Intensive Care Med
https://doi.org/10.1007/s00134-023-07235-0

EDITORIAL

Putting your trust in ICU clinical trials: the journal's role

Carol L. Hodgson[1,2,3,4*], Pedro Póvoa[5,6,7] and Giuseppe Citerio[8]

Clinical trials, especially randomised controlled trials (RCTs), have long been regarded as the definitive standard for generating evidence that informs clinical practice. Individuals who volunteer to participate in RCTs do so with the hope of gaining improvements in their health. In addition, their involvement in these trials will impact the future management of all people [1].

The intricate orchestration of a clinical trial, which encompasses ethical considerations, rigorous protocol adherence, and the sustained involvement of research personnel, contributes to a scenario where the overall health benefits of participating may indeed outweigh those of not participating. This remains true regardless of whether participants are assigned to an intervention or control group. In essence, the comprehensive nature of clinical trials fosters an environment where participants might experience enhanced health outcomes compared to individuals who do not partake in such trials [2].

Amid the numerous advantages of engaging in clinical trials, the precise dissemination of trial outcomes by investigators stands as a pivotal point for both patients and clinicians, shaping the landscape of clinical practice. Central to this process are editorial boards and journal reviewers, who wield a significant influence in scrutinising and refining submitted manuscripts detailing clinical trial findings, ensuring their accurate interpretation for real-world application.

An important question for all journal editorial boards, reviewers, researchers, clinicians and consumers is whether data is trustworthy [3]. In 2021, Carlisle analysed the baseline summary data of 526 randomised controlled trials submitted to Anaesthesia from February 2017 to March 2020. Seventy-three (14%) had false data, and 43 (8%) were categorised as fatally flawed [4]. The review of individual patient data of the submitted randomised controlled trials revealed false data in 44%. During the coronavirus disease 2019 (COVID-19) pandemic, at least eight clinical trials were retracted from six journals due to false or flawed data or errors in the statistical analysis [5]. These studies included information about eight different drugs that were tested.

The era of the COVID-19 pandemic magnified the significance of these roles, with editors and reviewers shouldering unprecedented demands [6, 7]. In this heightened environment, manuscripts might have undergone fewer and hurried reviews due to the constraints faced by busy healthcare practitioners. Tragically, this has occasionally culminated in the subsequent retraction of published papers, underscoring the criticality of upholding meticulous review processes in all circumstances.

Research misconduct may be defined as fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research results. Research misconduct does not include unintended errors or differences of opinion [8]. The number of researchers who have admitted to scientific misconduct is very low, estimated to be around 1.97% of published clinical trials [9]. Publications of clinical trials may be retracted by journals when their findings are not trustworthy. This can occur due to scientific misconduct or error, including data manipulation, fraudulent data, data duplication, non-replicability, or data errors. It can also occur due to violation of ethical guidelines, including duplicate publication, plagiarism, lack of institutional review board approval or authorship disputes. However, with regard to Intensive Care Medicine (ICM), while retractions have occurred due to concerns about data integrity, they are very uncommon [10] with the exception of Boldt's 18 old

*Correspondence: carol.hodgson@monash.edu
[1] Australian and New Zealand Intensive Care Reserach Centre, Monash University, Melbourne, Australia
Full author information is available at the end of the article

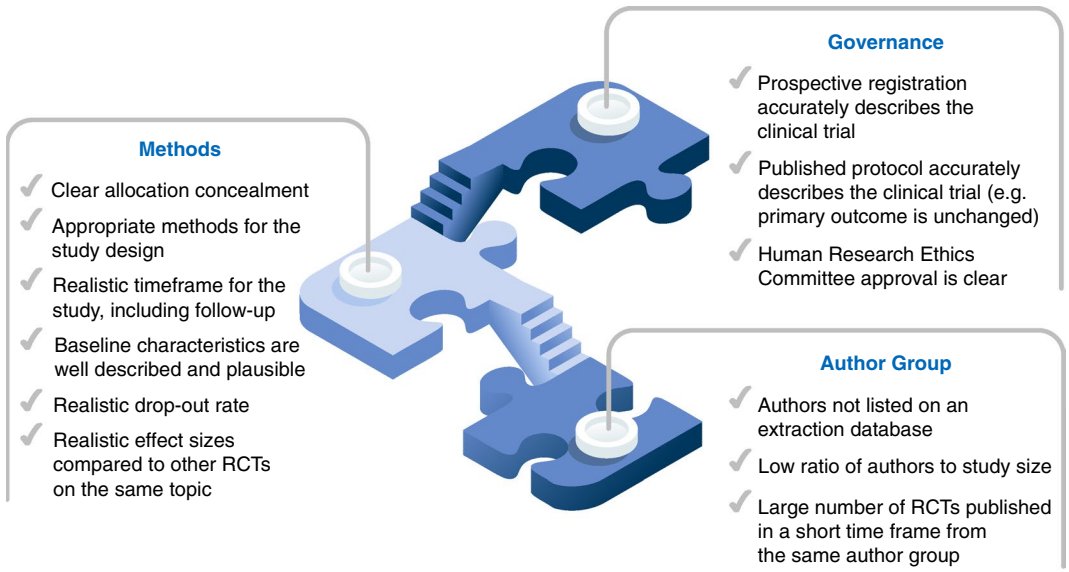

Fig. 1 Assessing clinical trial trustworthiness

publications retractions in the year 2023 by ICM alone. Ideally, pre-emptive detection mechanisms would flag these untrustworthy submissions before publication, thereby safeguarding readers' confidence in scholarly works.

There are several ways to minimise the risk of publishing untrustworthy clinical trials [11] that ICM is implementing (Fig. 1). A comprehensive strategy entails a meticulous review of prospective clinical trial registrations, the veracity of published protocols, and the unequivocal endorsement of institutional review boards. In addition, cross-referencing author names with retraction databases serves as a critical checkpoint in upholding the veracity of publications. Integrating checklists for evaluating trustworthiness also offers a valuable tool, albeit with inherent limitations, such as the potential for both false negatives and false positives in identifying unreliable papers [11]. Indeed, ICM may request access to the raw data to verify the results of clinical trials. In the future, our publisher may have tools that assist editors and reviewers to identify data that is potentially untrustworthy, and this will streamline the process. Funding supporting clinical trials must be disclosed, particularly if there is a conflict of interest, as it may lead to bias in the results.

Collectively, these measures suggest proactive commitment by ICM to reduce the dissemination of questionable research, reinforcing the cornerstone of trust that underscores the entire edifice of medical research.

Author details
[1] Australian and New Zealand Intensive Care Reserach Centre, Monash University, Melbourne, Australia. [2] The Alfred Hospital, Melbourne, Australia. [3] Critical Care Division, The George Institute for Global Health, Sydney, Australia. [4] Department of Critical Care, The University of Melbourne, Melbourne, Australia. [5] NOVA Medical School, NOVA University of Lisbon, Lisbon, Portugal. [6] Center for Clinical Epidemiology and Research Unit of Clinical Epidemiology, OUH Odense University Hospital, Odense, Denmark. [7] Intensive Care Unit 4, Dpt of Intensive Care, Hospital de São Francisco Xavier, CHLO, Lisbon, Portugal. [8] School of Medicine and Surgery, University Milano Bicocca, Milano, Italy.

Declarations

Conflicts of interest
The authors declare that they have no conflict of interest.

Publisher's Note

Received: 7 September 2023 Accepted: 12 September 2023
Published online: 16 October 2023

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