We Can’t Vaccinate This Pandemic Away

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Thirty frontline doctors in Australia recently treated over 600 patients with COVID-19. The treatment strategy was ivermectin (IVM) with doxycycline and zinc. Five patients required admission to hospital for progressive symptoms. There were no deaths. In a similar number of contemporary Australian patients not treated with IVM, 70 were hospitalised and six died.

This is consistent with world data bases: 31 randomised controlled trials show 62 per cent benefit with IVM, and seven meta-analyses recorded a reduction in death of between 57 and 83 per cent. Experienced clinicians have moved on to combine IVM with additional drugs, usually a broad-spectrum antibiotic such as doxycycline, and zinc, which has viricidal activity.

A logical conclusion would be that these results demand attention. With "freedom day" in NSW expected to be followed by increases in COVID-19 infections and hospital admissions, an IVM roll-out would be a logical outcome. That this has not happened may well prompt the question 'Why is that so?' The mainline press, which continues in its refusal to report and interrogate the evidence, also fails the public by presenting IVM as the antichrist of the medicine cabinet. A complex set of events has come together. These events and how they affect COVID-19 management and patient outcomes form the basis of this article.

FIRST, as patients were being treated with IVM in Sydney and Melbourne with the impressive results mentioned above, the Therapeutic Goods Administration (TGA) made an extraordinary move to shut down the prescribing of IVM by frontline doctors for the treatment and prevention of COVID-19. The TGA has form, as it made a similar ruling on hydroxychloroquine (HCQ), the other re-purposed off-patent drug shown to be effective in treating COVID-19. Importantly, the reasons given by the TGA to justify its decision were not correct.

The main TGA concern stated was that IVM would confuse the public and lead to hesitation to be vaccinated. That, too, is incorrect. Doctors overwhelmingly support vaccination against COVID-19. The combination of safe and effective IVM with a vaccination programme will enhance viral clearance, reduce disease severity, reduce hospital admissions and reduce deaths. However, groupthink quickly led to professional bodies such as the AMA uncritically accepting the TGA policy. Even the Australian Academy of Science weighed in with political support for the TGA's decision, doing so without any evaluation of the science.

Then came the coup: the regulatory body responsible for registration of doctors, the Australian Health Practitioner Regulation Agency, warned that prescribing, dispensing, or even publicly discussing IVM, "compromised expected standards of practise", leaving open disciplinary measures which have since

resulted in doctors having their licences revoked. A crescendo of intimidation has ensued, all based on a failure to interrogate the data and understand the clinical circumstance, with perhaps a touch of group hysteria thrown in.

The conclusion to be taken from these collective authoritarian decisions is that medical choice is no longer the prerogative of the doctor-patient relationship in Australia. Bureaucrats for any reason can decide and enforce medical issues without discussion with relevant medical experts. This is a problem throughout the Western world, but perhaps there is a light in the tunnel. Nebraska's attorney general recently ruled that the prescription of IVM for COVID-19 is a matter for the doctor and patient, not government.

THE SECOND development is a changing balance in evidence relevant to early treatment. Negative critique has been rebutted, and support has become stronger.

First, there has been a rebuttal of a misleading "Cochrane report". Traditionally, a Cochrane is considered the highest bar for drug efficacy, and the outcome of a Cochrane has profound influence on acceptance. The existing Cochrane report on IVM was ambivalent. This became the basis for rejection of IVM, and the cry for more studies. The National COVID-19 Health and Research Advisory Committee, established to counsel government on early treatment for COVID-19, took that flawed Cochrane report as gospel. From there a trickle-down effect informed opinion of both professional and government organisations, with vigorous support from an uncritical media. Recently, a group of respected non-aligned epidemiologists in the UK reviewed the Cochrane report and found it wanting. They showed defects in method, an exclusion of data points and studies, and a failure to include substantive regional and national experiences where IVM had been successfully adopted.

Not to be dismissed, IVM naysayers took a new tack: play the man (or the woman), not the ball. Their trick is to label IVM studies that do not fit their viewpoint as "fraudulent" while disparaging IVM's medical

supporters as, among other insults, “New Age quacks”. The value of the naysayers’ critique, indeed their motivation, has been challenged in detail (see IVMMETA.com), failing on numerous counts that include an absence of evidence and misinformation. The conclusion was that these frivolous activities confined to a couple of uncertain studies (which are not included in quality meta-analyses) had no impact on the overwhelming data supporting the benefit for IVM use againstCOVID-19.

The mainline press welcomed claims supporting the anti-IVM narrative, with the BBC News plumbing new lows in journalism by combining false conclusions with bias that included misrepresentation of a highly regarded epidemiologist. A recent *Sydney Morning Herald* article was little better, distorting the science with ideology and bias. The reporter involved has not responded to a request to host a debate on the topic. They never do!

Second, and more positive, is the accumulation of evidence supporting the benefit from ***early*** treatment. Two recent and compelling studies further support the value of both IVM and HCQ , the latter having been “cancelled” after being cited by Donald Trump as a potential treatment. All this came despite a meta-analysis of 32 early-treatment studies showing 64 per cent protection.

The first of those is a WHO study in Uttar Pradesh, India’s most populous state (230 million people). Medical teams visited 98,000 villages, providing kits (similar to those used in the Australian study) containing IVM for the treatment of those with COVID-19. Within five weeks, new cases had dropped by 97 per cent. Meanwhile in another Indian state, Kerala, with eight per cent the population of Uttar Pradesh, IVM was *not used* and as many as 31,000 COVID cases were recorded per day. Similar results are reported in areas of Peru, Mexico and elsewhere

The second recent study treated 8,300 French patients with HCQ. There was a 93 per cent reduction in mortality. A meta-analysis by the same authors included 32,000 patients from five countries and showed early HCQ treatment reduced mortality by 69 per cent.

The inevitable and unavoidable conclusions to be drawn are that Cochrane negativity can no longer dominate an honest argument about IVM's use and, further, that the medication must be accepted in Australia as a safe and effective treatment capable of reducing the expected post-lockdown load on health systems.

THE THIRD development has been the frenetic response by media and government to an orchestrated campaign by pharmaceutical giant Merck promoting its re-purposed antiviral agent, Molnupiravir, before significant data assessment has been completed. Merck is now joined by Roche and Pfizer with their versions of re-positioned "wonder drugs". All have limited and conflicting data yet make extravagant claims. These antivirals are less effective than IVM and none have acceptable safety profiles. However, we see the Australian government making extraordinary claims and committing large sums to acquire these unproven oral therapies. Who can be advising government to allow such dubious claims and acquisitions at the expense of IVM and the Australian taxpayer?

The charge of hypocrisy and cynicism must first be directed at Merck, but also at "the experts", Dr.Tony Fauci, governments and, of course, the media. Merck stated IVM had no clinical value mere days before receiving a US$300 million grant to develop Molnupiravir. Available data suggests it provides eight-fold less protection than that found for IVM in the Australian study. Merck acquired Molnupiravir, originally developed by Emory University, after it failed against other RNA virus diseases. Questions about undisclosed data remain to be answered. The drug is a "son of Remdesavir", a RNA polymerase inhibitor with that failed randomised controlled trials (RCT). The Australian government has bought 300,000 courses of Remdesivir (the US government pays US$1,000 per course). This is beyond logic, certainly not based on science. As the TGA prevented doctors prescribing IVM because it would reduce vaccination rates, the question is simple: How will the TGA draw a distinction between Merck's Molnupiravir and IVM?

The elephant in the room for Molnupiravir is safety. The

drug creates lethal mutants to terminate virus replication. Cell biologists express concern that some live mutants with resistance to vaccines are released into the environment. DNA mutations also occur, which could lead to disturbed growth and cross-generation transmission of genetic changes. The TGA will now have to wrestle with pressure from Big Pharma and government to register a drug with scant clinical data and untested safety concerns after denying the Australian a public cheap, safe and more effective treatment with IVM.

Any argument against IVM or HCQ use in treating COVID-19 is not based on science. Rather, it is politically driven, in tune with the pharmaceutical companies' profit motive. Who is pulling the strings?

THE FOURTH issue is the recognition that genetic vaccines have limited value. While doctors support the current vaccine roll-out, reported "danger signals" must be clarified. Both the DNA-vector vaccine (AstraZeneca) and mRNA vaccines (Pfizer and Moderna) behave as predicted by biology relevant to airways' protection (something not understood by the vast majority of "experts"): short duration of protection limited to control of systemic inflammation, with little impact on infection of the airways.

Israel was used as a laboratory for the Pfizer vaccine. Six months after vaccination, there was essentially no protection against infection or mild disease, although protection against severe disease remained at 85-to-90 per cent. Thereafter came a rapid and progressive loss of protection against more severe disease. Infected vaccinated and unvaccinated subjects have similar viral loads and transmission capacity. Immunity following natural infection is better and more durable than that induced by vaccination, so there is no sense in immunising those who have had COVID infection in the preceding six months.

In an Australian context, by New Year 2022, it is estimated about two million vaccinated Australians will have lost protection against infection and mild disease. Infections will increase as borders are opened and we re-

enter the international community.

Our lockdown policy has limited the acquisition of natural immunity. Although we can expect high levels of infection with less severe disease, pressure on hospitals will increase. The experience of Israel and Iceland, each with high vaccination rates of 85 per cent or more, provides a possible scenario for Australia. In Israel, with a population of less than 10 million, the "third wave" continues, with 1500 new cases and 30 deaths a day (at the time of writing). More concerning are reports of high COVID mortality in older vaccinated subjects in some jurisdictions. Variants such as the further-mutated Delta variant in the UK will continue to appear, with unknown infectivity, response to current vaccines and pathogenicity. Perhaps of greatest concern is the observation in the UK, and now in Sweden, that older vaccinated individuals have a higher incidence of COVID infection than those who are unvaccinated. At the same time others are describing a state of immune deficiency following vaccination with genetic vaccines.

At this stage it is unclear as to whether this "deficiency" of the immune response is limited to the antibody response to COVID virus. This should not be a surprise to anyone who has done "Immunology 101", as enhancing antibody (*ie* antibody that promotes infection, rather than limits it) is well recognised in RNA virus infections, and "antigen excess causing a downregulation of immunity" is a basic tenet of immunology. Forgotten by most, is that genetic vaccines cause a large and unregulated amount of antigen (*ie* the spike protein) to be synthesised within the cells of the body, and the immune response will be a function of those unknown dynamics. These facts and the concerns they raise should be front and centre for regulators as they examine data to make decisions in regard to booster shots. The duration of protection following boosters is completely unknown, as is whether genetic vaccine boosters distort the immune system with net suppression. Are we setting ourselves up for monthly boosters, higher incidence of infections, more serious adverse events, or even more concerning immune outcomes. We just do not know! If ever there was a need for a safe , cheap effective oral therapy, now is it.

The concern for all genetic vaccines is the damage

caused by uncontrolled release of toxic spike protein from cells throughout the body, and cell destruction due to T cells and antibody directed against spike protein, expressed on cell surfaces. It is too early to know if there are long-term complications caused by injected mRNA due to displacement of physiological mRNA by synthetic "capped" mRNA in vaccines, or prion disease such as Parkinson's disease, due to "prion sequences" in the spike protein.

There are disturbing signals reporting severe adverse events and post-vaccination deaths across the globe. A high percent of these "signals" appear to have a causal relationship in subsequent analyses, reinforced by post-mortem reports showing specific tissue changes. Yet we are now seeing a push to vaccinate children under 12 who neither get severe disease nor significantly spread it. The cost/benefit of immunising children has been widely criticised, while misinformation continues to be delivered through the press. Similar concerns persist with respect to vaccination of pregnant women despite short term data from Pfizer suggesting safety. Incidence of miscarriages remains unclear. Follow-up of infants must ber able to exclude complications due to placenta damage from spike protein and genetic changes due to injected mRNA.

TO CONCLUDE, we cannot vaccinate ourselves out of the pandemic. Most COVID deaths in England over the last seven months have been in vaccinated subjects, and studies across 68 countries confirm increases in COVID-19 infections are unrelated to levels of vaccination. Booster shots with current vaccines come with little support, and possible enhanced toxicity as reported to the FDA. There is very limited data showing prevention of serious disease, with the data presented to the FDA by Pfizer focussed on "infections" not serious disease. COVID deaths in older immunised subjects due to "enhancing antibody" need to be confirmed and investigated further. These concerns need to be resolved before booster shots are widely used.

Antigen-based vaccines such as NovaVax with its strong metrics on efficacy and safety, need to be considered. It is understood this vaccine will be available by year's end;

indeed, on October 29 an application for provisional approval was filed with the TGA. Yet the Australian government continues to support genetic vaccines. Who can be advising the politicians on such a concerning course?

The management of COVID-19 in Australia requires re-shaping as we move into the next stage of the pandemic. It is easy to identify problems. It is more useful to recognise that the pandemic has opened cracks in the administration of medical practise. Transparency, communication, and flexibility, once strengths of our health system, are harder to find. Bureaucrats appear to make critical decisions for political reasons, while doctors are threatened with de-registration for supporting early drug treatment because it may affect vaccine roll-out. It is easy to conclude the system has been corrupted. The question is, who pulls the strings?

Part of the answer is that transnational organisations, such as WHO and mega pharmaceutical companies, have imprinted their political and commercial agendas all over the COVID-19 story. The genesis of their power play appears to reside in the terms of their confidential contracts with national governments. From the inadequate "investigation" of the Wuhan source of the virus to its refusal to admit IVM is the reason for successful COVID-19 control in Uttar Pradesh and its suppression of all cheap and readily available early treatments, the WHO cannot be trusted to lead the world out of the pandemic. Pharmaceutical companies subvert any evidence supporting cheap medications that threaten their profits. Conflict exist at every level with cross-appointments between pharmaceutical companies, government bodies with financial interests in pharmaceutical companies, and research grants from pharmaceutical companies. The US Food & Drug Administration has long been a nursery for highly paid lobbyists and careers within the pharmaceutical industry. If an example is needed to illustrate how distorted the system has become, go no further than Merck's promotion of Molnupiravir and the cynical support given by politicians, academics and media only weeks after "cancelling" cheap, available, safer and more effective re-purposed drugs. Since the FDA in the US became funded through high application fees from the

pharmaceutical companies, a shift in acceptance of expensive drugs offering little advantage over existing unpatented drugs has been noted.

What is difficult to understand is the groupthink acceptance of the mantra promoted by so-called experts, and by many professionals. In part this is due to the power vacuum in medical leadership that has occurred in recent years, but it may also reflect in part processes known to psychiatrists as cognitive dissonance and mass hysteria.

The medical profession in Australia was built on a proud tradition of excellence, with College systems and medical faculties led by the best of the best providing trickle-down leadership based on respect, knowledge and experience. This leadership was tightly connected to primary care doctors. That has changed, with Colleges now reduced to a gateway function geared to specialist accreditation and with "leadership" provided by bureaucrats. Medicine has been dissected by specialisation, losing its connections along the way. Academic medicine has lost the allure of earlier times in a post-truth world of political correctness, with fewer medical graduates entering PhD training programmes. Recruitment into research career paths is no longer an attractive option. Most specialists today would not know the name of their College presidents, once the most revered of positions. Instead the pandemic has enabled this information vacuum to be filled with a new breed of "experts" who either are not medically trained, and thus cannot grasp the clinical imperative, or have a past-distant medical degree but are a long way from real-life medicine. This has facilitated promotion of influence-peddling by pharmaceutical companies with the goal of impacting COVID-19 management. The current situation manipulated by Merck to "cancel" IVM and replace this treatment option with the less effective but patented Molnupiravir should be a wake-up call. Yet this expensive drug is lauded in the press and elsewhere as the "breakthrough we all needed".

An example of pharmaceutical company "vigour" occurred with the launch of new anti-psychotic drugs in the 1990's. Companies manipulated a belief held by a few paediatricians and child psychiatrists that psychosis was common in young children, with funding,

promotion and strong media support. It took several thousand deaths before sanity was restored to gullible doctors.

Uncritical acceptance of misinformation on IVM, driven by pharmaceutical companies to protect their vaccines and patented drugs, and strongly reinforced by academia, government and health authorities, leads to many unnecessary hospital admissions and deaths. The media has a concerning role in the propagation of misinformation, preferring to support an ideological narrative, rather than engage in responsible journalism. The appalling example by BBC News has been discussed.

This article is about a watershed moment in COVID-19 management. It is brought into focus by the TGA closing down the legal use of IVM for COVID-19, while Merck promotes an inadequately documented, potentially dangerous and less effective (but patented and very expensive) "lethal-mutant" anti-viral. Yet not a squeak of concern from the mainline press. The moment is brought squarely into relief as health services face the pressure of handling infections that will follow "escape" from lockdowns. The limits of vaccination to control this "third wave" across the globe demands drug support. New data on enhancing immunity and related immune deficiency, discussed above, calls for caution and a re-think about genetic vaccines.

How will the TGA and its advisers handle this crisis? How can a quality information trail be provided to politicians? The Nebraska ruling on IVM, noted and linked above, has gone viral around the world. The question is, will legal sanity be sufficient to counter the pharmaceutical lobby and pressures they will bring on regulatory bodies? We all must live in hope!