OPEN LETTER

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Re: SECOND CALL for an Urgent Review of the NCCET Recommendation regarding the use of ivermectin in the management of COVID-19

I refer to my previous Open Letter calling for an urgent review of the NCCET recommendations regarding the use of ivermectin in the management of COVID-19 (dated 21 August) which remains unanswered (see copy attached)

Recent Developments

Since the writing of Open Letter there have been several important developments with regard to the COVID-19 pandemic, including:

1. The issuance of TGA "New restrictions on prescribing ivermectin for COVID-19 (10 Sept. 2021) https://www.tga.gov.au/media-release/new-restrictions-prescribing-ivermectin-covid-19
2. Notice of an amendment to the current Poisons Standard under paragraph 52D(2)(a) of the Therapeutic Goods Act 1989 (10 Sept. 2021)
3. Reports of the near eradication of COVID-19 in the Indian State of Uttar Pradesh (230 million people) using ivermectin combination therapy despite a vaccination rate below 6%.
4. Multiple reports of diminishing mRNA "vaccine" protection against the Delta COVID-19 virus strain following calls for "vaccine" boosters
5. An orchestrated and irresponsible mainstream "media science" campaign aiming to discredit the use of ivermectin on safety grounds.

Additional Public Information on the Safety of Ivermectin

The current NCCET recommendation continues to question the safety of ivermectin despite its worldwide use (4 billion doses) for more than 3 decades and the inclusion of ivermectin on the World Health Organisation Model List of Essential Medicines.

In fact, ivermectin is known to have a wide margin of safety compared to most drugs including many non-prescription medications.

Prior to the pandemic, the Australian Therapeutics Goods Administration (TGA) previously had no significant concerns regarding the safety of ivermectin. According to the TGA Australian Public Assessment Report for Ivermectin – 2013 (see attached).

- Page 11: “Escalation to a single dose of 120 mg (up to 2 mg/kg), 10 times the approved dose and 5 times the anticipated head lice dose, also produced no mydriatic effect. This supports the safety of ivermectin at the proposed dose and provides a significant margin of safety.”

- Page 18: the drug “showed good tolerability and no safety concerns at doses ranging from 30 to 120 mg, that is, up to 10 times the proposed dose of 200 µg/kg for treatment of scabies”.

- Page 39: The TGA clinical evaluator found that there were no significant safety concerns reported with the use of ivermectin in any of the published studies.

There were 3 stated reasons for the TGA action in preventing ivermectin from being used in the treatment of COVID-19:

Reason 1. ivermectin use might dissuade people from being vaccinated
Reason 2. ivermectin was associated with serious adverse events including “severe nausea, vomiting, dizziness, neurological effects such as dizziness, seizures and coma”.
Reason 3. ivermectin prescribing for COVID-19 might lead to shortages of this medication for other approved indications.

Reasons 1 and 3 do not justify the prohibition of ivermectin prescribing for the treatment of COVID-19.

With regard to Reason 2 – this contradicts the TGA’s prior assessment of the safety of ivermectin (above).

Ivermectin National Treatment Programmes

Clinical trials are fundamentally designed to randomly select a relatively small group of individuals for specified treatments and observe safety and efficacy. The results, if statistically powered correctly, can then be extrapolated to the population at large. However, in the case of ivermectin, not only are there more than 60 published clinical trials available, but several countries have embraced the use of ivermectin for the treatment of COVID-19 with success and treatment data is available on huge populations which provide important efficacy data.

In addition to the successful national treatment programmes in countries such as Mexico, Argentina and Peru, the NCCET should now be aware of the success in treating COVID-19 individuals with ivermectin in the Indian State of Uttar Pradesh.

https://www.thegatewaypundit.com/2021/09/huge-uttar-pradesh-india-announces-state-covid-19-free-proving-effectiveness-deworming-drug-ivermectin/?utm_source=Twitter&utm_medium=PostTopSharingButtons&utm_campaign=websitesharingbuttons

https://www.thedesertreview.com/opinion/columnists/indias-ivermectin-blackout---part-v-the-secret-revealed/article_9a37d9a8-1fb2-11ec-a94b-47343582647b.html

https://osf.io/preprints/socarxiv/r93g4/

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3765018

Ivermectin based combination therapy was administered as early and preventative treatment in all family contacts as part of the "Uttar Pradesh Covid Control Model". Using this therapeutic approach, COVID-19 was virtually eliminated in a population of 230 million people with a vaccination rate of less than 6% (compares to the US fully vaccinated rate at the same time of 54%). This result is in direct contrast to the comparable State of Kerala, a small state located in Southern India that is over-dependent on vaccines and restricted ivermectin use to more severe cases and late treatment if used at all.

Large scale observational studies such as this can provide valid and reliable real-world data and, in most cases, there is little evidence that the results of observational studies and RCTs systematically disagree (Reference 6).

https://www.researchgate.net/publication/261998443_Healthcare_outcomes_assessed_with_observational_study_designs_compared_with_those_assessed_in_randomized_trials

The regulatory agencies appear willing to provisionally release new drugs to treat COVID-19 on the basis of very limited safety and efficacy data (sometimes involving a relatively limited clinical trial data and/or no long-term safety data (eg. mRNA vaccines, molnupiravir and remdesivir). However, the NCCET appears to largely ignore the compelling body of evidence supporting the safe and effective use of ivermectin in more than 30 randomised clinical trials (RCTs) involving more than 20,000 patients and successful national ivermectin treatment programmes.

Literature Review and Meta-analyses

The NCCET continues to rely (and defends) an arbitrary selection of 18 published clinical trials upon which to base its current negative recommendation for ivermectin use. In contrast to the sophisticated meta-analysis methods employed in the published reviews on ivermectin (References 7 and 8), the NCCET has failed to detail or define its informal method of assessment which were used to arrive at the current recommendation.

Rather than relying on the results of any one clinical trial, properly conducted meta-analyses of a larger number of randomised controlled trials by highly trained and experienced staff are the most powerful tool in drawing reliable conclusions from pooled data. However, biases can be introduced in any meta-analysis. This is why it is important to publish the protocols and methods used in any meta-analysis so the work can be critically assessed for reliability.

A recent meta-analysis of ivermectin was conducted by the Cochrane group (Reference 9). However, according to a response to this meta-analysis by Fordham, Lawrie, MacGilchrist and Bryant (in pre-print, see attached Reference 10), the Cochrane report suffers from no less than 11 significant analytical and methodological defects rendering the conclusions unreliable – not the least of which, to give but one example, was the author's treatment of the important analysis of mortality.

Out of 24 available RCTs identified for the review, the authors chose only 4 to include in their mortality analysis, a small subset of those available. The Cochrane authors split this data up further into two separate analyses. This effectively dilutes their

findings to the extent that a meaningful result from meta-analysis was not possible. Instead of utilising all available evidence and presenting appropriate caveats around such wider evidence, as would normally be done according to accepted protocols, they present an empty review with considerable bulk but little useful analysis.

Conclusions

The reported diminishing efficacy of the COVID-19 vaccines to protect against the emergence of SARS-Co-2 variants demands an urgent review of the use of ivermectin.

I repeat my previous message (21 August Open Letter) to the NCCET and again request an urgent review of the recommendations regarding ivermectin:

"The current approach to symptomatic COVID-19 individuals is largely to do nothing and simply observe until they either get better or get worse, perhaps much worse, and need to go to hospital. The do-nothing approach places enormous strain on our health care system. Evidence for this 'do nothing, watch and observe' approach is lacking. Ivermectin offers a potentially effective, low cost, safe and rational approach to the management of such individuals with little or no disadvantage. The NCCET recommendation on ivermectin is considered to be misinformation by many experts and is viewed as contributing to needless hospitalisation – but for this recommendation, many Covid-19 infected individuals could be receiving early effective treatment."

Regards,

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