DSEN ABSTRACT

Active Surveillance for safety and effectiveness of health products for COVID-19: A scoping review

Summary

- This scoping review aimed to examine the evolution of AS systems throughout the COVID-19 pandemic by considering early- (2020) and later-stage (2021 or later) AS implementation.
- Findings are based on 13 AS systems identified, six for safety, two for effectiveness, two for both, and three with descriptive treatment data.

Key messages

- Of the 13 AS systems, 11 existing ones were repurposed and two were created early in the pandemic. Twelve were rapidly implemented for urgent use for COVID-19 treatments during the first half of 2020.
- Various data sources, technical tools, procedures and study designs were applied in those AS systems for people to actively access surveillance data and timely obtain signals or analyses regarding the safety and effectiveness of treatments used for patients with COVID-19.

Authors: Zemin Bai, Said Yousef Abdelrazeq, Shannon E. Kelly, Becky Skidmore, George A. Wells

For more information, please contact **George A. Wells**
gawells@ottawaheart.ca

What is the issue?

- Urgent response to the COVID-19 pandemic necessitated rapid implementation of experimental, re-purposed, or off-label treatment strategies, often with uncertainties around the safety and effectiveness. Active surveillance (AS) is a pharmacovigilance approach used to collect event reports via a continuous pre-organized process and reporting. AS can be used to identify and evaluate these effects.

What was the aim of the study?

- To identify, characterize and describe AS systems (including any AS methods, approaches, procedures, or tools) used to assess the safety and effectiveness of health products (drugs, biologics, or natural health products) for the treatment of COVID-19.

How was the study conducted?

- A scoping review was performed following the existing methodological guidance.
- MEDLINE, EMBASE, CENTRAL, Cochrane Database, Web of Science Core collection, global regulatory agency websites and registries were searched, and alerts were implemented until August 2022.
- Two reviewers independently screened titles and abstracts. One reviewer screened full texts and extracted data, and another reviewer verified the inclusion and data extraction. Discrepancies were discussed by two reviewers or resolved by a third party.
- The records with data source, active data access, and timeliness of reporting, applied in the treatment of COVID-19 were considered eligible.
- Descriptive and tabular summaries of all identified AS systems were reported.

What did the study find?

- Fifteen publications to describe 13 AS systems were identified from a total of 9,183 literature records of which 1053 were reviewed as full articles.
- Of the 13 AS systems, six were designed for safety, two for effectiveness, two for both, and three provided descriptive treatment data.
- Eleven AS systems were repurposed and two were created early in the pandemic. Twelve were initiated for COVID-19 treatments during the first half of 2020 and one existing system was applied in a WHO prospective cohort study for safety in 2022.
- Various data sources, technical tools, procedures and study designs were applied for researchers, clinicians, policy makers, or public to actively access surveillance data and timely obtain early signals and analyses of safety and effectiveness of antivirals, antibiotics, hydroxychloroquine, corticosteroid, and other health products used to treat the patients with COVID-19.

This research was funded by CIHR – Drug Safety and Effectiveness Network and conducted by investigators affiliated with the following institutions:

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

MAGEC Methods and Applications Group for Indirect Comparisons

Link to publication: publication pending