SPECIAL ARTICLE

How to review journal manuscripts

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ABSTRACT

Reviewing manuscripts is central to editorial peer review, which arose in the early 1900s in response to the editor's need for expert advice to help select quality articles from numerous submissions. Most reviewers learn by trial and error, often giving up along the way because the process is far from intuitive. This primer will help minimize errors and maximize enjoyment in reviewing. Topics covered include responding to a review invitation, crafting comments to editors and authors, offering a recommended disposition, dealing with revised manuscripts, and understanding roles and responsibilities. The target audience is primarily novice reviewers, but seasoned reviewers should also find useful pearls to assist their efforts.

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A common complaint of nearly all journal editors is the difficulty in finding competent reviewers to assess an increasing volume of submitted manuscripts. Identifying content experts is relatively easy, but finding those with expertise in *both* content and reviewing is quite another matter.

One question considered at some point by everyone contemplating a manuscript review is, "why bother?" Reviewing takes time, and time for intellectual pursuits is a luxury that few can afford. The short answer is, "because it is the right thing to do," but in more pragmatic terms, reviewing manuscripts is enjoyable, challenging, can generate continuing medical education (CME) credits, affords a privileged insight into the frontiers of knowledge, and, importantly, develops critical thinking skills that improve research, teaching, and clinical care.

Reviewing manuscripts is central to *editorial peer review*, which arose in the early 1900s in response to the editor's need for expert advice to help select quality articles from numerous submissions. When medical journals first appeared a century earlier, the editor had overwhelming importance as writer, spokesperson, and solicitor of content. As the twentieth century progressed, however, specialization of knowledge pressured editors into incorporating the advice of experts through peer review. Specialization ap-

plied not only to subject matter, but also to methods and techniques, with expertise at times limited to only a few specific research sites.

Society journals, like this one, initially resisted peer review because members of the organization assumed that the journal should print whatever was sent in or presented at meetings. Moreover, editors could not fill their pages if all manuscripts, many of mediocre quality, had to pass the filter of peer review. This is no longer a concern for *Otolaryngology–Head and Neck Surgery*, which receives nearly 2000 submissions annually, of which many are high quality but few are accepted for publication. Peer review today is an important extension of the scientific process, especially for society journals, because it champions expertise within the organization. Current goals of peer review are listed in Table 1.

Methods

The suggestions in this article are derived largely from personal experience acquired over more than 20 years in public health and biomedical publishing as an author, peer reviewer, associate editor, and editor in chief. Relevant articles were identified via a MEDLINE search from 1996 through 2009, using the medical subject heading (MeSH) term "Peer Review, Research," then limiting the set to English-language articles with the word "review" in the title. Additional resources included the World Association of Medical Editors (www.wame.org), International Committee of Medical Journal Editors (www.icmje.org), and the Council of Science Editors (www.councilscienceeditors. org). The material herein is presented as one of many potential approaches to manuscript review, not the best or only approach, and is intended primarily as a resource for current and future peer reviewers for Otolaryngology-Head and Neck Surgery.

Invitation to Review

An invitation to review a manuscript is initiated most often by the editor or an associate editor of the journal, and is based on the reputation and content expertise of the potential reviewer. Alternatively, a reviewer can express interest by contacting the editorial official and indicating topics of

Table 1 Goals of editorial peer review

- Assist editors in making decisions about publishing a manuscript
- Offer constructive feedback to authors that will enhance the final writing product
- Improve critical thinking and writing skills of editors, reviewers, and authors
- 4. Provide readers, researchers, and other users of the journal with polished, readable articles
- Reduce bias and improve the quality of published articles
- Ensure that published research adheres to ethical standards for biomedical publishing

interest with evidence of expertise (e.g., list of peer-reviewed publications). Either way, engagement with a specific manuscript begins with a request by e-mail to accept or decline an opportunity to review.

Reviewers should ask the following questions when deciding to review:²

- 1. Do I have expertise in the content or methods, or a valuable perspective on the issue? Unless the answer is an unequivocal "yes," decline the review offer.
- 2. Do I have time to devote to this review and complete it by the requested date? If there is any uncertainty, decline the request; another opportunity will always arise.
- 3. Do I have any conflicts of interest that preclude unbiased judgments? If yes, decline the request; if uncertain, perform the review but list potential conflicts under "comments to the editor."

The last question deserves further comment. As defined by the World Association of Medical Editors, "conflict of interest exists when there is a divergence between an individual's private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual's behavior or judgment was motivated by considerations of his or her competing interests." Conflicts of interest can taint the review process by introducing bias, either positive or negative, at the critical juncture of assessing both the suitability of a manuscript for publication, as well as its need for revisions to ensure a balanced presentation.

The presence of competing interests is central in determining whether a conflict exists. Examples of competing interests include financial ties that could be impacted by manuscript content, academic commitments, institutional affiliations, prior or present personal relationships with the authors, competing research, and strong political or religious beliefs (if affirmed or challenged in the manuscript) or strong beliefs (intellectual passion). Working in the same institution as the authors is also a conflict, unless the institution is large enough that authors and reviewers are not working colleagues.³ If the reviewer stands to gain finan-

cially or personally, he or she should ask to be removed from the review process.

Assuming the reviewer has appropriate expertise and is free of conflicts of interest, a final consideration is the ability to complete the review in a timely fashion. Most journals allow up to seven days to accept or decline the review invitation, then an additional two to four weeks to complete and submit the review. There is nothing wrong with declining an invitation *provided it is done promptly*; a nonresponse hurts both editors and authors by delaying peer review. Reviewers can avoid the problem of being asked to review when they are unable to do so by notifying the editorial office in advance of any dates they will be too busy or out of town.

How long does it take to review a manuscript? Experienced reviewers take two to three hours to perform a quality review with constructive and substantiated comments. The greatest time investment is required for good manuscripts that can be polished to a greater luster through revision; manuscripts with obvious fatal flaws in content or methodology can be completed more rapidly. Reviewers should not, however, devote excessive time, because spending more than three hours, on average, does not increase review quality as rated by editors and authors.⁴

Confidential Comments to the Editor

Table 2 offers a suggested structure for composing a manuscript review, beginning with comments to the editor, followed by comments to authors. Comments to the editor are entered in a section separate from those intended for the author because the former are strictly confidential. In contrast, comments to the authors are not confidential, but they are anonymous unless the reviewer explicitly requests otherwise or chooses to include his or her name at the end of the text.

Comments to the editor are usually provided *after* the review is complete, but they are discussed first in this article because many reviewers leave the section blank or misunderstand its purpose. Recall that peer review should assist editors in making decisions about publishing a manuscript (Table 1). Comments to the editor aid that goal if the reviewer provides a summary assessment of the manuscript with justifications for the recommended disposition (accept, reject, or revise). These comments can be brief, but they *should not* simply repeat what was said to the authors; rather, they should give a "bottom line" assessment of the manuscript, with supporting reasons.

A critical aspect of all reviews is consistency between the comments to authors and the recommended disposition, and comments to the editor are often the best solution. For example, a reviewer may "reject" a manuscript but ask the authors for a revision in the comments. This discrepancy can be handled effectively by the editor if comments to the editor are provided; for example: "There are many problems with this manuscript that individually may be correctable, but in aggregate are worrisome. Unless the journal really

Section	Content	
Comments to editor		
Conflict of interest	Real or potential competing interests related to the authors or manuscript content that might result in a biased review	
Confidential comments	Comments that will not be forwarded to the authors, including a "bottom line" summary, hunches, ethical concerns, and recommendations for an accompanying commentary	
Suggested disposition	Typically one of the following: reject, minor revision, major revision, or accep (without revision)	
Comments to authors		
Introductory paragraph	Summary of key findings, validity, and value to readers	
General comments: major vs. minor points	Relevance to mission, internal validity, external validity, level of evidence, and ethical conduct (see Table 3)	
Specific comments	Feedback by section (abstract, introduction, methods, results, discussion) or by specific page, paragraph, or line number	
Concluding paragraph	Summary of key positive and negative comments without any statement of recommended disposition	

needs a publication in this topic area I would pass and wait for better quality work." Conversely, a reviewer may seek a "major revision" but the comments may all be laudatory. Again, the editor will render a decision more effectively if provided with confidential comments explaining the underlying concerns that motivated a request for significant revision.

Another use of the comments to the editor section is for concerns regarding conflicts of interest, whether personal or related to the authors. If reviewers are unsure whether a competing interest of their own would disqualify them from assessing the manuscript, they should bring it to the editor's attention so the editor can decide. Likewise, if the authors disclose relationships that are problematic, or if undisclosed relationships are suspected by the reviewer, they should be brought to the editor's attention for further clarification.

Comments to the editor can also be used to:⁶

- Identify areas of the manuscript that the reviewer was unable to adequately assess and to suggest other professionals who should be solicited (e.g., statistician);
- Raise serious concerns that are not appropriate to state, or state so strongly, to the authors;
- Discuss ethical concerns, including plagiarism and redundant publication;
- Clarify whether concerns are evidence-based or simply hunches;
- Suggest a commentary to accompany the manuscript, if accepted, that offers a contrary viewpoint or places its importance in the appropriate context;
- Suggest a change to a manuscript type that is more appropriate for the content.

Comments to Authors

Comments to authors are the heart and soul of a review, offering critical feedback to substantiate rejection or im-

prove the manuscript for publication. With this in mind, reviewers must ensure that what is written in this section is congruent with the ultimate recommendation to accept, revise, or reject the manuscript. Nothing is more confusing to the editor than reviews offering minor criticism that "reject" a manuscript or highly critical reviews ending with a request for "minor revision" or "acceptance." A recommended disposition is, of course, decided after the review is complete, but the decision must always be consistent with the length, tone, and content of comments provided to the authors.

This section should ideally be composed of subsections that include (Table 2) an introductory paragraph, general comments (major and minor), specific comments, and a concluding paragraph. The introductory paragraph restates the study objective or hypothesis, methodology applied, and results obtained. Although the editor has read the manuscript and can easily obtain this information, a summary provides valuable insight into the reviewer's perspective. Different reviewers often have a different "bottom line" assessment of the same manuscript, and knowing these varying impressions is of tremendous use to the editor in rendering a final decision.

General Comments to Authors

After the introductory paragraph, the general comments to authors should focus on the five key areas identified in Table 3. Any concerns are best expressed under subheadings of "major points" (critical to validity) and "minor points" (important to correct, but not critical). Each concern should be a separate paragraph, to facilitate a point-by-point response by the authors. If a specific area is adequately addressed, the reviewer should state so explicitly: "This is an important topic that is relevant to the journal and important to readership. Methodology is sound, the results are generalizable and add significantly to what is already known

Criterion	Question to be answered	Importance
Relevance to mission	Is the information in this manuscript consistent with the journal's mission and relevant to the readership?	Do not waste time reviewing an irrelevant manuscript that will not be accepted, regardless of quality.
Internal validity	Are the study design, conduct, and analysis described in a manner that is unbiased, appropriate, and reproducible?	Credibility of results for the study sample depends on an appropriate protocol, sound methodology, and proper statistical tests based on the sample sizes, distribution of data, and number of groups compared.
External validity	Was the study sample chosen appropriately and described in adequate detail for the results to be generalized?	Credibility of results for subjects beyond the study (intended population) depends on fully described interventions, representative sampling, and confidence intervals that are not overly broad (imprecise).
Level of evidence	Does this manuscript significantly improve the knowledge base beyond what is already published on this topic?	The absolute level of evidence (e.g., clinical trial vs observational study) is less important than the relationship to what has already been published; new manuscripts should exceed, or at least equal, existing levels of evidence.
Ethical conduct	Is the manuscript original, approved by an institutional review board (if applicable), and unbiased with regards to conflicts of interest?	Manuscripts cannot be published, regardless of perceived importance, if they are redundant, plagiarized, or violate basic principles of ethical research that include justice, beneficence, and respect for persons.

about this topic. There are no problems with ethics or conflict of interest."

Relevance to Mission

Before investing time and effort in reviewing, first ask, "Is this manuscript appropriate for the journal?" If the journal publishes only clinical research, there is no point reviewing a basic science or animal study, unless there is obvious translational value. The best way to assess suitability is to read the journal's mission statement in the front matter or author guidelines. For example, the mission of *Otolaryngology—Head and Neck Surgery* is: "To publish contemporary, ethical, clinically relevant information in otolaryngology, head and neck surgery . . . that can be used by otolaryngologists, scientists, and related specialists to improve patient care and public health."

Society journals, especially those linked to a national academy representing a discipline, often have a broader mission than non-society journals or those published by subspecialty groups. This includes not only manuscript content, but also the types of manuscripts that are published (Table 4). Many journals do not publish case reports, photographs, or commentaries because they are rarely cited and lower the impact factor, a crucial measure of a journal's importance. Society journals may nonetheless include these article types to give members the broadest opportunity for publication. Always check that the manuscript type of an article under review is appropriate for the journal.

If a manuscript is clearly outside the journal's mission, simply state this in the author comments and explain why in the confidential comments to the editor; there is no need for an in-depth review. When the relevance to the readership is unclear, perform a full (or abbreviated) review, but alert the editor to this concern in the confidential comments. The same actions would be appropriate if the manuscript could be improved by changing to a different article type. For example, manuscripts submitted as "review articles" that are simple narrative summaries, not systematic reviews or meta-analyses, could be reformatted and submitted as "commentaries" if the content was deemed important. Similarly, a small case series submitted as "original research" could be reconsidered as a "short scientific communication," if warranted.

Internal Validity

Critical appraisal of a manuscript begins by asking, "Are the results valid for the study sample?" Since investigators can almost never include every eligible subject in a research study, they instead use a *sample* of accessible subjects, then generalize the findings to a larger population. Before considering whether the generalization is appropriate, however, the first step is to ensure the results are valid and credible at least within the study proper. This attribute is called *internal validity* and should be distinguished from *external validity*, which applies to subjects outside the study (generalizability).

Туре	Description	Size limits
Original research	Original, in-depth, clinical or basic science investigations that aim to change clinical practice or the understanding of a disease process. Article types include, but are not limited to, clinical trials, before-and-after studies, cohort studies, case-control studies, cross-sectional surveys, and diagnostic test	Structured abstract 250 words manuscript length 3000 words, 20 references, 10 images*
Systematic review (including meta-analysis)	assessments. Critical assessments of literature and data sources on important clinical topics in otolaryngology—head and neck surgery. Systematic reviews that reduce bias with explicit procedures to select, appraise, and analyze studies are highly preferred over traditional narrative reviews. The review may include a meta-analysis, or statistical synthesis of data from separate, but similar, studies.	Structured abstract 250 words manuscript length 4500 words, 100 references, 15 images*
Commentary	Communication of a novel, scientifically based opinion or insight as an independent contribution, or regarding a manuscript published in the journal in the past 6 months.	Unstructured abstract 150 words, manuscript length 1800 words, 10 references, 3 images*
Short scientific communication	Quick communication of preliminary results (including small sample studies and case series) or scientific research that is not yet ready for presentation in full form. Such research should have the potential to stimulate communications among researchers and clinicians that may lead to new concepts and supportive work.	Unstructured abstract 150 words, manuscript length 900 words, 5 references, 2 images*
Clinical techniques and technology	A short report of unique or original methods for 1) surgical techniques or medical management, or 2) new devices or technology.	Manuscript length 900 words, 5 references, 2 images*
Case report	Report of a truly unique, highly relevant, and educationally valuable case; should not be combined with a review of the literature.	Manuscript length 700 words, 5 references, 2 images
Clinical photograph	Color photograph (not picture of an x-ray) of a unique, relevant, and educationally valuable clinical entity with an accompanying discussion.	Manuscript length 400 words, 5 references
Letter to the editor	Letter regarding published material or information of timely interest. If related to a previously published article, it must be submitted within 3 months of the article's publication, and the article's authors will be invited to reply.	Manuscript length 400 words, 5 references, 1 image

A study has internal validity when the design is appropriate, measurements are valid, and data are analyzed with appropriate statistical tests. Table 5 offers a simple framework for assessing the internal validity of a manuscript through a series of questions about objectives, study design, methodology, sample size, and statistical analysis. This is not intended as a comprehensive overview, but rather as a broad, general approach that is suitable for a wide variety of study designs. While it is not expected that all reviewers be expert statisticians, they should have some familiarity with basic concepts;⁷ additionally, reviewers should feel free to

recommend external statistical review if the analysis appears deficient or overly complex.

Case series are the most common study design encountered by our reviewers and are of greatest value when they use valid methodology, report uncommon disorders or interventions, or deal with circumstances where randomized trials would be unethical or impractical. A case series is most likely to be published if the authors:⁸

1. Include a consecutive sample of subjects over a defined time period with explicit inclusion and exclusion criteria;

Table F

Issue	Related questions		
Research objectives	Are objectives stated clearly in the abstract and introduction?		
0	Are the objectives and hypotheses appropriate?		
Study design	Is the study design appropriate for the stated research objectives?		
	If data were collected during routine clinical care, do the authors discuss the consistency,		
	accuracy, availability, and completeness of source records?		
	If the study is observational, what precautions were taken to reduce bias?		
	Was a control or comparison group used, and, if not, should it have been? Does an uncontrolled study make unjustified claims of efficacy or effectiveness?		
	If appropriate, is natural history or spontaneous improvement discussed?		
	Do any problems exist with duration of follow-up, response rates, or dropouts?		
Methodology	Are the tests, surveys, and outcome measures appropriate, valid, and unbiased?		
	Are specific methods described in adequate detail?		
	Is there too much detail that would be better suited for an appendix?		
	Are the methods for statistical analysis described and referenced?		
Sample size	Is the sample size stated clearly in the abstract and text?		
	If appropriate, do the authors include a sample size calculation?		
	For studies that conclude "no difference" or "no adverse effects," does the sample size		
5	give adequate statistical power to make such a conclusion credible?		
Descriptive statistics	Are small samples or skewed data (e.g., follow-up time) described with median and interquartile range instead of mean and standard deviation?		
	For "significant" findings, do the authors also describe effect size (e.g., odds ratio, relative		
	risk, correlation coefficient) and discuss clinical importance?		
	Is survival analysis used for prospective studies with loss to follow-up or when events may not have occurred by study end (e.g., survival, recurrence)?		
Inferential statistics	Are claims of significant or important findings supported by statistical analysis?		
	Are paired or matched data (e.g., before and after) analyzed appropriately?		
	If there are less than 20 observations per group, do the authors check the data distributio for asymmetry or outliers that warrant nonparametric or exact tests?		
	When 3 or more groups are compared, do the authors first test for a global difference		
	(e.g., analysis of variance) before making pairwise comparisons?		
	When multiple factors are related to an outcome, do the authors use regression analysis		
	to avoid the false positive problem of multiple individual tests?		

- 2. Describe the sample fully so readers can judge the relevance to their own circumstances or to other patient populations;
- 3. Report interventions with enough detail for reproduction, including adjunctive treatments;
- 4. Account for all patients enrolled in the study, including withdrawals and dropouts, and ensure that follow-up duration is adequate to overcome random disease fluctuations:
- 5. Present results with appropriate descriptive and analytic statistics, including multivariate analysis if the sample size is sufficient;
- 6. Reach justifiable conclusions, recognizing that most case series are hypothesis generating and that statements about efficacy or effectiveness are not possible (authors can discuss "outcomes" after the intervention but cannot conclude the outcomes were caused by the intervention);
- 7. Discuss limitations of the present study and future research to address them.

A final point worth emphasizing with case series is that they should not be called "retrospective reviews" because most are not "retrospective" and none are "reviews." Instead, most case series begin with an exposure (surgery, disease onset), and future outcomes are reported. Since the direction of inquiry is forward looking, the study is "prospective," even if it occurred in the past. Only when a case series identifies subjects by outcome (e.g., complication of treatment) and then examines predictive factors can a "retrospective" designation be appropriate. To emphasize data quality instead of linguistic purity, the following nomenclature is suggested for study design: "case series with chart review" or "case series with planned data collection."

Randomized controlled trials represent a higher level of evidence than case series, but trials with inadequate methodology tend to exaggerate treatment effects. The best trials ensure adequate randomization, conceal treatment allocation (blinding), and analyze results by intention to treat. The intention-to-treat analysis maintains treatment groups that are similar apart from random variation, which may not occur if only subjects who adhere to treatment (on-treatment analysis) are included. A blinded trial is always superior to a nonblinded (open or open-label) trial in which everyone involved knows who received which interventions. Last, randomized trials should adhere to current

Bias	Description	Solution
Design bias	Occurs when the study is planned to include subjects, endpoints, comparators, or outcome measures that are more likely to yield results that support prior beliefs or expectations. Examples include uncontrolled studies (case series) and studies in poorly defined populations or with unsuitable control groups.	Appropriate study design based on principles of epidemiology.
Ascertainment bias	Caused by studying a subject sample that does not fairly represent the larger population to which the results are to be applied. The problem is greatest with convenience or judgmental samples.	Random or consecutive sampling and clear criteria for subject inclusion or exclusion.
Selection (allocation) bias	Occurs when treatment groups vary in prognosis because of different demographics, illness severity, or other baseline characteristics (measured or unmeasured). The problem is greatest for observational studies, nonrandomized trials, and for randomized trials with inadequate concealment of the allocation scheme.	Random and concealed allocation of subjects to treatment groups including all subjects randomized in the final analysis (intention to treat).
Observer (measurement or information) bias	Distorts the way exposures or outcomes are assessed if the observers are aware of the treatment received. The problem is greatest for subjective outcomes (e.g., symptoms, satisfaction) and when the observers believe they already "know" the effect of treatment, or when they may have particular reasons for preferring one treatment over another.	Masked (blinded) outcome assessment using objective or validated measures, by independent observers who are unaware of treatment status.
Reviewer bias	Leads to erroneous conclusions when an author selectively cites published studies that favor a particular viewpoint. The problem is greatest for commentaries and nonsystematic (narrative or traditional) review articles, but can also distort the introduction and discussion sections of original research	Systematic criteria for study selection, and balanced consideration of all available evidence when drawing conclusions.

reporting standards, which include a flow diagram of subject recruitment. 13

An important goal of internal validity assessment is to detect *bias*, defined as a *systematic deviation from the truth* during the collection, analysis, interpretation, publication, or review of data. ¹⁴ This deviation is most dangerous in studies of treatment effects, because of distorted conclusions on the value—or worthlessness—of interventions. Some of the most important biases that can undermine treatment studies are described in Table 6. When authors claim treatment efficacy or effectiveness, reviewers should look carefully for one or more biases as possible alternative explanations, regardless of evidence level (case series, controlled study, randomized trial).

A special circumstance exists when authors are attempting to demonstrate noninferiority or equivalence among two or more interventions. Failure to demonstrate significant differences between treatment groups may not truly be a function of equivalence, but may represent insufficient statistical power to demonstrate an effect. Reviewers should be careful to ensure that appropriate power calculations have been included in the manuscript and that the sample sizes

are sufficient to support statements of equivalence or non-inferiority.

Review articles must also be assessed for internal validity, and ideally are conducted with the same rigor as the original research being analyzed. The best reviews use a systematic protocol to reduce bias, in contrast to the more ubiquitous narrative reviews based on expert opinion. ¹⁵ A systematic review should be assessed for: ¹⁶

- 1. A focused review question;
- 2. Precise inclusion and exclusion criteria for source articles:
- 3. Explicit and repeatable search criteria and methods;
- 4. Selection of source articles and risk of bias assessment by two or more investigators;
- 5. Summary tables describing and comparing the source articles;
- 6. Data extraction performed independently by two or more investigators, for accuracy;
- 7. Statistical pooling of outcomes, when appropriate, using meta-analysis;
- 8. Graphical presentation of results using forest and funnel plots;

9. Assessment for heterogeneity and publication bias.

Authors submitting review articles or meta-analyses to the journal are asked to abide by published reporting standards, which include a flow diagram detailing how the original search of potentially relevant articles was reduced to the source articles ultimately included in the review. ¹⁷ Recognizing that the main value of a properly performed review is the unbiased snapshot provided by the current literature on a topic, the journal is interested in reviews of observational studies and diagnostic test assessments, with or without data pooling (meta-analysis), not just quantitative syntheses of randomized controlled trials.

External Validity

Having first determined that the investigator's conclusions correctly describe what happened *inside* the study (internal validity), the next task is to determine whether they can be applied (generalized) to the universe *outside* the study. Unfortunately, not all well conducted, internally valid studies have *external validity* (generalizability or applicability). This distinction is not trivial, because the key question for a reader is, "Can I apply the results to the patients in my practice?" For the answer to be "yes," the study should have appropriate selection criteria, an unbiased sampling method, fully described interventions, clinical importance (not just statistical significance), and quantifiable adverse events (Table 7).

The best sampling method is to randomly select members of the accessible population. Bias is minimized because all subjects have an equal probability of selection, but random sampling is rarely feasible in most clinical research studies. Fortunately, a consecutive or systematic sample offers a good approximation. Consecutive samples are common, and include all subjects over a specified time interval or until a specified sample size is reached. Systematic samples are obtained by using some simple rule, such as day of the week, date of birth, or first letter of the last name. The worst sampling method occurs when subjects are chosen based on convenience or subjective judgments about eligibility by the investigators. Convenience sampling should be assumed when no other method is specified.

A key aspect of external validity is clinical significance, defined as "an effect that is of practical meaning to patients and health care providers." Clinical significance depends on the magnitude of effect and the associated precision, or variability. A single *point estimate* of clinical effect (e.g., 52% recurrence, 2.3 odds ratio, 20 decibel hearing change, 90% 5-year survival) is impossible to interpret unless accompanied by a 95% confidence interval (CI) that defines a range of values considered plausible for the population. ¹⁹ A point estimate summarizes findings for the sample, but extrapolation to the larger population introduces error and uncertainty, which makes a range of plausible values more appropriate. The more subjects studied, the tighter (narrower) the CI, and the more certain readers can be about population conclusions.

Reviewers may find the following pointers helpful in understanding confidence intervals and their importance in defining external validity of a study:²⁰

 Accept uncertainty. Recognize that all observations based on a limited sample are uncertain, and must be viewed as a range of plausible results (95% CI) for the population of

Table 7 Assessing the external validity (generalizability) of a manuscript			
Issue	Related questions		
Selection criteria	Are the inclusion and exclusion criteria stated clearly? Do the inclusion criteria fairly represent the intended target population? Do the exclusion criteria fairly represent subjects to whom results should not apply?		
Sampling scheme	Is the sampling method and recruitment period (start and end) stated clearly? If the study sample is not consecutive or systematic, do the investigators deal with bias that may result from convenience or judgmental sampling?		
Interventions	Are interventions described with enough detail for repetition by the reader? Does achieving results similar to the investigators' require a level of expertise, experience, or technology that is unavailable to most readers? Have all adjunctive therapies or interventions been accounted for so the reader may distinguish their effects from those of the primary intervention?		
Clinical significance	Do the authors account for uncertainty by providing a 95% confidence interval (CI) that gives a range of values considered plausible for the target population? When the authors report "significant" or "positive" findings, is the <i>lower limit</i> of the 95% CI large enough to exclude a trivial or clinically unimportant outcome? When the authors report "nonsignificant" or "negative" findings, is the <i>upper limit</i> of the 95% CI small enough to ensure a clinically important effect was not missed? Do the authors discuss clinical importance, not just statistical significance?		
Adverse events	If relevant, do the authors explicitly describe adverse events? Are adverse events described by frequency and severity? Do the authors discuss the relationship of benefit versus harm and adverse events?		

interest. Your task as reviewer is to decide whether the level of uncertainty, imposed by sample size and by the inherent variability of the data, is low enough to make point estimates credible.

- Look for a 95% CI. All main results deemed important by the authors should have a 95% CI in addition to the point estimate. The "confidence" that can be placed in results that lack a 95% CI is difficult to determine unless you calculate it yourself using a statistical program or one of many electronic calculators readily available on the Internet.
- Interpret a "positive result" with the 95% CI lower limit. When the authors conclude that an outcome or group difference is statistically significant or clinically important, scrutinize the lower limit of the 95% CI. If the magnitude of effect at the low end is consistent with a trivial or nonimportant outcome, not enough subjects were studied to create credible confidence that the point estimate is meaningful.
- Interpret a "negative result" with the 95% CI upper limit. When the authors conclude that an outcome or group difference is not significant or important, scrutinize the upper limit of the 95% CI. If the magnitude of effect at the high end is consistent with a nontrivial or important outcome, not enough subjects were studied to ensure that a potentially important effect was overlooked (low statistical power).

Understanding confidence intervals makes clear why describing study results as simply statistically "significant" or "nonsignificant" is unacceptable. 21 A P value measures strength of evidence against the null hypothesis but offers no information on effect size. A P value approaching 0.05 often has precision that is too low to exclude a trivial effect, and a "nonsignificant" P value often has an associated 95% CI that contains clinically important sample means. Studies with narrow CIs have high precision and are most meaningful, regardless of the P values. Conversely, studies with broad CIs require careful scrutiny. 22

Level of Evidence

Science is a cumulative process, and new research should improve the knowledge base beyond what has already been published. Viewed in this context, there is no absolute level of "best" evidence, only a continuing effort for quality improvement. If current knowledge of treatment effects were limited to case series (Table 8), then a case-control or cohort study would be a welcome addition. Conversely, if high-quality randomized trials had already been published, then observational studies (level 2, 3, 4) would be unlikely to add any new insights. Additional studies within an existing level of best evidence are worth publishing if they equal, or exceed, the quality of existing work.

The *level of evidence* generally increases as we progress from uncontrolled observational studies (case reports, case series) to controlled observational studies (cross sectional, retrospective, prospective) to controlled experiments (ran-

domized trials). Levels of research evidence are most often applied to studies of therapy or prevention, but can also be defined for prognosis, symptom prevalence, and diagnostic test assessment (Table 8).²³ Reviewers should determine the level of evidence for the manuscript under review and how it compares with other related published work before offering a recommendation to reject, revise, or accept the submission.

As the lowest level of clinical evidence, *case reports* are suitable for publication (assuming the journal accepts this type of submission) if they provide important new information that offers understanding or management of a disorder. Examples include a unique or nearly unique case, an unexpected association of two or more diseases or disorders, an important variation from the expected pattern (outlier case), or a case that reports unexpected outcomes or adverse events.²⁴ Conversely, minor case reports not worth publishing include variations of a well known theme, the "high index of suspicion" or "everyone should remember" case, grand rounds presentations with literature reviews, and bizarre events that fail to impact future management.

Case reports worth publishing should not be assessed with the usual criteria of internal validity and generalizability, but instead should be checked for structure and clarity of presentation. A recommended structure for case reports is as follows:²⁴

- 1. Introduction: one paragraph stating how the case came to the author's attention, why the case is worth reading about, and what the main features are;
- 2. Case description: a full account of the case, usually chronologic, with only truly relevant data;
- 3. Discussion: details of the literature search, why the case is unique or unexpected, potential explanations for the findings, and implications for clinicians.

Ethical Conduct

Ethical behavior in the conduct and reporting of research is an essential part of biomedical publishing. Although the editor and editorial staff have primary responsibility for assessing manuscripts in this regard, peer reviewers should also consider the issues in Table 9 when performing a review. Reviewers may have special insight into industry relationships, conflicts of interest, or investigator relationships that impact validity of findings or conclusions. Even if only a hunch, these can still be reported confidentially in the comments to the editor section, allowing the editorial staff to further investigate and reach appropriate conclusions prior to manuscript acceptance.

Authorship credit should be based on criteria established by the International Committee of Medical Journal Editors: ²⁵ 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors must meet all three criteria, which are typically verified in writing in the manuscript submission

Level	Therapy, prevention, etiology, or harm	Symptom prevalence, or differential diagnosis	Prognosis	Diagnostic test assessment
1	Randomized controlled trial(s), or all-or-none case series†	Prospective cohort study (or studies) with > 80 percent follow-up, or all-or-none case series†	Inception cohort(s)§, or a validated algorithm (or scoring system)	Validating cohort study of ar existing test with good reference standards, or a validated algorithm (or scoring system)
2	Prospective (cohort) study with internal control group	Retrospective study, prospective study with ≤ 80 percent follow-up, or ecological study‡	Retrospective cohort study, follow-up of untreated control patients in randomized trial, or nonvalidated algorithm or scoring system	Exploratory cohort study that derives a new test, with good reference standards, or derives an algorithm (or scoring system) and validates it on part of the same study sample
3	Retrospective (case- control) study with internal control group	Nonconsecutive cohort study or very limited population	Not applicable	Nonconsecutive study, or without consistent reference standards
4	Case series without an internal control group (reviews, uncontrolled cohort)	Case series	Case series, or poor quality prognostic cohort with < 80 percent follow-up or no correction for confounders	Retrospective study, or use of a poor or nonindependent reference standard
5	Expert opinion without	critical appraisal, or based of		earch or first principles

^{*}Adapted from Philips et al.23

Sinception cohort: group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition, or before the condition develops.

process. Reviewers should again confidentially report any hunches to the editor if they suspect honorary authorship (e.g., department chairperson as mandatory last author), ghostwriters (industry employees) that are not disclosed, omission of individuals who likely contributed to the manuscript, or concerns about the role of any listed contributors.

Regulations were enacted in the United States in 1974 that established the Institutional Review Board (IRB) as a primary mechanism for protecting the rights of human subjects. The same commission published the Belmont report in 1978 with three quintessential requirements for the ethical conduct of research:²⁶

- 1. Respect for persons involves recognizing the personal dignity and autonomy of individuals, and protecting those with diminished autonomy. This requirement mandates informed consent, whereby a participant is given sufficient information to decide whether or not to participate, is able to comprehend the information provided, and voluntarily agrees to participate.
- 2. *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing

- possible risks of harm. The risk-harm assessment applies not only to individual participants but also to the societal impact that might be gained from the research.
- 3. *Justice* requires that the benefits and burdens of research be distributed fairly. The selection of research subjects must result from fair procedures, not simply because a participant is readily available, favored by the research (or held in disdain), or easy to manipulate because of illness, disability, or socioeconomic condition.

All research with human subjects, or material obtained from human subjects (e.g., cadavers, surgical specimens) *must have formal approval or exemption* by a named IRB or research ethics committee (if an IRB is not accessible). Clinicians in private practice often have voluntary appointments at teaching institutions, and those without can usually access the IRB through colleagues. International diversity (e.g., developing countries) and legal variations cannot be invoked to support a double standard for ethical oversight;²⁷ authors of *all* research manuscripts should indicate whether procedures followed were in accordance with ethical stan-

[†]All-or-none case series: patients died before the treatment became available, but some now die on it; or when some patients died before the treatment became available but none now die on it.

[‡]Ecological study: analyzes populations or groups of people, rather than individuals.

Issue	Related questions		
Authorship	Did all authors contribute substantially to the research, draft, or revision of the manuscript and approve the final version?		
Originality	Are any ghostwriters or hidden authors suspected based on the tone and style? Does the manuscript appear to duplicate already published work? Are there signs of plagiarism?		
	Is this an incremental manuscript that adds marginally to already published data (e.g., new subjects, outcomes, time points) without acknowledging the relationship? Is the manuscript simply a translation of published work in another language?		
Research subjects	If a review article, has it been submitted to more than one journal? Was the research approved, or explicitly exempted from approval, by an ethics panel or institutional review board?		
	Was informed consent obtained and documented, if appropriate? Has consent been obtained to use identifiable images or photographs?		
Conflict of interest	Do the content or conclusions of the manuscript appear to be biased because of a relevant conflict of interest (even if fully disclosed by the authors)?		
	For sponsored research, did the funding source influence access to data, writing of the manuscript (e.g., employees as authors), or the decision to publish? Are any undisclosed conflicts of interest suspected?		

dards of the responsible committee on human experimentation.

When research poses no more than minimal risk to participants, an expedited IRB decision and waiver of informed consent may be possible.²⁸ This often applies to surveys and case series, which still require scrutiny because they constitute research and involve identifiable private information. An author cannot claim that IRB oversight is irrelevant simply because research is observational or based on accepted treatments. Formal approval or exemption, in writing, must still be obtained. The need for IRB review of case reports varies by institution because the ability of a *single case* to develop or contribute to generalizable knowledge is unclear.²⁹ When a case report contains *more than one case*, however, it becomes research and must have IRB approval.

A redundant (or duplicate) manuscript is one that overlaps substantially with another manuscript that has been submitted, published, or accepted for publication elsewhere. Most journals explicitly caution against such submissions in the author guidelines, with the exception of complete manuscripts that follow abstracts or poster presentations at professional meetings.²⁵ Redundancy can involve content (plagiarism or similar text passages), duplicate subjects (report of 25 patients that includes 15 from an earlier publication), incremental time points (1-year follow-up of a cohort with published outcomes at 3 months), or piecemeal outcomes (one manuscript reporting objective measures and another reporting quality of life). More flagrant examples include attempts to publish the same manuscript in multiple journals or languages.

If reviewers suspect all or part of a manuscript is redundant, they should look carefully for an explanation in the methods sections that includes an appropriate citation of earlier work. At times it may be appropriate or important to

publish new data that enhance prior findings, but the incremental nature of the new manuscript should be evident in the title, abstract, and methods, without requiring detective work by the reviewer or reader. An incremental manuscript can also be kept brief by referencing already-published methods. Any doubts about originality of the work or its relationship to earlier publications should be noted in the author comments, confidential comments to the editor, or both.

All authors are asked to disclose potential *conflicts of interest* that could impact the credibility of published work. Disclosure standards continue to evolve but are becoming increasingly stringent given the great potential for financial ties to influence judgment. Current recommendations ask authors to disclose four types of information:³⁰

- 1. Associations with commercial entities that supported work in the submitted manuscript (at any time during the lifespan of the work);
- Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (within 36 months before submission):
- 3. Associations similar to #1 or #2 above involving a spouse or child under age 18 years;
- 4. Nonfinancial associations (e.g., personal, professional, political, religious) that a reasonable reader would want to know about in relation to the submitted work.

Reviewers should understand that the presence of significant associations does not preclude publication, nor does full disclosure guarantee it. Rather, it is up to the reviewers and editor to decide whether the data or opinions in the manuscript are biased because of an association, thereby compromising the validity of the work. If

so, the authors can be asked to revise the manuscript accordingly. At times, however, the conflicts are strong enough to preclude any chance of objective reporting, and the manuscript may be rejected regardless of the transparency in the disclosure.

Reviewers should assess the sponsorship and conflicts of interest disclosed by the author and consider their appropriateness, completeness, and potential to bias the manuscript. Equally important is that reviewers disclose to the editor any personal conflicts of interest and decline the review (as noted earlier) if an objective assessment is not possible. If a reviewer has no conflicts, this should be stated explicitly to the editor, or indicated in the appropriate section of the reviewer response form.

Specific Comments to Authors

This section contains comments related to a specific part of the manuscript, usually designated with a page, paragraph, and line number that identifies the relevant text. Examples include inappropriate language, biased statements, improper use or interpretation of a literature citation, vague or ambiguous terms, repeated use of brand names, and significant typographical errors or omissions. Anything that creates a mental roadblock when reading the manuscript could be reason for a specific comment. When a specific comment becomes a recurring theme, consider elevating it to the preceding section on general comments to authors.

Another useful way to develop specific comments is by considering the manuscript section by section, beginning with the abstract and ending with the references (Table 10). The sections should form a cohesive whole, each part serving its intended function with appropriate brevity, content, length, and clarity of thought.³¹ Is the abstract a valid snapshot of the work or does it omit key details about sample size, adverse events, or the magnitude of results? Is the introduction more of a review article than a justification for the work? Does the discussion section ramble on with unsubstantiated treatment paradigms or management flow-charts? Relate any concerns to the authors by stating the manuscript section (e.g., methods, results) and paragraph number, or the number of the related table, figure, or reference.

There is often confusion about the extent to which reviewers should correct grammar or spelling when providing specific comments. In general, the reviewer *should not waste his or her time* with extensive language corrections, which are the responsibility of the copy editors once a manuscript is accepted. When problems interfere with un-

Section	Signs of grandeur	Signs of decadence
Disclosures	Clear statements regarding funding, grant support, industry relationships, financial ties, and competing interests	Blank responses; vague or incomplete statements
Abstract	Structured summary of goals, methods, results, and significance; provides a "stand alone" snapshot of the manuscript	Unstructured qualitative overview of study; contains more wish than reality; not consistent with manuscript text
Introduction	Clear, concise, and logical; ends with study rationale or purpose; defines terms	Rambling, verbose literature review; no critical argument or hypothesis
Methods	Specific enough for the reader to reproduce the study; justifies choices made in designing the study	Vague or incomplete description of subjects, sampling, outcome criteria; no mention of statistical analysis
Results	Logical and orderly blend of numbers and narrative with supporting tables and figures	Difficult to read, with overuse or underuse of statistical tests
Discussion	Puts main results in context; reviews supporting and conflicting literature; discusses strengths and weaknesses	Full of fantasy and speculation; rambling and biased literature review; does not acknowledge weaknesses
Tables	Logical and relevant with appropriate row and column headings; should enhance, not duplicate, the text	Simplistic, single-column lists; dense listings of raw data more appropriate for statisticians than readers
Figures	Visually appealing; engages and enlightens the reader; use arrows or pointers for clarity	Confusing or simplistic designs; unnecessary use of 3D or color
Figure legends	Puts the figure in context; defines abbreviations, symbols, and error bars	Missing, incomplete, or excessively long
References	Demonstrates clearly that work of others has been considered	Key articles are conspicuously absent; excessively brief

derstanding or interpretation, however, it is appropriate to perform only a brief review and request that the authors rewrite the manuscript before further consideration. International submissions can often be improved if the authors consult a professional language service to ensure proper use of the English language.

Manuscript Disposition

The final disposition of a manuscript is determined by the editor in chief based on personal review and the comments from the associate editor and reviewers. Upon completing their assessment of the manuscript, reviewers must choose one of the following as a recommended disposition:

- Accept, if the work is valid, ethical, relevant, and adds to what is already published; writing should be clear and concise.
- 2. *Minor revision*, if the work has minor problems that once corrected should lead to acceptance for publication after satisfactory revision.
- 3. *Major revision*, if there are major concerns about ethics, study design, reporting of results, generalizability of the findings, or composition of the manuscript; a revised manuscript may result in acceptance, rejection, or a request for additional revision.
- 4. *Reject*, if the work is not consistent with the journal's mission, has one or more fatal flaws, or poses serious ethical concerns; the author should not submit a revised manuscript unless specifically requested.

Nearly all manuscripts can be enhanced by peer review, which also means that very few will be acceptable "as is" on initial submission. Reviewers who are tempted to accept a first submission should review the work one more time with a critical eye toward polishing it to an even greater luster. There is nothing wrong with an occasional "accept" first decision, but this should be very infrequent and supported by appropriate comments to the author and editor. Simple statements like "great manuscript" or "I congratulate the authors on their fine work" are not consistent with the principles or purpose of editorial peer review.

"Reject" is the most common disposition for many journals (including this one), because of one or more fatal flaws related to the content in Table 3. Reviewers should not feel uncomfortable about rejecting a manuscript *provided that* the comments to the author and editor fully substantiate the decision. Major flaws must be clearly stated, and the rationale for such designation must be justified. Some reviewers support the rejection with a lengthy review asking for extensive revisions, perhaps to avoid hurting the author's feelings with negative comments. This type of review, however, confuses both the editor and authors and usually delays but does not avert eventual rejection.

Asking an author to revise a manuscript implies it has value to the readership and is important to publish but first requires some polishing and clarification. If most of the comments to the authors are "major points" related to issues

in Tables 5, 6, 7, or 9, a major revision should be requested. Conversely, if the concerns are minor or related mainly to "specific author comments," as noted above, a minor revision would be appropriate. All revision requests should be specific enough for the authors to understand clearly what should be done to satisfy the request. The requests should also be comprehensive, because implicit in the concept of revision is that the manuscript will be accepted for publication if appropriate changes are made.

Requests for revisions must be reasonable. For example, asking an author to add a control group or double the sample size is well beyond what could likely ever be achieved. If the missing control group prevents meaningful assessment, or the small sample size has unacceptably low power or precision, the appropriate recommendation is "reject," with explanatory comments. The best revision requests add clarity and insight to acceptable methodology; the revision request should not ask authors to fix fatal flaws or completely restructure the research methods.

Final disposition is determined by the editor in chief on the basis of comments from the associate editor and reviewers. This decision often agrees with the reviewer's recommendation, but at times the editor may opt for revisions when a reviewer rejects, or vice versa. Just as the reviewer has an obligation to support a recommendation with appropriate comments, the editor should include comments clarifying his or her decision. Reviewers should not be offended if a final editorial decision differs from their own, because they see only a handful of the manuscripts submitted to the journal. The editor sees all submissions and is able to best judge the relative worth of a given manuscript and its potential appeal to readers.

Reviewing a Revised Manuscript

When the authors submit a revised manuscript, it will usually be forwarded to the original reviewer for reassessment, unless the revision request was for only minor clarifications or editorial changes. All revised manuscripts should contain a cover letter to the editor that summarizes all changes made, ideally as a point-by-point list that repeats the initial concern (from the comments to authors) followed by the author's response. This is followed with a revised manuscript that should ideally have all changes or revisions highlighted with a different colored font (e.g., red or yellow), for easy identification.

Reviewing a revision will take substantially less time than the original review if the authors provide the cover letter and highlighted changes. It is *not* the responsibility of the reviewer (or editor) to be a manuscript detective and spend tedious hours identifying changes by comparing the revision with the earlier version. Manuscripts without readily identifiable changes should be returned to the authors, with the review postponed until an appropriate revision is submitted.

The purpose of review at this stage is to ensure that all initial concerns have been fully addressed in the revised

manuscript. This is more likely to occur if the original review contained clear, constructive requests for specific changes or clarifications to improve the work. Reviewers should not raise new issues or revision requests that were not mentioned before, unless a critical flaw was overlooked. Authors who adequately address all issues in the request for revision expect (rightly so) that the manuscript will be accepted if the responses are adequate. Continuing requests for new revisions delay publication and are disrespectful to authors and editors.

Reviewers must use their judgment in deciding whether author responses to their revision requests are adequate. Sometimes authors will offer an explanation or rebuttal that is limited to only the cover letter and does not result in any changes in the manuscript text. If the reviewer feels this is unsatisfactory, a request can be made to modify the text so readers can also understand the logic. After reading the revised manuscript, the reviewer must provide the editor with a suggested disposition of accept, revise (further), or reject. If revision or rejection is recommended, the comments to authors should fully explain the basis for the decision, with constructive criticism.

Responsibilities of Reviewers

Reviewing the unpublished work of others is a privilege with responsibilities toward the authors, editors, and readers. Authors are entitled to timely, written, unbiased feedback, without personal comments or criticism. The review process must remain confidential, without any sharing or discussing of information with colleagues or third parties. Editors are entitled to a fair, constructive, and informative critique that indicates ways to improve the work and suggests a disposition based on whatever rating scale the editor deems useful. Reviewers should decline an invitation when a conflict of interest exists, and should not contact authors directly without permission from the editor. Readers are entitled to be protected from incorrect or flawed research and from omissions in citing the relevant work of others.

A primary purpose of peer review is to improve worthy manuscripts to a publishable quality. This requires a constructive critique that acknowledges positive aspects, identifies negative aspects constructively, and—most importantly—indicates the specific improvements required. The Council of Science Editors offers the following useful advice: "The purpose of peer review is not to demonstrate the reviewer's proficiency in identifying flaws. Reviewers have the responsibility to identify strengths and provide constructive comments to help the author resolve weaknesses in the work. A reviewer should respect the intellectual independence of the author." 32

The flip side of providing a fair and constructive review is to avoid impropriety. The following list from the Council of Science Editors is a terrific summary of what *not* to do:³²

- Misrepresent facts in a review;
- Unreasonably delay the review process;

- Unfairly criticize a competitor's work;
- Breach the confidentiality of the review;
- Propose changes merely to support the reviewer's own work or hypotheses;
- Use confidential information for personal or professional gain;
- Include personal criticism of the author(s);
- Fail to disclose a conflict of interest that would have excluded the reviewer from the process.

While perhaps not a true impropriety, the devastatingly negative review should be equally avoided. This so-called "pit bull review" does little to advance science, is insulting to the authors, and greatly complicates the editor's role in communicating a decision. ³³ Err on the side of kindness and respect.

Conclusions

Richard Burton might have been thinking about peer review when noting, "One of the mistakes in the conduct of human life is to suppose that other men's opinions are to make us happy." Indeed, peer review is not about happiness, it is about creating better, clearer, and more accurate manuscripts that, if published, contribute the most to science and patient care. Editors derive deep satisfaction in being part of this process—satisfaction that is also available to anyone willing to invest some time in learning and honing the principles of peer review. Hopefully this primer will jump-start the learning process and facilitate high-quality manuscript reviews.

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