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Prevalence of medical writing in hematological malignancy review articles

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Abstract

Background Medical writing services, initially developed to streamline manuscript preparation, have raised ethical concerns due to their association with industry influence and spin. While prevalent in oncology and malignant hematology clinical trials, medical writing involvement in review articles remains underexplored, particularly in the hematology literature. Furthermore, conflict of interests of the writers may also affect the content of review articles. This study investigates the prevalence, characteristics, and funding sources of medical writing in malignant hematology review articles and their relationship with the financial conflicts of interest (CoI) among authors.

Methods We conducted a cross-sectional analysis of review articles published in the five-year period between January 2019 and December 2023 in the ten highest-rated hematology journals (by 2023 Journal Citation Report Impact Factor). Inclusion criteria encompassed narrative and systematic reviews, guidelines, and clinical advice articles, excluding studies focused solely on benign hematology or basic science.

Results Among 663 included reviews, medical writing involvement was disclosed in 5.7% of articles in which in no instance the medical writer was included as a co-author; with as high as 21% of review articles in a single journal having disclosed medical writing assistance. Medical writers were primarily industry-sponsored (89%). Reviews on plasma cell malignancies had the highest medical writing usage (11%). Direct CoIs were identified in 28% and 34% of first and last authors, respectively, rising to 71% in drug-specific reviews. Only one journal had explicit policies regulating medical writing in reviews.

Conclusions Although the prevalence of medical writing in malignant hematology review articles remains low, at least one journal had over 20% of review articles disclosing medical writer usage. Review articles about specific drugs are often written by authors with direct payments from the manufacturer of the drug in question.

Keywords Medical writing, Reviews, Malignant hematology

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Background

Writing by professionally hired writers, as opposed to the investigators writing the paper exclusively themselves, is becoming increasingly prevalent in the medical literature, with over half of publications of major oncology trials in top journals utilizing medical writing services [1]. Medical writing also is an increasingly lucrative industry, with a projected value of $8.4 billion by 2030 [2].

The use of medical writers by companies and researchers may save time for writers, and may improve quality of a manuscript, with the hopes of increasing chances of having a manuscript published [3, 4]. Medical writing services and ethical guidelines were established in response to controversies in the late 1990s and early 2000s, where the practice of 'ghostwriting' in industry publications raised significant concerns such as spin and selective reporting to favor conflicts of interest [5, 6]. Ghostwriting, different from medical writing, refers to a practice were authors employ an undisclosed writer whose participation is not acknowledged in any part of the manuscript. To eliminate this unethical conduct, while preserving the potential benefits of medical writing services for researchers, medical writing was redefined to strictly require mandatory disclosure and acknowledgment of participation [7], however, concerns have been raised that this simply represents a rebranding of ghostwriting [8, 9].

The aforementioned issue has gained attention in the context of oncology and malignant hematology clinical trials, where the involvement of medical writers is both prevalent and associated with more favorable study conclusions compared to reports developed without the assistance of a medical writer [10, 11]. Previous work has shown the prevalence of medical writing in oncology and malignant hematology clinical trials [1, 10, 11], where it may be justifiable to some to utilize medical writing as it paramount to communicate results of new drugs and regimens in a timely and effective fashion [3]. It remains unknown how prevalent this practice is in review articles and guidelines. Literature reviews and practice guiding documents are expected to be written by authorities in the clinical field and may be trusted by clinicians to guide daily practice. Financial conflicts of interest of the authors involved in writing these authoritative review articles may also affect the impartiality and content of the articles [12].

In this study, we performed a cross-sectional analysis to assess the the prevalence and characteristics of medical writer involvement in review articles published in leading hematology journals. We also aimed to characterize policy on medical writing in these journals. A secondary key aim of our analysis was to explore direct financial conflicts of interest of the authors writing these review articles.

Methods

We carried out a cross-sectional, retrospective analysis of all review articles published between January 2019 and December 2023 in the ten highest-rated general hematology and hematology/oncology journals per the 2023 Journal Citation Report (JCR) Impact Factor (IF) list [13]. Articles labeled as literature reviews, narrative reviews, systematic reviews, guidelines, consensus, viewpoints, editorials, how I/we treat, and expert clinical advice were included. Publications focused solely on benign or classical hematology were excluded from the study. Original studies whether retrospective or prospective, opinion pieces that did not review or discuss literature (i.e. solely expressed the author's views on a topic and did not cite research in the field), and basic science studies were also excluded.

A manual search through each journal's tables of contents was conducted to identify all reviews that met the inclusion criteria. The following data was retrieved using a web-based data collection form: Digital Object Identifier (DOI), journal name, publication year, journal focus, disease in which the review was focused, type of review, existence of a study protocol, disclosed medical writer involvement, type of medical writing, funding source of medical writing, disclosed conflicts of interest (CoI) of first and last author, type of CoI of first and last author, existence of direct CoI with company manufacturing the review was about, if GRADE (Grading of Recommendations, Assessment, Development and Evaluation) assessment was performed, and journal's policies on medical writing.

The primary outcome was to determine the prevalence of medical writing in malignant hematology review articles. Secondary outcomes were to determine the type and funding of medical writing services, the prevalence of medical writing by disease, prevalence of disclosed CoI and types of disclosed CoI. As exploratory outcomes, we also analyzed CoI present with the maker of the pharmaceutical product in review articles about a specific drug. We also assessed the geographical distribution of authors utilizing medical writing services. Countries were classified based on their income (high income, high-middle income, lower middle income etc.) using the World Bank classification.

For the purposes of this study, medical writing utilization was considered disclosure and/or acknowledgement of the manuscript being written (partially or completely) by a professional medical writer or a receiving assistance and advisory regarding in any writing matters, including but not limited to language, redaction, and editing. The source of funding of medical writing services was classified as "industry" when it was disclosed a pharmaceutical company covered the expenses, "academic institution/government" when an academic institution of

government agency was acknowledged as funders of the service, or "non-disclosed" when there was no mention in the text. Type of medical writing was extracted and coded as mentioned in the article's disclosure of medical writing assistance.

A conflict of interest was considered to be present and disclosed when a financial relationship with a pharmaceutical, medical device or health services that produced any intervention was declared in the "disclosure" or "statements" section of the included papers; "direct CoI" were considered consulting payments, honoraria, allowances, management roles in pharmaceutical companies through service on their boards of directors or holding equity interests in such companies; and "indirect CoI" were considered research funding from pharmaceutical companies to the investigator or their institution.

Table 1 Characteristics of reviews

Characteristic	*N* = 663[1]
Journal type	
General Hematology	460 (69%)
Hematology/Oncology	203 (31%)
Type of article	
General review	523 (79%)
Non-protocolized guidelines	50 (7.5%)
Protocolized guidelines	11 (1.7%)
Specific how to treat	47 (7.1%)
Systematic review	32 (4.8%)
Protocol	
Yes	26 (3.9%)
No	637 (96%)
Written by medical writer	
Yes	39 (5.9%)
No	624 (94%)
CoI of first author	
Yes	230 (35%)
No	433 (65%)
CoI of last author	
Yes	272 (41%)
No	346 (52%)
N/A	45 (6.8%)
Disease	
Leukemia	235 (35%)
Lymphoma	134 (20%)
Mixed	105 (16%)
Myeloid neoplasia	1 (0.2%)
Myeloid neoplasias	65 (9.8%)
Plasma cell malignancies	123 (19%)
GRADE assesment	
Yes	12 (1.8%)
No	651 (98%)

[1]n (%)

Abbreviations: CoI, conflicts of interest. GRADE, Grading of Recommendations, Assessment, Development, and Evaluations. Heme/Onc, Hematology/Oncology

Descriptive analysis was performed presenting categorical data with percentages and absolute counts, while continuous data was presented with central tendency and dispersion measures selected upon normality testing with the Kolmogorov-Smirnov test. Fisher's exact test was employed for exploratory hypothesis tests of categorical variables. A p-value < 0.05 was considered significant for all tests. Data analysis and visualization was performed with the R statistical software and RStudio.

Results

General characteristics

A total of 663 reviews were included in this study from the following journals: Journal of Hematology & Oncology, The Lancet Haematology, Blood, Blood Cancer Journal, American Journal of Hematology, Blood Cancer Discovery, Leukemia, Experimental Hematology & Oncology, Haematologica, and HemaSphere.

Most of the reviews were published in general hematology journals (n = 460, 69%) with the remainder in hematology/oncology focused journals. Most of the articles (n = 523, 79%) were narrative reviews. Most of the studied records did not disclose having a protocol (n = 637, 96%). Articles from the studied cohort were focused most often on leukemia (n = 235, 35%), followed by lymphoma (n = 134, 20%), plasma cell malignancies (n = 123, 19%), more than one disease (n = 105, 16%), and myeloid neoplasia (n = 65, 9.8%). Characteristics of the studies are displayed in Table 1.

Medical writing prevalence

The prevalence of disclosed medical writing assistance in the whole sample was 5.7% (n = 38). The Blood Cancer Journal had the highest proportion of reviews disclosing medical writing assistance (n = 13, 21%). The highest prevalence of medical writing involvement was observed in reviews on 'plasma cell malignancies,' with 11% of these articles acknowledging medical writing assistance, although this was not statistically significant (p = 0.095, Table 2). None of the publications using medical writing services listed included medical writers as co-authors.

The trend of medial writing in reviews, categorized for different malignancies is demonstrated in Fig. 1.

The type of review with highest prevalence of medical writing were non-protocolized guidelines (n = 5, 10%). Medical writing was used in other classes of reviews as follows: 6.3% (n = 2) in systematic reviews, 5.7% (n = 30) in narrative reviews, 2.1% (n = 1) in specific how to treat, and 0% in protocolized guidelines. When analyzed by journal type, we observed a higher prevalence of medical writing in hematology/oncology-focused journals (n = 23, 11%) compared to general hematology journals (n = 16, 3.5%) (p < 0.0001).

Table 2 Medical writing prevalence in reviews by disease

Written by medical writer	Leukemia, $N=235$[1]	Lymphoma, $N=134$[1]	Mixed, $N=105$[1]	Myeloid neoplasias, $N=66$[1]	Plasma cell malignancies, $N=123$[1]	*p*-value[2]
Yes	12 (5.1%)	5 (3.7%)	4 (3.8%)	3 (4.5%)	14 (11%)	0.095
No	223 (95%)	129 (96%)	101 (96%)	63 (95%)	109 (89%)	

[1]n (%)

[2]Fisher's exact test

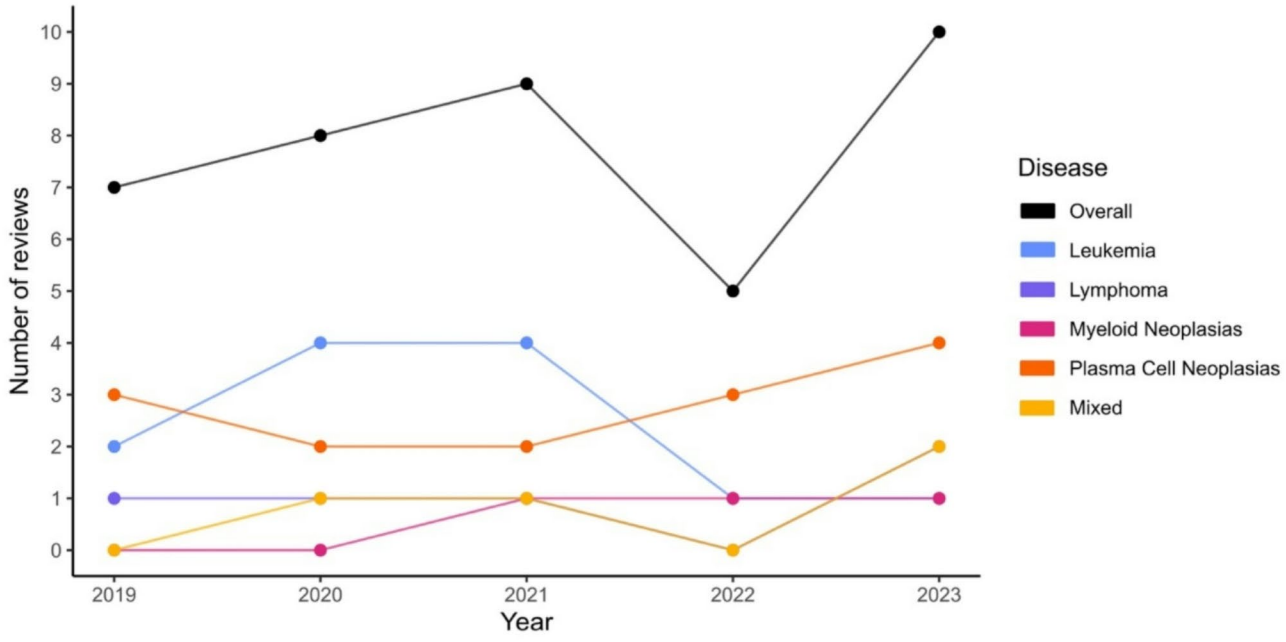

Fig. 1 Time trends in medical writing over time

Types of medical writing

Heterogeneity in the denomination of type of medical writing was observed. Disclosures and acknowledgements categorized medical writing as: "medical writing support" ($n=10$, 26%) "editorial assistance" ($n=7$, 18%), "medical writing assistance" ($n=7$, 18%), "writing and editorial assistance" ($n=7$, 18%), "editorial support" ($n=3$, 8%), "editorial and medical writing assistance" ($n=1$, 3%), "medical editing" ($n=1$, 3%), "medical writing and editorial support" ($n=1$, 3%), "medical writing and editorial assistance" ($n=1$, 3%), and "writing assistance" ($n=1$, 3%).

Funding of medical writing

Funding for medical writing services primarily came from pharmaceutical industry ($n=34$, 89.4%). In 2 articles (5.3%), authors reported that medical writing was funded by academic institutions or collaborative groups, while in 2 articles (5.3%), medical writing was used without specifying the funding source.

Conflict of interest

Regarding CoI disclosures, 227 (34%) articles reported a CoI from the first author, from which 11.5% were identified as direct, 6% as indirect, and 16.5% as both. Among reviews focused on a specific drug, first authors had a direct CoI with the drug's manufacturer in 71% of cases. Last authors had disclosed conflicts of interest in 272 cases (41%), 14% being direct, 7% indirect, and 20% both. In specific drug reviews, 72% of articles reported a direct CoI of the last author with the company producing the drug. Additionally, prevalence of medical writing involvement when there was a CoI from the first author present was 15%, versus 13% when there was a CoI from the last author.

Journal's policies on conflicts of interest from review authors

Most (9 out of 10) journals included a section in their submission guidelines dedicated to clarifying policies on manuscripts involving assistance from a medical writer, however, only one journal (*Blood)* provided specific guidance on review-like articles (detailed in Table 3).

Table 3 Journal's policies on medical writing disclosures

Journal	Policy on MW	Policy on MW specific to reviews
Journal of Hematology & Oncology	All contributors who do not meet the criteria for authorship should be listed in an 'Acknowledgements' section. Examples of those who might be acknowledged include a person who provided purely technical help or writing assistance, or a department chair who provided only general support	-
The Lancet Hematology	All authors, and all contributors (including medical writers and editors), should specify their individual contributions at the end of the text If a medical writer or editor was involved in the creation of your manuscript, we need a signed statement from the corresponding author to include their name and information about funding of this person. This information should be added to the Acknowledgements or Contributors section. We require signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgements section.	-
Blood	Any involvement by pharmaceutical or medical device company employees or medical writers supported by a pharmaceutical or medical device company in the writing of an article must be clearly defined and disclosed in the Conflict-of-interest Disclosure section of the manuscript (if the individual is an author) or the Acknowledgments section (if the individual is not an author).	Pharmaceutical or medical device company employees and medical writers supported by a pharmaceutical or medical device company are not permitted to have any role in writing Review, Perspective, How I Treat, or Blood Spotlight articles. The use of editing services for non-English speakers is permissible, but it must be disclosed. Please direct any questions regarding this policy to the Editor-in-Chief prior to submission.
Blood Cancer Journal	Medical writers and industry employees can be contributors. Their roles, affiliations, and potential competing interests should be included in the author list or noted in the Acknowledgments and/or Contributors section concurrent with their contribution to the work submitted. Signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgments section is also required. Failure to acknowledge these contributors can be considered inappropriate, which conflicts with the journal's editorial policy.	
American Journal of Hematology	-	-
Blood Cancer Discovery	Include funding information and the names of others contributing to the work who are not identified as authors. This should include any people, services, or generative artificial intelligence technologies that contributed to the generation of the manuscript.	-
Leukemia	Medical writers and industry employees can be contributors. Their roles, affiliations, and potential competing interests should be included in the author list or noted in the Acknowledgments and/or Contributors section concurrent with their contribution to the work submitted. Signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgments section is also required. Failure to acknowledge these contributors can be considered inappropriate, which conflicts with the journal's editorial policy.	-

Table 3 (continued)

Journal	Policy on MW	Policy on MW specific to reviews
Experimental Hematology & Oncology	The involvement of scientific (medical) writers or anyone else who assisted with the preparation of the manuscript content should be acknowledged, along with their source of funding, as described in the European Medical Writers Association (EMWA) guidelines. The role of medical writers should be acknowledged explicitly in the 'Acknowledgements' or 'Authors' contributions' section as appropriate.	-
Haematologica	Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, the corresponding author should obtain written permission to be acknowledged from all acknowledged individuals	-
HemaSphere	Other sources of support should be clearly identified in the Acknowledgments section of the manuscript. For example, these might include funding for open access publication derived from a grant or from an author's institution, or funding for writing or editorial assistance, or provision of experimental materials.	-

Geographic distribution of authors utilizing medical writing services

The vast majority (97.3%, $n = 37$) of reviews utilizing medical writing services originated from authors in high-income countries, with the United States representing the predominant source (64.9%, $n = 24$ of this group). Only a single review (2.7%) came from authors based in a middle-income country (China).

Discussion

In this analysis, we find that unlike clinical trials where the majority of publications are written by a medical writer, review articles remain mostly free of medical writing support in top hematology journals. Nevertheless, important exceptions exist – even though we limited our search to the top ten journals, at least one journal had over 20% of review articles written by a medical writer. We found that medical writer usage was almost exclusively funded by industry (89%), and that direct financial conflicts of interest of the first (28%) and last author (34%) were very common, often with the company making the drug the review article was being written about (71% and 72% of first and last authors, respectively, of a review of a specific drug). We also found an instance of a specific How I treat article with direct impact of pharmaceutical company sponsored medical writer support, which is concerning given that these articles directly impact practice [14]. Although not within the purview of our study which focused on top tier hematology journals, numerous other review articles guiding specific management have been written by industry recently, such as a general review of myeloma with translocation 11;14, written by the developer of a drug for t(11;14) myeloma, venetoclax [15], a narrative review of midostaurin for acute myeloid leukemia involving a medical writer funded by midostaurin's manufacturer [16], and a review about asciminib for philadelphia-positive chronic myeloid leukemia written by the drug producer [17].

To the best of our knowledge, there are no previous studies analyzing medical writing in review articles in malignant hematology. Our study complements previously published literature determining the extent of the utilization of this resource in clinical trials, where it is a much more prevailing practice and has grown over time [1, 10, 11, 18, 19]. Wooley and collaborators in 2006 investigated "original reports" in prominent medical journals and determined that in 6% of such articles it was disclosed complete or partial participation of medical writers, its prevalence being higher in studies from the pharmaceutical industry (9.8%) than in non-industry studies [18]. Almost a decade later, this issue seem to have grown, as an analysis from clinical trials published in BMC identified that 41% of their sampled articles disclosed the aid of a medical writer, as well as

more likelihood of adherence to reporting guidelines and better quality of written English when a medical writer was involved in the manuscript [19]. Investigation of the usage of medical writers is relevant, as the use of medical writers is associated with an increased likelihood of trials meeting their positive endpoints, more FDA approvals of the intervention [10], less common employment of overall survival as primary endpoint, more common usage of surrogate endpoints such as progression-free survival, and higher odds of favorable conclusions about the intervention (OR 1.81 (95% CI 1.04–3.14)) [1].

Financial CoI were also prevalent in our sample, with them being reported by the first author in 34% of a cases, and a higher prevalence in the last author at 41%. Direct conflicts were common among those authors with a CoI as they made up 28% of CoI from first authors and 34% from last authors. Remarkably, when reviews were focused on a specific drug, most of them had a CoI, with 71% of first authors and 72% of last authors reporting them. Other reports have highlighted the influence of industry sponsored research in oncology and malignant hematology clinical trials [20, 21], a phenomenon that we might be seeing disseminating to review articles.

In our study, we found that most journals have policies to at least encourage authors to report the usage of this service, but with just one journal having policies specifically extended to regulate this service in review articles. Our study highlights how even with guidelines to provide, acquire and report this service, heterogeneity in its disclosure is present with a huge range of definitions, from very clear and explicit "medical writing" to more ambiguous phrases as "medical editing" and "editing support".

We also found that some authors of reviews included in this study have previously published review articles where medical writing services were not employed, which leaves unanswered questions: how is it determined when and when not to use medical writing services for literature reviews? Could this be related to specific instances where conflicts of interest are present? Although not explored in this work, this could be an avenue for future studies.

There are limitations to our work. We analyzed only a limited fraction of top hematology journals. It is very likely that a higher prevalence of medical writing could exist had we chosen a broader section of journals to look at. Examples of medical writer written publications in hematology journals that were not included in our search strategy include a review article written by a medical writer funded by Sanofi that highlights how isatuximab is particularly effective in patients with myeloma and renal failure, even though no comparative literature exists that it is better than daratumumab [22], and a review article on treatment options for lower-risk MDS written by a medical writer funded by the maker of luspatercept (BMS) [23]. Future work should systemically assess the prevalence of medical writer written reviews in a broader segment of hematology journals. We found that a numerically higher proportion of review articles in the plasma cell malignant space were written by medical writers, which we speculate reflects the pharmaceutical company interest in this space, given the vast number of new drugs being approved and developed for myeloma. However, due to a small sample size because of our search strategy, we cannot make definitive comparisons or conclusions about subgroups. Finally, spin (defined as the misrepresentation of research findings), has historically been assessed for original research, rather than broader review articles, leading to an inability for us to systematically analyze spin in our cohort of studies [24]. The spin can be subtle, such as in an article included in our cohort about developments in maintenance therapy written by a medical writer from Takeda (the maker of ixazomib), that disproportionately focused on, and portrayed ixazomib in a positive light [25].

Conclusions

In summary, we demonstrate that although the prevalence of medical writing in malignant hematology review articles remains low, there are instances of medical writing in top hematology journals, with at least one journal having over 20% of its review articles written by medical writers. The prevalence varies across specialties, with the highest numerical prevalence in plasma cell dyscrasias. We also find that review articles about specific drugs in question are often written by writers with direct payments from the manufacturer of the drug in question. Our results call for policies to limit the usage of medical writers in future review articles and highlight the importance of transparency.

Abbreviations

CoI	Conflicts of interest
DOI	Digital object identifier
GRADE	Grading of recommendations, assessment, development and evaluation
IF	Impact factor
JCR	Journal citation reports

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None.

Author contributions

G.R.M., H.A.V.A., D.R.G. conceived the research project and planned the project. H.A.V.A., E.N., Y.O.M. performed the search and retrieved records. G.R.M., H.A.V.A., E.N., Y.O.M., A.G. wrote the first draft of the manuscript. H.A.V.A. performed the data analysis and visualization. All authors read and approved the final version of the manuscript.

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Data availability

Complete data sets are available from corresponding author upon request.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
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Competing interests
The authors declare no competing interests.

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