9 (outcome)	297 (12%)	168 (9%)	297 (12%)	65 (9%)	232 (13%)
Child variables					
Male	1335 (54%)	992 (53%)	1335 (54%)	380 (53%)	955 (54%)
Non-white	840 (34%)	692 (37%)	890 (36%)	251 (35%)	639 (36%)
Birthweight (g), mean (SD)	3395 (605)	3671 (523)	3410 (597)	3361 (583)	3458 (609)
Gestational age (weeks), mean (SD)	39 (1.7)	40 (1.2)	39 (1.3)	38 (1.9)	39 (1.7)
Gestational age <37 weeks	445 (18%)	225 (12%)	470 (19%)	151 (21%)	319 (18%)
Maternal variables					
Age of mother (years)	28.1 (5.0)	29.0 (4.3)	28.7 (5.2)	30.1 (4.7)	28.1 (5.1)
Age of mother (categorized)					
<25	1014 (41%)	824 (44%)	1039 (42%)	258 (36%)	780 (44%)
25-35	964 (39%)	692 (37%)	939 (38%)	308 (43%)	631 (36%)
>35	494 (20%)	355 (19%)	494 (20%)	151 (21%)	344 (20%)
Any maternal smoking in first trimester	544 (22%)	318 (17%)	519 (21%)	129 (18%)	390 (22%)
Maternal education					
< High school	222 (9%)	75 (4%)	198 (8%)	65 (9%)	133 (8%)
High school	939 (38%)	655 (35%)	915 (37%)	250 (35%)	664 (38%)
Some college	1064 (43%)	916 (49%)	1112 (45%)	323 (45%)	790 (45%)
>=College	247 (10%)	225 (12%)	247 (10%)	79 (11%)	168 (10%)

[1]Reported as n (%) unless otherwise specified.
Abbreviations: g, grams; SD, standard deviation.

Figure 3.
Example construction of Table 1 for a hypothetical cohort study with missing data.