Scandal of the suppressed case for ivermectin

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By Edmund Fordham
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'WE don't doubt this is an important paper,' wrote the senior editor of *Lancet Respiratory Medicine*on March 9 in response to our paper 'Ivermectin for prevention and treatment of COVID-19 infection: a systematic review and meta-analysis', the brainchild of Dr Tess Lawrie and the world's first Cochrane-standards 'meta-analysis' of clinical trials of the long-established anti-parasitic drug ivermectin, for treating, and preventing, Covid-19.

Four expert reviewers were satisfied by revisions already made. 'The effort of the authors is praiseworthy in this pandemic situation,' one said. Their critiques had been technical: some of the statistical methods break down when there are no 'events' (in this case, deaths) in both 'arms' of a clinical trial. Our lead statistician ran more checks; we fixed the criticisms. This is what 'peer review' is supposed to do. It's normal.

One might take such a comment from the senior editor as the preamble to acceptance for publication. But no, this was the editors' reason for *not* publishing the paper. This isn't normal. What was the problem?

'We don't doubt this is an important paper, and would likely be widely taken up.' Hang on, *Lancet Respiratory Medicine* wants to *avoid* printing something it recognises as an important paper, that four of their own experts have passed, because it might be 'widely taken up'? This is what they usually want.

Of course, the *Lancet* has a lot to live down, having moved into the business of publishing fake news, as with the notorious hydroxychloroquine fraud which I reported on for*TCW* last year. Not only did the *Lancet* publish an obvious fake, it did so with hostile editorial commentary and briefing to BBC Radio 4 *Today* for maximum impact. So media briefing for planted fake news, but a *Lancet* specialist title won't touch an 'important paper'.

I was told in January, by a senior clinical researcher who knows him personally, that Richard Horton, editor in chief of the *Lancet*, was 'very ashamed' at having let through the fake news. Horton, whose Twitter bio reads 'welcome to a permanentattack on the present',wrote in 2015:

'Much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness . . . Journal editors deserve their fair share of criticism too. We aid and abet the worst behaviours . . . Our love of "significance" pollutes the literature with many a statistical fairy-tale. We reject important confirmations . . . And individual scientists, including their most senior leaders, do little to alter a research culture that occasionally veers close to misconduct.'

Horton was right. The only aspect that the fake news had going for it was the huge sample size: 96,000 patients. Except that the true number was actually zero, since the paper was fake.
The *Lancet* was certainly seduced by a 'fashionable trend of dubious importance', namely 'Big Data', a flavour-of-the-month set fair to corrupt many other sciences as well as medicine.
The *Lancet* 'aided and abetted the worst behaviours', not just those 'veering close to misconduct', but those clearly crossing the line.

Has anything changed? In 2015 Horton bemoaned journals that 'reject important confirmations', but in March 2021, 'after lengthy discussions with the editorial team', *Lancet Respiratory Medicine* did it again, rejecting our 'important confirmation' (passed by four of their own experts, remember) that yes, ivermectin works for Covid-19.

So there we have it. Horton's 2015 editorial remains true, but he doesn't seem to have done anything about it. He's only the man in charge, after all.

I had feared as much, but we were all keen to give our findings maximum visibility. But *Lancet Respiratory Medicine* did what its friends wanted, which was 'kill the story' for as long as possible, which in the event has been over three months, whilst we searched for a journal with enough integrity to publish an article which had already passed four-fold peer-review at the *Lancet*, and would get yet further examination elsewhere. As of last Friday the paper is now published in the *American Journal of Therapeutics*, and you can read it here. More importantly your doctor, or your family's doctors, can read it too. Take it to them, as many as possible.

So what does this dry-as-dust research paper actually show ?

The starting point was another review article on ivermectin for Covid-19, also in the *American Journal of Therapeutics*, published on May 1. Take that paper to your doctor too. Dr Pierre Kory

and his Front-Line Covid Critical Care alliance (FLCCC) of US-based intensive care doctors had their four-times peer-reviewed paper accepted for a special issue on repurposed drugs for Covid-19, but then revoked, by the journal *Frontiers in Pharmacology*. This unprecedented *volte face* was charted recently in *TCW* by Dr Michael Yeadon. The same 'kill the story' orders delayed publication by over five months.

The FLCCC know what they are doing with Covid-19. Their 'MATH+' treatment delivers the world's best survivals from serious, late-stage, hospitalised Covid-19. It remains almost unknown in the UK and unused in the NHS. (All Brits should be very angry about this). FLCCC luminary Dr Joseph Varon, mentioned *en passant* in my coverage of the Oxford RECOVERY trial, has the best track record of them all. The FLCCC have used several anti-virals in their continuing evolution of the best treatments, but by late autumn realised that one drug, ivermectin, stood out because it worked at all stages of the Covid-19 disease, from prophylaxis through to the intensive care that the FLCCC specialise in. They wrote up the evidence, posting a preprint in mid-November.

They explain the back-story to ivermectin, little-known in Western countries but worldwide one of the most widely-used drugs at 3.8billion doses and counting. Earning the 2015 Nobel Prize in Physiology or Medicine for its discoverers, it has crushed the hideously disabling infestation of onchocerciasis or 'river-blindness' across the tropics. A potent anti-parasitic, it is used for threadworms, scabies and head-lice. It costs pence per pill. It is a known anti-viral, working across a range of RNA viruses, (and some DNA ones). It may even be an anti-cancer drug, and has prolonged lives in leukaemia. Specifically against the SARS-CoV-2 virus, a team at Monash University in Australia showed that ivermectin killed off the virus *in vitro* in April 2020. The usual suspects declared that this meant nothing (which on its own is true), that that you couldn't get it strong enough *in vivo*; nevertheless the Monash paper set off a series of clinical trials of ivermectin for Covid-19, usually in Low and Middle Income Countries (LMICs), or in plain English poor countries. There is a good reason for this: if you are dirt poor, you need your medicines to be dirt cheap. Nothing else will be any use. What did they find? Ivermectin works for Covid-19, at entirely tolerable doses.

Kory's paper showed how cases and deaths in Peru came crashing down where ivermectin was freely distributed, and not where it wasn't. The same phenomenon has been repeated in India more recently; states such as Goa that adopt mass distribution of ivermectin crush their cases; those that refuse it such as Tamil Nadu (Chief Minister M K Stalin) don't.

Dr Kory's paper identifies and charts the evidence, but doesn't do a formal meta-analysis, which is where Dr Tess Lawrie came in. Her Evidence-Based Medicine Consultancy does nothing but rigorous systematic reviews, and only for public clients such as the NHS and the WHO. Their objectives are clinical practice guidelines, providing the evidence for decisions on licensing and implementation.

A 'meta-analysis' is a synthesis of data from multiple sources – typically clinical trials of a new drug – using recognised statistical methods. A meta-analysis of clinical trials that are themselves 'randomised' clinical trials (where patients are allocated at random to receive, or not, the treatment) lies at the summit of the 'evidence quality' pyramid, in the doctrines of Evidence-

Based Medicine, ruthlessly insisted upon by regulatory authorities. To rehearse a cliché, the Randomised Controlled Trial or RCT is the 'gold standard' of medical evidence. If so, a meta-analysis of RCTs is platinum.

What makes the paper a first is being carried out according to the standards of the Cochrane organisation, requiring a protocol to be observed (i.e. no favouritism), data extraction from primary sources by two researchers independently, and the 'grading' of those sources for the quality of the evidence. Indeed the paper began life as a Cochrane Review, and was finished by the end of January. But to cut short a long story (parts of which are covered elsewhere by the ever-vigilant *France Soir*) the Cochrane organisation did not want a systematic review on a topic already approved by a specialised researcher and colleagues whose consultancy does nothing else, and who have contributed nearly 80 such reviews between them. Sounds familiar? It should do by now: the 'capture' of learned journals by powerful interests who will suppress, by fair means or increasingly by foul ones, any knowledge that threatens those interests.

The reason for doing a systematic review is that that is what is required by regulatory authorities such as the FDA (in the US) the European Medicines Agency (for the EU), our own Medical and Healthcare products Regulatory Agency (MHRA) and the World Health Organisation (WHO). It's what they require to decide on licensing new drugs (though ivermectin isn't new at all).

Dr Lawrie didn't stop at the meta-analysis, but pressed on to a 'Evidence to Decision' process, the formal procedure which those regulators are supposed to use in coming to decisions. On February 20, the British Ivermectin Recommendation Development (BIRD) panel voted that 'ivermectin should be adopted to reduce morbidity and mortality associated with Covid-19 infection and to prevent Covid-19 infection among those at higher risk.'

That was February. The essentials were already clear from Dr Kory's paper in preprint in November, his testimony to the US Senate in December, Dr Lawrie's first meta-analysis issued on January 3, and our submission to the *Lancet* on 5 February (preprint posted March 11). *BMC Systematic Reviews* were kind enough to post a preprint on March 18 but though they still say it's 'under review' we haven't heard from them in three months, so it looks like 'kill the story' orders apply there too. Our published paper has since been revised and updated.

The paper makes clear that there's no real doubt that ivermectin is an effective medicine for Covid-19. Multiple clinical trials show it. The Randomised Controlled Trials that our paper analyses are just the tip of the iceberg. Plenty of other trials show it too, but if they were not randomised, according to regulators they don't count, so our meta-analysis did not include them. Although Risks of Bias are carefully evaluated, disregarding the mountain of evidence from elsewhere, not least the experience and testimony of doctors actually using it, is itself a potent source of bias. You are throwing away all the data that might force you to think. A critic of our paper wrote: 'a technical *tour-de-force* based on ritualised ideas'. He's right, but let's not argue: our meta-analysis was upon the Regulators' terms. We played by their rules. That was the point. You want a strict meta-analysis of RCTs only? Take two dozen.

How many do they need? When governments, or regulatory agencies, *want* to approve medicines, one will do. Dexamethasone, to huge fanfare, was approved last summer on the

evidence of just *one* RCT, though it helps only ventilated patients in the inflammatory stages of the illness, and on its own, by not very much. The FLCCC doctors had been using a different corticosteroid, methylprednisolone, and at higher equivalent doses, long before. In our analysis, ivermectin reduces deaths overall by around 62 per cent, and works at all disease stages. As a prophylactic, it prevents 6 out of every 7 infections that would otherwise occur, and stops household transmission in its tracks. Corticosteroids are vital in the inflammatory phase of the illness, but are useless in the purely viral stage or for prophylaxis.

So where does all this leave ivermectin, for those affected by Covid-19, those worried about it, and vulnerable people at risk?

Ivermectin isn't new. Its safety record, from those billions of doses, is second to none. Its cost is negligible. The WHO, in its BC (Before Covid) era, listed it as an 'Essential Medicine' in their catalogue of the 'minimum medicine needs for a basic health-care system' (though our 'envy of the world' NHS doesn't have it).

In the USA, ivermectin is licensed by the FDA, albeit not for Covid, so is available to any American doctor to prescribe 'off-label' (i.e. not according to the originally licensed 'advertising label'). However the fact that it isn't 'labelled' for Covid makes it easy to refuse. Patients' families have had to go to court for injunctions ordering hospitals to give ivermectin. The FLCCC still swims against the tide, though legal barriers are lower than elsewhere, for open-minded doctors.

In the UK, ivermectin has never been licensed by the MHRA. This makes it easy for doctors to refuse, and for those who want to help to be obstructed. My GP refused me ivermectin for prophylaxis, even after I showed him the evidence. Hospital doctors can't get it except to special order at pharmacies. The bureaucracy won't allow them to prescribe it. Listen to Dr Nyjon Eccles having to bring his own ivermectin for his 84-year-old mother in hospital with Covid-19, dependent on oxygen, and failing every time she came off. She was discharged five days after her first dose.

As for the WHO itself, on March 31, 2021, its 'Living Guideline' for Covid treatments was updated, declaring: 'We recommend not to use ivermectin in patients with Covid-19 except in the context of a clinical trial.' The cherry-picking of studies that helped give the Right Answer, and rejection of those that didn't, the cavalier appraisal of risks of bias and evidence certainty, make their analysis a complete travesty, but nevertheless potently influential.

In India, seeing the damage that the WHO had done to their Covid-19 policy, and finding the pile of evidence compiled by the FLCCC and BIRD, the Indian Bar Association served two legal notices upon the chief scientist of the WHO, Dr Soumya Swaminathan (an Indian national). The first (May 25) accuses her of a 'disinformation campaign against ivermectin' and the second June 13) ups the ante by joining Dr Tedros (director general of the WHO), and accusing them of 'contempt of court and aggravated offences against humanity by spreading disinformation'. If these move to actual litigation, watch this space.

Meanwhile, patients and their families, and even Bar Associations, should not have to go through the courts or to smuggle medicines into hospital to get treatment for sick patients. At some point, officials who obstruct access to safe medicines are going to have to explain the moral difference between their actions and corporate manslaughter.

Will our own MHRA see sense and 'license' this WHO Essential Medicine of unparalleled safety record and negligible cost for use in the UK for treatment and prophylaxis of Covid-19? There's none so deaf as those that will not listen. We have a Government that has lied to us throughout the Covid-19 pandemic and continues to do so. The oxymoronic Sage, fronted by the Gruesome Twosome, receive no challenges from equally or better qualified scientists, except through volunteer groups like HART or BIRD. The Prime Minister, having 'landed from another planet and having absolutely no clue of what he is talking about' appoints a Task Force to have 'antiviral treatments ready for deployment by autumn 2021'.

This article has been about an anti-viral treatment that is already known, already exists, with an unparalleled safety record, is on the Essential Medicines list of the WHO, costs virtually nothing, and has anti-inflammatory properties to boot. It requires only formal endorsement. Johnson's Task Force is redundant.

Preparing a formal application to the MHRA, we take comfort from the editors of *Lancet Respiratory Medicine*: 'We don't doubt this is an important paper'.