Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Archives of Medical Research 53 (2022) 539–540

LETTER TO THE EDITOR

Regarding the Article: A Multimodal Strategy to Reduce the Risk of Hospitalization/death in Ambulatory Patients with COVID-19

Dear editors,

Ascencio-Montiel IJ, et al. (1) present a study that pragmatically assesses the use of a kit for outpatient treatment of COVID-19 in 28,048 adult patients and its impact on hospitalization and death.

Authors evaluate a real-life strategy, but they omit essential methodological details such as a) criteria to assign the intervention (kit acceptance vs. kit availability); b) description of "telephone follow-up" and "oximeter use" allowing replicability; c) characteristics of subjects who rejected the kit or did not participate; d) differences between subjects with complete *versus* incomplete follow up; e) adherence, f) loss to follow up and g) treatment provided outside the institution.

We are troubled by the journal acceptance of a manuscript without formal evaluation by an Institutional Research Committee and a Research Ethics Committee, per national and international regulations (2). The "Institutional Review Board" concept does not apply in Mexico. Arguing that ethical review and informed consent were not required is problematic since patients were located and interviewed. Furthermore, subject participation was part of a clinical action established as a standard within the institution (in the absence of any official guideline for the management of COVID-19).

The authors justified the intervention based on the scarce information available at a specific moment of the health emergency when avoiding hospitalizations and deaths was a priority. However, it was also urgent to generate scientific knowledge, ideally requiring a controlled clinical trial. The article should have been presented as a retrospective review of a large-scale strategy with numerous limitations to adjust for confounders. Nevertheless, the work offers innovative approaches to improve health management in future emergencies.

The reduction of mortality or hospitalization by half in patients receiving the kit is remarkable. The kit included an oximeter, various medications, and an "information brochure." Close monitoring of oximetry is of paramount importance in the management of COVID-19 and promotes better patient care. However, limited information on the intervention, the patient's condition, and the actions to correct hypoxemia make it impossible to determine the impact of each kit's component on the outcome.

Telephone follow-up of patients is not widely practiced, and its usefulness is still debated. This study was an excellent opportunity to assess the effectiveness and feasibility of this intervention component.

Possible strengths of the manuscript and its interpretation can be diminished by the fact that some authors might present conflicts of interest that were not duly reported.

Large-scale intervention studies are complex and expensive, especially in countries where this type of clinical research is poorly developed. The referred manuscript would have had a more significant impact if, during the review process, the methodological limitations had been adequately flagged and corrected (or a proper clinical trial had been performed). Therefore, we urge editors and reviewers to positively promote methodological rigor during the peer-review process to ensure confidence in the results and avoid the perception of laxity within the country's scientific system (3).

Conflicts of Interest

None.

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https://doi.org/10.1016/j.arcmed.2022.05.001

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Received for publication March 18, 2022; accepted May 4, 2022 (ARCMED-D-22-00360).