Remdesivir during the COVID-19 Pandemic – Analysis of the First Year of Global Spontaneous Disease-Specific Adverse Drug Reaction Reporting

Elena Rocca1,2, Oskar Gauffin1, Ruth Savage1,3,4, Sara Hedfors Vidlin1, Birgitta Grundmark1

Background
Remdesivir is conditionally approved for the treatment of COVID-19 in several countries. With its poorly characterised safety profile, global monitoring of adverse drug reaction (ADR) reporting is essential.

Objectives:
Reviewing global ADR reporting for remdesivir by investigating severity of these, co-reported COVID-19 medications, early therapy cessation and ADRs in individual case safety reports (ICSR).

Methods
All ICSRs from 2020 that included the COVID-19 indication (for any reported drug) were retrieved from the WHoS global ICSR database, Vigibase, by scanning incoming ICSR indication, free text and laboratory test result fields through an in-house developed algorithm. Drugs in extracted ICSRs were classified by two independent coders as either COVID-19 specific (identified from scientific literature) or non-COVID-19 specific. Analysis of the remdesivir ICSR’s demographics, co-reported drugs, therapy duration, (identified from scientific literature) or non-COVID-19 specific. Analysis of the remdesivir or tocilizumab ICSRs. Disproportionality, marked red, was performed. Disproportionality analysis (measured by Information Component (IC)), and ADRs coded as MedDRA preferred terms (PTs), was performed.

Results
Disproportionality (red bars) were largely in evidence with labelled reactions (*) and showed additional potential signals that were incompletely labelled (**) or unlabelled including breathlessness and renal injury with remdesivir but not tocilizumab.

Conclusion
Remdesivir ICSRs show a complex pattern of care and polypharmacy, making causality assessment complex. In-depth analyses of case narratives, including adverse event safety concerns in the scientific withdrawal patterns, may aid in further evaluating disproportionate ADRs such as those related to hepatic, renal and cardiac function.