







REVIEW

Ethical Aspects in Occupational Health Research: A narrative literature review

Aspectos Éticos en Investigación en Salud Laboral: revisión narrativa de la literatura

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ABSTRACT

Introduction: the field of occupational health research is not immune to ethical concerns and has encountered challenges of an ethical and moral reflective nature. Consequently, the research methodologies employed in this area have been epidemiological, facilitating enhanced understanding and gaining insights that inform decisions regarding workers' safety, hygiene, and occupational health while also addressing the ethical considerations pertinent to this population.

Objective: to determine which ethical aspects are involved in research in the field of occupational health.

Method: narrative bibliographic review; the sources of information consulted were three databases: Web of Science, Scielo, and Pubmed, consulted during April and May 2024, in addition, normative documents of the Superintendence of Social Security and the International Commission on Occupational Health were incorporated; the keywords research, occupational health, and ethics were used. The data were analyzed according to content analysis.

Results: each author and their articles delineate the ethical considerations relevant to occupational health research and briefly describe these features.

Conclusion: according to the analysis and discussion, it can be determined that ethical aspects are mandatory, and Emanuel's seven requirements could be considered as basic to complying with the ethical aspects of occupational health research.

Keywords: Ethics; Occupational Health; Research.

RESUMEN

Introducción: el área de la investigación en salud laboral, no ha estado exenta de dilemas éticos, igualmente se ha visto enfrentada a dificultades de tipo reflexivas ético/morales. Por lo tanto, los diseños de investigación que se utilizan en esta área han sido epidemiológicos, los cuales permiten mejorar los conocimientos y obtener respuestas que permitan tomar decisiones en relación con la seguridad e higiene y la salud laboral de los trabajadores, sin dejar de lado los aspectos éticos que deben ser considerados en esta población.

Objetivo: determinar cuáles son los aspectos éticos que están involucrados en la investigación en el campo de la salud laboral.

Método: revisión bibliográfica narrativa; las fuentes de información consultadas fueron tres bases de datos: Web of Science, Scielo y Pubmed, consultada durante los meses de abril y mayo del 2024, además se incorporaron documentos normativos de la Superintendencia de Seguridad Social y de la Comisión Internacional de Salud Laboral, se utilizaron las palabras claves investigación, salud laboral y ética. Los datos fueron analizados según análisis de contenido.

Resultados: cada uno de los autores y los documentos analizados establecen cuáles son los aspectos éticos que deben ser considerados en la investigación en salud laboral y los describen brevemente. **Conclusión:** según lo analizado y discutido se puede determinar que los aspectos éticos son obligatorios y se podrían considerar los siete requisitos de Ezekiel Emanuel como básicos para dar cumplimiento a los aspectos éticos de las investigaciones en salud laboral.

Palabras clave: Investigación; Salud Laboral; Ética.

INTRODUCTION

Using human subjects in research has facilitated advancements in the diagnosis and treatment of diseases. Yet, as beneficial as it may be, the history of such research has shown that serious human rights infringements occurred every time the practice distanced itself from ethical/moral reflection. It has, therefore, become necessary to enact national and international regulations to govern such activities.⁽¹⁾

The research conducted in occupational health primarily utilizes an epidemiological design. This design encompasses a range of procedures, methods, and techniques that researchers employ to select workers, collect data, and analyze results. Depending on the specific study objectives, this approach aims to enhance existing knowledge and provide insights for decision-making regarding safety, hygiene, and occupational health.

⁽²⁾ Nevertheless, it has encountered ethical challenges and dilemmas, particularly concerning issues such as confidentiality and informed consent, authorization for data management, selection of health surveillance methods, workers' right to information and autonomy in decision-making, honesty among coworkers, and adherence to professional quality standards.⁽³⁾ In this context, in the absence of a universal ethical framework to guide researchers in the ethical evaluation of clinical research protocols, and based on the philosophical principles that underpin the main codes and declarations on human research, Ezekiel Emanuel proposes seven basic requirements that provide a methodical and consistent framework for determining whether a clinical study is ethical.⁽⁴⁾ The seven requirements are: 1. Social or scientific value. 2. Scientific validity. 3. Equitable selection of subjects. 4. Favorable risk-benefit ratio. 5. Independent assessment. 6. Informed consent. 7. Respect for registered subjects.⁽⁵⁾

Therefore, this narrative literature review aims to identify the ethical considerations associated with research conducted in occupational health.

METHOD

A bibliographic literature review was performed in the initial phase of the search to compile the data. The three databases consulted were Pubmed, Scielo, and Web of Science (WoS). The search took place in April and May 2024 with the following eligibility criteria: documents in English and Spanish, unlimited years, full text, review articles, and articles. The phenomenon of interest was the ethical dimensions involved in occupational health research on workers. The search strategy was based on key terms: Occupational health research, ethics, and the Boolean operators AND and OR. Articles that mentioned ethical aspects but were not related to ethics in research on workers were excluded. The search equations for each of the databases were as follows: Pubmed: ("Occupational Health research"[All Fields] AND "ethics"[All Fields]) AND ((fft[Filter]) AND (english[Filter] OR spanish[Filter])). SciELO: (occupational health research) AND (ethics) AND la: * AND type:("research-article"). WoS: (TS=(Occupational Health research) AND ALL=(ethics)) AND (LA==(“ENGLISH” OR “SPANISH”) AND DT==(“ARTICLE”) AND OA==(“OPEN ACCESS”).

The first database consulted was Pubmed, which yielded 27 articles, then eligibility criteria were applied, and 27 remained. There were no duplicates. The WoS database was then searched and yielded 10 articles; the eligibility criteria were used, and 4 duplicates were eliminated, leaving 6 articles.

Finally, the Scielo search yielded 58 articles; eligibility criteria were applied, and 7 duplicates were eliminated, leaving 51 articles. Duplicate articles were automatically removed using the Zotero reference manager.

Of the total of 84 articles selected and after reading the title and abstract, 77 articles were excluded because they were not relevant and did not address the phenomenon of interest, mentioning topics such as financial conflicts of interest in research on occupational and environmental health, work motivation of physicians and occupational health, health research that arises as a concern about hazards in the workplace, ethical aspects in the work environment, but not of research on this population. A Prisma Flow Diagram is attached (figure 1).

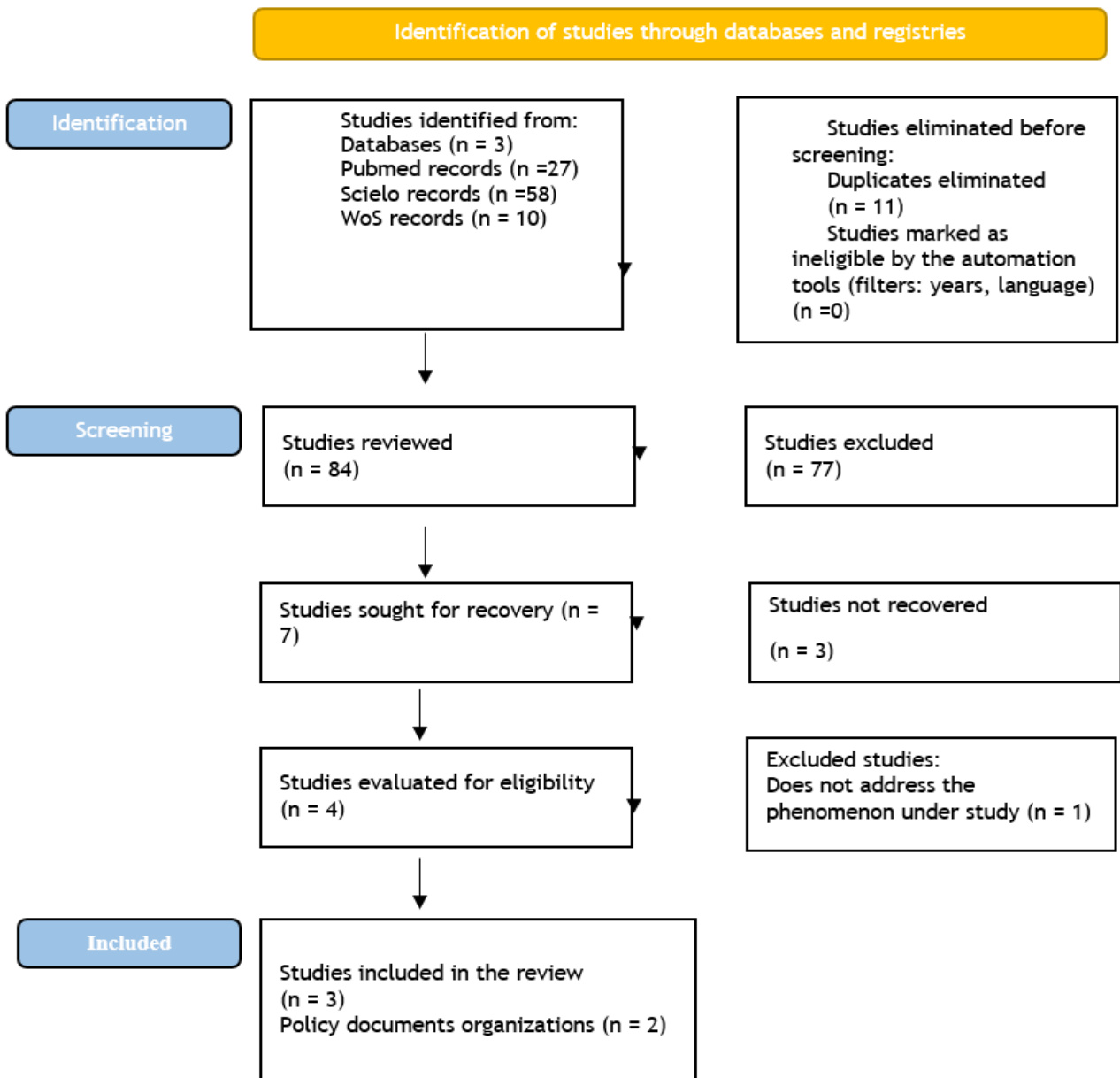


Figure 1. Prisma 2020 Flow Diagram

Source: Prepared by the authors based on Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372: n71. Doi: 10.1136/bmj.n

Of the 7 articles selected, only 6 full-text articles were retrieved. After the full reading, 3 were eliminated for not addressing the phenomenon of interest. Although they mention ethical aspects, they are not focused on the research on workers and what aspects should be considered and respected with this group. Therefore, only 3 articles were selected, downloaded from the databases, read, and analyzed.

Considering that the database search yielded a small number of articles, a manual search was conducted in national and international occupational health-related policy documents describing ethical aspects in this group. The Social Security Superintendence (Suseso) and the International Commission on Occupational Health regulations were reviewed.

The included articles will be briefly described, highlighting their relevance in addressing the review objective. The national and international policy documents will be described, analyzed, and discussed. The discussion will be organized according to the 7 requirements outlined by E. Emanuel, whether they are present or not.

RESULTS

With respect to the findings of ethical aspects in occupational health research, the first part corresponds to what was found in the scientific articles, also described in Table 1. Each of the authors analyzed determines the ethical aspects involved in occupational health research and describes them briefly. The three referenced

articles were published in 1999, 2001, and 2013; two were published in the UK and one in Japan, respectively.

In 1999, Kalman pointed out that, although articles published in journals allow academic dissemination and achieve some consensus in Great Britain, the articles can be presented at a press conference prior to written publication, as this can achieve immediate awareness among the general population. However, this approach raises some doubts as the workers (participants) were not notified beforehand. It is important to remember that results should be presented in a setting that is regulated and where concerns can be resolved.⁽⁶⁾

Table 1. Articles included in the review

Title Article	Author	Country of origin	Methodology	Findings/Conclusions
Ethical requirements for occupational health research compliance arrangements for a single company in relation to a major nuclear industry study	Kalman CJ.	United Kingdom, 1999	Descriptive	Following the dissemination of the hypothesis to workers and families through the media that parental exposure to radiation at work was associated with the incidence of leukemia in their children, the medical directors of four civilian nuclear companies decided to develop a brief ethics policy for future participation in occupational health-related research. The policy was based on four basic ethical principles: medical confidentiality, worker information, worker consent, and worker access to the study results prior to any publication.
Ethics in occupational health research	Coggon D.	United Kingdom, 2001	Descriptive	Describes ethical aspects involved: a) Study question: some could be harmful, evaluate benefits before starting. b) Study design and implementation: same principles apply as in humans. Focus on subjects' rights, maintaining privacy and confidentiality. c) Communication of results: they should be delivered to individual participants and other interested parties. Prevent data breaches. Researchers determine to whom they will deliver the results, the first obligation being participants, coworkers, employers, regulatory bodies, funding companies, the scientific community, and, ultimately, the general public. d) Application of the research: ethical principles must prevail, and based on this, it must be decided whether the results can be used and how.
Ethics and occupational physicians: ethics and mission required for occupational physicians.	Fujino A.	2013 Japan	Descriptive	Addresses three topics: a) Compliance with national and international ethical standards. b) The importance of ethics committees: The project can only be executed if it has approval from the ethics committee and if there is conflict of interest committee approval. c) Characteristics of occupational medical research. This differs from general medical research primarily because workers are part of a corporate organization. Request authorization from the immediate supervisor, then the conflicts of interest committee and ethics committee, prior to beginning the study. In addition, permission must be requested from the workers' union. The worker's informed consent must be given in accordance with ethical guidelines for clinical and epidemiological research, ensuring that the work is not impeded. Create protocol in agreement with the company's operator prior to data disclosure.

Table 2. Summary of National and International Policy Documents included in the review

Agency	Document	Content
Social Security Superintendence	Compendium of Social Security Rules for Occupational Accidents and Occupational Diseases: Book IV. Preventive benefits/ Title III. Research and Innovation Studies/ B. Research Projects/ 8. Ethical aspects	Collaboration with workers must be voluntary. Participation must be evidenced by the signature of an individual consent form. Cooperation of employing entities requires the employee's participation to be voluntary. The entity's involvement will be accredited through a statement from the organization's legal representative. The consent of workers and the organization must be kept at the disposal of Suseso for up to 3 years after the study ends. The design of research projects must have ethical evaluation. These evaluations shall be made available to Suseso when required. The administering agency must notify Suseso as necessary if the ethics committee makes observations that the project cannot accommodate. In this case, it will be deemed impractical to proceed. In cases where resources have been allocated, they must be provided for the following year's call for proposals.

International Commission on Occupational Health	Code of Ethics for Occupational Health and Safety	All occupational health professionals engaged in research should design and develop their activities on a sound scientific basis. They must respect ethical principles related to health and medical research work. Ethical principles include social and scientific values, scientific validity, equitable subject selection, favorable risk-benefit ratio, informed consent, respect for potential and registered subjects, review of protocols and potential conflicts of interest by an independent and competent ethics committee, and protection of confidential data.
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The author refers to the “Gardner Study” and its hypothesis, where workers and their families were informed through the media that parental exposure to radiation in the workplace was associated with the incidence of leukemia in their children.⁽⁶⁾ This information was provided without having a document available to support and validate such information and to respond to any concerns raised by the workers. Following this publication, the medical directors of four civilian nuclear companies developed a brief ethics policy for future participation in occupational health-related research.⁽⁶⁾

This policy was based on four basic ethical principles: medical confidentiality, worker information, worker consent, and worker access to study results prior to any publication.⁽⁶⁾ The author points out that medical confidentiality does not require further discussion in this article. However, the requirements for worker information and consent extend the criteria established for invasive medical trials and recognize the rights of workers as clients of all such work.⁽⁶⁾ Now, on the issue of consent, it was not specified in detail in the company policy and, in practice, may vary depending on the research protocol between individual consent for clinical trials and consent of workforce representatives for more general study activities.⁽⁶⁾ It was made explicit in the article that the delivery of information prior to publication will be guaranteed to ensure that any questions and concerns that may arise are resolved in a timely and appropriate manner.⁽⁶⁾ Another crucial point is that the function of occupational health should not undermine the researcher’s independence. Thus, the authors can provide the preliminary findings for review and criticism by occupational health professionals, but “industry” representatives should never have any involvement in the interpretation or conclusions of the results.⁽⁶⁾

In 2001, Coggon pointed out that ethical issues in medical research are categorically questioned when the risks do not outweigh the benefits. However, in occupational health research, ethical issues go beyond study design and implementation and relate to some of the following aspects: research question, study design and implementation, communication of the results, and application of the research.⁽⁷⁾

For this kind of population, certain research questions could be harmful; thus, it is important to weigh the potential benefits before beginning. In the design and implementation of the study, the ethical principles used are the same as those used for human studies.⁽⁷⁾ These principles serve as a framework, but they must be examined within the particular context of each design, considering that special considerations might be needed depending on the study type. For instance, worker privacy and data confidentiality must be maintained in studies where data is collected and analyzed on identifiable individuals, particularly when the data is used without consent. Likewise, on the subject of the communication of results, prior leaks to the media must be avoided; however, the researchers determine to whom they will deliver their results first. Participants will have the highest priority, followed by coworkers exposed to similar risk factors, employers, regulatory agencies, project funding companies, the scientific community, and lastly, the general public.⁽⁷⁾

Likewise, there must also be safeguards in handling the results, and they must be reported in the scientific literature as opposed to non-specialized publications where they could spark unmanageable controversy. It is also necessary to foresee and be prepared for possible adverse outcomes, plan for them, and have predetermined actions for each particular situation, all while ensuring the participant’s safety.⁽⁷⁾

Finally, the author asserts that ethical standards should be prioritized in the study’s design when applying the findings. On this basis, the author suggests determining whether the data can be utilized and, if so, how to do so. However, he specifies that no general ethical agreement on what is acceptable has been established and, furthermore, values could be modified depending on the societies.⁽⁷⁾

The review also includes an article by Fujino from 2013, which highlights three key considerations regarding the ethical aspects of research in occupational medicine: a) Ethical standards of national and international research require compliance with these ethical guidelines. It is detailed that in Japan, there are a variety of local and international guidelines.⁽⁸⁾ b) The importance and role of the ethical review committee posits that research in industrial medicine shall be carried out respecting these ethical guidelines, but in the case of research involving human beings, the ethical review committee shall demand compliance, and the study may only be carried out when it has been approved both by the conflict of interest committee that guarantees transparency regarding conflicts of interest, and by the ethics review committee that guarantees human rights, the welfare of the subjects, evaluates risks-benefits, and confirms specific procedures for informed consent,

as well as ensures scientific validity.⁽⁸⁾ c) Characteristics of industrial medical research, and its main difference from clinical medical research, is that the workers are part of a corporate organization. However, when conducting research on workers over a long period, it is desirable to create a “memorandum of understanding” with the employer, similar to a contract for occupational medicine research.⁽⁸⁾ The informed consent of the workers must align with ethical guidelines for clinical and epidemiological research to prevent any obstacles to the work. The author suggests establishing in advance, through a health committee, rules on the specific procedures to be carried out within the company, as well as the disclosure of results from the perspective of corporate social responsibility.⁽⁸⁾

A summary of what is described in the policy documents of national and international organizations in relation to the subject is summarized in table 2.

The Social Security Superintendence (Suseso) document titled “Compendium of Social Security Rules for Occupational Accidents and Occupational Diseases”, Book IV. Preventive care / Title III. Research and innovation studies / B. Research projects / 8. Ethical aspects, from 2018, emphasizes that the collaboration of workers must be voluntary, and any objection they may have must be respected. Participation requires the individual signing of a consent form.⁽⁹⁾

However, if the cooperation of the employing entities is considered, the employee’s participation must also be voluntary. The entity’s involvement will be accredited through a statement from the organization’s legal representative. The consent of both the workers and the organization must be kept available for any request from Suseso for up to 3 years after the end of the study.⁽⁹⁾

The design of research projects should have an ethical assessment and, if necessary, should also be submitted to an ethics committee accredited by the corresponding health authority. These assessments must also be made available to Suseso when required. It should be taken into account that the project must have been submitted for evaluation by an accredited ethics committee at the time of signing the agreement with the administering agency, as required. Should the ethics committee make observations that the project cannot accommodate, it will be considered impractical to proceed, and the administering agency must inform Suseso as appropriate. In those cases where resources have been allocated, they must be provided for the following year’s call for proposals.⁽⁹⁾

Now, the International Commission on Occupational Health points out in its 2014 document titled “International Code of Ethics for Occupational Safety and Health Professionals” that all those occupational health professionals engaged in research must design and develop their activities on a sound scientific basis, with full professional independence and respecting ethical principles related to health and medical research work. These include social and scientific values, scientific validity, equitable subject selection, favorable risk-benefit ratio, informed consent, respect for potential and registered subjects, review of protocols and potential conflicts of interest by an independent and competent ethics committee, and protection of confidential data.⁽¹⁰⁾

DISCUSSION

The analyzed articles and policy documents indicate that the International Commission on Occupational Health provides a general framework for guiding research in this population, outlining Ezekiel Emanuel’s seven requirements as fundamental principles of compliance. These must also be tailored to the research environment’s economic, cultural, and technological contexts. The seven requirements are: 1. Social value: improvements in health or knowledge should be derived from the research; 2. Scientific validity: the research should be methodologically rigorous; 3. Equitable selection of subjects: this implies that the scientific objectives of the research should be the basis for determining which groups and individuals will be recruited to participate in the study, which should be made explicit in the inclusion and exclusion criteria; 4. Favorable risk-benefit ratio: within the context of standard clinical practice and the research protocol, the risks should be minimized, the potential benefits increased, and the potential benefits to individuals and the knowledge gained for society should outweigh the risks; 5. Independent review: unaffiliated individuals should review, approve, modify, or terminate the study; 6. Informed consent: individuals should be informed about the research and give voluntary consent; 7. Respect for enrolled subjects: subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored.^(4,5)

The three articles determine which ethical aspects must be fulfilled, but not all mention E. Emanuel’s requirements. Kalman CJ states that the policy developed was based on only 4 basic principles: medical confidentiality, worker information, worker consent, and worker access to study results prior to any publication, with only one of these, informed consent, coinciding with the seven requirements. The other author, Coggon, from the United Kingdom, also points out the aspects involved, and they have to do with a) the study question, b) the study design and implementation, c) the communication of results, and d) the application of the research. Aspects a, b, and d could be included in E. Emanuel’s requirement two, scientific validity, where it is stated that the methodology must be rigorous so that the data are valid and reliable; if a study lacks scientific rigor, it can be considered unethical immediately.⁽⁴⁾

However, in the case of a validity problem, depending on the type of study (e.g., self-report measurement of a situation under study), the principle of methodological triangulation could be applied, which consists of finding three different types of evidence to validate the information.⁽¹¹⁾ Aspect c can be included in requirement seven. Finally, the Japanese article points out general aspects of occupational health research, highlighting the importance of compliance with both national and international regulations. In this item, it could be considered that the seven requirements are key to complying with national and international ethical standards. The second item of this article notes the importance and role of the ethics review committee, which can be framed in requirement five: independent review. The third item describes the general features of occupational medical research and its differences with general clinical medical research. It also mentions obtaining informed consent, which aligns with E. Emanuel's requirement six.

CONCLUSIONS

Occupational health research must adhere to ethical standards, including national and international ethical regulations, similar to other types of research involving human subjects. It is imperative to consider Ezekiel Emanuel's seven requirements as fundamental for undertaking research in occupational health. This ensures that the research is ethically and scientifically rigorous.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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