Section 8-
Reporting Results

Karen Pieper and Gina Petroni

- Participant discussion of 9Jan97 NEJM articles using the checklist
- Review Checklist for Writing Manuscript
- *Induced Abortion and the Risk of Breast Cancer.* Mads M, Wolfhart J, Olsen JH, Frisch M, Westergaard T, Helweg-Larsen K., Andersen PK. Vol. 336, No.2, pp 81-85.
- *Medical Care Costs and Quality of Life after Randomization to Coronary Angioplasty or Coronary Bypass Surgery.* Hlatkey MA, Rogers WJ, Johnstone I, Boothroyd D, Brooks MM, Pitt B, Reeder G, Ryan T, Smith H, Whitlow P, Wiens R, Mark DB, Vol 336, No.2, pp. 92-99.
- *An Outbreak of Gastroenteritis and Fever Due to Listeria Monocytogenes in Milk.* Dalton CB, Austin CC, Sobel J, Hayes PS, Bibb WF, Graves LM, Swaminathan B, Proctor ME, Griffin PM, Vol 336, No.2, pp. 100-105.

Checklist for Manuscripts

_____**Title Page**
_____Title: short, descriptive, catchy, jargon-free
_____Authors: full names and degrees
_____Institutional affiliation for all authors
_____Funding: all sources of support for the research, including grant numbers
_____ Address for correspondence and reprints, including telephone and fax #s, e-mail

_____ **Structured Abstract**
_____ Followed specifications of the target publication: format and length
_____ May need Condensed Abstract of ~100 words

_____ **Introduction**
_____ Identified the problem
_____ Described the problem: scope, history, prior solutions
_____ Stated the primary and secondary hypotheses of your study

_____**Methods**

_____Detailed enough so that another can reproduce the results

_____Patients: inclusion/exclusion criteria,
informed consent,
IRB approval
Account for all registered patients
Comparability of treatment groups in relevant patient characteristics

_____Sites: any criteria (volume of operations, size etc.)

_____Study Design: abbreviated if details have already been published.
Otherwise, identify:
blinding method if blinded,
randomized
random allocation of pts,
details of randomization design
generation of random assignment,
retrospective,
consecutive, etc.

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_____Treatment arms and ancillary treatments or procedures

Patient compliance

Physician compliance

Summary of actual vs planned treatment

Proportion of pts who completed treatment if longterm

_____Toxicity, side effects and complications

_____Important dates listed (study open, last pt entered, last time of f.u.

_____Monitoring: Planned formal monitoring of the data, interim analyses

_____Sample size: Planned and actual. Discussion if different. Statement of power or precision if a negative study.

_____ Endpoints: Primary and secondary. Identified other endpoints. Gave definitions of “soft” endpoints like angina, indices such as for bleeding, and composites.

_____ Follow-up,

Accounting of pts were lost to fu

Descriptions of how drop-outs are treated in analyses

Description of censoring

Some measure(s) of the duration of f.u.

_____Identified any core laboratories.

_____ Statistical Analyses: Indicated how continuous and categorical variables were summarized. Identified all specific comparisons made, method of analysis for each comparison, and criteria for significance. Detail any modeling that was done (univariable, multivariable). Discuss all assumptions that are relevant for the tests used and show that they are justified. Give enough detail to enable a reader to reproduce the results if the data were available.

_____ **Results**

_____ Disposition of patients: numbers enrolled, excluded, lost to follow-up if not given above

_____ Baseline demographic and relevant clinical characteristics (usually a table), discussed major (clinical or statistical) similarities and differences

_____ Primary endpoint analyses: presented positive and important negative findings, used tables/figures to display data efficiently

_____Secondary and other endpoint analyses

Discussion

- _____ Identified the primary finding, validation of primary hypothesis?
- _____ Discussed how this adds to previous knowledge- similarity or contrast
- _____ Discussed reasons (methodological, clinical, pathophysiological) for different results compared with prior studies (or why they are similar)
- _____ Discussed secondary findings
- _____ Discussed limitations of the study
- _____ Discussed additional analyses that would be helpful
- _____ One- or two-sentence summary

References

- _____ Avoided using abstracts, personal communications, unpublished data

Figure Legends

- _____ Identified the data that are being displayed (axes, units)
- _____ Defined all symbols and abbreviations
- _____ Define chart so clearly that all data presented can be understood

Tables

- _____ Gave each a short title
- _____ Defined all symbols and abbreviations
- _____ Presented only data relevant to the analyses