CADTH COVID-19 PANDEMIC

COVID-19 CADTH Health Technology Review

Sotrovimab for the Treatment of COVID-19

This report was published on September 3, 2021.
To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to **requests@cadth.ca**

Key Messages

- There is a lack of published peer-reviewed evidence regarding the clinical effectiveness of sotrovimab for the treatment of individuals with coronavirus disease 2019 (COVID-19).
- Results from an ongoing trial, which are expected later this year, should provide decision-makers with an increased understanding of the potential role of sotrovimab for the treatment of individuals with COVID-19.

Context and Policy Issues

Sotrovimab (also known as VIR-7831) is a human monoclonal antibody that binds the spike protein of severe acute respiratory syndrome coronavirus 2, the virus that causes COVID-19.[1] Engineered from an antibody isolated from a patient who recovered from severe acute respiratory syndrome in 2003,[1] this investigational therapeutic received an Emergency Use Authorization by the FDA in May 2021[2] and was authorized under Interim Order by Health Canada in July 2021.[3] These regulatory decisions were based on preliminary results of the COVID-19 Monoclonal antibody Efficacy Trial — Intent to Care Early (COMET-ICE).[2-4] The objective of the current report is to summarize the available evidence regarding the clinical effectiveness of sotrovimab for the treatment of COVID-19.

Research Question

What is the clinical effectiveness of sotrovimab for the treatment of coronavirus disease 2019 (COVID-19)?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, PubMed, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was sotrovimab. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2019 and August 30, 2021.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Criteria	Description
Population	Individuals with confirmed COVID-19
Intervention	Sotrovimab (alone or in combination with other therapies)
Comparator	No treatment; placebo; other active treatments (e.g., casirivimab-imdevimab)
Outcomes	Clinical effectiveness (e.g., mortality, length of hospital stay, severity of clinical symptoms, viral load, safety [e.g., adverse events])
Study designs	Health technology assessments, systematic reviews, RCTs, and non-randomized studies

COVID-19 = coronavirus disease 2019; RCTs = randomized controlled trials.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2019.

Summary of Evidence

Quantity of Research Available

A total of 16 citations were identified in the literature search. Following screening of titles and abstracts, 13 citations were excluded and 3 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 4 publications were excluded for various reasons, and no publications met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA[5] flow chart of the study selection. Additional references of potential interest are provided in Appendix 2.

Summary of Findings

Clinical Effectiveness of Sotrovimab for the Treatment of COVID-19

No relevant evidence regarding the clinical effectiveness of sotrovimab for the treatment of individuals with confirmed COVID-19 was identified; therefore, no summary can be provided.

Conclusions and Implications for Decision- or Policy-Making

No relevant literature was identified regarding the clinical effectiveness of sotrovimab for the treatment of individuals with confirmed COVID-19. While results from a preplanned interim analysis[6] from an ongoing randomized controlled trial[4] investigating the effectiveness of sotrovimab (i.e., VIR-7831) versus placebo for the early treatment of non-hospitalized COVID-19 patients are available in a preprint, these results are preliminary and have not been peer-reviewed, and thus were not eligible for inclusion in this review. The final results of this clinical trial,[4] as well as any subsequent studies, should provide decision-makers with some clarity with respect to the potential role of sotrovimab for the treatment of COVID-19.

References

1. Tuccori M, Ferraro S, Convertino I, et al. Anti-SARS-CoV-2 neutralizing monoclonal antibodies: clinical pipeline. *MAbs.* 2020;12(1):1854149.

2. Coronavirus (COVID-19) update: FDA authorizes additional monoclonal antibody for treatment of COVID-19 [news release]. Silver Spring (MD): U.S. Food and Drug Administration; 2021: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19. Accessed 2021 Sep 1.

3. Regulatory decision summary - [Pr]Sotrovimab - Health Canada. Ottawa (ON): Goverment of Canada; 2021: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00836. Accessed 2021 Sep 1.

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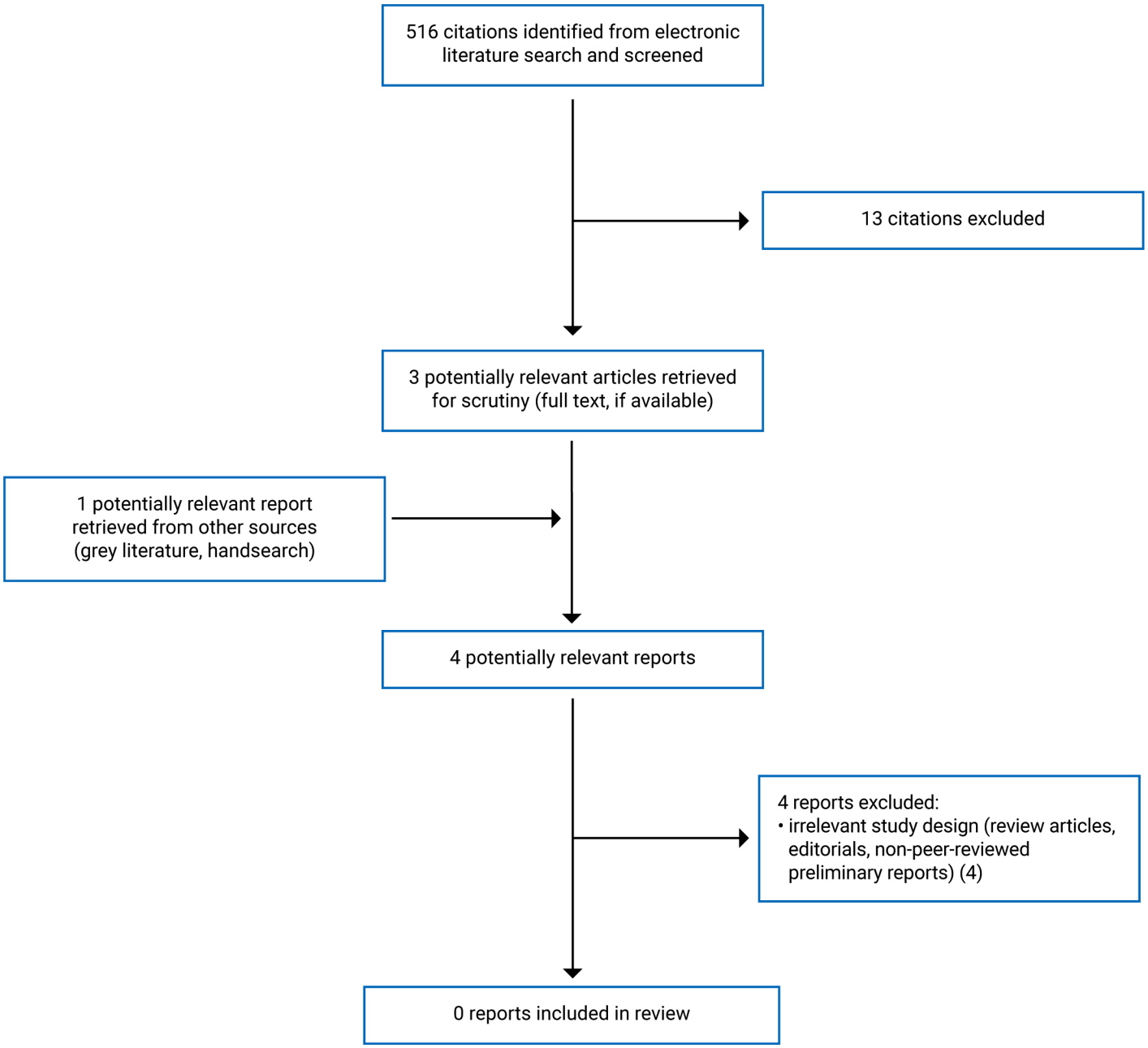
5. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1-e34.

6. Gupta A, Gonzalez-Rojas Y, Juarez E, et al. Early Covid-19 treatment with SARS-CoV-2 neutralizing antibody sotrovimab **[non-peer reviewed preprint]**. *medRxiv.* 2021 May 28:doi: 10.1101/2021.1105.1127.21257096. https://europepmc.org/article/PPR/PPR349174. Accessed 2021 Aug 31.

Appendix 1: Selection of Included Studies



Appendix 2: References of Potential Interest

Previous CADTH Reports

Tocilizumab and sarilumab: evidence review and appraisal. Ottawa (ON): CADTH; 2021 Feb. (CADTH Health Technology Review). https://cadth.ca/sites/default/files/covid-19/hc0014-001-tocilizumab-and-sarilumab-update1-mar25.pdf

Review Articles

Case JB, Winkler ES, Errico JM, Diamond MS. On the road to ending the COVID-19 pandemic: are we there yet? *Virology.* 2021 May;557:70-85. PubMed: PM33676349

Goyal M, Tewatia N, Vashisht H, Jain R, Kumar S. Novel corona virus (COVID-19); Global efforts and effective investigational medicines: a review. *J Infect Public Health.* 2021 July;14(7):910-921. PubMed: PM34119845

Sun Y, Ho M. Emerging antibody-based therapeutics against SARS-CoV-2 during the global pandemic. *Antib Ther.* 2020 Dec;3(4):246-256. PubMed: PM33912795

Regulatory Documents and News Releases

Notice: Prescription Drug List (PDL): sotrovimab (COVID-19). Ottawa (ON): Health Canada: 2021: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/amendment-sotrovimab-covid-19.html.

Drug and vaccine authorizations for COVID-19: list of authorized drugs, vaccines and expanded indications. Ottawa (ON): Health Canada: 2021: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/list-drugs.html

Fact sheet for healthcare providers emergency use authorization (EUA) of sotrovimab. Silver Spring (MD): U.S. Food and Drug Administration: 2021: https://www.fda.gov/media/149534/download

Letter of authorization: sotrovimab. Silver Spring (MD): U.S. Food and Drug Administration: 2021: https://www.fda.gov/media/149532/download

Emergency Use Authorization (EUA) for sotrovimab 500 mg. Center for Drug Evaluation and Research (CDER) Review. Silver Spring (MD): U.S. Food and Drug Administration: 2021: https://www.fda.gov/media/150130/download

Paediatric investigation plan: sotrovimab. *EMEA-002899-PIP01-20.* Amsterdam (NL): European Medicines Agency; 2021 Aug 19: https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002899-pip01-20.

TGA approves new COVID-19 treatment for use in Australia. Canberra (AU): Australian Department of Health: 2021 Aug 20: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/tga-approves-new-covid-19-treatment-for-use-in-australia