Flaws in ivermectin data suggest COVID-19 meta-analyses need rethinking

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Credit: Twitter / FDA

Data from individual patients in clinical trials should be made available by researchers, and then requested and reviewed, for meta-analyses of potential therapeutics for COVID-19, argue Kyle Sheldrick and colleagues in a Correspondence published in *Nature Medicine*. Using the

example of research into the use of ivermectin to highlight the risks inherent in current approaches, the authors contend that immediate remediation is needed in order to prevent potential harm to patients.

The COVID-19 pandemic has resulted in a surge in demand for randomized clinical trials of novel treatments and accompanying meta-analyses—the statistical approach used for the analysis of data from multiple studies. However, relying on low-quality or questionable studies for these analyses in the current global climate could present severe and immediate harm.

Kyle Sheldrick and colleagues draw upon the example of research and meta-analyses into the use of the anti-parasitic drug ivermectin as a prophylactic or treatment for COVID-19. Examining the available evidence, the authors note disparities in original trial data that are then amplified by meta-analyses. These include irregularities, randomization failures and substantial methodological weaknesses, which have led to withdrawal of some of this research. These disparities could in turn affect the reliability of meta-analyses into the effectiveness of the drug against COVID-19.

The authors argue that to counteract these problems, a change is needed in the way that COVID-19 clinical trial data are analyzed. In particular, the authors call for meta-analyses to be published on the basis of data from individual patients. This would include scientists' requesting and reviewing data at the level of individual patients in all studies, with every clinical trial investigating novel treatments for COVID-19 following best-practice guidelines and making individual-patient-level data available. Any ethical privacy concerns, the authors claim, can be easily addressed with early trial planning and anonymization. Research that does not share individual-patient-level data should be excluded from any meta-analyses.

In this way, Kyle Sheldrick and colleagues emphasize, steps can be taken

to prevent any apparent favorable conclusions from relatively weak trials from being rapidly translated into widespread clinical practice and public policy.

More information: Jack M. Lawrence et al, The lesson of ivermectin: meta-analyses based on summary data alone are inherently unreliable, *Nature Medicine* (2021). DOI: 10.1038/s41591-021-01535-y