What’s New in AMA Style?

Cheryl Iverson, Stacy Christiansen, and Annette Flanagin

AMA Manual of Style Committee Members

Council of Science Editors Annual Meeting, May 6, 2019
Presenter disclosures

• We are paid employees (SC, AF) or contractors (CI) for the American Medical Association, which owns the *AMA Manual of Style*.

• SC and AF are unpaid members of the Council of Science Editors short course faculty. SC serves on several CSE committees, also unpaid.

• AF is an unpaid board member of STM: International Association of Scientific, Technical and Medical Publishers

• Other *AMA Manual of Style* Committee Members include Lauren Fischer, Phil Fontanarosa, Tracy Frey, Brenda Gregoline, Edward Livingston, and Connie Manno (all editorial staff of the JAMA Network).
Updates to be reviewed in this session

- The stylebook revision process
- Manuscript Preparation items
- References: changes and updated examples
- Tables and figures: style and formatting changes
- Grammar, Punctuation, and Abbreviations
- Preferred and Correct Usage: new terms and usage examples
- Nomenclature: drugs and genetics
- Units of Measure and Numbers

- Statistics
- Mathematical Composition
- Typography, tagging, display
- Resources and Publishing Glossary
- Corrections and pervasive errors
- Updates on authorship policies
- Intellectual property: access and copyright
- Data sharing statement
- Ethical review of research and informed consent
- How to access stylebook updates
Manuscript preparation: e words and web words

In line with contemporary usage, we have removed the hyphen in email and now lowercase internet and website.

- In text: “Send me an email.” In titles: “How Physicians Use Email”
- The hyphen is retained in other e- compounds (eg, e-cigarette, e-book).
- In titles, capping of words that follow e- will be on the first letter of the word that follows: “State Restrictions on e-Cigarette Use”
- website, webcam, webcast, webpage, the web
Manuscript preparation: death dagger

Discontinuation of the death dagger

The convention of using a dagger (†) next to a name in an article byline, connected to a footnote to indicate a deceased author, has been discontinued.

If desired, this information can be included in the Acknowledgment section at the end of the article.

For example:

Additional Information: Coauthor John Doe, MD, died January 30, 2018.
References: publisher location

Publisher location for books and reports no longer required

In the 11th edition, AMA style will no longer recommend including the publisher’s location for several reasons:

• Many publishers have more than 1 location and determining which location is appropriate to include can be challenging
• Location can be difficult to determine if looking at an online resource (eg, an e-book)
• Publisher location is not a necessary piece of information in retrieving the reference.
Publishers in book citations

Formerly:


Future style:

DOIs in reference list

When a DOI is included for journal references, no period follows

- The ability to easily and accurately copy and paste DOIs is important.
- Because of this, a period should not be included after the DOI; the risk of the period becoming a part of the DOI itself is too great and would create problems with linking.
- Online linking is one of the key reasons to have a DOI.

URLs in reference list

In reference lists, the URL will be the last item, following dates posted/updated/accessed. No period follows it.

This style will mirror current formatting for citations with a DOI.

Social media references

**Facebook:** Mayo Clinic Healthy Living Facebook page. Accessed February 10, 2016. [https://www.facebook.com/mayoclinichealthylivingprogram/](https://www.facebook.com/mayoclinichealthylivingprogram/)

**Twitter:** @AMAManual. The human immunodeficiency virus is widely known by its abbreviation HIV, to the extent that AMA style no longer requires the expansion (especially true in the construction “HIV/AIDS”). Posted October 12, 2018. Accessed October 27, 2018. [https://twitter.com/AMAManual/status/1050763170825076737](https://twitter.com/AMAManual/status/1050763170825076737)

Preprints and digital references

References chapter will include citation guidelines for **preprints**, **apps**, **podcasts**, **databases**, and much more


Tables and figures: style and formatting update

Change to sentence-style capitalization in all elements of tables and figures (axis labels, column headings)

Current style (cap all major words in column headings):

<table>
<thead>
<tr>
<th>Table 7. Percent Change in Age-Standardized Summary Exposure Values for the Leading 10 Risk Factors for the United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>% (95% Uncertainty Interval)</td>
</tr>
<tr>
<td>High Body-Mass Index</td>
</tr>
<tr>
<td>Smoking</td>
</tr>
<tr>
<td>High Fasting Plasma Glucose</td>
</tr>
<tr>
<td>High Systolic Blood Pressure</td>
</tr>
<tr>
<td>Drug Use</td>
</tr>
<tr>
<td>Alcohol Use</td>
</tr>
<tr>
<td>United States</td>
</tr>
<tr>
<td>53.2 (41.5 to 67.2)</td>
</tr>
<tr>
<td>-42.8 (-47.1 to -37.2)</td>
</tr>
<tr>
<td>76.0 (44.4 to 144.2)</td>
</tr>
<tr>
<td>-13.3 (-13.9 to -12.6)</td>
</tr>
<tr>
<td>10.1 (7.5 to 12.8)</td>
</tr>
<tr>
<td>6.0 (-24.2 to 42.1)</td>
</tr>
<tr>
<td>Alabama</td>
</tr>
<tr>
<td>66.7 (48.0 to 94.3)</td>
</tr>
<tr>
<td>-24.3 (-33.0 to -15.2)</td>
</tr>
<tr>
<td>123.2 (53.3 to 289.8)</td>
</tr>
<tr>
<td>-12.7 (-15.8 to -9.7)</td>
</tr>
<tr>
<td>9.1 (5.6 to 11.8)</td>
</tr>
<tr>
<td>4.7 (-51.0 to 99.5)</td>
</tr>
<tr>
<td>Alaska</td>
</tr>
<tr>
<td>32.2 (19.0 to 49.3)</td>
</tr>
<tr>
<td>-32.0 (-41.2 to -22.9)</td>
</tr>
<tr>
<td>36.4 (7.8 to 101.6)</td>
</tr>
<tr>
<td>-12.0 (-14.8 to -9.1)</td>
</tr>
<tr>
<td>39.2 (26.5 to 53.5)</td>
</tr>
<tr>
<td>12.0 (-50.8 to 139.6)</td>
</tr>
<tr>
<td>Arizona</td>
</tr>
<tr>
<td>60.7 (40.6 to 88.9)</td>
</tr>
<tr>
<td>-48.4 (-54.5 to -40.8)</td>
</tr>
<tr>
<td>61.7 (22.0 to 164.0)</td>
</tr>
<tr>
<td>-12.6 (-15.4 to -9.6)</td>
</tr>
<tr>
<td>6.5 (3.2 to 9.3)</td>
</tr>
<tr>
<td>7.5 (-48.7 to 120.4)</td>
</tr>
<tr>
<td>Arkansas</td>
</tr>
<tr>
<td>56.0 (36.8 to 80.3)</td>
</tr>
<tr>
<td>-27.3 (-34.6 to -19.4)</td>
</tr>
<tr>
<td>78.6 (30.1 to 205.2)</td>
</tr>
<tr>
<td>-12.7 (-15.7 to -9.7)</td>
</tr>
<tr>
<td>-0.9 (-4.3 to 1.8)</td>
</tr>
<tr>
<td>3.1 (-49.8 to 103.7)</td>
</tr>
<tr>
<td>California</td>
</tr>
<tr>
<td>54.4 (36.6 to 75.6)</td>
</tr>
<tr>
<td>-60.5 (-67.2 to -51.3)</td>
</tr>
<tr>
<td>42.6 (16.3 to 117.8)</td>
</tr>
<tr>
<td>-12.9 (-15.8 to -9.7)</td>
</tr>
<tr>
<td>11.3 (8.4 to 14.5)</td>
</tr>
<tr>
<td>10.6 (-43.1 to 124.6)</td>
</tr>
</tbody>
</table>
Tables and figures: style and formatting update

Future style: all elements in sentence style (reduces confusion about which style to use where, makes long phrases easier to read)

And – left alignment of all cells

<table>
<thead>
<tr>
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</thead>
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</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
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<td>(41.5 to 67.2)</td>
</tr>
<tr>
<td>Alabama</td>
</tr>
<tr>
<td>(48.0 to 94.3)</td>
</tr>
<tr>
<td>Alaska</td>
</tr>
<tr>
<td>(19.0 to 49.3)</td>
</tr>
<tr>
<td>Arizona</td>
</tr>
<tr>
<td>(40.6 to 88.9)</td>
</tr>
<tr>
<td>Arkansas</td>
</tr>
<tr>
<td>(36.8 to 80.3)</td>
</tr>
<tr>
<td>California</td>
</tr>
<tr>
<td>(36.6 to 75.6)</td>
</tr>
</tbody>
</table>
Sentence-style caps in figures

• Current style

• Sentence style
Grammar update: singular “they”

*AMA Manual of Style* will join other resources, such as *The Chicago Manual of Style* and *AP Stylebook*, in permitting use of *they* as a singular pronoun when rewriting the sentence as plural would be awkward or unclear. [Note: rewording usually is possible and preferable.]

“Authors are responsible for the accuracy and completeness of their references.”

“Every patient should take their medication.” Could be reworded “Patients should take their medication.”

This construction can be useful in medical articles in which patient identifiability is a concern (eg, removal of gender-specific pronouns).

“The patient was adamant that they were not taking illicit substances.”
Grammar for social media

Scientific articles often have a life beyond their formal full-text publication, including social media such as Twitter and Facebook. Because these posts have strict space limits (Twitter allows just 280 characters) or expectations of brevity from followers, it is usually not possible, or even desirable, to strictly adhere to grammar, punctuation, and usage norms. However, some standards are necessary to ensure clarity.
Grammar for social media

In blogs and social media posts about scientific content:

• Use proper capitalization; capital letters don’t take up more characters than lowercase.

• Use basic punctuation to help ensure clarity.

• Avoid texting jargon, such as “U” for “you” or “L8” for “late”; these abbreviations are too colloquial (even, in some cases, regional) and may not be widely understood.

• Contractions are fine, as are easily recognized symbols such as &, <, and =.
Punctuation: when not to use hyphens

Expanded list of nonhyphenated terms

- Do not hyphenate modifiers in which a letter or number is the second element.
  - type 1 diabetes
  - phase 2 study

- Some combinations of words are commonly read as a unit.
  - amino acid levels
  - bone marrow biopsy
  - deep venous thrombosis
  - health care system
  - lower extremity amputation
  - medical school students
  - open access journal
Abbreviations: new entries

New abbreviations added

ACEI  angiotensin-converting enzyme inhibitor
ACL  anterior cruciate ligament
CKD  chronic kidney disease
GWAS  genome-wide association study
LGBTQ  lesbian, gay, bisexual, transgender, and queer/questioning
MERS  Middle East respiratory syndrome
OUD  opioid use disorder
SNV  single-nucleotide variant
Abbreviations: fellowships removed from bylines

Omission of all fellowship designations

- Fellowship designations are generally not listed in bylines or elsewhere. These can be difficult to police (in current style, what qualifies for inclusion?). Straightforward rules keep things fair, simpler for editors.

- FRCP, FRCPC, etc, have been removed from the list of degrees published with author names

- Emphasis is on academic degrees. Honorary degrees and other awards (eg, knighthood) are not included.
Addition of socioeconomic status

- **11.12.5 Socioeconomic Status.**—Avoid labeling people with their socioeconomic status, such as *the poor* or *the unemployed*. Instead, terms such as *low income* and *no income* are preferred.

- **low-income, limited-income, resource-limited, resource-poor, transitional** terms added

- Use of the terms *first world/third world* and *developed/developing* are not recommended as descriptors when comparing countries or regions.
Usage: more terms

Addition of terminology on addiction

- Avoid use of “alcoholic,” “addict,” “user,” and “abuser” — replace with “she was addicted,” “people with opiate addiction,” “he abused alcohol,” “alcohol misuse disorder”

New additions to correct and preferred usage list

- nauseous, nauseated
- foreign-born — replace with specifics, eg, “non-US born”
- elicit, illicit, solicit
- alternative, alternate
Spelling and spacing preferences

Spelling and spacing variations added to Correct and Preferred Usage chapter.

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Avoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>health care</td>
<td>healthcare, health-care</td>
</tr>
<tr>
<td>data set</td>
<td>dataset</td>
</tr>
<tr>
<td>email</td>
<td>e-mail, Email (unless in title)</td>
</tr>
<tr>
<td>website</td>
<td>Web site, Website</td>
</tr>
</tbody>
</table>
Nomenclature: drugs

Drugs: we no longer include manufacturer location

- In section 15.5 (page 583 in the print), Equipment, Devices, and Reagents, we no longer require the inclusion of the location of the manufacturer.

- This is so easy to look up online, should anyone desire more detail, that we believe it is not necessary to continue this.

  “The 9-valent HPV vaccine (Gardasil 9, Merck & Co) was administered to 5 vaccination cohorts.”

  “The active medication was 1 mL of triamcinolone (purchased from Bristol-Myers Squibb), 40 mg/mL, for injection.”
Nomenclature: genetics

Genetics: Discourage use of aliases/nicknames for genes and proteins

<table>
<thead>
<tr>
<th>Gene symbol</th>
<th>Gene description</th>
<th>Acceptable expression</th>
</tr>
</thead>
<tbody>
<tr>
<td>TP53</td>
<td>tumor protein p53 (Li-Fraumeni syndrome) gene</td>
<td>The <em>TP53</em> gene (p53 is the alias; the official term is preferred to the alias)</td>
</tr>
</tbody>
</table>

May be necessary to “dual report” for aliases well-entrenched in use: “ERBB2 (previously HER2/neu)”
Nomenclature: genetics

The Human Genome Variation Society recommends avoiding the terms *mutation* and *polymorphism*, preferring instead the terms *sequence variant, sequence variation, alteration,* or *allelic variant*.

In view of this recommendation, single-nucleotide variation (SNV) is now more frequently used instead of SNP (single-nucleotide polymorphism) and may become standard.

To aid readers’ understanding during this transition, at first mention SNV may be used, with SNP in parentheses:

“…SNV (formerly SNP)…”
Units of measure: currencies

Currencies will be updated, including African denominations

- Ethiopian birr (ብር)
- Ghana cedi (GH₵)
- Malawi kwacha (MK)
- Nigeria naira (₦)
- Uganda shilling (USh)
- Zimbabwe dollar ($)
Units of measure: spacing in temperature

Per SI convention, we will no longer close up degree symbols in temperature but use a space after the number:

**Preferred**

- temperature of 37.5 °C

**Avoid**

- 37.5° C or 37.5°C
In the list of abbreviations (**Section 14.11**, page 504 in the print), an asterisk was added after CI to indicate that this abbreviation no longer needs to be expanded.

- “Low-quality evidence has shown that risedronate reduces the risk of fragility fractures (hazard ratio, 0.27; 95% CI, 0.09-0.83; \( P = .02 \)).”
- “The primary analysis followed a modified intention-to-treat principle and used a 1-sided 95% CI for noninferiority.”
Statistics: terms updated

The terms *multivariable* and *multivariate* are not synonymous, as the entries in the current Glossary suggest (Section 20.9, page 881).

*Multivariable* refers to multiple independent variables for a single outcome (dependent variable).

*Multivariate* refers to 1 or more independent variables for multiple outcomes. See the [Update](#) on the stylebook site.

- Most clinical studies use a *multivariable* approach (a single outcome)
- “Using sex-stratified multivariable-adjusted Cox proportional hazards models, black women and men were more likely to develop diabetes than white men and women (black women: HR, 2.86 [95% CI, 2.19-3.72]; black men: HR, 1.67 [95% CI, 1.28-2.17]).” Diabetes is the single outcome; sex and race are independent variables.
Typography, tagging, display

- XML (extensible markup language) provides rules for naming and defining parts of a document and their relationship with each other.

- XML uses tags in start-end pairs (such as `<title>Title of the Article</title>` and `<body></body>`) to define the elements in that piece of content.

Publishing glossary: updates

Many additions and deletions, especially to reflect technological updates to publishing, document creation and retrieval, and communication

- Removal of CD-ROM, CPU, DOS, elite type, fax, hard disk, internet, keyboard, LAN, mainframe, mouse, page proof, password, PC, program, RTF, storage

- Addition of cloud, ghost writer, IP address, JATS, landscape, NISO, open access, scholar’s margin, stylesheet, STEM, thin space, Unicode
Editorial assessment: corrections

- Corrections are important to the integrity of the published literature
- Errors range from relatively minor and inconsequential errors to major errors that invalidate the results and the underlying science
# Editorial assessment: corrections

<table>
<thead>
<tr>
<th>Minor error</th>
<th>Substantive errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconsequential error (eg, a typographical error that could result in misunderstanding)</td>
<td>Errors requiring a Correction notice (eg, author name misspelled, incorrect numbers, important missing information)</td>
</tr>
<tr>
<td>Article corrected online</td>
<td>Correction notice published</td>
</tr>
<tr>
<td>An indication of correction and date of correction are added to the article information (HTML and PDF versions)</td>
<td>Article is corrected online with indication of correction added to the article information (HTML and PDF)</td>
</tr>
<tr>
<td>No Correction notice</td>
<td>Correction notice and corrected article are reciprocally linked</td>
</tr>
</tbody>
</table>

An indication of correction and date of correction are added to the article information (HTML and PDF versions). Correction notice and corrected article are reciprocally linked.
Pervasive errors

• Inadvertent errors that result in the need to correct important or numerous data and information in the abstract, text, tables, figures, and supplement (eg, a coding error)

<table>
<thead>
<tr>
<th>No major changes</th>
<th>Change and valid</th>
<th>Change and invalid</th>
</tr>
</thead>
<tbody>
<tr>
<td>If none of the conclusions or interpretations are</td>
<td>If the direction or significance of the results,</td>
<td>If the results, interpretations, and conclusions change—</td>
</tr>
<tr>
<td>affected and there are no statistically significant</td>
<td>interpretations, and conclusions change—and the</td>
<td>and the science is no longer valid</td>
</tr>
<tr>
<td>changes in the results</td>
<td>science is still valid</td>
<td></td>
</tr>
<tr>
<td><strong>Letter of explanation and Correction</strong></td>
<td><strong>Retraction and Replacement</strong></td>
<td><strong>Retraction</strong></td>
</tr>
</tbody>
</table>
New option: retraction and replacement

Why? 21% of retractions are due to error, not misconduct
This mechanism allows authors to do the right thing without the stigma or penalties associated with retractions

When? Used judiciously – for cases of inadvertent pervasive errors that when corrected change the findings, interpretations, and/or conclusions
And after review – the science is still considered valid

How? Requires a Letter of explanation from all authors
An itemization of all errors and corrections
Replacement article retains the original article DOI and any usage and citation metrics
No “retraction” or do not use watermark
Retraction and replacement

Article Information
Retraction and Replacement: This article was retracted and replaced on August 23, 2018, to fix errors throughout the article and tables (see Supplement 2 or the retracted article with errors highlighted and Supplement 3 for the replacement article with corrections highlighted).
Retraction and replacement

Association of Cataract Surgery With Mortality in Older Women
Findings From the Women’s Health Initiative


Background: Previous studies have suggested an association between cataract surgery and mortality. A recent analysis found that, for older men, the association was not statistically significant; however, it was statistically significant for older women.

Objectives: To evaluate the association between cataract surgery and all-cause mortality among older women.

Design, Setting, and Participants: This retrospective cohort study included 7,421,056 women aged 65 years and older in the Women’s Health Initiative (WHI) cohort who had undergone cataract surgery from January 1, 2000, through December 31, 2014. The mean follow-up was 6.5 years.

Main Outcomes and Measures: All-cause mortality was ascertained through the National Death Index and linked to the WHI cohort. The main outcome of interest was death from any cause occurring within 1 year of cataract surgery.

Results: Among 7,421,056 women aged 65 years and older, 228,069 had undergone cataract surgery. Compared with women who did not undergo cataract surgery, women who underwent cataract surgery had a lower risk of all-cause mortality (hazard ratio, 0.75; 95% confidence interval, 0.71-0.79).

Conclusions and Relevance: Although cataract surgery is generally associated with improved visual function, it may also be associated with improved mortality. Further research is needed to determine the mechanisms underlying this association.

Authorship updates

• **Contributor**: anyone – an author, a collaborator, writer, assistant, etc

• **Author**: meets all 4 ICJME criteria and completes an authorship form
  - **Byline author**: author name in byline
  - **Nonbyline author**: author name not in byline – listed at the end of article

• **Group author**: a group of individuals, usually involving multicenter study investigators, working groups, and expert boards, panels, or committees, who wish to display a group name to indicate authorship

• **Collaborator**: nonauthor member of a formal group who contributes significantly
Authorship – who is who?

- Authors
  - Corresponding Author(s)
- Collaborators
  - Nonauthor investigators or members of a formal group
- Contributors
  - Assistance with research, analysis, writing, editing, reviewing

CSE
Trends in Authorship and Team Science in Major Medical Journals

From 2005 to 2015

Authors per article, increased from 8 to 18 per article

Research articles with group authorship, increased from 16.5% to 45.1% per year

Articles with authors who contributed equally increased from 3% to 27% per year
Shared authorship positions

• It has become increasingly common for authors to request “co-first authorship,” “co-senior authorship,” or some other indication of equal contribution.

• Journals accept indication of co-first authorship – but someone’s name will need to go first in the byline or author list.

• Requests for “co-first authorship” beyond 3 or 4 named authors may not be justifiable.

• This information can be displayed in the Acknowledgment just before the list of author contributions, such as
  
  • “Drs Brown and Jones served as co-first authors and contributed equally to the work.”
Cash payments to Chinese first authors

Quan W, Chen B, She F. Publish or Impoverish: An Investigation of the Monetary Reward System of Science In China (1999-2016).

Co-corresponding authors

- Requests for having up to 2 individuals listed as corresponding authors on a published article will be considered if justified.
- In such cases, 1 author must be designated as the primary point of contact who will
  - Serve as primary corresponding author for all communications with the journal
  - Will review an edited manuscript/proof
  - Make decisions regarding release of information to the news media
  - Handle any postpublication inquires, errors/corrections, etc
- Two can be listed in the Corresponding Author section of the published article, but the primary corresponding author will be listed first.
From same institution

Corresponding Authors: Jie Qiao, MD, PhD (jie.qiao@263.net), and Tianpei Hong, MD, PhD (tpho66@bjmu.edu.cn), Peking University Third Hospital, 49 N Garden Rd, Beijing 100191, China.

From same institution, different departments

Corresponding Authors: Jie Qiao, MD, PhD, Center of Reproductive Medicine (jie.qiao@263.net), and Tianpei Hong, MD, PhD, Department of Endocrinology and Metabolism (tpho66@bjmu.edu.cn), Peking University Third Hospital, 49 N Garden Rd, Beijing 100191, China.

From different institutions

Corresponding Authors: Linhong Wang, PhD, Chinese Center for Disease Control and Prevention, Beijing 100050, China (linhong@chinawch.org.cn); Yonghua Hu, MD, Department of Epidemiology and Biostatistics, School of Public Health, Peking University, Beijing 100191, China (yhhu@bjmu.edu.cn).
Intellectual property updates

- Public access and open access in scientific publication
- Open access and publication licenses
- Copyright – what’s protected and what’s not protected
- Updates on copyright terms and when works enter the public domain
- Copyright and social media
- Updates on trademark and protections for website domain names
- Data sharing
Intellectual property updates: data sharing

• Many research sponsors and government agencies have policies to encourage data transparency and sharing.

• A number of journals have had data sharing or availability policies, ranging from encouragement to strict requirements, for different types of data for more than a decade, including Nature, Science, PLOS journals, Annals of Internal Medicine

• In 2018, the International Committee of Medical Journal Editors (ICMJE) began requiring the publication of a data sharing statement for clinical trials. (JAMA. 2017;317[24]:2491–2492. doi:10.1001/jama.2017.6514)

• Optional for other study types

• Statements are required, but actual sharing is not yet required
Data sharing statement – questions for authors

- **Will data be shared?** Yes or no (with optional explanation)
  - If yes, **what types** of data?
    - Deidentified participant data
    - Participant data with identifiers
    - Data dictionary
  - **How** shared and where to access?
  - **When** will data be shared?
- **Will supporting documents** be shared?
  - Trial protocol and statistical analysis plan
  - Statistical/analytic code
  - Informed consent document
- **Who** can access? For what types of analyses? By which mechanisms (eg, with investigator support or a signed agreement)? Any restrictions on access or use?
Data sharing statement
JAMA example

Data Sharing Statement:
See Supplement 4.
(This is a PDF)

Data Sharing Statement

Data
Data available: Yes
Data types: Deidentified participant data
How to access data: Data can be shared by accessing the following link, https://neonatal.riti.org/index.cfm?fuseaction=DataRequest.Home
When available: With publication

Supporting Documents
Document types: None

Additional Information
Who can access the data: Researchers whose proposed use of the data has been approved following the NIH data sharing policies.
Types of analyses: Analysis of those approved proposals. Mechanisms of data availability: After approval and with a data use agreement.
Data sharing statement – other examples

• **New England Journal of Medicine**: Links to a structured table in PDF

  A [data sharing statement](#) provided by the authors is available with the full text of this article at NEJM.org.

• **Annals of Internal Medicine**: Included in Article Information section

  **Data Sharing Statement:** The following data will be made available beginning 1 January 2020 and ending 3 December 2021: deidentified participant data and participant data with identifiers (contact Rajnish Mehrotra; e-mail, [rmehrotr@uw.edu](mailto:rmehrotr@uw.edu)). The following supporting documents will be made available beginning 1 January 2020 and ending 31 December 2021: informed consent form (contact Rajnish Mehrotra; e-mail, [rmehrotr@uw.edu](mailto:rmehrotr@uw.edu)). These data will be made available to investigators with a methodologically sound proposal, with institutional review board approval and demonstration of resources to be able to undertake the proposed analyses, for a wide range of purposes subject to review and approval by the study's publication committee, with support of the principal investigator, and after approval of the proposal, consistent with guidelines of the University of Washington.
Data sharing statement – other examples

- Other examples are provided for *BMJ, Nature, Science*
- Center for Open Science Transparency and Openness Promotion (TOP) Guidelines [https://osf.io/ud578](https://osf.io/ud578)
  - Citation of data and materials
  - Data transparency (eg, posting in an accessible repository)
  - Transparency of analytic methods and code
  - Transparency of research materials
  - Transparency of design and analysis for review and publication
  - Preregistration of studies
  - Preregistration of analysis plans
  - Encouragement of replication studies
Protecting rights of research participants

• Contemporary rules for protecting the rights of research participants and patients in scientific publication have their foundations in ethical principles and national and international guidelines and regulations

• The primary policy governing biomedical research in the US is the *Regulations for the Protection of Human Subjects* (45 CFR §46), also known as the “Common Rule”

• Why “Common?” - Signed by 20 federal agencies and departments (DHHS, VA, NSF….CIA…)

• Since its release in 1991, the Common Rule has been amended briefly over the years - was revised substantially in 2017, with these revisions taking effect in January 2019
Ethical review, approval, or exemption or research

• All reports of research involving human participants should include indication of ethical review and approval or exemption or exclusion based on institutional policies or regulations

• For US research, according to the revised Common Rule, categories of research that involve human participants that may be exempt or excluded from IRB review are based on the level of risk posed to the study participants

• A list of these categories and additional specific protections for studies including pregnant women, human fetuses, neonates, children, and prisoners are available in the Final Revisions to the Common Rule

Ethical review, approval, or exemption or research

• An example of low-risk research that may be exempt from formal IRB/ethical review and informed consent requirements includes secondary research of nonidentifiable information or biospecimens from existing or publicly available datasets.

• Research using cadaver specimens is exempt because the Common Rule defines human study participants as “living individuals.”

• However, investigators should not make independent determinations of exemption or exclusion of IRB review because of the potential for conflicts of interest and should follow the formal policies of their respective institutions or national regulations.
Requirements for informed consent

• Authors should indicate **in the Methods section that informed consent was obtained** in a manner consistent with the Common Rule requirements or regulations of other countries or the Declaration of Helsinki

• From all adult participants and from parents or legal guardians for minors or incapacitated adults

• Should include indication of **how consent was obtained** (ie, written or oral); if oral, authors should explain why

• Should also indicate whether research participants received **compensation** or were offered any **incentive** for participating in the study

• **If informed consent was waived or not needed, authors should cite relevant institutional policy or national regulation**
Other changes in the Common Rule

• A single IRB may review and approve studies conducted at multiple sites or centers in the United States, unless the study is governed by other US laws or conducted in other or multiple countries.

• US federally funded clinical trial investigators should post a copy of the consent form used in enrolling participants on a publicly available website (eg, ct.gov).
Requirements for animal studies

• For research that involves animals, authors should report that the study or relevant animal-handling protocol was reviewed and approved by an independent animal care and use committee as required by national regulations, such as

• US National Institutes of Health Office of Laboratory Animal Welfare requirements

• Guidelines of the International Association of Veterinary Editors

• ARRIVE (Animals in Research: Reporting In Vivo Experiments) guidelines
Almost all other chapters have been extensively revised and updated to reflect best practices and developments in scientific research, writing, and publishing, with numerous new examples.

23 Chapters with numerous numbered cross-referenced and linked subsections to the x.x.x.x.x level

The section on indexing has been removed, and the design, typography, and editing chapters have been combined

Other major updates include

- New comprehensive list and definition of study types
- Major update to statistics and methods chapter
- Many new terms in the nomenclature section, new abbreviations, new usage examples
- Many examples of new types of figures (eg, heat map, network meta-analysis, mediation analysis) – this chapter is in full color
Stylebook updates: amamanualofstyle.com

Updates: Any new policy decisions are published on the Updates page, which is freely available to anyone: http://www.amamanualofstyle.com/page/updates

Twitter: Regular communication via @AMAManual

Stay tuned! Every chapter has been peer reviewed, revised, and submitted to the publisher, and plans are in motion for print book and website publication in 2019.

Stacy Christiansen and Cheryl Iverson
Committee co-chairs: stylemanual@jamanetwork.org