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SPECIAL ARTICLE

European Heart Journal quality standards

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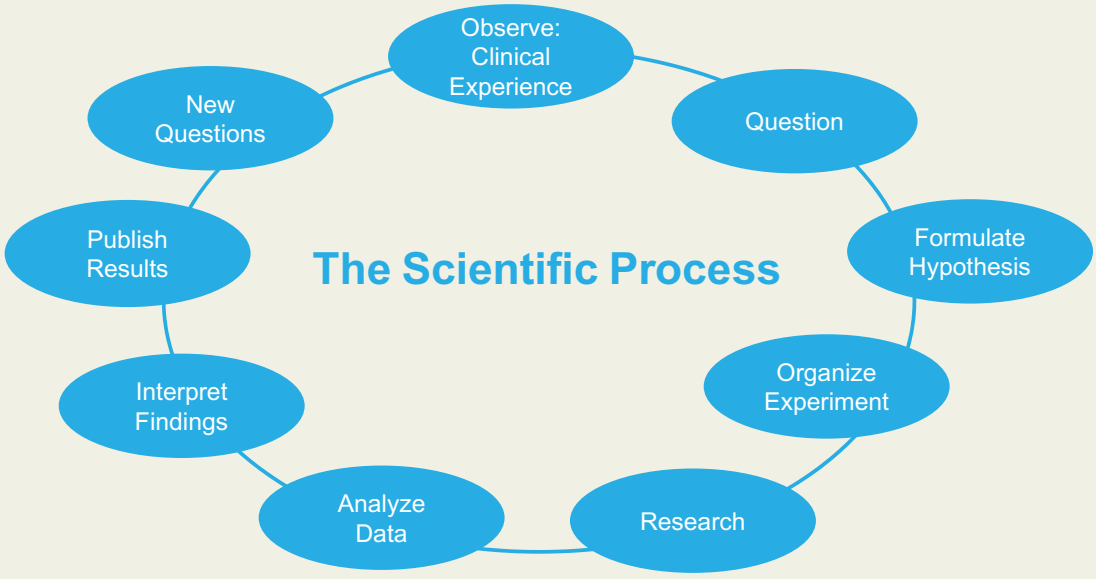
The aim of the *European Heart Journal* (*EHJ*) is to attract innovative, methodologically sound, and clinically relevant research manuscripts able to change clinical practice and/or substantially advance knowledge on cardiovascular diseases. As the reference journal in cardiovascular medicine, the *EHJ* is committed to publishing only the best cardiovascular science adhering to the highest ethical principles. *EHJ* uses highly rigorous peer-review, critical statistical review and the highest quality editorial process, to ensure the novelty, accuracy, quality, and relevance of all accepted manuscripts with the aim of inspiring the clinical practice of *EHJ* readers and reducing the global burden of cardiovascular diseases. This review article summarizes the quality standards pursued by the *EHJ* to fulfill its mission.

Graphical Abstract



Summary of the elements that support scientific progress.

Keywords Biomedical journals • Publication ethics • Editorial recommendations • Scientific process • Authorship • Peer-review • Trial registration

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Introduction

The aim of the *European Heart Journal* (*EHJ*) is to attract innovative, methodologically sound, and clinically relevant research manuscripts able to change clinical practice and/or substantially advance knowledge on cardiovascular diseases.[1–3] As the reference journal in cardiovascular medicine, the *EHJ* is committed to publish only the best cardiovascular science adhering to the highest ethical principles.[1–6] *EHJ* uses highly rigorous peer-review, critical statistical review, and the highest quality editorial process, to ensure the novelty, accuracy, quality, and relevance of all accepted manuscripts with the aim of inspiring the clinical practice of *EHJ* readers and reducing the global burden of cardiovascular diseases[1–6] (*Figure 1*).

The *EHJ* subscribes to the recommendations of the International Committee of Medical Journal Editors (ICMJE) for the conduct, reporting, editing, and publication of scholarly work in biomedical journals.[4] The *EHJ* is a registered member of the Committee on Publication Ethics (COPE) and endorses this code of conduct on ethical issues in research and publication.[5,6]

Authorship criteria

According to the ICMJE guidelines,[4] authorship should be based on the following four criteria: (i) substantial contributions to conception or design of the work, or the acquisition, analysis, or interpretation of data for the work; (ii) drafting of the work or revising it critically for important intellectual content; (iii) final approval of the version to be published; and (iv) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. As noted in the ICMJE guidelines, 'This final criterion helps Editors solve potential issues that may arise during or after the publication of the work'. All those designated as authors should meet all four criteria for authorship. Those who do not meet all four criteria but contributed to the study should be acknowledged after obtaining permission. One author should be identified to take responsibility for the integrity of the work as a whole.[4,7–12] Authors should certify the validity of the work and also that the manuscript has not been previously published or is considered for publication in another journal[4,7–12] (*Figure 2*).

The *EHJ* will accept requests to recognize joint authorship (e.g. joint first or senior authors) as it is known that modern science requires advanced, multidisciplinary teams to address many questions of interest. Generally, it is expected that these joint roles will be shared by two authors.[4] In the instances where a small subset of authors is largely responsible for leading the manuscript, and there is a larger body of investigators that provided supplemental support for the manuscript, a paper written on behalf of a named pool of investigators identified by a study team in the authorship line should be considered.[4] Detailing individual contributions in the manuscript is the best way to give the required credit to each author.

Conflicts of interests

The *EHJ* is fully committed to transparency and this includes disclosure of potential conflicts of interest[13–17] (*Figure 2*). The proposed

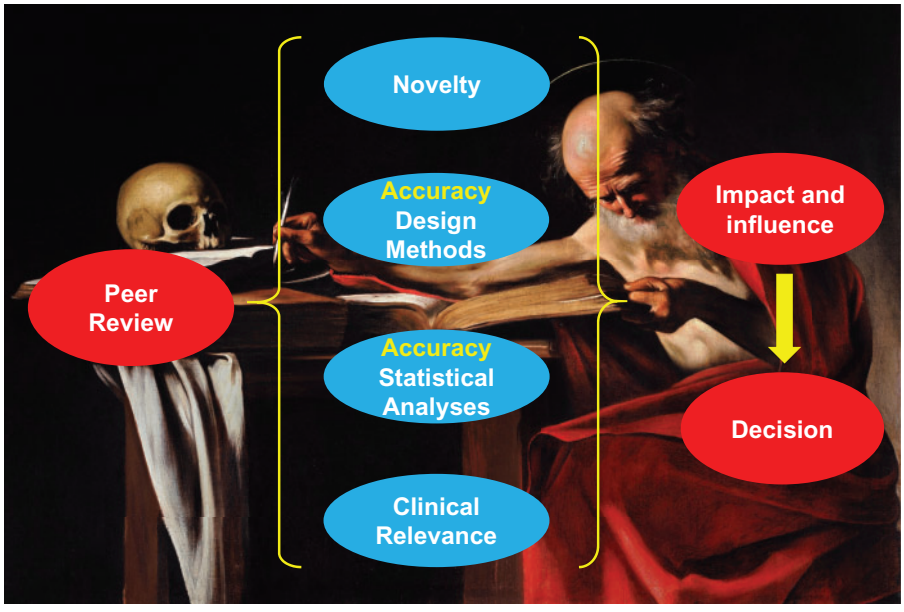

Figure 1 Value of the peer-review process. Peer-review remains the best tool to inform the editors on originality, quality, and accuracy of the design and methods, soundness of the statistical analysis, robustness of the results, and clinical and scientific relevance of the submitted work. Editors will further judge on the scientific impact and clinical influence of the study. The editorial decision-making process includes relative priority as compared with competing papers, alignment with the scope of the journal, and readers' interest. Only the best papers will be published in the *European Heart Journal*.

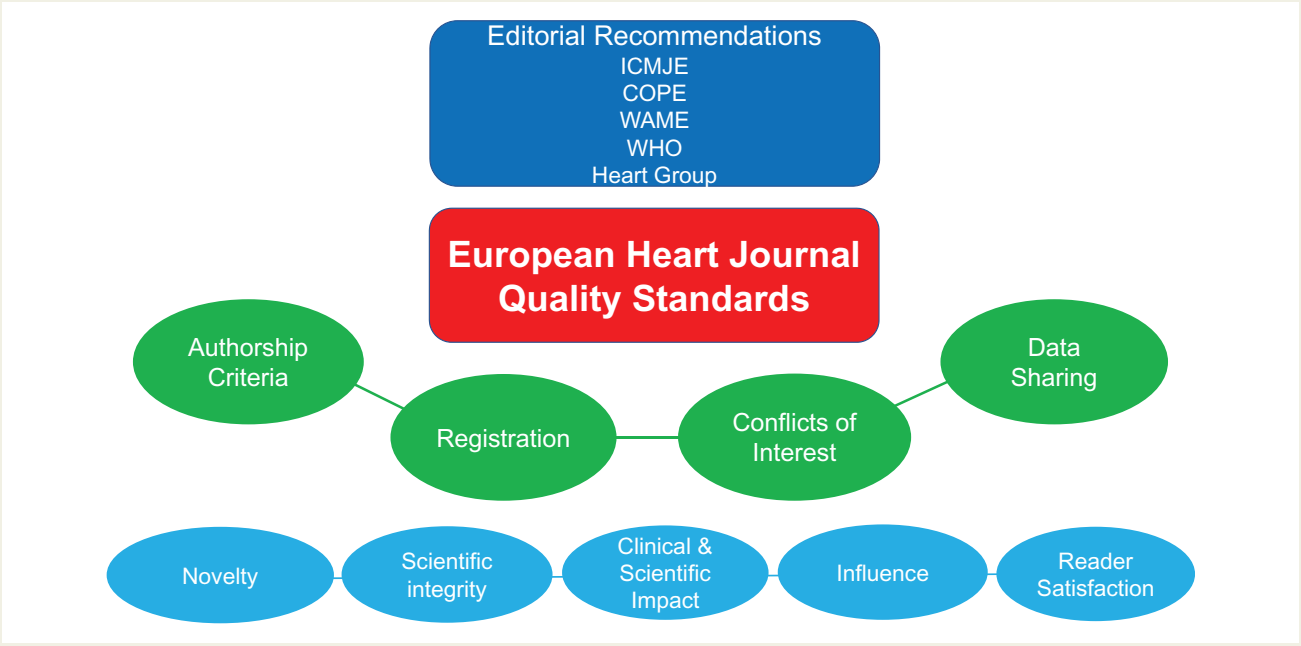

Figure 2 The quality standards of the *European Heart Journal* are based on the widely respected and accepted international editorial recommendations. These include authorship criteria, conflict of interest, trial registration, data sharing initiatives, and sound statistical analyses, among others. Scientific integrity is paramount to ensure the credibility and clinical influence of the research findings. COPE, Committee On Publications Ethics; HEART Group, group of cardiovascular journals for editorial issues; ICMJE, International Committee of Medical Journal Editors; WAME, World Association of Medical Editors; WHO, World Health Organization.

new ICMJE disclosure form suggests using the term 'relationships and activities' rather than the classic 'conflicts of interest' to ensure a more balanced interpretation by readers.[4] However, both terms may be used for disclosure. The rationale for disclosure is to preserve trust in the scientific process and the credibility of published material.[13–17] Financial and non-financial relationships and activities pertinent to the submitted work that may be perceived by the reader as potential conflicts of interest should be disclosed. It is important to recognize that bias may exist when professional judgement on a primary interest may be influenced by a secondary interest (e.g. economic gain). When in doubt it is better to err on the disclosure side. Readers' perceptions of competing interests (independent of the authors' opinion) may erode trust in the scientific process. These relationships and activities may be 'directly' related or 'topically' related to the submitted work. Financial issues relate to payments to authors or their institutions.[4] The time frame for those relationships or activities *directly* related to the submitted work is from initial conception of the work to present. For those *topically* related, the time frame to be considered is from 36 months ago to the present.[4] The ICMJE recently updated the form and included the possibility of accepting disclosures from well-selected web-based repositories.[17]

The *EHJ* requires that all authors complete the standardized electronic ICMJE 'Disclosure Form' and a conflict of interest statement to be included under the 'Disclosures' heading in the submitted manuscript.

In addition, all sources of support for the work should be separately disclosed in detail. The role of the funding source (sponsor) in the design, analysis, interpretation, and writing of the manuscript should be clarified. Any potential restriction to publication agreed upon with the sponsor should be detailed. The corresponding author should declare 'I had full access to all the data and I take complete responsibility for the integrity of the data and the accuracy of the analysis'. For multicentre or international studies, a 'guarantor' of the entire study should be identified.[4]

Trial registration

The process of best practices for clinical trials led by the World Health Organization (WHO) includes universal prospective registration, public disclosure of results from clinical trials, and data sharing.[18–21] The *EHJ* promotes transparency of the research process with systematic online publication of the protocols of clinical trials and also large prospective observational studies, registries, surveys, and meta-analyses (*Figure 2*). The Cochrane collaboration provides an excellent tool in this regard. Meta-analyses should be pre-registered in specific repositories (e.g. PROSPERO).[22]

Clinical trials should be 'registered' in a public trial's registry as a condition for publication.[4,18–21] A 'clinical trial' is defined as any research project that prospectively assigns people to an intervention (with or without concurrent comparison or control group) to study the relationship between a health-related intervention and a health outcome. Interventions are modifiers of biomedical or health-related outcomes, including procedures, devices, dietary or behavioural treatments, educational programmes, quality improvement, and process-of-care changes.[4]

The registries for prospective registration should be managed by a not-for-profit organization, be open, publicly accessible at no charge, electronically searchable, and ensure validity of the registration data. Prospective clinical trial registration should be performed in any registry of the WHO International Clinical Trials Registry Platform that includes the minimum acceptable 24-item trial registration dataset.[4] ClinicalTrials.gov (https://www.clinicaltrials.gov) and the EU Clinical Trials registry (https://www.clinicaltrialsregister.eu) fulfill all these criteria. The entire 24-item dataset should be completed.

Trial registration prevents selective publication and duplication of research and ensures consistency in methods and predefined outcome measures (primary and secondary endpoints).[18–21] Trial registration should include a detailed description of the statistical plan, particularly the primary and secondary endpoint definitions and any pre-specified subgroups that will be considered. Potential discrepancies between data on the registry and final publication (protocol amendments, etc.) should be avoided and, if present, should be explained and justified in detail to the Editors. The registration numbers, name of the register, and date of registration in these public repositories should be provided. Registration is required to occur *before* the time of the first patient enrolment. When the final paper is published, registration should be eventually updated to include the journal citation.[18–21]

Prospective registration is required for all clinical trials but the *EHJ* strongly recommends preregistration of other studies as meta-analysis and observational studies. Registration number should be included at the end of the abstract and corresponding methods section. The clinical trial protocol, including the complete statistical analysis plan, should be submitted to the journal as online supplementary material. Publication of study designs is important to ensure credibility in the scientific process, yet these contributions rarely achieve the priority needed for publication in the *EHJ*.

Pre-prints

Pre-prints (author's original version) are permitted and the *EHJ* accepts manuscripts previously posted on a not-for-profit preprint server following some conditions as detailed in the Instructions to Authors (https://academic.oup.com/eurheartj/pages/General_Instructions#5.6). Authors of original research and review articles, excluding ESC Guidelines, retain the right to make a pre-print available through various channels. Should a work have been published in a pre-print server, this should be disclosed to the editors.

Data sharing

Data sharing facilitates independent validation of study results, fosters new hypotheses, and allows new analyses of the data. This not only promotes further advancements in scientific knowledge but also remains an ethical obligation to participants in a trial. Data sharing aims to maximize knowledge gained from published studies and increases confidence and trust in clinical trials.[23–25] Data sharing does have important limitations. The *EHJ* recognizes that there may be data use agreements, regional laws, and ethical considerations that will limit the availability of some data sets, particularly large electronic health record studies and studies involving advanced imaging and rare diseases. Thus, the *EHJ* requirement for a data sharing plan is to document the plan—whether data are made publicly available is a separate construct (*Figure 2*).

The data sharing plan should be explicitly disclosed in the manuscript.[23–25] Data sharing statements must indicate whether individual de-identified participant data will be shared (link to data repository), what data in particular will be shared (data dictionaries and codes), and when and under what specific circumstances or terms (types of analyses permitted) will be shared. Authors of secondary analysis should always seek collaboration of primary authors, clearly acknowledge the data source, and give substantial credit to initial investigators. Many secure online repositories for research data allow the archive of any type of file assigning a unique digital object identifier (DOI). An open data repository would offer obvious advantages for authors, institutions, funders, and journals, including greater transparency and enhanced feasibility of patient-level meta-analyses. Data sharing is a major endeavour that will affect how clinical trials are planned and conducted. This is an opportunity to define criteria for data collection and sharing that will make outcome events comparable and potentially combined among trials. However, unresolved issues remain in this editorial initiative, including appropriate scholarly credit to those sharing the data, resources needed to implement data access, transparent processing of data requests, and tools for data archiving.[23–25] Therefore, the *EHJ* considers that, at this time, the requisite mechanisms to 'mandate' universal data sharing are not yet in place. Where ethically feasible, the journal strongly encourages authors to make all data and software code on which the conclusions of the paper rely available to readers. A clear data availability statement must be included in the text of the manuscript and requires that all publicly available datasets are fully referenced in the reference list with an accession number or unique identifier such as a DOI.

General guidelines for authors

As a result of the *EHJ* commitment to research integrity, formal review, and approval (or waiver) by the corresponding institutional review boards or ethic review committees is required for all original research article.[4] In addition, all studies should follow the principles outlined in the Declaration of Helsinki. Finally, all human participants should provide written informed consent.[4] Oral informed consent alone will be accepted in rare occasions and the reason to justify oral consent should be clarified. Authors of studies including a waiver of informed consent (nationwide registries, massive data sources, biobank results, etc.) should justify this decision in detail with the editor. Research conducted as 'not human subjects research' by means of use of certified de-identified healthcare data should detail how the determination of approval was obtained and the certifications for the data's de-identification whenever possible.

Before submission, the *EHJ* instructions to authors (https://academic.oup.com/eurheartj/pages/General_Instructions) should be carefully reviewed for technical details. In addition, the authors at the time of submission will be asked to complete a general check-list confirming adherence to the quality standards of the *EHJ*. This check-list is reported in *Table 1*.

Table 1 EHJ check-list

Before submission the corresponding author should confirm the following requirements regarding the present work:

1) The *EHJ* instructions for authors have been read and the manuscript has been prepared accordingly. (*https://academic.oup.com/eurheartj/pages/General_Instructions*)
   Yes ____
2) The submitted work is original and has not been published nor is being considered for publication in another Journal.
   Yes ____
2) All named authors are aware of this submission and fulfil the 4 criteria for authorship including being accountable for the entire work. If requested they will respond to the Editor on an individual basis.
   Yes ____
3) All sources of support for the work and relevant conflicts of interest are disclosed in detail in the main manuscript. All authors will submit the uniform Conflict of Interest disclosure form when requested (before publication).
   Yes ____
4) The manuscript includes a statement regarding the required approval of the corresponding Ethical Committee or Institutional Review Board and the patient informed consent or specifically disclose and discuss the reason for a potential waiver
   Yes ____
5) The study includes a statement declaring that has been pre-registered in an accepted repository and the date of preregistration
   Yes ____
6) The study includes a data availability statement clarifying whether or not data sharing will be possible and on what specific terms
   Yes ____
7) Special care has been paid to report the data on relevant diversity aspects (including age, gender, ethnicity and socioeconomic status), when available
   Yes ____

EQUATOR provides an excellent source of general guidelines for authors detailing specific recommendations for the different types of studies.[26] The *EHJ* requires that authors complete check-lists for reports of certain specific studies. Overenthusiastic reporting of new findings to the scientific community should be tempered. These guidelines help to provide a clear vision of how the work was made. Causal language is only permitted for randomized clinical trials; for the remaining types of studies, methods, results, and discussion should be described in terms of 'associations' and 'correlations' but should avoid cause–effect implications.

i. *Randomized clinical trials* (RCTs) should be presented following the CONSORT recommendations.[27–29] The CONSORT flow-chart must be presented as an independent 'Figure' (flow diagram) to be published in the main manuscript or as supplementary electronic-only material. For non-inferiority or equivalence studies, cluster trials and for pragmatic and safety studies (reports of harm), the 'extensions' of the CONSORT recommendations should be followed.[28,29] RCTs should be primarily analysed according to the 'intention-to-treat' principle. Modifications of the intention-to-treat approach should be justified and described.
ii. *Meta-analyses* should be pre-registered in dedicated repositories[22] and be presented following the PRISMA recommendations (flow diagram and check-list)[30] and MOOSE reporting guidelines (check-list).[31] These studies require the use of statistical techniques for quantitatively combining results of multiple studies with the same outcome measure into a single pooled or summary estimate. Systematic reviews should provide a critical assessment of the literature. Systematic reviews will be considered as review articles whereas meta-analyses will be considered as original investigations. Systematic reviews and meta-analyses should represent a major step forward with new insights from available data. An 'updated' meta-analysis that includes only one additional study to a previously published meta-analysis is expected to be very low priority for *EHJ*.
iii. *Observational studies*. The STROBE recommendations[32] should be followed to accurately and completely report observational studies. Most biomedical research is observational. Adequate reporting of observational studies is required to assess their strength, weaknesses and generalisability (external validity). STROBE covers cohort, case–control, and cross-sectional studies in a 22-item check-list.
iv. Studies of *diagnostic accuracy* (diagnostic tests) should follow the STARD guidelines (flow diagram and check-list).[33]
v. *Genetic* association studies should be reported according to the STREGA guidelines.[34]
vi. Authors of *microarray* papers should follow the MIAME guidelines. Accession numbers and repository name should be provided.[35] Reporting of transcriptomics or sequencing data should comply with the latest guidelines and data must be accessible in a public repository.
vii. *Cost-effectiveness* analysis should follow the CHEERS recommendations.[36]
viii. Studies on *global health* estimates should follow the GATHER statement.[37]
ix. For studies on *animal experimentation*, the *EHJ* aims at detailed and high-quality reporting of animal experiments and suggests authors follow the ARRIVE guidelines when preparing their manuscript.[38] Authors may be required to provide evidence that they obtained ethical and/or legal approval prior to conducting the research. Authors of basic science studies should provide clear documentation of data (e.g. 'jittered' dot plots instead of bar and error plots). For most data summaries, mean and standard deviation are expected. If variation of the mean is desired (i.e. standard error), use confidence intervals instead.
x. The *EHJ* publishes clinical practice guidelines and position papers of the ESC. These documents follow the Governing Policies and Procedures for the Writing of ESC Clinical Practice Guidelines and adhere to the ESC Declaration and Management of Conflict of Interest Policy.[39]

Statistical analysis

General

The statistical analyses of a study should preferably be based on a statistical analysis plan that was finalized prior to the completion of the study. Statistical analysis plans are expected, just as the protocol, to be made available in a public repository. Regardless of whether a

statistical analysis plan has been registered, manuscripts should clearly distinguish between pre-planned analyses and further analyses generated from examination of data. These should clearly be labelled as '*post hoc*' analyses.

Statistical thresholds for claiming an effect of association should ideally be limited to analysis for which the analysis plan outlines a method to control for type I error. Two-sided *P*-values are expected for all studies. If one-sided testing is desired, the overall significance level as 2 × alpha (e.g. one-sided testing at alpha = 0.05 is equivalent to two-sided testing at alpha = 0.10) should be reported.[40] Correction for multiple testing may be used, but it is recommended that an adjusted level of significance is used instead of using scaled p-values. For example, a Bonferroni correction for $g = 2$ results in a level of significance per test at 0.05/2. This is preferable to multiplying the observed *P*-value by 2 to 'correct' it.

The statistical analyses of any study should aim at presenting the results and uncertainties in a clinically relevant manner. The description requires a balancing of focus between *P*-values and estimates of effect to better ascertain clinical implications. With large datasets, *P*-values may not reflect an important difference.

Methods used to produce reproducible research should be discussed.[41] Details on statistical packages, software, versions, and manufacturer should be provided. Along with the data sharing requirements detailed above, provisions for sharing computation code, fitted models, and other general dissemination of the work should be considered and detailed in the methods of the manuscript.

Descriptive statistics

Distributional properties of the observed data (means, counts, missing data, etc.) should be clearly presented. Authors should select summary statistics that best present the data concisely. Means (± SD) can be used for normally distributed data and medians and interquartile ranges for data that are not normally distributed or are skewed. Frequently, the extreme values (minimum or maximum, or other percentiles, such as the 95th percentile) play an important role in the interpretation of the data and should also be provided. In general, 'outliers' should not be removed from the dataset to fit distributional assumptions. Instead, a more robust statistical method should be considered.

Comparisons between groups

Comparisons between groups should include summaries of the relative difference between the groups. Standardized differences are useful for comparing the relative imbalance between groups, particularly so for analyses that use weighted selection of subjects to justify control for confounding.[42] More generally, differences between groups should be described with measures of effect size. Reporting effect size and precision or uncertainty is required to complement hypothesis testing (e.g. adding confidence intervals and relative measures of association in addition to numeric *P*-values). When reporting these relative differences, the underlying data used to estimate the differences should be clearly presented. Please note that absolute differences between groups should be provided in addition to relative differences. For differences in means, this implies reporting the group means and standard deviations. For data involving binary endpoints, the underlying counts, percentages, and if applicable, exposure time ('person years') should be reported individually for each group. Care should be taken to avoid reporting differences solely based on *P*-values.[43–45] The primary endpoint should be presented as difference between groups with the corresponding confidence intervals. The calculation of sample size and power of the study for its primary endpoint should be explained in detail.

The *EHJ* suggests caution with the interpretation of significance testing. *P*-values do not provide information on the strength (effect size) or variability of an estimated association. All *P*-values for planned comparisons should be reported regardless of the observed significance level. The use of *P*-values for secondary endpoints should be made with caution. Point estimates and margin of error should be preferred. Tables of descriptive statistics should include columns of *P*-values as relevant for the context.

Observational studies are required to have a detailed approach to address potential sources of confounding. Sensitivity analyses that examine complementary analysis approaches are required. Unadjusted results should be provided for context but not reported as primary findings in the abstract. Adjusted estimates are preferred for summaries and graphical abstracts. Authors may select from a number of traditional and modern approaches to adjusting for confounding in the data. The discussion should try to compare and contrast the results, particularly if there is attenuation towards the null value in the more sophisticated analyses.

Authors must refrain from using 'data not shown' anywhere in the manuscript. If an empirical statement is made, the statement should be supported with data presented in line with the text, in a table or figure in the main body of the paper, or as a supplemental table or figure.

For clinical trials designed to test superiority hypotheses, data are generally expected to be reported in accordance with the intention-to-treat principle. A 'full analysis set' may be used if there is no post baseline data on some cases.[40] Non-inferiority study designs, however, need to include also a 'per protocol' analysis set to provide a conservative interpretation of the data and avoid biasing the results towards 'equivalence' with the intention-to-treat analysis set. The methods and results should clarify the analysis set reported in the paper.

The impact of missing data on findings should be addressed in the paper through sensitivity analyses which compare the final results with alternative means of addressing the missing data. Multiple imputation and other methods that facilitate 'chained' estimation of missing observations are preferred techniques over mean imputation or complete case analysis. Statements focused on the missing data mechanism (e.g. missing completely at random) should be provided with the sensitivity analysis.

For survival plots numbers at risk and censored patients in each group should be described along the *X*-axis. For the *Y*-axis, the entire range of 0–100% is expected to be reported when survival is the unit displayed.

For studies developing predictive equations using either standard model-based approaches or machine learning techniques, results for model fitting and validation are expected.[46] Model optimization should be assessed, via bootstrap or any dedicated technique to select and validate datasets, when there are no external validation data available. Calibration of model predictions is to be included alongside measures of discrimination (e.g. area under the curve and lift plots are encouraged).

Regression models with more than one independent variable should be defined as multivariable and those with more than one dependent variable as multivariate.

Association, prediction, risk

A large proportion of cardiovascular studies address the relation between findings and future outcomes. These relations are presented as associations, as predictions, and as risk. The *EHJ* requires authors to use the concepts carefully and avoid the frequent misuse of terms. Almost all statistical models can be used to claim association, but it is much more requiring to claim prediction or risk.

If a new measure is claimed to improve *prediction*, the statistical method should reflect recommendations for such analysis.[47] This will require directly addressing discrimination and, when possible, calibration of a new measure. The common use to just presenting a statistical significance of a new marker is insufficient. It is important to exercise care when choosing parameters to present. While the *c*-index, defined as the area under the receiver operating characteristic curve for prediction at a defined time horizon is appropriate, Harrell's *c*-index from a Cox model is inappropriate,[48] and the popular integrated discrimination improvement and net reclassification index have been shown to be flawed.[49]

The concept of *risk* should also be used carefully. The hazard ratio of a Cox model is often presented as relative risk. In reality, a hazard ratio is very difficult to interpret in many situations.[50] This can become particularly critical in a situation where there is not only an outcome to examine but also a competing risk—most often 'death from other causes'. In this situation, a hazard ratio may be misleading and the association between the immediate risk estimation with hazard ratio and long-term risk estimation can be very different.[51,52] Given these limitations authors should carefully address what they mean by risk whenever the concept is used. In most cases, analyses of risk should be long-term risk at a defined time horizon (e.g. 1 and 5 years). Such a result has a straightforward clinical interpretation.

Other general editorial issues

Pre-submission inquiry should include a detailed outline of the proposed article. Fast track review and online publications will be coordinated with late-breaking clinical trials presentation. This will provide the opportunity to publish new research simultaneously with the first presentation in selected international scientific meetings. Fast track submissions will also be considered if they impact on urgent public health issues or if they provide scientific breakthrough. The *EHJ* will consider publication of negative or neutral results of studies performed with a sound methodology addressing relevant clinical questions.

Manuscripts will be checked for plagiarism at the *EHJ* editorial office using dedicated software. Reviewers will provide a thoroughly evaluation of all manuscripts considered for potential publication and should ensure implementation of the highest standards in manuscript presentation.

Ongoing initiatives from major funders of public research supporting open access publications (i.e. plan S) are becoming implemented this year. Irrespective of the final editorial business model which will be adopted by the journal (current mixed model or Open Access), the editors are strongly committed to implement the high quality standards defined in this special article.

Attention to diversity is important to guarantee a global vision of science.[3] Diversity is richness.[3] The *EHJ* considers that this should include authors, reviewers, and Editorial Board. Accordingly, the new Editorial Board who started his activity on September 2020 is characterized by his global composition with 13 co-editors from the five continents. The number of women editors has increased from 4 to 25 in 2020 and the journal remains committed to further efforts to increase diversity, equity, and inclusion. In regard to manuscript submission, according to the pledge on diversity recently published by the *EHJ*, authors are requested to report results according to age, gender and ethnic characteristics of participants.[3]

The editors believe that the consistent implementation of the high-quality standards defined in this special article will help improving the virtuous circle that supports the scientific process (*Graphical abstract*).

Author contributions

All authors have reviewed and approved the final manuscript. This work is original and is not under consideration in any other journal.

Conflict of interest: none declared.

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