ACT Research Program Proposals & Publications Committee: Guidelines for Manuscript Development[1]

These ACT writing guidelines should be applied to any manuscript or other scholarly work that arises from the use of ACT data. The guidelines are designed to assist authors in collaborating to efficiently develop high-quality publications that include:

- consistent descriptions of the ACT cohort and data resources of the study,
- uniform definitions of dementia endpoints and other variables of interest,
- suitable statistical and methodological approaches,
- appropriate acknowledgements of ACT funding sources, research volunteers and website

I. Guidance related to background information and descriptions of study population and data resources

All manuscripts should reference major key methods and other relevant ACT publications.

Researchers should search the ACT Research Program Publications Database to identify key publications and overlapping and/or complementary papers to cite related prior work. Overlap may include a similar analysis using a similar data set resulting in similar findings.

Researchers should describe the ACT Research Program including the Cohort and Data Resources in a consistent manner. Researchers are further advised to utilize information about the ACT Cohort and Data Repository located on the ACT Study website including,

- information about the ACT Cohort to inform the manuscript/presentation's description of the sample included in the study, as appropriate.
- information about the ACT Data Repository to inform the description of the data and methods in the manuscript/presentation, as appropriate.

II. General guidelines related to statistical methods

Two-sided p-values should be used. Point estimates with confidence intervals (CIs) are preferable to simply providing p-values.

Avoid interpreting results based upon statistical significance alone. Consider scientific context, plausibility, magnitude of effects, and clinical importance of observed differences.

In situations where results were consistent with 'no difference', describe whether results were indeterminate (e.g., wide confidence intervals, in need of further study, etc.), or were negative (clinically meaningful differences were ruled out).

Subgroup analyses should be clearly delineated as to whether they were pre-specified vs. post-hoc and address the possibility of excessive Type I error.

The statistical significance of differences in exposure-outcome associations between subgroups should be assessed by tests of the exposure x subgroup interaction terms. There may be limited power for testing interactions, and this should be addressed in the discussion.

When applicable, Kaplan-Meier curves should be presented as cumulative incidence rather than disease-free survival and should include a suitable amount of follow-up time.

[1] Adapted from the Women's Health Initiative, with permission.

For observational studies, plots of cumulative hazard ratios (HRs) over time may be more suitable than overall HRs because Cox regression models readily allow for time-dependency in HR models.

Survival analyses should carefully consider the primary time scale of interest (e.g., time-on-study, age, calendar time, etc.) and modeling implications. For example, a Cox regression model might use time-on-study as the time scale and adjust for (or stratify by) baseline age. Alternative approaches might use age as the time-scale but will need to properly account for left truncation (not everyone in ACT is under observation starting at age 65).

For manuscripts that consider many outcomes, nominal CIs and nominal p-values alone may be presented, but the text should address the possibility of excessive Type I error.

Consider presenting estimates of the exposure's effect in both absolute and relative terms so results are more comprehensive and interpretable. For example, when reporting hazard ratios, also report the number of events and incidence rates.

Longitudinal analyses should be considered if response data were collected at more than 1 time point. Common longitudinal methods include likelihood models (e.g., linear mixed effect [LME] models) and generalized estimating equations (GEEs) that account for within participant correlations over time.

Missing data and length of follow-up (if longitudinal analysis) should also be considered when selecting a method. GEE models assume that data is missing completely at random, which is often a problematic assumption. LME models make weaker assumptions regarding missing data. Modeling the missing data (or selection) mechanism and generating inverse probability of non-missingness (or selection) weights may be considered for incorporation into these methods for a more substantial missing data provision. This is especially relevant for analyses of the ACT autopsy sample.

III. Guidelines related to Race and Ethnicity Data

Race and Ethnicity are distinct socio-political constructs that are not rooted in biology. Ancestry and genetic admixture are not interchangeable with "race" or "ethnicity". Ethnicity is distinct from Race. Both should appear in ACT characteristics tables.

Individuals should be referred to by their self-identified race and ethnicity. Terms used to group race and ethnicities should be well conceptualized in the manuscript.

Authors should address the representativeness of the U.S. older adult population, per Census data, of the ACT cohort when interpreting analytic results.

In reporting of demographic data on race and ethnicity, ACT manuscripts should:

- state that ACT participants self-identified their race and ethnicity
- provide rationale for use of race as a key variable; if race is the primary exposure of interest or where analyses are stratified by race and/or ethnicity

In analyses by race and/or ethnicity, ACT manuscripts should:

- Comparisons between race or ethnic groups should be informed by research questions.
- Comparisons of race or ethnic groups to Non-Hispanic White participants is not required in ACT; this should only be done when supported by a research question
- Within group analyses should acknowledge the heterogeneity within racial and ethnic groups.

In interpretation & reporting of race and/or ethnicity data:

- Statistical power for race and ethnicity subgroup analyses should be sufficient to detect differences by that group. Authors should acknowledge that sample selection limits interpretation of findings to the

overall U.S. population or racial or ethnic subpopulations identified in the manuscript.

- Limitation: Race and ethnicity are defined and interpreted within a socio-political framework as a proxy for both historical and ongoing differences in advantages arising from racism in social determinants of health, such as education, income, resilience and stressful life events. Other structural factors may be important for the data interpretation of racially disparate outcomes but are not available in ACT.

IV. Acknowledgement of ACT

Researchers must include appropriate acknowledgements of ACT funding sources, research volunteers and the ACT website (if applicable) in publications and other scholarly works. Recommended acknowledgement text can be found in the Manuscript Acknowledgement Guide.

V. Authorship

The ACT Study follows recommendations for authorship issued by the International Committee of Medical Journal Editors (ICMJE)[2].

The underlying principle for these guidelines is that all individuals who meet the criteria for authorship should be included as authors and all that do not meet these criteria should not. Individuals who made significant contributions but who do not meet authorship criteria can and should, with their permission, be given credit in the Acknowledgments section. Notably, individuals contributing heavily to the writing of a manuscript but not sufficiently involved in other aspects of the project to warrant authorship should be named in the Acknowledgments section. Furthermore, decisions regarding authorship depend on contributions to a specific paper rather than contributions to a project or project team. This applies, for instance, to senior collaborators who may be responsible for securing funding or initiating a project but may not have made contributions sufficient to warrant authorship on all papers arising from the project. A member of a project team may appropriately be included as a co-author on some papers produced by a project but not included as a co-author on others.

ICMJE which specify that authorship credit is based on the following three criteria:

1) Substantial contributions to conception, design, or acquisition of data or analysis and interpretation of data, such as providing statistical expertise, obtaining funding, providing administrative, technical or material support, or supervision;
2) Drafting the article or revising it critically for important intellectual content; and
3) Final approval of the version to be published.

For authorship, conditions 1, 2, and 3 must all be met. Thus, acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

Authors should provide a description of what each contributed. All others who contributed to the work and are named in the Acknowledgments should have their work described there.

Increasingly, authorship is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix.

[2] International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Updated May 2000 (http://www.icmje.org)

The order of authorship on the byline should be a joint decision of the coauthors. Authors should be prepared to explain the order in which authors are listed. Senior or last author should not necessarily be assigned to the PI of a project but should be determined by contributions to the specific paper.

Final authorship order should be determined based on the relative contributions of each co-author. Authorship order can be changed at any point during the writing process based on the actual relative contributions of the coauthors. Discussion with the senior author is an appropriate way to resolve concerns about order.

VI. Acknowledgments of contributors who are not authors

List all contributors who do not meet the criteria for authorship, such as a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described, for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."

Because readers may infer their endorsement of the data and conclusions, all persons must have given written permission to be acknowledged.

VII. Authorship responsibilities as relates to manuscript submission

Using JAMA Authorship Responsibility, Criteria and Contributions, the following must hold for any submission:

- The manuscript represents valid work and that neither this manuscript nor one with substantially similar content under similar authorship has been published or is being considered for publication elsewhere;
- If requested by the editors, authors will provide data or will cooperate fully in obtaining and providing data on which the manuscript is based for examination by the editors or their assignees; and
- For papers with more than one author, the corresponding author (lead) is to serve as the primary correspondent with the editorial office, to review the edited typescript and proof, and to make decisions regarding the release of information in the manuscript to the media, federal agencies, or both.