

1 PEER REVIEW IN MEDICAL JOURNALS: BEYOND QUALITY OF REPORTS  
2 TOWARDS TRANSPARENCY AND PUBLIC SCRUTINY OF THE PROCESS  
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21 ABBREVIATIONS: COI, conflicts of interest; DOI, Digital Object Identifiers; ORCID, Open  
22 Researcher and Contributor ID

23

## 24 ABSTRACT

25 Published medical research influences healthcare providers and policy makers, guides patient  
26 management, and is based on the peer review process. Peer review should prevent publication  
27 of unreliable data and improve study reporting, but there is little evidence that these aims are  
28 fully achieved. In the blinded systems, authors and readers do not know the reviewers'  
29 identity. Moreover, the reviewers' reports are not made available to readers. Anonymous peer  
30 review poses an ethical imbalance toward authors, who are judged by masked referees, and to  
31 the medical community and society at large, in case patients suffer the consequences of  
32 acceptance of flawed manuscripts or erroneous rejection of important findings. Some general  
33 medical journals have adopted an open process, require reviewers to sign their reports, and  
34 links online prepublication histories to accepted articles. This system increases editors' and  
35 reviewers' accountability and allows public scrutiny, consenting readers understand on which  
36 basis were decisions taken and by whom. Moreover, this gives credit to reviewers for their  
37 apparently thankless job, as online availability of signed and scored reports may contribute to  
38 researchers' academic curricula. However, the transition from the blind to the open system  
39 could pose problems to journals. Reviewers may be more difficult to find, and publishers or  
40 medical societies could resist changes that may affect editorial costs and journals' revenues.  
41 Nonetheless, also considering the risk of competing interests in the medical field, general and  
42 major specialty journals could consider testing the effects of open review on manuscripts  
43 regarding studies that may influence clinical practice.

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## 45 INTRODUCTION. PEER REVIEW: THE BASE OF EVIDENCE-BASED MEDICINE

46 Medical journals disseminate scientific information that helps understanding, preventing, and  
47 treating diseases. Editors decide which data will be available to the medical community and to  
48 patients also based on reports of experts in the field who, acting as consultants, verify if  
49 research findings meet the necessary standards. Although editors retain the authority and  
50 responsibility to override reviewers' recommendations regarding the final disposition of  
51 manuscripts, reviewers appear to be influential, and it has been reported that in two top-tier  
52 specialty journals a recommendation for rejection or acceptance was eventually accompanied  
53 by, respectively, 93% rejection and 67% acceptance rates [1]. Therefore, peer reviewers play  
54 a crucial role in the selection of those studies that, once published, will inform health care  
55 decisions.

56 Through the years, the peer review system has undergone increasing enquiry and  
57 criticisms, mainly due to the possibility of bias, conscious or unintentional (see, as reviews on  
58 the different types of bias, [2-4]) and the considerable effects they can have on the scientific  
59 literature that will eventually inform health care decisions [5]. Moreover, when the peer  
60 review process fails, there are additional negative consequences, as scientists who got  
61 published without deserving it, or scientists who got rejected despite deserving to be  
62 published, respectively gain or lose credits incorrectly, and this has an indirect impact on  
63 reputation and grants. This causes distortions in the mechanisms through which science self-  
64 regulate itself also in terms of resource allocation, and has an indirect effect on the value of  
65 knowledge produced by the system.

66 Modifications of the process have been studied with the goal of improving the quality  
67 of reviewers' evaluations and, consequently, that of reports of biomedical studies and of the  
68 evidence offered to health care providers, policy makers, and consumers [2,3,6-8]. In

69 particular, some medical journals have adopted an open peer review system, thus revealing  
70 the reviewers' identity to authors [9], whereas reviewers are usually kept anonymous (blind or  
71 closed peer review). Given the critical importance of peer review and the potential effect of  
72 any editorial decision, recommendations have been made to assess the feasibility of a  
73 transition from the blind to the open system also within specialty journals [10,11]. Some  
74 advantages and disadvantages of open versus blind pre-publication peer review are here  
75 examined.

## 76 METHODS

77 The best quality evidence was selected with preference given to the most recent and  
78 definitive original articles and reviews. Information was identified by searches of MEDLINE  
79 and references from relevant articles, using combinations of MESH terms “peer review”,  
80 “blind peer review”, “open peer review” “medical publishing”, and “conflict of interest”. The  
81 search was limited to peer-reviewed, full-text articles in the English language. Papers  
82 published in the last 20 years were considered. Open pre-publication review (e.g., as adopted  
83 by PeerJ) and post-publication review (e.g., as adopted by F1000Research) will not be  
84 addressed owing to lack of adequate evaluation in the medical field.

## 85 BLIND PEER REVIEW: THE DARK SIDE OF SCIENCE?

86 In theory, single-blind peer review (reviewers know the authors' identity whereas reviewers  
87 are kept anonymous to authors) should allow unconditioned judgments without concerns  
88 regarding potential consequences on one's career and personal relationships [12]. This system  
89 would protect especially young researchers assessing manuscripts submitted by senior or  
90 academically powerful investigators [13]. However, this closed model is not immune from  
91 systematic bias, as reviewers may not limit themselves to an objective evaluation of research  
92 methodology and findings' validity, but may interpret the study according to personal

93 convictions or friendship/enmity with authors [9, 14]. This may occur frequently in  
94 subspecialty fields, where most experts know each other well. The possibility for authors to  
95 suggest/exclude reviewers could hypothetically further complicate the issue, but no  
96 differences in quality of reports were observed when reviewers were suggested by authors or  
97 by editors [15].

98         To prevent bias, double-blind peer review (reviewers and authors do not know each  
99 other's identity) has been studied or implemented by some general and specialty journals [16-  
100 18]. Nonetheless, interested authors can make themselves easily recognizable [19]. Therefore,  
101 to achieve adequate blinding, the entire manuscript should be accurately de-identified before  
102 sending it out for review, thus imposing a burdensome and costly extra-work to editorial  
103 offices. In spite of these efforts, reviewers are still able to identify authors in up to 40% of  
104 instances [20]. Independently of the preference expressed by both authors and reviewers, [21]  
105 double-blind peer review was not associated with better quality reports compared with single-  
106 blind peer review [22-24]. In particular, neither blinding reviewers to authors' identity and  
107 provenience of the manuscript, nor asking them to sign their reports, improved the errors'  
108 detection rate [17]. Moreover, knowledge of authors and origin of data might be considered  
109 important [3].

110         Finally, neither system prevents the risk of intellectual plagiarism, attempts at delaying  
111 manuscript publication, or the influence of financial conflicts of interest (COI). Reviewers  
112 must disclose COIs, but it is not always clear if this leads to their exclusion in case of relevant  
113 financial ties. For a subspecialty or small journal, finding competent and available reviewers  
114 already may be difficult, and selecting only those without financial and non-financial COIs  
115 might be impracticable.

116 PROS AND CONS OF OPEN PRE-PUBLICATION PEER REVIEW

117 Junior reviewers who have to sign reports on manuscripts written by powerful academicians  
118 may refrain from negative judgments because of fear of unfavorable consequences on their  
119 career [13]. Senior peers may fear revenges in case of future reversal of roles in manuscript  
120 evaluation [12]. Conversely, a sort of reciprocal favoritism may ensue, with a "credit" to be  
121 cashed when the reviewer will in turn submit a manuscript indicating the author's name  
122 among the suggested reviewers. In other words, once everything is public, scientists could  
123 even rationally start to game the system. For instance, considering peer review as a  
124 cooperation dilemma, scientists can reciprocate favorable reviews to known reviewers who  
125 previously ensured positive reviews to them, and sanction those ones who did not. This can  
126 increase evaluation bias [25]. As mentioned before, this may happen also with reviewers'  
127 recommendations. However, the fact that studies did not fully capture this effect is due to  
128 sample bias, as scientists could play sophisticated reciprocity strategies across different  
129 journals, and this is hardly empirically traceable through data on single journals. The above  
130 risks may be higher in a specialty field where experts in specific areas of research are limited.  
131 Moreover, specialty journals may face increasing difficulties in finding available reviewers  
132 [26]. According to Khan [13], one expert out of four already declines the invitation to review  
133 by a specialty journal adopting the single-blind system, but this percentage could increase up  
134 to 40% in case of open review. In addition to inconveniences for the editorial office,  
135 excessive reviewers' self-selection may lead to a further systematic (and undetectable) bias.

136 In short, there could be a trade-off between full transparency and quality of the  
137 process. According to its detractors, open review may thus result in worse reports compared  
138 to blind review, but this has not been observed in randomized, controlled trials [10,11, 27].  
139 Noteworthy, a similar study conducted by a specialty journal observed a small difference in  
140 the quality of reports in favor of open reviewers [28]. This lack of major differences has been  
141 ascribed to the Hawthorne effect, as reviewers allocated to both signed and unsigned groups

142 could have performed better than usual just because they knew they were participating in a  
143 trial [10, 28]. However, no such effect was apparent when a group of anonymous reviewers  
144 unaware they have been recruited in a study was included [27]. A slight improvement in the  
145 quality of reviewers' reports has been observed also in a recent retrospective study comparing  
146 open and single-blind peer review in two very similar specialty journals [29]. Moreover,  
147 reports of inappropriate or rancorous authors' reactions following an unfavorable open review  
148 are exceedingly rare [11], although unblinding reviewers in specialty/subspecialty journals  
149 may reveal less safe compared with large general medicine journals.

150 Proponents of open review maintain that masking reviewers identity generates an  
151 ethical imbalance, as it is improper to undergo an evaluation by anonymous judges when they  
152 know who the "defendants" are [10]. Because a completely closed system (with only an  
153 editorial assistant knowing the authors' identity and only the editor knowing the reviewers'  
154 identity) is impractical, open peer review would be the only ethically sound option [30]. Open  
155 review has been already adopted not only by general medical journals such as The BMJ, BMJ  
156 Open, and the Journal of the Royal Society of Medicine, but also by specialty journals,  
157 including those within the BMC series.

158 In addition to requesting reviewers to sign their reports, some journals now make the  
159 entire pre-publication history of accepted manuscripts available online [31]. Thus, the  
160 scientific community, and not only authors, may read the reviewers' and editors' comments,  
161 the authors' response and the original and revised versions of the manuscript. The advantages  
162 of such a policy are multiple, and include accountability of reviewers. Owing to reputational  
163 costs, the risk of favorable judgments of methodologically flawed studies or provision of  
164 shallow reviews should be reduced [32]. Reviewers' reports could be publicly evaluable in  
165 order to verify if methodological shortcomings were correctly identified and if the suggested  
166 modifications were appropriate or unwise. Moreover, posting of pre-publication histories,

167 increases also editors' accountability for their choice of reviewers, and decisions regarding  
168 manuscripts [6, 30, 32].

169 Peer reviewing papers is one of the scientists' most important tasks, for which they are  
170 not paid and rarely get credit. An open review system linking reviews to published papers  
171 would give credit to peers undertaking a job which implies opportunity costs, but no obvious  
172 recognition [6, 30, 32]. Pre-publication reviews are usually discarded after articles are  
173 published. Sometimes this means that time, expertise, efforts, valuable content and insight are  
174 wasted [33]. Posting reviews could allow Internet access through common search engines  
175 [30]. Signed reports could help build the reviewer's reputation and curriculum, especially if  
176 standard evaluative instruments are systematically used [34,35] and scores shown, and might  
177 constitute a teaching and training modality for junior reviewers and scientists [10]. In  
178 addition, if reviews are publicly accessible, the theoretical risk of retaliations by vengeful  
179 authors would be counterbalanced by the appreciation of a multitude of colleagues who could  
180 influence one's career as much as enemies [32].

181 Indeed, some initiatives have been recently undertaken with the objective of crediting  
182 reviewers. In 2012 Publons [36], an academic networking platform based in New Zealand  
183 was launched. Publons enables authors to post their reviews on the platform. Contributions  
184 are assigned Digital Object Identifiers (DOI), thus allowing the best reviewers to track and  
185 record their reviews for potential inclusion in their curricula [37]. Of note, following the  
186 recent integration of Publons with Altmetrics, a new scoring system was developed with the  
187 aim of increasing exposure to social networks and to measure alternative impact of the  
188 reviews [38-40]. Pre-val is another emerging tool gaining traction in the peer review world.  
189 Pre-val, a program working to facilitate transparency and integrity of peer review, has been  
190 recently backed by the American Association for the Advancement of Science [41].



191           Also a scholarly publisher recently explored a new modality to facilitate transparency  
192 of the peer review process and to give credit to reviewers. Elsevier launched a pilot trial  
193 publishing peer review reports as articles [42]. For five participating journals, selected  
194 reviews of accepted articles appear next to their published articles, with a separate DOI, on  
195 ScienceDirect [43]. However, editors of participating journals “can” choose to have review  
196 reports published, and, although the review reports are freely accessible to all [44], reviewers  
197 are given the option to remain anonymous. Moreover, editors’ comments and reviewers’  
198 comments to the editors are not included [42].

199           Making peer review reports citable could create an incentive for reviewers. However,  
200 this also poses a serious problem, that is, how can journals publish and credit negative reports  
201 that led to manuscript rejections? This aspect has further implications, such as inducing  
202 reviewers to express negative recommendations in case they prefer not to be exposed to the  
203 public. Finally, publishers, especially commercial ones, or scientific societies owners of  
204 journals, might be reluctant to accept changes that may increase management costs for  
205 editorial offices, and potentially affect revenues from selling of reprints and advertising [45-  
206 48]. In fact, particularly in specialty fields, manuscripts regarding trials sponsored by industry  
207 might be submitted preferentially to journals with anonymous peer review rather than to those  
208 adopting an open review system with links to pre-publication history. In fact, publishers and  
209 societies might consider medical journals also as business ventures that must make profits  
210 [49,50], and anything that might threaten income, at least in the short term, could be regarded  
211 with skepticism.

212 MEDICAL PUBLISHING, ETHICAL RESPONSIBILITY, AND THE DIFFICULT  
213 CHOICE BETWEEN OLD AND NEW MODELS

214 Substantial differences in the quality of reviewers' reports were not observed in the now  
215 numerous primary and secondary studies conducted on the proposed modifications of the peer  
216 review process [10,11,15,17,51-54], as methodological shortcomings and study bias often go  
217 undetected independently of the system adopted [55]. What can be obtained by reviewers  
218 seems to be associated with their knowledge, motivation, and dedication, and not with a  
219 specific peer review model.

220 Additional weaknesses of the closed models were recently uncovered as peer-review  
221 frauds based on auto-fabricated reports hacked the publication process [56]. Surprisingly, not  
222 only authors were involved but, occasionally, editors as well [56]. Several measures have  
223 been suggested in order to increase the overall system safety, including turning off the  
224 reviewer-recommendation option, integrating the Open Researcher and Contributor ID  
225 (ORCID) to verify reviewers' identities, and reducing the vulnerability of the editorial  
226 software [57]. In this regard, the open-review model would further discourage these illegal  
227 practices. In fact, the possibility to timely identify fake reviewers would be increased, as  
228 personal data and institutional affiliations would undergo public scrutiny in addition to pre-  
229 publication editorial check.

230 Beyond the above aspects and considerations, the open system with posting of  
231 prepublication histories indeed changes the overall perspective and the goal itself of peer  
232 review, as it brings under the spotlights all the editorial activities linked to article publication,  
233 overcoming the limits of an excessive focus confined to reviewers' role [4,30,45,58,59].  
234 Publications greatly influences prescribing patterns and clinical practice. It seems ethically  
235 sound that each step that leads to publication of studies that may imply consequences for  
236 patients is rendered transparent. Editors decide which manuscripts are to be rejected outright  
237 after internal assessment and which are to be sent out for external review, they select  
238 reviewers, interpret their comments, and have the power and the responsibility to accept or

239 override their recommendations [4,6,59]. In a blind system, all these crucial phases are  
240 generally kept secret, and this may appear inappropriate. Moreover, much emphasis is put on  
241 authors' COIs, but also COIs of editors, associate editors, and reviewers may unduly influence  
242 the manuscript fate [4,45,47,60,61]. Furthermore, COIs may be additive, in case reviewers are  
243 chosen who share the same competing interests of editorial board members who have the  
244 power to take decisions regarding manuscripts. It has been suggested that specialty journals  
245 may be at higher risk of COIs compared with general medical journals [62]. In an open  
246 system, all COIs would undergo public scrutiny, and authors and readers could also identify  
247 COIs that reviewers failed to declare and editors are unlikely to detect [4,30].

248         Thus, a key aspect of a transition to an open system would be to reveal the identity, the  
249 reports, and the competing interests, if any, of all those who influenced acceptance of a  
250 manuscript to the entire medical community [4,6,31,32]. According to van Rooyen *et al.* [11]  
251 "for important decisions that affect us, we now expect to know who made them and how they  
252 arrived at their decision".

## 253 CONCLUSION

254         In medicine, several costly new drugs, devices, diagnostic tools, and surgical  
255 procedures are regularly evaluated. The choice among alternatives may imply different effects  
256 on the limited financial resources of individual families or public health systems. At the same  
257 time, the first Open Payment data shows that several manufacturers of drugs or devices are  
258 among the top highest spending US companies by payment to physicians, with orthopedic  
259 surgery, internal medicine, cardiology, and psychiatry being the specialties that receive the  
260 most payments. In addition, orthopedic surgery, obstetrics and gynecology, gastroenterology,  
261 cardiology, and ophthalmology are the specialties with the highest value of shares held by  
262 physicians [63]. Therefore, especially in the above fields [26,61,64], the risk of competing

263 interests' influence on medical publishing [4] may constitute an additional good reason why  
264 an open review system that links the full prepublication history, including editorial and  
265 reviewers' COIs, to selected published articles, could be adopted. This seems particularly  
266 important also considering that primary research constitutes the basis for systematic reviews  
267 and meta-analyses, which in turn inform clinical practice guidelines. Open review of original  
268 trial reports and clinical education articles covering new commercial diagnostic or therapeutic  
269 products, i.e., those that could influence patient management, would also further increase trust  
270 of the medical community and society in medical journals.

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## 273 LEARNING POINTS

- 274 • Peer reviewers play a crucial role in the selection of those studies that, once published,  
275 will inform health care decisions.
- 276 • Although editors retain the authority and responsibility to override reviewers'  
277 recommendations regarding the final disposition of manuscripts, reviewers appear to  
278 be influential.
- 279 • The single-blind peer review system has undergone increasing scrutiny and criticisms,  
280 mainly due to the possibility of bias and the considerable effects they can have on the  
281 scientific literature.
- 282 • Modifications of the process (i.e., double-blind and open peer review) have been  
283 studied with the goal of improving the quality of reviewers' evaluations and,  
284 consequently, that of reports of biomedical studies and of the evidence offered to  
285 health care providers, policy makers, and consumers.
- 286 • Substantial differences in the quality of reviewers' reports were not observed in the  
287 numerous primary and secondary studies conducted on the proposed modifications of  
288 the peer review process, as methodological shortcomings and study bias often go  
289 undetected independently of the system adopted.
- 290 • Independently of theoretical pros and cons, the open system with posting of  
291 prepublication histories changes the overall perspective and the goal itself of peer  
292 review, as it brings under the spotlights all the editorial activities linked to article  
293 publication, overcoming the limits of an excessive focus confined to reviewers' role.
- 294 • It seems ethically sound that each step that leads to publication of studies that may  
295 imply consequences for patients is rendered transparent.

296 CONFLICT OF INTEREST

297 Paolo Vercellini is associate editor of Human Reproduction Update; Laura Buggio state  
298 that she has no conflict of interest to declare; Paola Viganò is associate editor of Human  
299 Reproduction and received grant for “Fertility Innovation” by Merck Serono; Edgardo  
300 Somigliana is deputy editor of Human Reproduction. The authors report no other  
301 competing interests.

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