

IT-Structures and Algorithms for Quality Assurance in the Medical Advisory Service Institutions in Germany. Step 2: To err is Human. Consensus-Conferences

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Abstract: 16 Regional Medical Advisory Service Institutions perform medical expertise assessments upon German in- and out-patient care. Assessments have to accomplish a nationwide quality assurance plan with mandatory public reporting. We developed strategies to resolve conflicting quality measurement evaluations in the same item by different peers without unveiling the identity of the criticised medical expert or peer in the processes. All workflows are completely digitalized using mathematical IT-based procedures for randomized sampling and for an equal distribution of the medical expertise assessments to be reviewed. We even allow for smaller sample sizes, so regional heterogeneity and the heterogeneity of the types of medical expertise assessment pose a constraint satisfaction problem. We discuss models addressing this kind of problem type and present possible solutions. Our technical framework for peer review distribution, data collection and final result analysis includes a completely IT-based workflow not only masking the origin of the medical expertise assessments discussed, but routing the peer review processes in a way that independent and impartial review sheets are produced by peers that were previously not yet involved in the reviewing process. Finally, the statistical distribution and outcomes of the review results are analysed.

1 INTRODUCTION

To err is human and occurs among medical experts as well. Our aim is to establish a continuous mutual learning situation within a benchmark framework for a nationwide quality assurance plan covering all medical expertise assessments performed by the Medical Service Institution. We present a valuable tool creating maximum transparency of outcomes but founded on positive criticism without blaming individual institutions or individual medical experts.

This quality initiative is unique in Europe by creating nationwide outcome quality assurance standards within the legal institutions that advise the German health care insurance funds in declaring cost

assumption for health care service. The health care providers deserve that the legal institution appraising quality benchmarks its own performance.

This innovative project was initiated in November 2016 by the head physicians' board of the 16 Regional Medical Advisory Service Institutions (MD). In 2018, a mutual agreement was reached regarding the quality objectives, the criteria applied and the central IT platform conception, its architecture and technical workflow implementation (Ries et al., 2021). The nationwide implementation started from November 2019 and will be accomplished by April 2023.

Meantime, the self-initiated nationwide quality assurance became mandatory by a law amendment of the German Social Code in December 2019 (Merkel and Spahn, 2019).

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2 LEGAL FRAMEWORK

The 16 Regional Medical Advisory Service Institutions performing medical health care expertise are legally established by the German social legislation (Gaertner and Gnatzy, 2011). A pre-existing peer review based quality assurance system was mandated by law in 2004, but restricted on long term care assessments (Schmacke, 2016). The current nationwide quality assurance plan's initiative started in 2016 (Ries et al., 2021) and was mandated by law ex post in 2019 (Merkel and Spahn, 2019), adding a supplementary advisory service institution.

2.1 Getting Started

In analogy to industrial quality standards for production, quality is defined to measure the degree of correspondence between the service provided by a supplier and the service expected by the customer (Masaaki, 1986; Gerlach, 2001; Kamiske and Brauer, 2011; Institute of Medicine, 1990 and 2001; Internationale Organisation fuer Normung, 2015).

The aim here was to review the kaleidoscope of singular quality assurance measures regionally performed and to merge it into one mutual commitment based nation-wide quality perspective. Based on this conception, a new quality assurance plan for medical expertise assessments started in 2019, addressing the two main topics for medical expertise assessments:

- In-patient care: hospital quality and billing control on behalf of the health care insurance funds (Thiele et al., 2018; Kreuzer et al., 2022);
- Incapacity for work in out-patient care: case management consultancy and medical expertise assessment in insurance questions arising in the area of incapacity for work service (Nuechtern, 2008; Nuechtern und Mittelstaedt, 2015; Ries et al., 2022);

By choosing those two assessment topics, more than 70 % of all medical expertise assessments were covered within the pilot phase.

2.2 Rollout Schedule

By April 2024, the quality assurance plan covers all medical expertise assessments performed on all medical topics (Gostomzyk and Holleder, 2022):

- factual or putative medical treatment errors;
- dental medicine / oral maxilla-facial surgery;
- prevention and rehabilitation;
- medical assistance supplies and prostheses;

- plastic surgery, bariatric surgery, gender reassignment surgery;
- psychotherapy, occupational therapy, speech therapy, physiotherapy, intermittent home nursing, palliative home care, hospice care;
- new and unconventional diagnostic and therapeutic methods or medical devices, drug prescription and drug treatment.

3 CHALLENGES

We had to solve challenging distributional problems.

3.1 Regional Heterogeneity

Germany is characterised by a huge regional and sociodemographic heterogeneity of the 16 federal states, leading to 20 % of the population agglomerating in North Rhine Westphalia, but five other institutions in federal states representing less than 4 % of the population, either due to their historically profiled tiny regional size (Saar, Bremen) or to their rather scarce population density (former Eastern Germany). This creates institutional size variations from 100 to up to 1.500 employees per regional institution.

3.2 Structural Heterogeneity

Our innovative workflow validates the internal quality assurance within the regional advisory service institutions in a double-check way by the external quality assurance of another advisory service institution, creating a new and nationwide perspective.

Putting this challenging aim into reality was further complicated by the heterogeneity of the IT-systems. To tackle this problem, we implemented a web-based portal that can be reached by any software solution, processing data from different assessment databases.

Conflicting regional legal regulations on data protection are posing a constant challenge for cooperation on a nationwide level.

4 ACCOUNTING FOR INEQUITY

4.1 Adaption of Sample Size

The quantity structure of the nine topics of health care benefits leads to more than 70 % of all assessments performed in the single field of in-patient care, being 2.5 million medical expertise assessments per year.

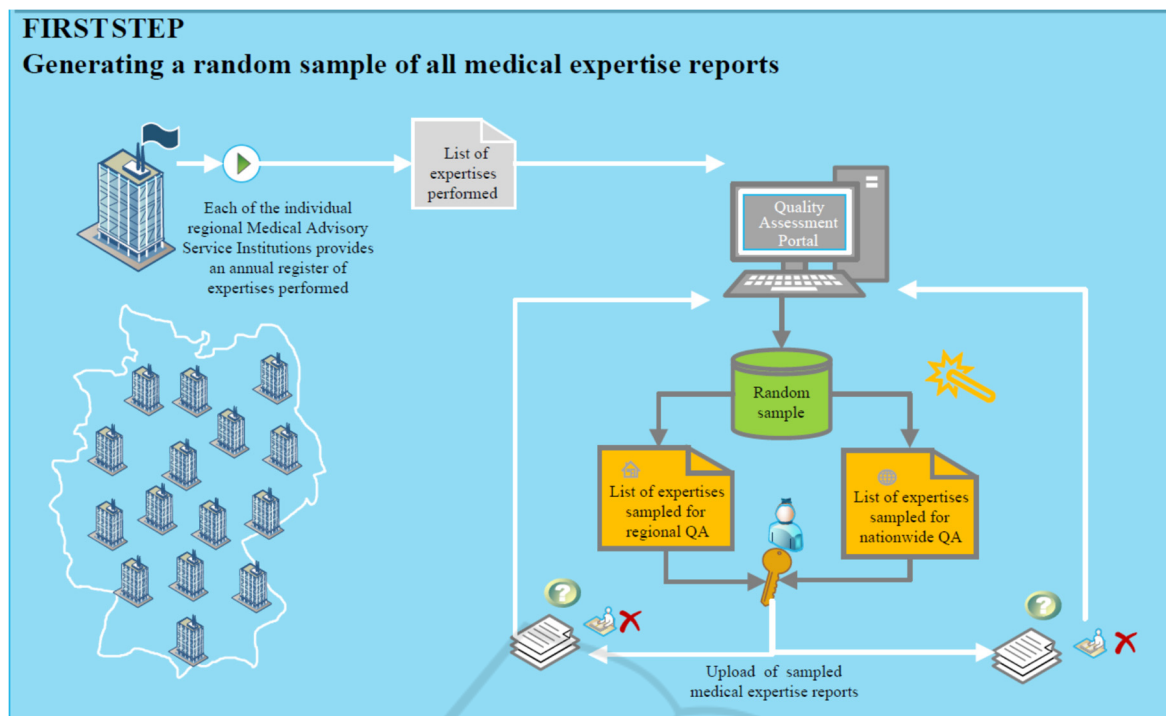


Figure 1: IT-architecture: Performing two quality reviews for a 10 % subset of the 0,5 % sample of all expertise assessments performed by each of the 16 Medical Advisory Service Institutions.

- A random sample of 0.5% is chosen for regional quality assurance using peer reviews.
- 10 % of the previously chosen assessments are randomly chosen for a double check peer review by another regional institution generating the nationwide perspective.

This sampling leads to 12,500 regional peer reviews and 1,250 nationwide peer reviews for in-patient care.

The remaining medical treatment topics generate only a total of 650.000 assessments per year. For reliability, we fixed minimal random sample sizes to

- 112 per year for regional quality assurance;
- 56 of the previously chosen assessments for a double check peer review.

Since the peer review process is organized quarterly, this provides every participant with a review by any of the other participants in a quarterly rhythm, validating internal quality assurance results.

4.2 Positive Criticism

Even this rigorous reduction was not yet feasible for the five federal states representing less than 4 % of the population, so we had to further reduced it to

- 56 per year for regional quality assurance and
- 28 randomly chosen for double check review.

From a psychologic point of view, it was revealing that this concern was concealed by the

participants in the regular meetings of the quality assurance working group, but proclaimed "out of the blue" by the executive board.

This incident acted as an eye-opener to us. Quality assurance management is a communication process, first and foremost. Obviously, we had not yet managed to create that situation of mutual trust and learning within our working group that is crucial to allow individual participants to raise word to focus on important short-comings of the process.

Background analysis initiated by quality outcome discussions reveal structural variations or even space for clarifying procedural questions. Therefore, at least one member of the corresponding medical expert committee for the topic takes part in the consensus conference, as well as at least one member of the head physicians' board.

4.3 Pseudonym-Protected Knowledge Transfer

Nobody wants to get passed on the red lantern, so it is crucial to create an environment of positive criticism and trustful mutual learning preventing the participants of feeling embarrassed by raising concerns or outing important short-comings (Beauchamp and Childress 2001; Varkey, B. 2021). A user-friendly and trustful shaping of the quality assurance

communication process remains a constant quest (Woodward, 2019). The nationwide quality assurance plan conceals the identity of the peer reviewer and the provenance of the medical expertise assessment.

Quality measurement and validation takes place comparing all double-check review sheets, i. e.:

- The internal review sheets: self-evaluation review by an experienced peer within the regional medical advisory service institution of provenience.
- The external review sheets: impartial evaluation by an experienced peer belonging to another regional medical advisory service institutions.

5 IT PROCESSES FOR THE CONSENSUS CONFERENCE

5.1 Structured Quality Review

The review sheets are composed of 20 core quality criteria for all topics of health insurance benefits. Several topics add specific quality criteria to check in depth for medical accuracy in complex medical assessment procedures like drug administration, transsexualism or dental surgery.

Quality criteria ratings are colour-coded as "adequate" green, "potential for improvement" yellow and "inadequate" red. Synoptic review sheets contrasting "green" with "red" in the same quality criterion are eligible for a joint meeting of medical experts designated by all regional institutions to resolve conflicting views (consensus-conference).

		external evaluation		
		correct	improvement potential	incorrect
internal evaluation	correct	256	97	49
	improvement potential	72	42	32
	incorrect	26	23	18

Table 1: Validating internal quality assessment outcomes by comparing with the outcomes by mutual peer review for the same expertise assessments. In the topic shown above, 49 + 26 = 75 reviews are eligible for consensus.

5.2 Structured Peer Review Communication

We consider the random sample of medical expertise

assessments from each of the nine topics for a period of six months in three steps:

1. internal review by the author's peer (1° peer)
2. external review by a second peer, belonging to another regional institution (2° peer),
3. possible modification of the internal evaluation by the first peer in regard to the external evaluation, creating the synoptic review outcome sheet.

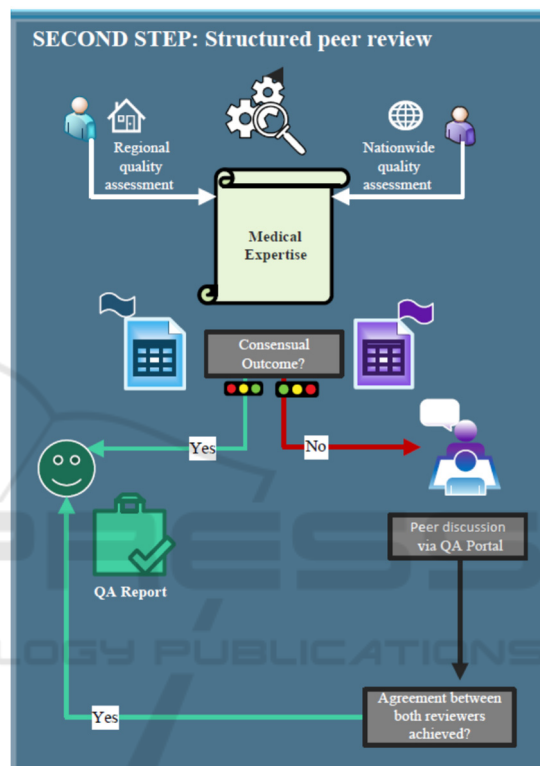


Figure 2: Peers gathering assessments to be treated in the consensus-conference by discussing conflicting reviews via the QA-Server.

5.3 Resolving Conflicting Reviews

To facilitate joint decision making, they are randomly distributed into four groups with four participants each. To guarantee objective judgements, no participant can be involved in discussing reports generated by himself (only third-party peers admitted).

Usually, we discuss 16 or 32 expertise assessments per conference day. In order to solve the allocation problem, we start with a random order, followed by group assignment to the first possible position in a cyclic order. If there are no valid assignments left, we search from top to bottom for possible replacements. Opting for a few more candidate expertise assessments to choose from, will facilitate the exchange process. Other options are to change the initial

random order of the expertise assessments or the random group assignment of the institutions.

During the consensus conference, controversial review sheets are processed by third party review. If a common judgement within the third party peers remains disputed, this expertise assessment will be routed into the plenary discussion.

As soon as the third party groups have fixed their group voting, persisting conflicting reviews are open to discussion, leading to a final plenary voting in each conflicting quality criterion, involving all 16 medical experts. The final review results of the consensus-conferences are stored as part of the public reporting.

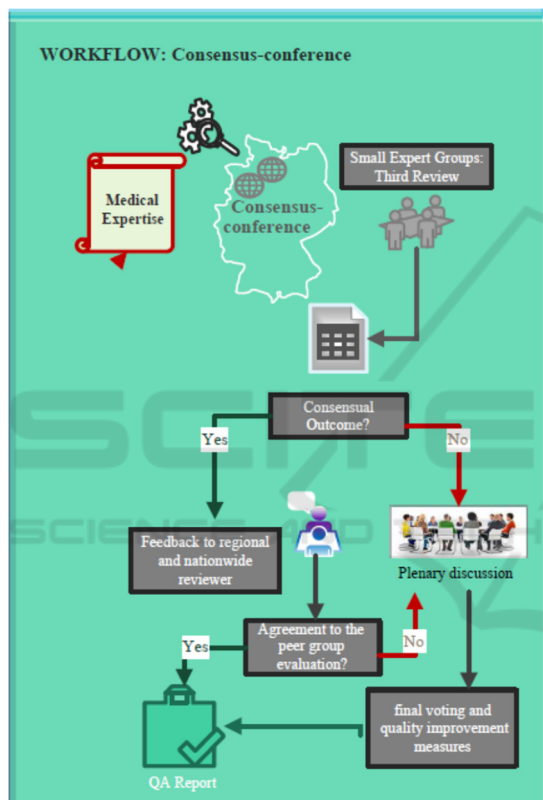


Figure 3: IT implementation of the consensus process.

5.4 Logistic Framework

The red/green differences showed to be unevenly distributed as well among the regional institutions as across the quality criteria, so unveiling the provenance of the reports and of the reviewer proved to be of capital importance to maintain an objective, factual and open exchange among the peers in order to revisit critical process checkpoints in passing an expert opinion, creating a common ground of agreement.

We usually started resolving the conflicting reviews by establishing third party groups.

Alternatively, polarizing expertise reviews showing a high load of red/green differences can be prepared for individual live evaluation by every peer to discuss the range of opinions openly during the consensus-conference. To select the most polarizing reviews, we performed a ranking by summing up the evaluation differences between the internal and external review (from green to red distance 2, otherwise 1). We advise to check for the kind of assessment problem in order to exclude reports addressing the same problem repeatedly but in different criteria.

All previously described points are automatically implemented via the QA-server, presenting to each medical expert only those decisions he has to discuss with his peers. If votes are necessary, they are carried out live on the QA-server. Each peer sees the results and the documented remarks in real time, which are then transferred to the database to be available for quality assessments reports.

6 PUBLIC REPORTING

The provident decision of the head physicians' board in 2016 happened to gain the attention of the German health politics. The Health Care Act in 2019 introduced mandatory reports of the activities of the regional Medical Advisory Service Institutions every two years, including the nationwide quality assurance plan's evaluation, starting in 2024.

We will now present preliminary statistical results for some paramount quality dimensions we analysed so far. The following figures show the outcomes concerning the medical assessment topic "incapacity for work" displaying the first nine months in 2021.

6.1 Quality Dimensions

The quality assurance results were investigated within several dimensions:

- Cumulative internal quality assurance results benchmarked against cumulative external quality assurance results, using both a visualisation as a bar plot and a secondary diagram showing confidence intervals for differing results.
- Comparing the mutual peer review results on a descriptive level in a table, indicating reliable differences found by confidence values initiating quality improvement measures.
- Focussing on quality outcomes within the own institution for all criteria applied on all medical topics addresses systematic weak points as comprehensible language avoiding needless

technical terms, deploying medical facts and recommendations in a well-structured way.

6.2 IT-Server Assisted Access

For training purposes, the expertise assessments are shown in the QA-Server sorted by bad scores, selecting for the highest number of criteria marked as incorrect. Clicking on a cell on table 1 takes you directly to a synoptic view of the internal and the external reviews, provided both online and as file export. A link to the original expertise assessment is embedded in the synoptic review sheet, so all peers can check for appropriate rating in every criterion.

All institutions can export the charts with the individual results highlighted on a daily accurate basis as a freely configurable graphic from the QA-server, selected for quality criterion and for medical assessment topic.

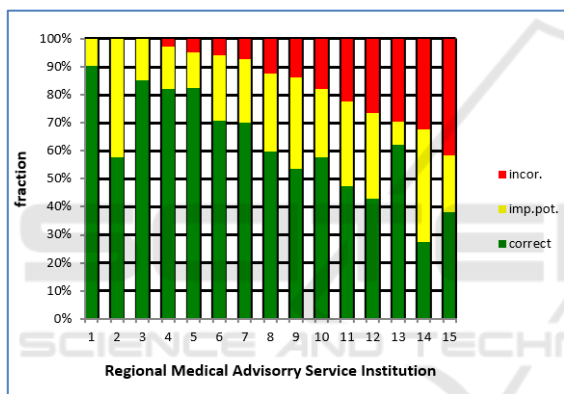


Figure 4: Individual quality assurance results of all regional Institutions in one criterion for topic "incapacity for work".

6.3 Preliminary Quality Assurance Results for Internal Peer Review

The benchmark of the cumulative internal results shows varying results between the regional institutions (MD), "MD 1" stating no incorrect assessments and "MD 15" stating more than 40 percent of incorrect expertise assessments. The criterion checks if all the medical information was available. The divergent evaluation results judging the same assessments highlights the need to reach a uniform understanding of the quality standards, initiated by the consensus conference discussions.

Each peer can see the position of his own institution in the benchmark telling him whether he acts particularly strictly or tolerantly (and possibly inaccurate) as compared to the peers of the other regional institutions. The other MD are concealed, the

number ID changing from chart to chart since the position is sorted by growing amount of red ratings.

6.4 Benchmarking the Individual Quality Assessment Results: Outcome Validation by Mutual Peer Review

Validation of individual internal quality assurance by external review by a second peer focusses mainly on the quality of the expertise assessments. The external review is a representative mix of all other MDs over a sufficiently long period of time. The left part of the column graphic below always shows the internal assessment and the right part the external review. In "MD 9" the external evaluation is much more critical than the internal. For "MD 15" the situation is reversed.

Evaluation differences in a criterion spring to the eye instantly, making analyses easy for the peers. Additionally, confidence intervals are displayed:

In case the intervals are disjoint, there is a statistically significant difference calling for action, either inside the institution or even on a nationwide level.

A critical reappraisal of the quality criteria concerned will be proposed as subject for the consensus conference discussion to discuss the need for nationwide improvement measures.

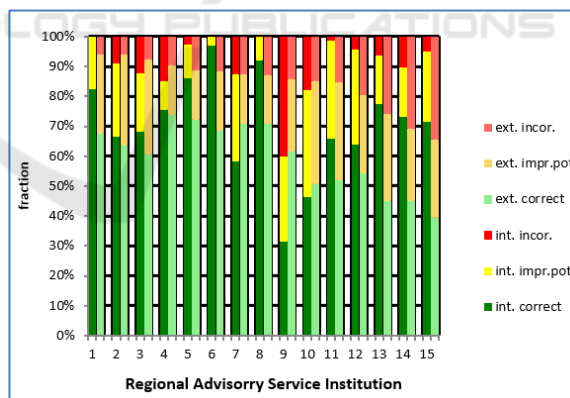


Figure 5: Validation of quality assurance results by direct comparison of the individual quality assurance vs. the external mutual peer reviews for the same expertise assessments (author peer vs. external second peer).

The confidence intervals of the external assessment in Figure 6 are disjunct even in a horizontal perspective for "MD 1" and "MD 15", additionally indicating a significant difference in the quality of medical expertise assessments between "MD 1" as compared

to "MD 13", "MD 14" and MD15", an intriguing finding of regional disparity.

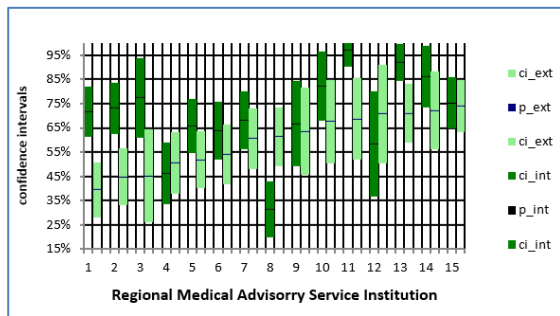


Figure 6: Checking the variations found in a quality criterion for statistically significant differences render possible quality improvement measures.

6.5 Scope of Individual Improvement

It is of paramount importance for each regional institution to gain this innovative perspective in order to realise new improvement potential.

Quality assurance results vary a lot between the criteria and are an ample monitoring tool to focus on potentials for improvement in several topics, profiling a general improvement measure like special trainings for the medical experts authoring the assessments.

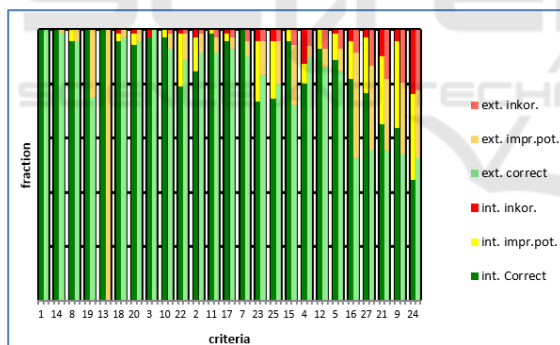


Figure 7: Specific charts for each individual regional institution display all quality criteria within a medical expertise assessment topic.

6.6 Future Prospects

The results of quality assurance will be published in great detail in accordance with the recently adopted statistics guideline. Thousands of real-time tables and graphics are created by the QA-server processing huge amount of data (Schuster, 2022).

Our next quality assurance tools to be developed are:

- Time series including statistical significance will monitor the effects of quality improvement measures and possible confounders.

- Monitoring the inter-rater-reliability within an institution helps to identify internal evaluation bias, benchmarking the nine medical assessment topics against each other.
- Analysing quality assurance outcome data within a medical topic in regard to the nationwide inter-rater-reliability will enable us to assess the process for differences in review behaviour between the institutions involved as a possible confounder.

7 CONCLUSIONS

The German health care insurance funds rely on institutionalised medical experts to allocate the appropriate health care service. The nationwide quality assurance plan will empower the Medical Advisory Service institutions to consolidate quality performance on a nationwide level, strengthening the legal task as an unimpeachable healthcare advisor.

We hope that this powerful tool will ease the improvement processes, fostering a mindful dialogue within the 16 Medical Advisory Institutions involved.

Consensus-conferences are meant to be a very satisfactory and efficient quality assurance tool to ascertain high quality in the peer review process.

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