

Reconsidering Ivermectin

Despite a skeptical Cochrane review, the antiparasitic is still a valuable tool for combating COVID.

✦ BY CHARLES L. HOOPER AND DAVID R. HENDERSON

Natural immunity from repeated infections, the development of vaccines against the virus SARS-CoV-2, and antivirals to treat infection have dramatically reduced serious illness and death from COVID-19. Still, COVID remains a meaningful cause of illness and death around the world. Even in the United States, COVID now kills about 20,000 a year. For that reason, it is helpful to look for cheap, widely available medicines as additional treatments.

While the COVID pandemic was raging, we wrote in *Regulation* that the antiparasitic drug ivermectin showed promise as a treatment and preventative. In Hooper and Henderson (2022a), we disagreed with researchers who dismissed it because studies showed “only” 93 percent confidence that it was effective. In Hooper and Henderson (2022b), we argued that, contrary to the reported results of a major trial of the drug that was conducted in Brazil known as the TOGETHER Trial, the data suggested it was effective for many who were in the trial.

In science, of course, no one ever gets the last word. Controversies are ongoing. A prominent analysis of ivermectin by the highly reputable Cochrane Library, Popp et al. (2026), claims that the consensus of the academic literature is that ivermectin was ineffective against COVID. This conclusion is faulty. As we document below, Popp et al. were too selective on which studies to include in their analysis, and several of those studies were of poor quality. Instead of upholding Cochrane’s reputation for quality and, therefore, being the last word on ivermectin, this analysis is, unfortunately, unreliable.

Written in 2022, Popp et al. is a meta-analysis: It combines the results of many individual clinical trials to create one large data set. In this way, the results can be evaluated for many more patients than are typically tested in any individual trial.

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Meta-analysis can be a very useful tool when assembling a large trial is impractical.

While meta-analyses strive for and claim unbiased objectivity, they can fail in two important ways: They can rely on poor research conducted by others, and they can poorly synthesize the results of that research. A failure in either results in a poor final product. This can be analogized to making a hamburger: Both the ingredients and the technique must be right to produce a good burger; if either is flawed, the burger will be bad. Below, we argue that both the Popp et al. “ingredients” and the “technique” were bad.

THE CITED RESEARCH

There have been 106 clinical studies of ivermectin in combating COVID-19, and many were good. However, some weren’t. Table 1 lists some of the most egregious studies, and some of these were used by Popp et al. and other meta-analyses critical of ivermectin’s effectiveness against COVID.

These nine studies highlight how *not* to run a clinical trial. We have no doubt that if studies of this quality were referenced by those who claim that ivermectin is effective for SARS-CoV-2 infections, critics would have had a field day skewering them. This did happen with one study, Elgazzar et al. (2020), which is the only one of the Knackered Nine that showed a clear benefit for ivermectin treatment and was subsequently retracted.

THE ANALYSIS

Popp et al. was not comprehensive but was, rather, a selective and incomplete look at the studies of ivermectin’s effectiveness. The review included just nine studies that examined mortality, resulting in sparse results that don’t meet the threshold of statistical significance. Because statistical significance is so important to many in the medical field (whether such a perspective is justified or not), and the Popp et al. analysis included so few clinical studies, its conclusions that



ivermectin didn't show statistically significant benefits were essentially guaranteed from the outset. An ivermectin "win," given the Popp et al. recipe, was just about impossible given the sparsity of the data evaluated. In statistical language, the Popp et al. analysis was underpowered.

For instance, for inpatient mortality, the meta-analysis included three studies that covered 230 patients and there were only 14 "events," which in this case means deaths. Five of those deaths were among the 121 patients on ivermectin and nine were among the 109 patients on placebos or other treatments. Given those results, ivermectin would seem to have half as many fatalities. But alas, those sparse results are not statistically significant because a study of only 230 patients is underpowered; more patients would have been needed to show that the 50 percent reduction was statistically significant.

For outpatient mortality, Popp et al. included six studies that covered 2,860 patients and there were 66 events. The TOGETHER Trial data recorded 45 of the 66 total deaths, meaning it comprised 68 percent of the recorded outpatient deaths. In this case, ivermectin seems to have had 27 percent fewer fatalities.

To give a sense of how narrow the Popp et al. focus was, in all the studies of ivermectin that included mortality, 123,452 patients were covered and there were 4,165 events (deaths). But when analyzing ivermectin and mortality, the Cochrane team focused on just a few studies, covering less than 2 percent of the deaths, saying that was enough to "provide a complete evidence profile." To be fair, some of the studies were published after the Cochrane report was completed. And yet, Popp et al. acknowledged 125 possible studies to include (both clinical

and non-clinical). Not all those studies measured mortality, but 53 did. How many of the 53 were included in this "complete evidence profile"? Only nine, or 17 percent.

One might expect researchers who were selective to have good judgment about which studies to select. But that doesn't appear to be the case here. The Popp et al. meta-analysis included four of the Knackered Nine clinical studies in Table 1: Buonfrate et al. (2022), López-Medina et al. (2021), Reis et al. (2022), and Vallejos et al. (2021). This shouldn't be surprising when we consider that the Popp et al. authors include some of the authors of the Knackered Nine, such as Stefanie Reis and Stephanie Weibel. Reis was the lead author of the TOGETHER Trial study; Weibel was a coauthor of Buonfrate et al. In fairness to the authors, it's natural to include your own study, but it's also natural to overlook the weaknesses of your own study. It's important to note that the TOGETHER Trial (Reis et al.) was both big and bad, raising serious questions about its final results.

Given the flaws, it's not surprising that two of the Popp et al. authors, Maria Popp and Weibel, later stated: "Overall, the outlook for ivermectin's use to treat or prevent SARS-CoV-2 is poor. While laboratory results showed some promise, real-life outcomes suggest no or very little impact on mortality rates, illness, and length of infection." And yet the data suggest that there were substantial benefits from ivermectin. That's the myopia imposed by the statistical orthodoxy that claims that 50 percent and 27 percent reductions in mortality don't count if the analysis was underpowered to the extent that an arbitrary threshold of confidence wasn't met. And there's no acknowledgment by the authors of the tension between

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the promising results and the doctrinal rejection of those promising results.

OTHER META-ANALYSES

Popp et al. isn't the only game in town. It's interesting to note that six other meta-analyses, listed in Table 2, concluded that there was a lower risk of mortality for patients on ivermectin, while two others—in addition to Popp et al.—didn't. All six of the positive meta-analyses derived results that were all highly statistically significant. The one with the lowest p-value still had $p = 0.005$, which is one-tenth the standard accepted significance level.

The three meta-analyses that didn't report a benefit from ivermectin had fundamental problems. While ignoring studies comprising 98.1 percent of all deaths of studied patients, Popp et al. still found a 50 percent lower risk for patients in inpatient settings with moderate to severe disease and a 27 percent lower risk for patients in outpatient settings with asymptomatic or mild disease. And yet Popp et al. reported that ivermectin “probably has little or no effect on all-cause mortality at day 28.” Why? As stated above, so few studies made it through the inclusion criteria that the results weren't statistically significant.

A second meta-analysis, Song et al. (2024), reported, “There was no significant difference in all-cause mortality rate between [ivermectin] and controls.” And yet 62.7 percent of the mortality results used to develop that conclusion came from one of the Knackered Nine, Elshafie et al. (2022). The next highest mortality share, 12.6 percent, came from Rezai et al. (2022), another of the Knackered Nine. The most serious and damning complication was that one of that study's researchers, Andrew Hill, was recorded on video admitting that the conclusions of his ivermectin research were not based on the data but were requested by a funding organization.

Song et al. has a curious sentence in the abstract, ending with “databases

Table 1

The Knackered Nine

Problematic research that is often cited on ivermectin's effects on COVID. (The Cochrane review cites Buonfrate, López-Medina, Reis, and Vallejos.)

Bramante, Carolyn, Jared D. Huling, Christopher J. Tinanelli, et al., 2022, “Randomized Trial of Metformin, Ivermectin, and Fluvoxamine for Covid-19,” *New England Journal of Medicine* 387(7): 599–610.

Problems: The study had many serious problems, including 18 that were judged critical, 17 that were deemed serious, and three that were rated major by some who reviewed it. The problems ranged from giving patients ivermectin on an empty stomach to results that appear erroneous.

Buonfrate, Dora, Fabio Chesini, Davide Martini, et al., 2022, “High-Dose Ivermectin for Early Treatment of COVID-19 (COVER Study): A Randomised, Double-Blind, Multicentre, Phase II, Dose-Finding, Proof-of-Concept Clinical Trial,” *International Journal of Antimicrobial Agents* 59: 106516.

Problems: The study exhibited some important flaws, including “significant unadjusted group differences, with 3 times as many patients in the ivermectin arms [different treatment groups in the clinical trial] having the baseline visit in a hospital setting, and arm C having large differences in baseline gender, weight, cough, pyrexia, and anosmia” (c19early.org, n.d.). The study received criticism because of those flaws.

Elgazzar, Ahmed, Basma Hany, Shaimaa Abo Youssef, et al., 2020, “Efficacy and Safety of Ivermectin for Treatment and Prophylaxis of COVID-19 Pandemic,” Research Square, November 16, 2020.

Problems: The study was withdrawn amidst allegations of plagiarism and faked data.

Elshafie, Ahmed Haneif, Hozaifa Khalil Elsayah, Mohamed Hammad, et al., 2022, “Ivermectin Role in COVID-19 Treatment (IRICT): Single-Center, Adaptive, Randomized, Double-Blind, Placebo-Controlled, Clinical Trial,” *Expert Review of Anti-Infective Therapy* 20(10): 1341–1350.

Problems: The study was retracted because of data validity and integrity concerns.

López-Medina, Eduardo, Pío López, Isabel C. Hurtado, et al., 2021, “Effect of Ivermectin on Time to Resolution of Symptoms among Adults with Mild COVID-19: A Randomized Clinical Trial,” *JAMA* 325(14): 1426–1435.

Problems: The study was partially funded by drug companies Sanofi Pasteur, GlaxoSmithKline, Janssen, Merck, and Gilead and was condemned as fatally flawed by more than 100 physicians in an open letter to *JAMA*. Criticisms include charges that investigators gave ivermectin too late, on an empty stomach, or to mildly ill and healthy patients, and that many of the patients in the control group had already taken ivermectin. Further, the primary endpoint of the study, which is the main data element being collected to enable the researchers to say whether ivermectin works or not, was abruptly changed halfway through the trial. This was an egregious violation of clinical trial protocols and should have caused the study to be aborted.

Naggie, Susanna, David R. Boulware, Christopher J. Lindsell, et al., 2023, “Effect of Higher-Dose Ivermectin for 6 Days vs Placebo on Time to Sustained Recovery in Outpatients with COVID-19: A Randomized Clinical Trial,” *JAMA* 329(11) 888–897.

Problems: The study had substantial errors and anomalies. It was criticized for flawed data and calculations. For example, 16% of the patients were missing from the original analysis. The study's authors addressed the criticisms and updated the results. But the results changed so much that critics are reasonably left wondering how they can trust the new results. For instance, 8.0% of the patients in the original analysis had an adverse event while only 0.4% of the newly added patients did. Also, 2.4% of the patients in the original analysis were missing a symptom severity measurement while 32% of the newly added patients were. These results were unlikely to have occurred without the presence of deeper problems.

Reis, Gilmar, Eduardo A.S.M. Silva, Daniela C.M. Silva, et al., 2022, “Effect of Early Treatment with Ivermectin among Patients with Covid-19,” *New England Journal of Medicine* 386(18): 1721–1731.

Problems: A sampling of the problems with Reis includes a severe conflict of interest, broken trial blinding, failures with treatment randomization, multiple impossible numbers, uncorrected errors, protocol violations, a broken promise to release the data, and no responses from the authors regarding queries. See our previous articles in *Regulation*.

Rezai, Mohammad Sadegh, Fatemeh Ahangarkani, Andrew Hill, et al., 2022, “Non-Effectiveness of Ivermectin on Inpatients and Outpatients with COVID-19: Results of Two Randomized, Double-Blinded, Placebo-Controlled Clinical Trials,” *Frontiers in Medicine* 9: 919708.

Problems: The researchers specified seven clinical outcomes that would be collected and analyzed before the trial started. However, the paper included only three of the seven, raising questions about the study's completeness.

Vallejos, Julio, Rodrigo Zoni, Maria Bangher, et al., 2021, “Ivermectin to Prevent Hospitalizations in Patients with COVID-19 (IVERCOR-COVID19): A Randomized, Double-Blind, Placebo-Controlled Trial,” *BMC Infectious Diseases* 21: 635.

Problems: The trial was underpowered given that most of the patients were low-risk and they recovered quickly without treatment, leaving minimal room for improvement with treatment. Furthermore, 55% of the potential patients were excluded because of ivermectin use in the previous seven days.

Table 2 Meta-Analyses that Find Benefits in Using Ivermectin Against COVID

Bryant, Andrew, Theresa A. Lawrie, Edmund J. Dowswell, et al., 2021, "Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review and Meta-Analysis," *American Journal of Therapeutics* 28(3): e299–e318.

62% reduced risk of mortality with ivermectin. Bryant et al. referenced three of the Knackered Nine: Elgazzar, López-Medina, and Rezai.

Hariyanto, T.I., A.R. Halim, A. Jodhinata, et al., 2021, "Ivermectin and Outcomes in Patients with COVID-19: A Systematic Review and Meta-Analysis," *Clinical Epidemiology and Global Health* 11: 100755.

69% lower risk. Hariyanto et al. referenced two of the Knackered Nine: Elgazzar and López-Medina.

Kory, Pierre, Gianfranco Umberto Meduri, Joseph Varon, et al., 2021, "Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19," *American Journal of Therapeutics* 28(3): e299–e318.

71% lower risk. Kory et al. didn't appear to use any of the Knackered Nine.

Lawrie, Theresa A., Tess Lawrie, Edmund J. Dowswell, et al., 2021, "Ivermectin for Preventing and Treating COVID-19: A Systematic Review and Meta-Analysis," Evidence-Based Medicine Consultancy Ltd.

83% lower risk. Lawrie et al. referenced just one of the Knackered Nine: Elgazzar.

Nardelli, Marco, Giulia Gentile, Andrea Setti, et al., 2021, "Ivermectin: Potential Antiviral Mechanism Against SARS-CoV-2," *Journal of Infection in Developing Countries* 15(3): 285–292.

79% lower risk. Nardelli et al. referenced just one of the Knackered Nine: Elgazzar.

Zein, Siti, Muhammad R. Raffaello, and Fathiyah Isbaniah, 2021, "Ivermectin and Outcomes in Hospitalized COVID-19 Patients: A Retrospective Cohort Study," *International Journal of Infectious Diseases* 113: 252–257.

61% lower risk. Zein et al. referenced two of the Knackered Nine: Elgazzar and López-Medina.

were searched for relevant observational studies on the risk of RA in migraineurs." "RA" means rheumatoid arthritis, and migraineurs—those who suffer from migraines—have about double the risk of developing rheumatoid arthritis. Of course, this was a mistake—rheumatoid arthritis has nothing to do with the Song meta-analysis of ivermectin for COVID-19. This sentence, prominently shown in the abstract, suggests some cutting and pasting from another article and indicates that this paper wasn't carefully edited, leaving us with questions about what else wasn't carefully analyzed, calculated, written, and reviewed. This mistake implicates both the study's authors and the journal's editors.

Further, the Song authors stated that "the pandemic is likely to last for a long time." And yet, the manuscript was received by the journal *Heliyon* in August 2023, over three months after the World Health Organization declared an end to the public health emergency for COVID-19.

Song sets the record for bad ingredients. In total, it referenced eight of the Knackered Nine: Bramante, Buonfrate, Elshafie, López-Medina, Naggie, Reis, Rezai, and Vallejos.

A third meta-analysis, Hernandez et al. (2024), employed many deeply flawed studies as well. Consider the results for all-cause mortality in Hernandez, in which the results of nine studies with 6,353 patients were included. By far the most important study for this meta-analysis was the infamous Reis et al., which comprised 80 percent of the recorded patient deaths (45 of 56). There were 11 authors of Hernandez. Did none of them notice the problems with the TOGETHER Trial? Or were they blindly pulling numbers out

of that paper to put into their statistical models? In total, Hernandez referenced six of the Knackered Nine: Buonfrate, Bramante, López-Medina, Naggie, Reis, and Vallejos.

In the three meta-analyses that reported no benefit for ivermectin, on average three Knackered Nine studies were referenced in each. Of the six meta-analyses that reported a benefit, the average number of Knackered Nine studies referenced was 1.5. Fewer bad ingredients, better overall final product.

And yet it's worse than that. Not all bad ingredients are equal. The TOGETHER Trial (Reis et al.) was big and bad, and it served to overwhelm other results. All the meta-analyses that came to a negative conclusion on ivermectin employed Reis, while none of the meta-analyses that concluded positively did. The inclusion or exclusion of Reis appears to be the key difference

among these nine meta-analyses.

CONCLUSION

If we average the mortality benefit of ivermectin in the nine meta-analyses (including the three that claimed no benefit), we calculate a 47 percent reduction in mortality when the drug is used. If that is roughly accurate, it would mean that ivermectin had the potential to reduce the death toll from COVID-19 during the worst years of the disease by nearly half. Millions could have lived. Even today, in the United States where COVID kills about 20,000 a year, wider use of ivermectin could help to save lives.

In short, the Popp et al. Cochrane report on ivermectin was too selective on which data to include and a large percentage of the data that it did use was of poor quality. That's not the way to make a good hamburger or a good meta-analysis. R

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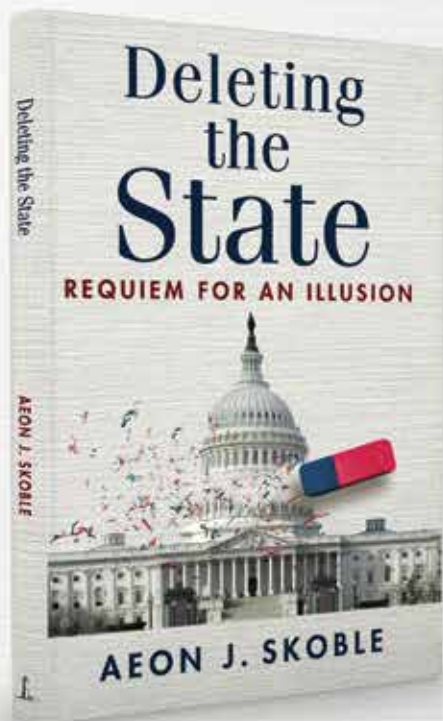
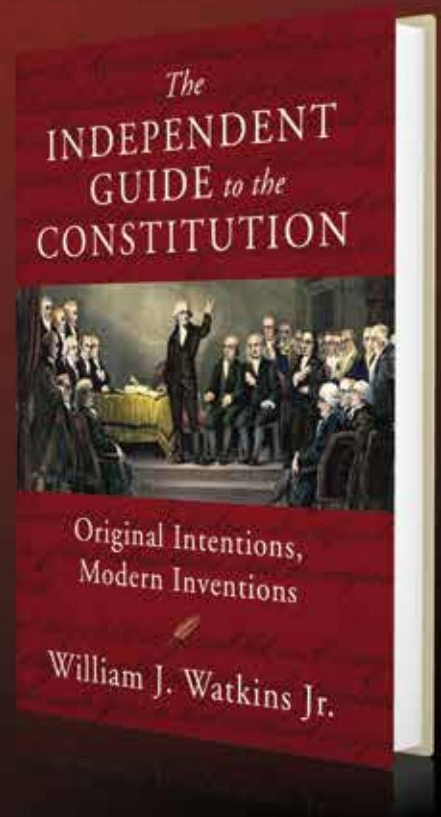
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