

The COVID-19 pandemic and the strain it placed on healthcare systems highlighted a key role for real-world data in quickly generating health evidence. A growing demand for large-scale health data analysis has resulted in the existence of large health data networks, which consist of health data owners who agree to report data in a common format. This facilitates research as one single analysis code may be used to analyse data at all sites within a network without the need to account for differences in data formats at multiple sites.

The existence of such networks provides more opportunities for the incorporation of observational evidence from daily practice in addition to clinical trial evidence in the health regulation decision-making process. As such, this study collected observational evidence on COVID-19 treatments effects on short-term mortality among patients hospitalised with COVID-19 from the European Health Data and Evidence Network (EHDEN) and synthesised these data with evidence from clinical trials. The European Health Data and Evidence Network is an observational health data network comprised of 187 data partners across 29 European countries. EHDEN collaborates closely with the Observational Health Data Sciences and Informatics program, a global collaborative which produces software tools to facilitate large scale health data analytics.

Observational evidence was collected through the EHDEN network using OHDSI tools and included hospitalised patients who were aged 18 years or over at cohort entry, had at least one year of observation prior to treatment, had no prior exposures to studied treatments in the year before the study, and were diagnosed with COVID-19. Many data partners attempted to run the study, and one data partner with 475 eligible patients completed the study. Although target treatments included aspirin, baricitinib, heparin, remdesivir, and tocilizumab, only data for remdesivir and tocilizumab were available.

Evidence from clinical trials was collected through literature search, including two published works and two trial databases. 21 trials including 15,246 patients were identified and results concerning short-term mortality among hospitalised patients with COVID-19 receiving remdesivir or tocilizumab were combined.

This study generated inconclusive evidence for the comparative effectiveness of remdesivir and tocilizumab in reducing short-term mortality among hospitalised patients with COVID-19. Evidence from clinical trials showed no evidence for a difference between remdesivir or tocilizumab, while observational evidence showed remdesivir to significantly reduce short-term mortality compared to tocilizumab.

The observational data results indicate a need for more streamlined observational data collection pathways, but show that it is feasible to collect observational evidence through EHDEN that can be compared with clinical trial evidence. Future research will focus on the recruitment of more hospitals to produce a larger sample of observational evidence, and future studies investigating the practicality of observational evidence may build upon the infrastructure developed for this study at participating hospitals.