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'A Total Lack of Therapeutic Perspective' 22nd August 2021 Comments (6)



Ivermectin Tablets IVERWELL 6 Wellona Pharma 10 X 1 Tablets r. Julian Elliott is the Executive Director of the National COVID Clinical Evidence Taskforce, a body that advises policymakers and has been staunchly opposed to the use of ivermectin as an early treatment for COVID-19.

Frustrated and at a loss to understand why a considerable and growing body of evidence in favour of the cheap, off-patent medication is being not merely ignored but actively rejected, Dr Phillip M. Altman, a veteran of the drugtesting and appraisal industry, wrote to Dr Elliott to demand "revised recommendations for the use of ivermectin within 14 days". That letter is reproduced below.

Call for an Urgent Review of the NCCET Recommendation regarding the use of ivermectin in the management of COVID-19 within 14 days I refer to the current recommendation by the National COVID Clinical Evidence Taskforce (NCCET) regarding the use of the drug ivermectin for the management of COVID-19. The NCCET serves an important role in reviewing and recommending treatment for COVID-19 to peak health professional bodies across

Australia. The current recommendation (Communique Ed. 48 – 5.8.21)

to recommend for or against the use of ivermectin and therefore the

regarding the use of the drug ivermectin is as follows:

ivermectin...

required.

prescription drugs

new evidence becomes available."

Taskforce recommends ivermectin not be used outside of randomised trials. The certainty of the current evidence base varies from low to very low depending which on outcome is being measured, as a result of serious risk of bias and serious imprecision in the 18 included studies.

The available research evidence does not yet provide reasonable certainty

In addition to uncertainty around benefits for patients with COVID-19, there are common side effects and harms associated with ivermectin, including diarrhoea, nausea and dizziness.

Given this uncertainty of benefit, and concerns of harms; we recommend

potential to generate further evidence on the effectiveness, or otherwise, of

... This is a <u>high priority</u> recommendation and will be updated as soon as

that ivermectin only be provided in research trials, where there is the

Ivermectin has been the subject of more than 60 clinical trials, including more than 30 randomised controlled trials and used successfully in national COVID-19 mass treatment campaigns in India, Mexico and several other countries to reduce the number of cases and prevent serious complications of the disease leading to hospitalisation and death.

"This assertion lacks any logic": Read the damning appraisal

of two English consultants engaged by Dr Altman to examine and

critique

the NCCET's case against ivermectin Despite this, and in the absence of NCCET members' personal experience in treating COVID-19 patients with ivermectin, the NCCET has selected in an arbitrary and imprecise manner a small number of published clinical trials (18) upon which to base its current negative

recommendation for ivermectin use. NCCET has failed to apply

in widely discussed published reviews on ivermectin (see references

sophisticated, defined, and detailed meta-analysis techniques as employed

attached). When lives are at risk, the highest standards of evaluation are

The emphasis on minor and generally uneventful "harms associated with

ivermectin, including diarrhoea, nausea and dizziness" contained in the

above NCCET statement demonstrates a total lack of therapeutic

perspective in relation to the much more serious side effects of other

drugs used to treat COVID-19, including many over-the-counter non-

The NCCET has sought to respond to critics of its recommendation on ivermectin in the Communique of 5 Aug. 2021 by justifying its limited consideration of the ivermectin literature by posing, and then, answering its own question in the following way:

NCCET: "But hasn't ivermectin been shown to be effective as an early

NCCET: "Despite some early suggestions that ivermectin may provide

both prophylactic and therapeutic benefit, the available research evidence

does not yet provide reasonable certainty to recommend for or against the

use of ivermectin. More robust, well-designed randomised controlled

"Some widely discussed meta-analyses of ivermectin studies (e.g. The

has been discredited and retracted (Elgazzar et al.). Even in these

reviews, when patient populations are separated by severity and

Given the national importance of the NCCET advice on ivermectin, I

invited internationally recognised and experienced literature review

specialist Tess Lawrie (MBBCh PhD) and Edmund Fordham (PhD

The analysis reveals and details (with references) serious flaws in the

selective NCCET interpretation of the 'cherry-picked' literature. It

ignores the broad sweep of clinical evidence from other randomised

controlled clinical trials, observational trials and national treatment

In addition, related to the current NCCET recommendation is the

use of ivermectin, doxycycline and zinc (either separately, or in

In reality, there is insufficient evidence **not** to support the use of

considered an appropriate treatment option."

combination) for the prevention or treatment of COVID-19. More

robust, well-designed clinical trials are needed before they could be

ivermectin while new and expensive drugs are being expedited through

priority to review this recommendation in the national interest.

statement by the TGA (18 Aug 2021):

programs and demands (in the NCCET's own words) as a matter of high

"There is currently insufficient evidence to support the safe and effective

British Ivermectin Research Development (BIRD) Group meta analysis)

have significant weaknesses, for example they include a large trial which

comparisons to active treatments removed, no meaningful effect is found."

trials are needed to demonstrate whether or not ivermectin is effective."

COVID-19 treatment in randomised controlled trials overseas?":

FlnstP) of Evidence Based Medicine Consultancy Ltd (UK) and EbMCsquared, a Community Interest Company located in Bath, England, to comment on the above NCCET interpretations of the literature. Their expert analysis is attached and entitled, "Commentary upon NCCET Statement" dated 7 August 2021.

the regulatory process and given provisional approval with far less clinical trial, efficacy and safety data supporting their use. Australia is in the grip of a pandemic of enormous consequences. Every possible useful therapeutic approach is needed in this crisis. Ivermectin, especially in combination with zinc and doxycycline, has shown to be effective in relation to COVID-19 management. Other new antiviral medications have been recently approved by the TGA with relatively minimal safety and efficacy data by comparison to ivermectin. Ivermectin has been in use for more than three decades. Four billion

doses have been administered, it is on the World Health Organisation

List of Essential Drugs and is one of the world's most useful and well

Omura and Irish biologist William Campbell, who were awarded the

Nobel Prize in Medicine in 2015, reflecting the magnitude of their

perhaps much worse, and need to go to hospital. The do-nothing

achievement and the importance of ivermectin to medicine.

tolerated drugs. Its breakthrough discovery is attributed to Prof. Satoshi

The current approach to symptomatic COVID-19 individuals is largely

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

misinformation by many experts and is viewed as contributing to needless

management of such individuals with little or no disadvantage. The

hospitalisation – but for this recommendation, many COVID-19

infected individuals could be receiving early effective treatment.

NCCET recommendation on ivermectin is considered to be

to do nothing and simply observe until they either get better or get worse,

Hon. Greg Hunt MP, Minister for Health and Aged Care, has written regarding ivermectin in a reply to Sen. Malcolm Roberts (27 July 2021). "It remains open for doctors to prescribe existing medicines 'off-label' based on their own clinical judgement". Indeed, this has always been the case. Given the evidence available, doctors should be able to prescribe

ivermectin as monotherapy or in combination without stigma or

TGA. Both the NCCET and the TGA should re-examine the

hindrance by a restrictive recommendation from the NCCET or the

accumulating international experience with ivermectin from all sources

I request the NCCET review and issue revised recommendations for the

use of ivermectin within 14 days in light of the submitted information as

Dr Altman is a well known Australian authority on clinical trials and

and regulatory affairs. He is a graduate of Sydney University with an

regulatory affairs with more than 30 years experience in clinical research

Honours degree in Pharmacy, Master of Science and Doctor of Philosophy

(pharmacology and pharmaceutical chemistry) degrees. Dr Altman also co-

supporting its safe and effective use and should actively support and

encourage ongoing efforts by many to clarify the important role of

ivermectin in the management of COVID-19.

a matter of urgent priority and national interest.

Regards,

Phillip M. Altman

Inform Clinical Guidelines.

Show your support

Dr Altman, Excellent letter, and outstanding support from Dr Lawrie and her colleague. I

There is no need for me to add to the evidence you summarise, other than to say that

the British Medical Journal asked me to review a paper showing rapid virus clearance

would be rejected on the basis that the information is not new. It will probably be

has focussed on mucosal immunology and host-parasite relationships at mucosal

following IVM. In normal times, given the many studies showing exactly that, the paper

As one of the senior clinical immunologists in Australia, and the only one whose research

Pharma support (and patents) focussed on RNA polymerase such as Remdesivir that has

The cynicism of Merck having publicly dismissed ivermectin the day before it announced

a \$US300 million government grant to develop an "early treatment", starting its "rolling

repositioned "Molnupirivir", as a "breakthrough" oral treatment (recently sold to the US

government before its trials are completed at \$1,000 per course), is not lost on anyone.

parenteral genetic vaccines available to us will be important in short term Covid control,

create variants that will severely compromise efficacy. They will settle along influenza-

vaccine lines. Moreover, genetic vaccines by stimulating uncontrolled synthesis of spike

protein will cause highly concerning adverse events of a short and long-term nature that

All these outcomes have come about. My point was, and is, that ivermectin and like drugs

reduce community spread; to treat early disease; to reduce progression to severe disease

are immediately needed, not to compete with vaccines, but to complement them: to

Making ivermectin available across the Covid community now will shorten the current

community crises where infection is out of control, will be synergistic with the vaccine

programme facilitating movement through the planned stages, and greatly facilitate our

nation, and vaccines are looking a little iffy. There is a drug available for early treatment of

drugs I use every day. Why are we not using this drug? What on earth has my patient got

Dr Altman, I support your plea to those who can make decisions, based on evidence as

summarised in your open letter. Lives are lost while positions are defended.

Covid-19 with more evidence supporting its safety and efficacy than there is for most

The question almost every experienced clinician is asking in Australia is 'we have a

problem that we are doing nothing for, one that is threatening the very fibre of our

requiring admission to hospital and possible death; and to reduce the growing

they will have little impact on infection, will be short in duration, and that antigen drift will

I wrote 8 months ago that the biology of Covid-19 infection dictates that while the

failed repeated randomised controlled trials (RCT's) yet continues to be used in our

intensive care units at \$4,000-\$5,000 a course, while on the other, safe, cheap and

effective repositioned drugs without patents that focus on changing the way cells

process infectious agents, with numerous supporting RCT's, are dismissed.

registration" around the world (our TGA last week) for son-of Remdesivir, the

data confirming the clinical value of Ivermectin (IVM) appears on a daily basis. Yesterday

assume you have a strategy when you do not get a response.

rejected this time on political and ideological grounds.

6 comments

Robert Clancy – 22nd August 2021

we can only surmise at this stage.

community repository of "long Covid".

to lose?' Where is the leadership?

Best wishes,

Robert Clancy

STD – 22nd August 2021

Stephen Due – 22nd August 2021

reconnect with the world outside the bubble.

BPharm(Hons), MSc, PhD

Please confirm receipt of this Open Letter by return email.

founded and is a Life Member of the largest professional body of pharmaceutical industry scientists involved in clinical research and regulatory affairs (Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry Ltd – ARCS). As well as working in senior management positions for several multinational companies including Merrell-Dow, Hoechst, Roussel and GD Searle, Dr Altman established his own company, Pharmaco Pty Ltd, one of the first contract research organizations (CRO's) where he served as a Senior Industry Consultant. **REFERENCES** Bryant, A, Lawrie, TA, Dowswell, T, Fordham, EJ, Mitchell, S, hill, SR and Tham, TC.

Ivermectin for Prevention and Treatment of COVID-19 infection: A

Systematic Review, Meta-analysis, and Trial Sequential Analysis to

American Journal of Therapeutics 28, e434-e460 (2021).

surfaces in man (squarely relevant to Covid-19 infection), I find the current disinformation with respect to early treatment of Covid-19 infection beyond my understanding and without precedent in 50 years of practise. The two principles on which Australia has forged the highest levels of medical practice are neglected: the rule of science, and the rule of the doctor-patient relationship. The situation that defies logic and sense is that, on one hand, repositioned drugs with

Yesterday, Australians, whether they were Doctors, Lawyers, Bus Drivers or people who worked in retail or even Priests, Teachers or even advisedly politicians, such as the likes of Chifley, Curtin, Menzies and the ex shearer Jack Renshaw- what was the commonality? They were all fair dinkum and loved Australia. All possessed that wonderful quality of

In addition, there is now a vast amount of clinical experience overseas with Ivermectin in

testimony of highly-qualified, senior clinicians who have successfully treated thousands

of Covid patients is readily available online (bearing in mind that it is censored on some

platforms). They have adopted a therapeutically rational, evidence-based approach that

There is no question now that the vaccines cannot stop this virus i.e. Zero Covid is not a

Australian doctors are ideally placed, once the government roadblock is removed, to

staged multi-drug protocols such as those developed by the FLCCC Alliance. The

common sense. Today that type of character has all but disappeared with the

sophisticated crap that infected our culture and sense of egalitarianism.

effectively addresses the clinical challenges of each stage of the disease.

viable policy based on mass vaccination alone. The big drug companies themselves are already working on new drug treatments for Covid that have the potential to enhance their profits. The disease is clearly treatable, and deaths are largely preventable with early treatment. It would be sensible for Australia not to let the pharmaceutical industry have the last word, and sell us yet another costly experimental medicine, when cheap alternatives using repurposed drugs are readily available.

nfw – 22nd August 2021

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benefit from this wealth of overseas experience.

the holiday in the UK with his family at taxpayer expense man and the selfish Hazzard are not cheap and they may require constant doses. Follow the money. Biggles – 22nd August 2021 As to the current anti-Covid vaccines, the following from a vaccine scientist is well worth hearing. https://www.bitchute.com/video/FPehpfdTleDo/ Post a comment

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Kory, P, Meduri, U, Varon, J, Iglesias, J and Marik, PE. Review of the Emerging Evidence Demonstrating the Efficacy of Invermectin in the Prophylaxis and Treatment of COVID-19. American Journal of Therapeutics 28, e299-e318 (2021.

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rod.stuart – 22nd August 2021 Previously I had thought that Australia's NUMBER ONE health hazard was the NSW Minister of Health. Obviously the much greater hazard is the NCCET and the TGA. Ivermectin is cheap and proven as a generally one dose anti-parasitical drug. The experimental wonder drugs being pushed by the dealers in Australia, ie Glads, Morrison

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