

Ethics in publication, part 2: duplicate publishing, salami slicing, and large retrospective multicenter case series

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Bibliography

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ABBREVIATIONS

COI	conflict of interest
COPE	International Committee on Publication Ethics
ICMJE	International Committee of Medical Journal Editors
IRB	institutional review board
LAMS	lumen-apposing metal stent
POEM	per-oral endoscopic myotomy
SAE	serious adverse event

The goals of scientific publishing – to advance our knowledge of disease mechanisms and treatments – sometimes come into conflict with the professional and personal benefits of publishing. Authors may feel pressure to publish as many scientific articles as possible to advance their careers and reputations. It is the role of journal editors to ensure that scientific articles minimize this conflict by ensuring that each provides a “substantial new contribution to their field.”[1]

In this article, we present the second part of an ongoing series focused on ethical principles in publication in the field of gastroenterological endoscopy [2, 3]. We review what constitutes duplicate publication, “salami slicing,” and ethical concerns in large multicenter retrospective case series.

Duplicate publication

Duplicate publication is defined by the International Committee on Publication Ethics (COPE) as “Major overlap/redundancy (i.e. based on same data with identical or very similar findings and/or evidence that authors have sought to hide redundancy, e.g. by changing title or author order or not citing previous papers).” In its most obvious form, the same article may be published in more than one journal or translated into another language and republished. In its more common but subtle form, duplicate publication involves republication of the same data set with minor alterations such as the slight addition of patients, or using a subset of the original cohort.

There are many legitimate examples of large cohort studies in which the author(s) publish multiple articles based on the same group of patients. These may include large, prospectively maintained registries that allow multiple new and substantial questions to be addressed. The key principles for avoiding duplication are these:

- Clearly indicate that the new article is an extension of prior work and explain what substantial new questions are addressed.
- Reference the prior work to demonstrate how the new work builds a body of knowledge with novel and significant information.
- Clearly indicate what information overlaps with prior work, such as what proportion of patients in the new study were previously reported.

A full statement by the International Committee of Medical Journal Editors (ICMJE) on proper reporting of duplicate material reads as follows:

“The author must alert the editor if the manuscript includes subjects about which the authors have published a previous report or have submitted a related report to another publication. Any such report must be referred to and referenced in the new

paper. Copies of such material should be included with the submitted paper to help the editor decide how to handle the matter." (available at www.icmje.org) [4]

Salami slicing

Salami slicing refers to the practice of submitting multiple articles derived from the same data set, typically in the "minimum publishable unit of research." [1] Although each new unit may be "new," it is not "substantial" and thus pollutes the scientific literature with excess text that requires readers to sift through multiple articles to extract a significant body of information. As with salami itself, it is difficult to know the proper boundary between a slice that is too thin and a slice that is too thick. Authors are encouraged to err on the side of substance, making a single article stronger by addressing multiple relevant hypotheses, and avoiding numerous, thinly sliced reports.

A theoretical example of salami slicing is reporting multiple subgroups of a cohort who have a common condition or treatment. For example, a study that evaluates the serious adverse events (SAE) of colonoscopy could present one article on SAE in women, a separate article on SAE in men, and a third article on SAE in older individuals. It is preferable to report the entire cohort and address multiple variables (sex, age, comorbidity) within a single manuscript.

A particularly common example is the republication of outcomes of an ongoing series, with each series slightly larger than the previous one (eg, outcomes in my first 100 cases, 200 cases, 1000 cases). In such cases, the subsequent studies should naturally build from a small case series to a large definitive cohort, to a controlled clinical, ideally randomized trial. In this case, 3 articles would be appropriate because each addresses a new and substantial question: Can it be done? What are the outcomes in a larger population? Is it better than current standards of care?

Large retrospective case series

There has been a particular trend recently to aggregate multiple small case series into large (sometime with more than 50 institutions) multicenter case series. These typically involve a new procedure or device. Recent examples include per-oral endoscopic myotomy (POEM) and lumen-apposing metal stents (LAMs), in which individual centers may have only a small number of cases. The potential benefits of such data aggregation include more precise estimations of outcomes, adverse events, and technical refinements of the procedure. As with all case series, it is appropriate to present initial experiences of a novel procedure, but it is crucial to understand the limitations of case series and the significant potential for biased or even incorrect information.

A common misconception is that a larger series provides more accurate information. In fact, the size of the study may improve precision (tighter confidence intervals), but size does not improve accuracy unless careful efforts are made to avoid bias. In uncontrolled studies, particularly cases series, there is a significant risk of bias such as selection bias by only choosing

patients most likely to benefit from a procedure, reporting bias by only submitting successful cases, and publication bias where editors publish only positive outcomes.

There are also ethical concerns when centers perform new off-label procedures without institutional review board (IRB) oversight. Although IRB oversight is not always required for the performance of novel procedures, it is required for the publication of such data, even when data analysis is performed retrospectively.

Duplicate publishing is also a common concern in such series, especially where multiple competing groups form consortia to collect cases, often through email requests with standardized spreadsheets. In such cases, if one contributing group sends its data to multiple consortia, those data are duplicated. When another group later aggregates such data in formal or informal meta-analyses, the duplicated patients are overcounted and thus give a false estimate of precision. How can we preserve the value of aggregating data and minimize the risk of duplicate publication and bias? The following are basic principles.

- Individual centers that submit data for publication should obtain IRB approval specific to that study. General, overarching IRB approvals should be avoided.
- Once small case series are published, larger series should ideally be collected under a prospective, IRB-approved, registered (eg, clinicaltrials.gov) study that includes all patients who are eligible for and who undergo such procedures.
- Individual centers should submit data to only 1 consortium when the studies are similar. Whenever questions of overlap arise, the contributing center should notify the coordinating center of potential overlap. It is the responsibility of both the contributing center and the coordinating center to ensure no duplication.
- As with all manuscripts, all authors should disclose conflict of interest (COI), which is especially relevant when a specific company's product is described. It is the joint responsibility of all authors to report COIs and of the corresponding author to ensure that reporting is complete and correct. Many journals, including ours, cross-check COI with public databases of industry support, such as <https://openpayments-data.cms.gov/search/physicians>.

The authorship of such articles that involve many centers should follow the ICMJE guidelines, which are reproduced below. Authors must meet all 3 criteria set out here. Of note, simply contributing patients to a registry does not qualify as authorship.

- "Substantial" contributions to conception and design, or acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content

Final approval of the version to be published (available at www.icmje.org) [5]

When and how do editors of different journals share information?

For the vast majority of manuscripts, journals function independently without sharing of information. This is done to ensure the confidentiality of each article. Even in cases of suspected ethical violations, most journals, including ours, conduct investigations with every effort to protect the reputation of authors and institutions during that investigation. Sharing of information is permissible when there is concern about ethical violations and when such sharing is necessary to avoid scientific misconduct. Our journals, *Gastrointestinal Endoscopy* and *Endoscopy*, follow the guidance of COPE as outlined below.

“In view of the importance of confidentiality in the scientific publishing process, COPE believes that sharing of information between Editors in Chief (EICs) should only be undertaken when the disclosing EIC feels that such sharing is a necessary part of fulfilling the EIC’s obligation to prevent and respond to suspected research misconduct.” [6] (available at www.publicationethics.org)

Summary

Medical journals and their editors have a responsibility to ensure that what is published is scientifically rigorous, novel, and relevant to the journal’s audience. Fortunately, most manuscripts submitted to our journals follow the basic principles of publication ethics. In the rare cases of suspected ethical violations, we vigorously investigate such activity while following international guidelines by COPE and ICMJE to ensure that improper manuscripts are not published, proper disciplinary activity is followed when violations are proven, but, at the same time, authors are guaranteed that they will be treated with a respectful and fair process.

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Competing interests

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