Journal of the Malta College of Family Doctors

Guidelines for Authors – December 2023

Authors are encouraged to submit material for publication in The Journal of the Malta College of Family Doctors (JMCFD), provided that the work submitted is original and not submitted or intended for publication elsewhere. Suitable material includes research and review articles, study reports, case presentations, and other articles of medical interest. Articles with particular relevance to the discipline of Family Medicine will be given preference. Articles of general interest, including cultural and historic themes, may also be accepted.

Manuscripts should conform to the Uniform Requirements of the International Committee of Medical Journal Editors [ICJME] (https://www.icmje.org/icmje-recommendations.pdf). These include roles and responsibilities re *protection of research participants*, issues re *overlapping publications* and disclosure of any *conflicts of interest* (the ICJME COI Disclosure Form available at https://www.icmje.org/disclosure-of-interest/ must be completed and forwarded along with the submitted article). For reporting of randomised trials, authors are advised to follow the guidelines in the CONSORT statement (https://www.consort-statement.org/consort-2010). Authors of systematic reviews are advised that their work should follow the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement and include the checklist at the time of submission (https://prisma-statement.org/PRISMAStatement/).

The Editorial Board reserves the right to edit, style and, if necessary, to shorten material accepted for publication. Letters to the editor and comments on published articles are welcome but should not be longer than 500 words. The Editorial Board reserves the right to edit and decide whether to accept or not any letters submitted, which decision cannot be contested.

One soft copy of the article should be submitted with a covering letter signed by the corresponding author providing consent for review and publication, declaring that the work submitted is original and not submitted or intended for publication elsewhere, and transferring of copyright to the Journal if published. The article and letter should be sent by e-mail to the address: mcfdjournal@mcfd.org.mt.

Ethical requirements and other important issues

The following important requirements and issues are addressed in the Appendix at the end of these guidelines:

- *Declarations*: the authors should make the appropriate declarations in the manuscript.
- *Health data*: personal data obtained from the health sector for reasons other than that it was principally designated should be processed appropriately.
- *Vulnerable populations*: research involving vulnerable populations should involve specialized ethical review.
- *Persons with mental disorders*: research engaging research participants who suffer from mental disorders requires the appropriate authorization.
- *Minors*: any research involving minors involves specific requirements.

- *Incidental findings*: a strategy should be in place for incidental findings of concern to health or well-being in research activities.
- *Animal research*: in research involving animals, the appropriate recommendations and national legislation should be followed.
- *Insurance claims*: where applicable, authors must ensure that they are covered by adequate insurance.
- *Changes to authorship*: the corresponding author should write to the Editorial Board if there are requests for changes to authorship.
- *Plagiarism and fraud*: authors should be extremely careful when preparing the manuscript to avoid plagiarism and fraud.
- *Artificial intelligence*: artificial intelligence may only be used to improve grammar and punctuation and should be disclosed.
- *Errors post-publication*: authors are ethically bound to report any errors noted post-publication.
- *Retraction*: in rare cases, articles may be retracted given significant errors in compiling a study or unethical practices.

Format

Articles will be submitted for peer review and may be returned to the author for modification if suggested by the peer reviewers. Articles must be submitted in the English language and ideally should not exceed 3000 words. Manuscripts should be typed in Microsoft Word® in the Times New Roman font and point size 12, using double-spacing and with one-inch (2.54 cm) margins. Articles which do not conform to the Guidelines for Authors will be rejected.

Key Words

Up to 5 key words or phrases should be provided when submitting the manuscript. Terms from the Medical Subject Headings (MeSH) available on PubMed could be considered (see: <u>http://www.nlm.nih.gov/mesh/authors.html</u>). These should be presented in alphabetical order.

Title Page

A title page should be submitted with each manuscript and should include:

- Title of the paper.
- Full names, position titles and institution of all the contributing authors.
- Current full address and email of the corresponding author.
- Any acknowledgements or declarations (e.g. funding or conflicts of interest).
- Any other information which is not anonymous, and therefore cannot be included in the manuscript files.

- Disclosure of artificial intelligence assistance in producing their work (such as ChatGPT, Grammarly) and how it was used.
- Separate word counts for the article and the abstract.

Article Categories

The following categories of articles are suitable for publication in the JMCFD

- 1. Research articles
- 2. Reviews and Systematic Reviews
- 3. Editorials
- 4. Commentaries
- 5. Guidelines
- 6. Case Reports
- 7. Short Communication
- 8. Qualitative Research Articles/Qualitative Reviews

1. Research Articles

Research articles should report original findings.

A ~250-word abstract should introduce the paper, and preferably be structured into sections as follows: background, objective/s, method/s, results and conclusion.

The main body of the paper should preferably be divided into sections according to the following order:

Introduction: This should provide the background to the study, together with its objective/s, research question/s or hypothesis/es.

Method: This should be detailed enough to allow the reader to reproduce the study. If research on human subjects is involved, approval from a research ethics committee is necessary.

Authors with access to the study data must disclose to what extent the data was accessible, the nature and degree of access provided, and whether access to the data is still ongoing. Personal health data mining from secondary sources should be performed by a third party that can ensure non-identifiable data sets are provided to the research team.

The anonymity of participant/s in research should be ensured by avoiding potentially identifiable information unless it is essential for scientific purposes. When privacy cannot be guaranteed patients must consent to this possibility. Authors must inform patients and institutions if potentially identifiable information will be published on the internet after publication. The consent of patients and contributors should be stored by the Author and documented in the manuscript.

Research participant selection criteria must be included in the article. The inclusion and exclusion criteria, the characteristics of the source population, and how representative the sample tested is compared to the population's ethnographic background should be documented

to avoid type I and II errors. Studies that consider ethnic, genetic, or racial backgrounds should include an intervention that is respectful and of benefit to those concerned.

Ethical considerations relevant to the research and how they were addressed should be included in the manuscript. Research trials must include their respective reference numbers and how post-trial provisions were provided.

Results: After describing the study population, the result/s should be provided, making good use of tables and figures without replicating information in the text. Artificial intelligence should not edit figures as this may have repercussions on the image's validity.

Authors must provide a statement if funders or sponsors provide data with a financial or private interest, such as, "I had full access to all of the data in this study, and I take complete responsibility for the integrity of the data and the accuracy of the data analysis" (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html). Further information is provided on the ICJME website.

Discussion: This should arise directly from the results, and include their interpretation according to the literature, a discussion of the study's strengths and limitations, and implications for practice, education, policy or research.

Conclusion: This should concisely state whether the objectives have been reached, the answers to the research questions, or if the hypothesis has been proved or disproved.

References preferably should not number more than 30. Authors should provide direct references whenever possible. Articles from pseudo-journals or predatory journals should not be cited. Authors must ensure that a reliable source provides the information cited.

Tables: These should be as few as possible (preferably not more than five). Each table should be on a separate page, numbered (e.g. Table 1) with a clear title, and must be cited in the text.

Figures: These should be in monochrome (not colour) and as few as possible (preferably not more than five). Each figure should be on a separate page, numbered (e.g. Figure 1) with a clear title, and must be cited in the text. It should also be submitted as a separate file (preferably in JPG format) and suitably named (e.g. 'Figure 1').

2. Reviews and Systematic Reviews

The JMCFD has particular interest in reviews or systematic reviews that are relevant to the practice of Family Medicine. These should be authoritative and identify any gaps in our knowledge or understanding. Systematic Reviews must contain a brief section entitled "Search strategy and selection criteria." This should state clearly: the sources (databases, journal or book reference lists, etc) of the material covered, and the inclusion and exclusion criteria used. The maximum word count is 3,500 words with a ~ 250-word structured abstract, 5 tables or figures, and with, ideally, no more than 50 references.

Authors are advised to follow PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidance, and all systematic reviews must be accompanied by a completed

checklist (available on the PRISMA website: <u>http://www.prisma-statement.org/</u>). This checklist is to be submitted as a supplementary file during submission.

3. Editorials

On rare occasions, the JMCFD welcomes editorials dealing with important topics on which the author feels the need to express an opinion. These editorials will have a maximum of 1000 words and 15 references. An editorial need not have an abstract.

The Editorial Board of the JMCFD may also commission Editorials on papers appearing in the journal.

4. Commentaries

Commentaries include debate articles, long comments or personal observations on current research or trends in Family Medicine that is likely to be of interest to JMCFD readers. The maximum word count is 1,500 words with a ~250-word abstract, one table or figure.

5. Guidelines

Clinical guidelines are designed to help practitioners and patients decide on the most appropriate healthcare, including providing information on both benefits and risks. Their development should be systematic and evidence-based. The journal welcomes Guidelines relevant for Family Medicine practice in Malta. Guidelines submitted for publication should not exceed 3000 words. Guidelines should have a 250-word abstract, a maximum of 30 references and up to 5 tables or figures.

6. Case Reports

Case reports relate to clinically interesting cases that provide new insight, describe rare but modifiable disorders or present new treatment or understanding. A Case Report should not exceed 1000 words. It should have a 150-word abstract, with a maximum of 1 figure or table and a maximum of 5 references.

A Case Report submitted to the JMCFD for publication must have obtained written informed consent from the patient or their proxy to publish their clinical details and/or clinical images. Proxy consent is needed for deceased persons. The report needs to strictly anonymise the clinical data so that the patient or their family cannot be identified. The consent form is not to be sent to the JMCFD to safeguard the anonymity of the patient and their relatives but needs to be sent to the institution overseeing the provision of data. Confirmation of consent provided

by the Data Protection Officer (DPO) of the institution concerned should be submitted along with the manuscript.

The author/s should retain the consent form to present it when required. Submissions must declare that the DPO, or institution delegate, has confirmed the participant's consent to be included in the case report.

The information that should be collected for a Consent Form (including model consent forms)canbefoundontheCOPEwebsite:https://publicationethics.org/sites/default/files/Best_Practices_for_Ensuring_Consent_for_Publishing_Medical_Case_Reports_guidance_from_COPE.pdf.

7. Short Communication

Research findings with smaller datasets or scope can be presented. Preliminary research data can also be accepted. The word limit is 1500 and a ~150-word abstract. Up to 10 references and 3 figures/tables can be included.

8. Qualitative Research Articles/Qualitative Reviews

The journal accepts qualitative papers that shed a new light on any area of interest to Family Medicine or to our clinical readership. The methodology of these qualitative papers needs to be rigorous with a maximum word count of 5000 words, a ~250-word abstract, not more than 5 figures or tables and a maximum of 30 references.

Acknowledgements

Contributors who do not meet the criteria for authorship should be listed in this section. The role of these individuals should be clearly specified (for example, participation solely in the collection of data). Affiliation, financial or material support should also be included in this section.

References

References should be comprehensive and accurate. These should be written using the Harvard System of Referencing (authors may wish to refer to the guide on the Anglia Ruskin University website: <u>http://libweb.anglia.ac.uk/referencing/harvard.htm</u>.)

Appendix to JMCFD Guidelines for Authors – December 2023

Declarations

Where appropriate, the authors should make the following declarations in the manuscript:

- Approval from the respective ethical review board when human research is planned, conducted, and reported.
- Conformity with Subsidiary Legislation 528.10 of the Laws of Malta on the "Processing of Personal Data (Secondary Processing) (Health Sector) Regulations".
- Conformity with the Helsinki Declaration as amended by the 64th WMA General Assembly convened in 2013.
- Conformity with the Data Protection Act, Chapter 586, of the Laws of Malta.
- Conformity with the Uniform Requirements of the International Committee of Medical Journal Editors.
- Conformity with the Mandatory Reporting Guidelines for Professionals in terms of the Minor Protection (Alternative Care) Act, Cap. 602 of the Laws of Malta, published September 2020, if child abuse or maltreatment is observed, including the measures taken.
- Conformity with the Mental Health Act if persons with mental disorders are included in the research, including approval from the Commissioner for Mental Health.
- Conformity with Directive 2010/63/EU on the protection of animals used for scientific purposes and the Protection of Animals used for Scientific Purposes Regulations if animals are included in the study (https://legislation.mt/eli/sl/439.20/eng/pdf).
- Disclosure of Artificial Intelligence (AI) technologies in assisting manuscript publication.
- The ICJME Conflict of Interest (COI) Disclosure Form (<u>https://www.icmje.org/disclosure-of-interest/</u>).

Health data

The processing of personal data obtained from the health sector for reasons other than that it was principally designated is called "secondary processing". Such data is domestically regulated by the Data Protection Act and the "Processing of Personal Data (Secondary Processing) (Health Sector) Regulations", Subsidiary Legislation 528.10. Both laws reflect EU regulation 2016/679 "on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)" (https://eur-lex.europa.eu/eli/reg/2016/679/oj)

Researchers who cannot be provided with anonymous health data should follow Article 4 of Subsidiary Legislation 528.10. Such processing should be conducted only when research is in the public interest:

"(a) following approval by the Health Ethics Committee within the Ministry of Health, where the research activity is conducted within the Ministry for Health or its partners, and after obtaining prior authorisation from the Commissioner for Data Protection in terms of Article 7 of the Data Protection Act;

(b) following approval by any other Ethics Committee recognised by the Information and Data Protection Commissioner where the research activity is conducted by academics or students, or any other NGO or public body having the remit to assist patients in need for health services,

and after obtaining prior authorisation from the Commissioner for Data Protection in terms of Article 7 of the Data Protection Act.

Provided that processing of such data is conducted using pseudonymised data, and where this is not possible appropriate measures are taken to safeguard the rights and fundamental freedoms of the data subject by providing that data should be anonymised as soon as the research or the statistical study no longer requires identifiable data."

Vulnerable populations

Research involving vulnerable populations should involve the ethical review board/s specialised in overseeing adequate protections. Research on such groups must align with the 2013 version of the Declaration of Helsinki (DoH). Such groups should "benefit from the knowledge, practices or interventions that result from the research" and be considered if "the research cannot be carried out in a non-vulnerable group". (<u>https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/</u>)

Minors

The Convention on the Rights of the Child and the Maltese Civil Code define minors as any human being less than 18 years of age. In any research involving minors, their best interests shall be paramount. Any research on a cohort of children should be for their specific intended benefit and cannot be reproduced in less vulnerable cohorts.

Written informed consent should be obtained from the parent/s or legal guardian before submission of the article. The minor should also grant written informed consent if they are capable. The criteria by which capacity was ascertained should be included in the article. Authors must detail the protocol for minors to refuse or exclude them from further participation in the research.

Incidental Findings

A strategy should be in place for incidental findings of concern to health or well-being in research activities. The methodology and results should explain how research participants will be informed of incidental findings and, if applicable, how complaints, abuse or harm on research subjects and contributors to the study were reported, managed and their outcome.

Animal research

The COPE website recommendations and national legislation should be followed. If animals are included in the study, authors must declare in their manuscript that they abided by the Directive 2010/63/EU on the protection of animals used for scientific purposes and the "Protection of Animals used for Scientific Purposes Regulations" (https://legislation.mt/eli/sl/439.20/eng/pdf). Research involving animals should include whether approval by the respective ethical review body and national standards of care were followed. If this was not possible, the corresponding author should clarify why.

The process by which the principles of reduce, refine, and replace were addressed should be declared appropriately. Measures to ensure minimal harm, pain, and suffering should be

disclosed. Harm to animal subjects occurring from research should also be reported, including how they were treated, and the treatment outcome should also be noted.

The source of animals used in research, the reason for their involvement in research, the breed, living environments, animal trainers, euthanasia practices, the space provided for accommodation and the number of animals used must be disclosed. Death should not be an endpoint for animals in research.

Given the elaborate amount of information that must be provided, authors are advised to follow guidelines on submitting animal research, such as PREPARE (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence) (https://norecopa.no/prepare/). If a particular format is used, this should be noted in the article for reproducibility by other authors.

Insurance claims

Where applicable, authors must ensure that they are covered by adequate insurance to cover any harm that may occur to a research subject because they participate in research.

Changes to authorship

The corresponding author should write to the Editorial Board if there are requests to add an author, remove an author or change the order of the authors. All the authors should provide a written agreement, following the COPE protocol (<u>https://publicationethics.org</u>).

Plagiarism and fraud

The Editorial Board regards plagiarism and fraud as serious matters. Authors should be cautious when preparing the manuscript, referencing the work of others and the work of their previously published material (self-plagiarism).

Should false information be provided or alleged, the Editorial Board reserves the right to clarify with the corresponding author the veracity of their source and establish the authenticity of the information provided with the respective host institution or funding entity, per the COPE recommendations. The Editorial Board may ask the corresponding author to publish material such as correspondence clarifying a matter of concern raised by readers or the Editorial Board. Plagiarism and fraudulent reporting of research is unacceptable.

Artificial Intelligence

Artificial intelligence (AI) may only be used to improve grammar and punctuation in a research article. Authors should proofread their articles for any changes in tone and innuendo that AI may create and change the significance of the information provided. The use of AI should be disclosed in the manuscript as to how it contributed to the research article. Authors remain responsible and liable for the content of their published research.

Errors post-publication

Authors are ethically bound to report any errors noted post-publication in the content of their research paper. Should a third-party report to the Editorial Board an error, the latter will contact

the author. Authors must liaise with the Editorial Board on how to amend such errors. Editors may ask authors to provide evidence of the correct information that should be published.

Retraction

In rare cases, articles may be retracted given significant errors in compiling a study or unethical practices. In such cases, the article may be removed from the JMCFD website or will remain visible but will appear as retracted. This provides authors who may have cited the paper and readers verifying secondary sources to acknowledge the update in its status.