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POSITION STATEMENT

American College of Medical Toxicology (ACMT) Cautions Against Off-Label Prescribing of Ivermectin for the Prevention or Treatment of COVID-19

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There is no current indication for the use of ivermectin to prevent or treat COVID-19. Decisions on medical care should be made by the clinician and the patient, not the judicial system. Off-label prescribing of therapies for COVID-19 should occur only in the context of rigorous clinical research.

Background

Ivermectin is an anthelmintic used for a variety of parasitic infections. It is approved by the US Food and Drug Administration for human use to treat intestinal strongyloidiasis and onchocerciasis ("river blindness"), and is commonly used in the USA as a veterinary medicine, to treat heartworms in dogs and horse parasites. It has gained tremendous popular attention of late for claims of efficacy for COVID-19 treatment and prevention. After a large number of studies with varied design, inconsistent patient selection, and uneven peer review, the effectiveness of the drug for COVID-19 is unclear [1, 2].

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Toxicity of Ivermectin

The American College of Medical Toxicology's Toxicology Investigators Consortium (ToxIC) collects data on poisonings, including adverse reactions related to COVID-19 drug treatments, through the Food and Drug Administration ACMT COVID-19 ToxIC (FACT) pharmacovigilance project. From August 2021, we have received several reports of patients who became ill from using ivermectin formulations to prevent or treat COVID-19 infection, including some severe toxicity and morbidity [3]. This trend is mirrored in national data reporting a surge in ivermectin poisoning cases reported to Poison Control Centers and the US Centers for Disease Control and Prevention (CDC) [4].

Although ivermectin is generally safe when used as prescribed, toxicity can occur in the setting of overdose or inappropriate use. Formulations for large animals may be especially likely to cause toxicity for humans because they are dispensed in high doses, contain highly concentrated drug, and contain other ingredients not investigated for use in humans [5, 6]. Clinical manifestations range in severity and include gastrointestinal effects (e.g., nausea, vomiting, abdominal pain, and diarrhea), headache, dizziness, fatigue, visual changes or problems, fast heart rate, low blood pressure, and skin rashes [7, 8]. More severe central nervous system effects have been reported and include coma, altered mental status, seizures, hallucinations, and tremors [4].

Clinicians, Not Courts Should Direct Medical Care

With great concern, we have seen reports of physicians and hospitals being directed by courts to prescribe ivermectin to patients [9, 10]. We believe that clinicians should direct

care and engage in shared decision-making with patients when appropriate. Although patients may choose to decline therapies or to seek treatment elsewhere, a clinician should not be compelled to administer treatments that they believe to be harmful. The doctor has a professional responsibility to use their expertise to act in the best interest of their patients. Although administration of an unproven medicine for a critically ill patient may be well-intentioned, we do not know at this time if ivermectin makes the course of the disease better, worse, or has no effect.

Consequences of Off-Label Prescribing

Because ivermectin is FDA-approved for other indications, the drug can be legally—although inappropriately—prescribed off label for treatment or prevention of COVID-19. ACMT has previously cautioned against harms of off-label prescribing when not supported by evidence [11]. Diversion of a medication for an unproven indication reduces availability for those who need the drug. Ivermectin is included in the World Health Organization list of essential medicines for parasitic disease worldwide [12]. Another concern is the practice of hoarding, which has been seen previously with unproven COVID-19 therapies such as hydroxychloroquine. At a time when supply chains are already compromised, hoarding unjustly encourages allocation of a limited resource without consideration for need.

Off-label prescribing does not just impact drug supply, but also affects clinical research, which remains the best way to understand if therapies work. When patients take ivermectin outside of the research setting, we do not gain understanding about whether the medication is helpful or harmful. Moreover, patients who take ivermectin may be unable to receive other potentially beneficial remedies in clinical trials. Patients who desire ivermectin should receive the drug in the context of clinical research and should be encouraged to accept approved therapies such as COVID-19 vaccination.

Disclaimer

While individual practices may differ, this is the position of the American College of Medical Toxicology at the time written, after a review of the issue and pertinent literature.

Declarations

Conflicts of Interest None

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