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.

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Appraisal

Clinimetrics: Core Outcome Set for trials with Coronavirus disease 2019 (COVID-19-COS)

Summary

The Core Outcome Set (COS) for trials in Coronavirus Disease 2019 (COVID-19-COS) aimed to establish a consistent and standardised list of outcomes to be measured and reported, as a minimum, in trials treating patients with COVID-19.[1] The COVID-19-COS was developed according to the Core Outcome Measures in Effectiveness Trial (COMET) framework, using a series of online workshops involving adults who had experienced suspected or confirmed COVID-19, their family members, the general public and health professionals from 111 countries.[1] The COVID-19-COS specifies mortality, respiratory failure, multiple organ failure, shortness of breath, and recovery as the most critically important outcomes for trials involving participants with COVID-19.[2]

Core outcome measures for the COVID-19-COS outcome domains were proposed,[2] using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) framework to identify appropriate measures and their clinimetric properties. Mortality is measured, according to World Health Organization (WHO) recommendations, at hospital discharge or at 60 days.[2] The outcome measure for respiratory failure is a modified version of the WHO clinical progression scale, with scores between 4 (hospitalised with no oxygen therapy) and 9 (extracorporeal membrane oxygenation) reflecting the increasing need for respiratory support.[2,3] Validation of this scale is not yet available; however, it has already been used in COVID-19 trials.[4,5]

Multiple organ failure is measured using the Sequential Organ Failure Assessment (SOFA) score, which is commonly used in research and clinical practice. It has been validated for use in hospital and ICU settings and also provides prognostic information regarding survival.[6] Shortness of breath is measured using the Modified Medical Research Council (MMRC) dyspnoea scale, with minor adaptations to the original wording and the addition of a recall period of 24 hours to capture daily fluctuations. The MMRC is a simple 5-point scale that has been extensively validated in patients with chronic respiratory disease.[7,8] No existing outcome measure for recovery was identified, so a new COVID-19-COS recovery measure was proposed, consisting of a 5-point Likert scale with anchors 'not recovered at all' and 'completely recovered'. No clinimetric data are available for this new recovery measure.[2]

Commentary

Researchers across the world have rapidly responded to the urgent need for clinical trials of treatments for COVID-19. Maximising the health impacts of this research effort will need trial outcomes that can be interpreted, compared and applied across different populations and countries. The decision regarding which outcomes should be measured in clinical trials needs to take into consideration the relevance to clinicians and researchers but also to patients, policy makers and funders.[9] A strength of COVID-19-COS is the identification of a small number of outcome domains relevant to all stakeholders, which can be measured using simple outcome tools, some of which are familiar to clinical trialists and already in common use. Another important strength is the use of robust frameworks (COMET and COSMIN) to identify outcomes and understand the clinimetric properties of the proposed measurement tools.

Because COVID-19-COS was developed early in the pandemic (March and April 2020), the top 10 priorities identified by participants comprised only acute and severe outcomes. As a result, the most robust elements of COVID-19-COS reflect the outcomes of acute care (mortality, respiratory failure, multiple organ failure). The steering group elected to add a patient-reported outcome (shortness of breath) and a longer term outcome (recovery). Since the development of COVID-19-COS, knowledge of the long-term sequelae of COVID-19 infection has dramatically increased, including the importance of other debilitating symptoms such as persistent fatigue.[10] The absence of dyspnoea in acutely unwell patients has also been recognised,[11] such that this measure may vary in its utility across patients. The authors are to be commended for developing a simple measure of recovery following COVID-19, given the absence of existing measurement tools, and this should be validated in future studies. The greatest value of COVID-19-COS is in trials located or commenced in acute care settings, where it provides opportunities to generate high-quality evidence and results that can be readily compared and combined with other studies.[9]

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References

1. Tong A, et al. *Crit Care Med*. 2020;48:1622–1635.
2. Tong A, et al. *Crit Care Med*. 2021;49:503–516.
3. WHO Working Group. *Lancet Infect Dis*. 2020;20:e192–e197.
4. Cao B, et al. *N Engl J Med*. 2020;382:1787–1799.
5. Rodionov RN, et al. *Lancet Microbe*. 2021;2:e138.
6. Seymour CW, et al. *JAMA*. 2016;315:762–774.
7. Tsiligianni IG, et al. *Int J Chron Obstruct Pulmon Dis*. 2016;11:1045–1052.
8. Sandberg J, et al. *J Pain Symptom Manage*. 2018;56:430–435 e2.
9. Williamson P, et al. *J Health Serv Res Policy*. 2012;17:1–2.
10. Logue JK, et al. *JAMA Netw Open*. 2021;4:e210830.
11. Tobin MJ, et al. *Am J Respir Crit Care Med*. 2020;202:356–360.

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