

**Faculty Information Exchange**  
**February 13, 2023**

**Publishing in academic journals**

***Reporting guidelines  
and peer review***

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# Reporting Guidelines

## Principles and background

- Scientific research should be reported so as to allow reproduction/replication of the study
- Readers can only judge quality and weigh inferences and application from what is reported
- Reporting guidelines do not prescribe design or analysis, but should help to improve them
- Poor reporting precludes inclusion in systematic reviews and meta-analyses

# Replication and reproducibility

**nature** International weekly journal of science

Home | News & Comment | Research | Careers & Jobs | Current Issue | Archive | Audio

Archive | Volume 533 | Issue 7604 | News Feature | Article

NATURE | NEWS FEATURE

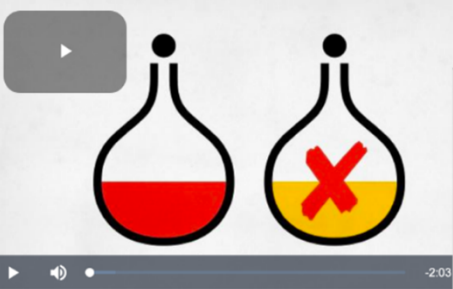
## 1,500 scientists lift the lid on reproducibility

Survey sheds light on the 'crisis' rocking research.

**Monya Baker**

25 May 2016 | Corrected: 28 July 2016

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PLOS MEDICINE

BROWSE PUBLISH ABOUT SEARCH

OPEN ACCESS

## Why Most Published Research Findings Are False

John P. A. Ioannidis

Published: August 30, 2005 • <https://doi.org/10.1371/journal.pmed.0020124>

68,836 Save 3,131 Citation

2,794,862 View 10,482 Share

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## Rein in the four horsemen of irreproducibility

Dorothy Bishop describes how threats to reproducibility, recognized but unaddressed for decades, might finally be brought under control.

Volume 73, 2019 | Vol 72, 2018 | Vol 71, 2017 | Vol 70, 2016

Supplement 1 | Issue 1

## Statistical Inference in the 21st Century: A World Beyond $p < 0.05$

Editorial

Moving to a World Beyond " $p < 0.05$ "

Ronald L. Wasserstein, Allen L. Schirm & Nicole A. Lazar

Page: 1-19

66892 Views

7 CrossRef citations

# Why is reporting often incomplete or poor?

- Lack of clarity at the planning or design stage
- Lack of awareness of correct methods
- Lack of perspective or awareness of reporting
- Preference for significant differences
- Wish for novelty
- Pressure to publish

# Common substantial issues

- Lack of (description of ):
  - Definition of primary outcome(s)
    - Consistent with the (stated) objective and hypothesis
  - Basis of the sample size
  - Method of randomization
  - Blinding of evaluators
  - Nature of grouping of subjects; contextual data
  - Statistical methods
    - Inclusion and exclusion criteria, especially for (unplanned) subgroup analyses
    - Losses to follow-up
    - Accounting for experimental unit and clustering
  - Candid and complete discussion of strengths and limitations

# Methods

- Sufficient detail that others can replicate your work
  - Validation of assays in the bovine
  - Limits of quantification
  - Assay CV's
- Can use Supplementary data for details
- "Proc Mixed in SAS" is not a method!
- Make clear that correct method is used for the data
  - Binary outcomes
  - Time to event
- Specify the experimental unit
- How you accounted for repeated measures and clustering

# META-RESEARCH

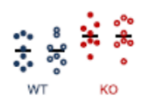
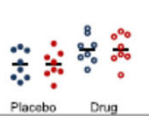
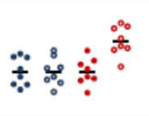
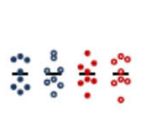
## Why we need to report more than 'Data were Analyzed by t-tests or ANOVA'

**Abstract** Transparent reporting is essential for the critical evaluation of statistical methods for studies in the biomedical sciences is often limited. The quality of reporting for two statistical tests, t-tests and ANOVA, for papers published in June 2017. Of the 328 original research articles examined, 277 (84.5%) both. However, papers in our sample were routinely missing essential information: 95% of the papers that used ANOVA did not contain the information that ANOVA was performed, and 26.7% of papers did not specify what post-hoc tests were omitted the information needed to verify ANOVA results. Essential information was omitted in many papers. We conclude by discussing measures that could be taken to improve reporting.

DOI: <https://doi.org/10.7554/eLife.36163.001>

TRACEY L WEISSGERBER\*, OSCAR GARCIA-VALENCIA, VICTORIA M MILIC† AND STACEY J WINHAM†

[doi.org/10.7554/eLife.36163.001](https://doi.org/10.7554/eLife.36163.001)

Type of Effect	Sums of Squares	
	1-way ANOVA	2-way ANOVA
The sums of squares tell us what proportion of the total variability in the data is unexplained vs. explained by different factors in the model.	All variability explained by the model is lumped into one factor (Group) even though the study design has 2 factors. We cannot determine how much of the variability is explained by each factor, or by an interaction between factors.	The variability explained by the model is divided into two factors and an optional interaction term. We can determine which factor, or combination of factors, explains differences between groups.
<b>Main effect of Strain</b> 	Group: ? 8.0 Residual: 23.7 Total: 31.7	Strain ( WT vs. KO ): 8.0 Treatment: <0.1 Strain x Treatment: <0.1 Residual: 23.7 Total: 31.7
<b>Main effect of Treatment</b> 	Group: ? 8.0 Residual: 23.7 Total: 31.7	Strain: <0.1 Treatment ( ● vs. ○ ): 8.0 Strain x Treatment: <0.1 Residual: 23.7 Total: 31.7
<b>Interaction</b> 	Group: ? 24.1 Residual: 23.7 Total: 47.8	Strain: 8.0 Treatment: 8.0 Strain x Treatment: 8.1 Residual: 23.7 Total: 47.8
<b>No main effects, no interaction</b> 	Group: ? <0.1 Residual: 23.7 Total: 23.7	Strain: <0.1 Treatment: <0.1 Strain x Treatment: <0.1 Residual: 23.7 Total: 23.7

Variability explained by the model

Unexplained variability

Total variability

Sums of squares for treatment & strain are not informative with an interaction. Post-hoc tests are needed to understand differences.

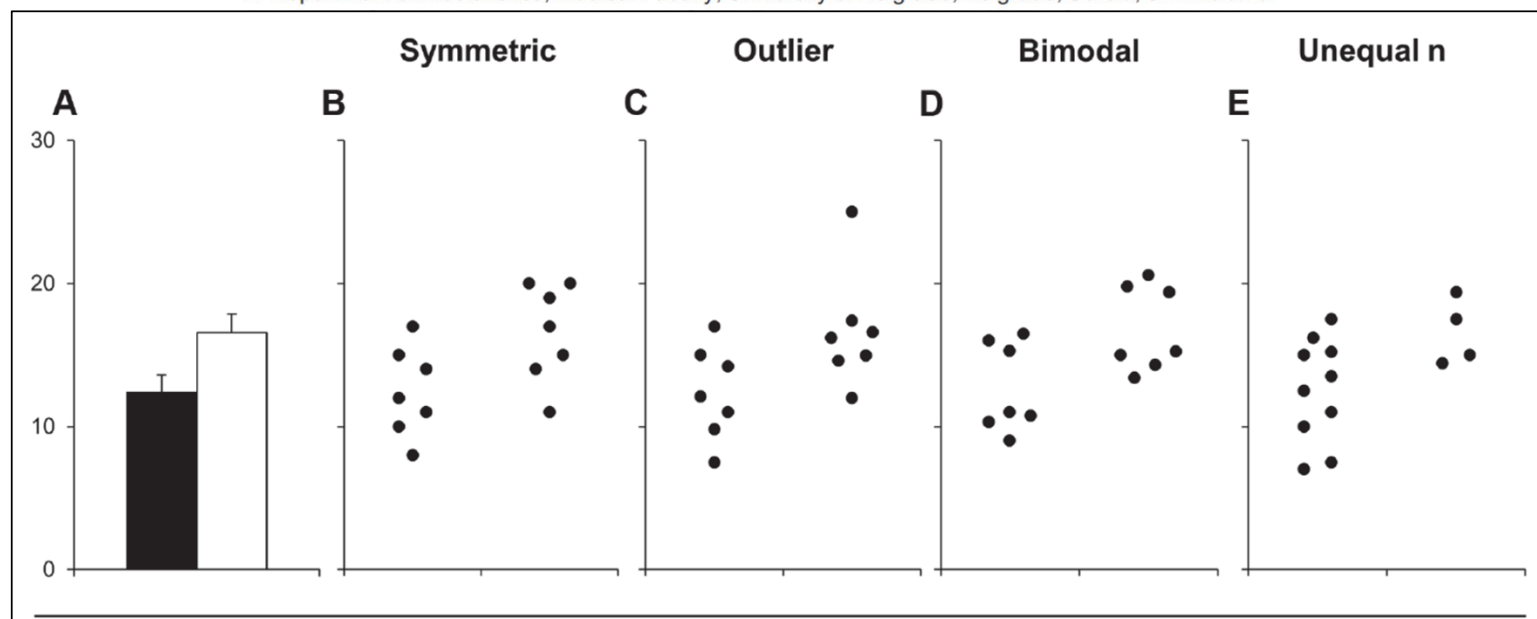
PERSPECTIVE

# Beyond Bar and Line Graphs: Time for a New Data Presentation Paradigm

Tracey L. Weissgerber<sup>1\*</sup>, Natasa M. Milic<sup>1,2</sup>, Stacey J. Winham<sup>3</sup>, Vesna D. Garovic<sup>1</sup>

<sup>1</sup> Division of Nephrology & Hypertension, Mayo Clinic, Rochester, Minnesota, United States of America,

<sup>2</sup> Department of Biostatistics, Medical Faculty, University of Belgrade, Belgrade, Serbia, <sup>3</sup> Division of





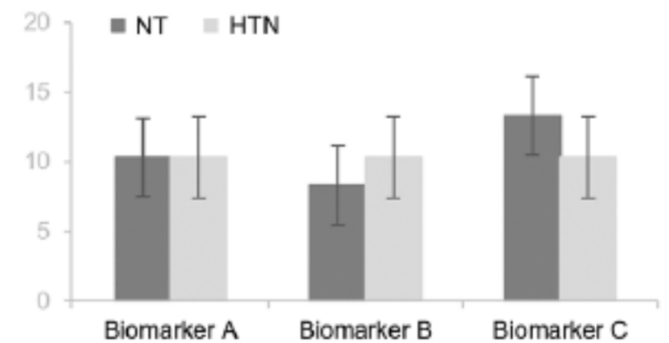
# Reveal, Don't Conceal

Transforming Data Visualization to Improve Transparency

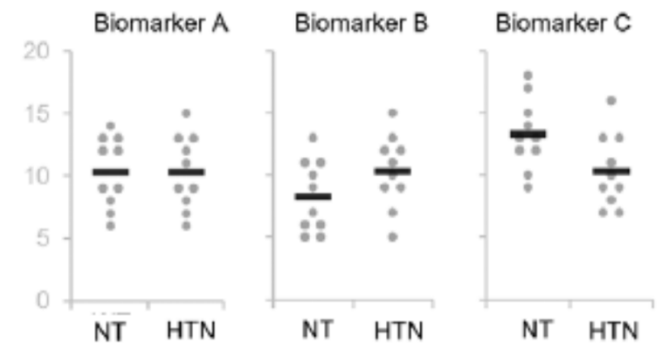
DOI: 10.1161/CIRCULATIONAHA.118.037777

**Experimental goal:** Compare normotensive (NT) vs. hypertensive (HTN) patients  
**Statistical analysis:** t-tests were used to compare values for each dependent variable (biomarker A, B and C)

**A Sending mixed messages**  
 Figure structure erroneously suggests that authors also intended to compare biomarkers A, B and C



**B Clear communication**  
 Figure structure matches study design & analysis, shows that the authors did not intend to compare biomarkers



# Results

- Text should highlight and point to tables and figures, but not repeat them
- Pay attention to significant digits – how precise are your measurements?
- Use solid colours in Figures
- Every outcome requires a measure of variation
- Always report absolute values (mean, median, times) with relative measures of effects (OR, RR, HR)
- Report actual P values to 2 decimal places

# Discussion

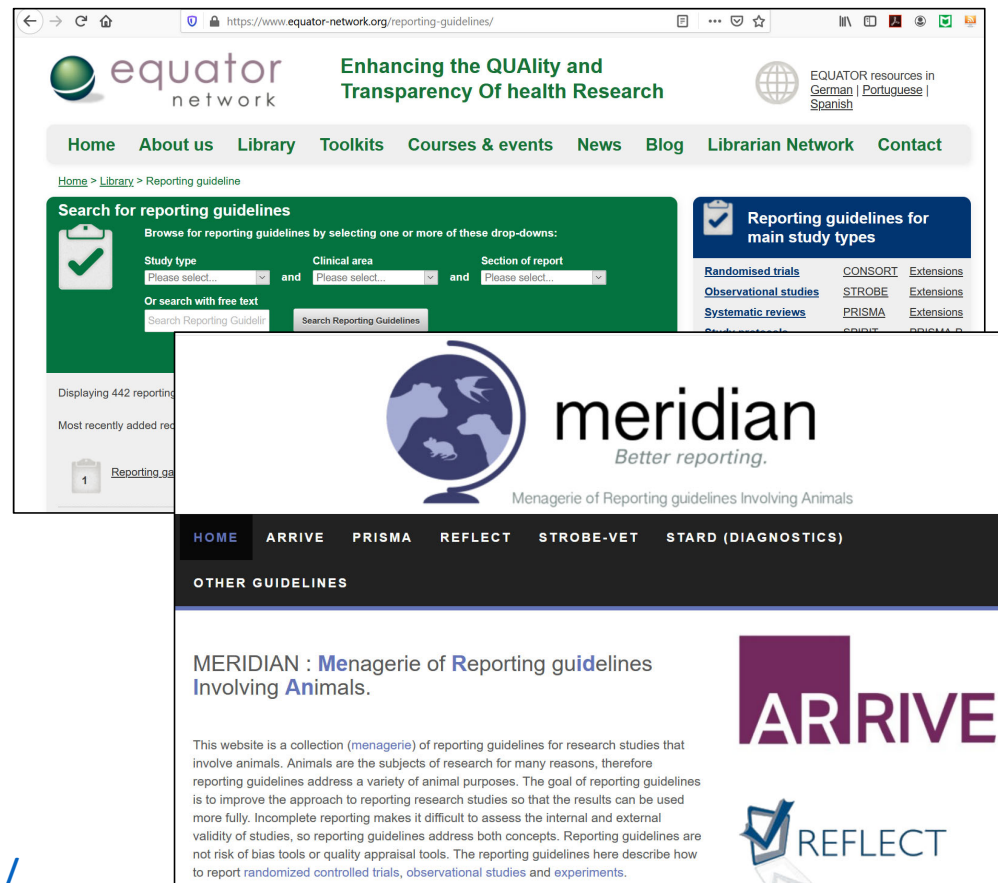
- Start with statement of the main finding of the study
  - Refer to objectives
- What is new or different here? In any case, why is it important?
- Focus on the designed objectives
- Ensure reference to relevant, recent literature
- Explicitly discuss limitations

# Why use reporting guidelines?

- Adoption and use of CONSORT was associated with improved quality of reporting of trials
- Transparency is stronger than trust
  - Is incomplete reporting just sloppy or selective?

<https://www.equator-network.org/>

<https://meridian.cvm.iastate.edu/>





# Completeness of reporting of experiments: REFLECTing on a year of animal trials in the *Journal of Dairy Science*

CB Winder<sup>1</sup>, KJ Churchill<sup>2</sup>, JM Sargeant<sup>1,2</sup>, SJ LeBlanc<sup>1</sup>, AM O'Connor<sup>3</sup>, DL Renaud<sup>1</sup>

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J. Dairy Sci. 102:4759–4771  
<https://doi.org/10.3168/jds.2018-15797>  
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## ***Invited review: Completeness of reporting of experiments: REFLECTing on a year of animal trials in the *Journal of Dairy Science****

**Charlotte B. Winder,<sup>1\*</sup> Kathryn J. Churchill,<sup>2</sup> Jan M. Sargeant,<sup>1,2</sup> Stephen J. LeBlanc,<sup>1</sup> Annette M. O'Connor,<sup>3</sup> and David L. Renaud<sup>1</sup>**

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<sup>3</sup>Department of Veterinary Diagnostic and Production Animal Medicine, College of Veterinary Medicine, Iowa State University, Ames 50011-3619





**Checklist for REFLECT statement: Reporting guidelines For randomized control trials in livestock and food safety.** Bold text are modifications from the CONSORT statement description (Altman DG et al. Ann Intern Med 2001; 134(8):663-694).

Paper section and topic	Item	Descriptor of REFLECT statement item	Reported on Page #
Title & Abstract	1	How <b>study units</b> were allocated to interventions ( eg, "random allocation," "randomized," or "randomly assigned"). <b>Clearly state whether the outcome was the result of natural exposure or was the result of a deliberate agent challenge.</b>	
Introduction Background	2	Scientific background and explanation of rationale.	
Methods Participants	3	Eligibility criteria <b>for owner/managers and study units at each level of the organizational structure</b> , and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group, <b>the level at which the intervention was allocated</b> , and how and when interventions were actually administered.	
	4b	<b>Precise details of the agent and the challenge model, if a challenge study design was used.</b>	
Objectives	5	Specific objectives and hypotheses. <b>Clearly state primary and secondary objectives (if applicable).</b>	
Outcomes	6	Clearly defined primary and secondary outcome measures and the levels at which they were measured, and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. <b>Sample-size considerations should include sample-size determinations at each level of the organizational structure and the assumptions used to account for any non-independence among groups or individuals within a group.</b>	
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence <b>at the relevant level of the organizational structure</b> , including details of any restrictions (eg, blocking, stratification)	
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence <b>at the relevant level of the organizational structure</b> , (eg, numbered containers <b>or central telephone</b> ), clarifying whether the sequence was concealed until interventions were assigned.	

Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled <b>study units</b> , and who assigned <b>study units</b> to their groups <b>at the relevant level of the organizational structure</b> .
Blinding (masking)	11	Whether or not <b>participants</b> those administering the interventions, <b>caregivers</b> and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated. <b>Provide justification for not using blinding if it was not used.</b>
Statistical methods	12	Statistical methods used to compare groups for all outcome(s); Clearly state the level of statistical analysis <b>and methods used to account for the organizational structure, where applicable</b> ; methods for additional analyses, such as subgroup analyses and adjusted analyses.
Results Study flow	13	Flow <b>of study units</b> through each stage <b>for each level of the organization structure of the study</b> (a diagram is strongly recommended). Specifically, for each group, report the numbers of <b>study units</b> randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.
Recruitment	14	Dates defining the periods of recruitment and follow-up.
Baseline data	15	Baseline demographic and clinical characteristics of each group, <b>explicitly providing information for each relevant level of the organizational structure. Data should be reported in such a way that secondary analysis, such as risk assessment, is possible.</b>
Numbers analyzed	16	Number <b>of study units</b> (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, <b>accounting for each relevant level of the organizational structure</b> , and the estimated effect size and its precision (e.g., 95% confidence interval)
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
Adverse events	19	All important adverse events or side effects in each intervention group.
Discussion Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes. <b>Where relevant, a discussion of herd immunity should be included. If applicable, a discussion of the relevance of the disease challenge should be included.</b>
Generalizability	21	Generalizability (external validity) of the trial findings.
Overall evidence	22	General interpretation of the results in the context of current evidence.

# Methods

Sample of 120 papers published in JDS in 2017

- REFLECT items without subjective interpretation (excluded 2,20,21,22)
- Yes/no questions on presence or absence of information<sup>1</sup>
- Some questions subdivided to gain more information
  - *e.g.* randomization
- Additional question on washout period for cross-over trials
- Assessed by two authors, independently in duplicate
- Conflicts resolved by consensus

<sup>1</sup>Totton *et al.*, 2018



# Results

- Description of study settings: 126/137 (92%)
- Precise details of intended interventions: 134/137 (98%)
- Study objectives: 127/137 (93%)
- Level of outcome measurement: 127/137 (93%)
- Description of statistical methods: 135/137 (99%)

# Results

- Stated hypothesis: 97/137 (71%)
- Study unit eligibility: 75/137 (55%)
- Random allocation to treatment group: 104/137 (76%)
- Blocking factors reported: 51/104 (49%)
- Denominator for each group in analysis: 78/137 (57%)
- Summary results presented for each group: 89/137 (65%)

# Results

- Farm level eligibility: 6/137 (4%)
- Sample size justification provided: 22/137 (16%)
- Method to generate random allocation: 7/104 (7%)
- Allocation concealment: 3/104 (3%)
- Blinding of caregiver and/or outcome assessor: 17/137 (12%)
- Multiplicity of analyses: 1/137 (1%)

# Responding to reviewers

- Be brief
- Don't thank them for every comment
- Accept that you may have to re-analyze some things
- Put important information in the text, not just the response
- Make it easy for them
  - Correct line numbers
- Choose your battles

Dr. Glaucomflecken on academic publishing :

- <https://www.youtube.com/watch?v=8F9gzQz1Pms>
- [https://www.youtube.com/watch?v=ukAkG6c\\_N4M](https://www.youtube.com/watch?v=ukAkG6c_N4M)