Monograph One. The Coronahysteria Series: 'SARS-CoV-2', the 'novel Coronavirus'. A monograph by an independent research consultant on the accuracy of the tests.

WHERE IS THE EVIDENCE FOR THE EXISTENCE OF THE 'NOVEL CORONAVIRUS', 'SARS-CoV-2', AND THE ACCURACY OF THE TESTS?

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KEY ARGUMENTS

Test regulators must publish evidence for this 'novel Coronavirus' ('SARS-CoV-2') showing viral purification and visualization in order to underpin the gold standard for the respective RT-PCR and antibody tests.

WHERE IS THE EVIDENCE?

No Gold Standard

Viral purification and visualisation prior to test manufacture is the scientific approach for validating how accurately tests perform - 'gold standard' (White and Fenner,1986 p9). Many renowned virologists have asserted that purification of viral particles is an absolute requirement for the discovery of new viruses and the development of diagnostic tests (PCR and antibody). These assertions (Appendix XX list of virologists' statements) were cited within sworn evidence by expert witnesses in a court of Australian law [2007]. http://www.theperthgroup.com/paperscontinuum.html

Currently there are no published data that document the PCR/Antibody test parameters for the 'novel Coronavirus' 'SARS-CoV-2'. A forthcoming scientific paper on current RT-PCR/antibody tests for the 'novel Coronavirus' ('SARS-Cov-2') by leading scientists in the U.S. state of Georgia states this:

"There is no gold standard for COVID-19 since this specific virus has never been properly purified and visualized. Thus, the accuracies of the tests are unknown. The development of these test kits is contrary to the FDA's guidance document."

Reliable analytical data is critical for the correct determination of the real presence or absence of COVID-19 infection." (Ogenstad et al 2020 pp3-4)

The above extract – confirmed by the Georgia State U.S. authors - reveals that the way these tests perform when testing patients/staff has never been properly *evaluated* in relation to the gold standard

of "purified virus". This means that the accuracy of these tests is currently unknown and impossible to judge until more work is completed.

Britain Is Using Flawed Tests

Investigative journalists at London's Daily Telegraph (Donnelly and Gardner 2020) report that the British test regulator - Public Health England (PHE) - is using flawed 'novel Coronavirus' tests (for 'SARS-CoV-2') with no real capacity to roll out national screening and testing (Open Democracy 2020) on thousands of UK National Health Service (NHS) patients and workers. PHE is also reportedly giving 'discordant' (+/-) results, running in-house testing (aka 'home brew'), and creating differences between the PHE 'in-house' tests and commercially available tests (Donnelly and Gardner 2020). The Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) Test – used for initial hospital screening for the disease Covid-19 (assumed to be caused by this supposed 'novel Coronavirus') is thought to detect what is believed to be bits of 'RNA' from this 'novel Coronavirus'. Similarly, the antibody test for this 'novel Coronavirus' is assumed to detect viral 'antibodies' but in Britain it was proven to be unsuitable (Smythe et al, 2020).

Data sheets (e.g. Roche, 2020) rushed out from the test manufacturers and fast-tracked for clinical use by the US Federal Drug Administration under Emergency Use Authorisation have dropped the requisite caveats that such tests MUST be confirmed by comparison with purified infectious virus - and not just from bits of RNA, the so-called *'RNAaemia'* of Huang et al (2020 p499) assumed to come from a 'novel Coronavirus' based only on molecular/genetic similarity.

All of the above arguments (and more) were first advanced about the 'isolation' of 'HIV' and its role in AIDS by Papadopulos-Eleopulos et al (2012). However, these sorts of arguments were vehemently and continuously rejected by 'mainstream' scientists. As Ogenstad et al are 'mainstream' scientists; it is now interesting, one could say *highly worrying*, to see how these so-called 'rejected arguments' are now so adamantly advanced by Ogenstad et al for these RT-PCR/antibody tests. It is highly worrying because the implications and ramifications stemming from what Ogenstad et al are now admitting is that the science underpinning the Lockdown and the continued erosion of our liberties is not just questionable (as is all 'normal science' (Kuhn (2012)) but is **wrong at worst** or **fatally misguided** at best.

The gold standard for any 'novel Coronavirus' test is the best *independent* way to measure the test's accuracy at truly detecting those patients with and without the virus, the *positive predictive value* of the tests (Griner et al 1981). Logically, as the Georgia State U.S. scientists imply, the gold standard must not be bits of RNA ('*RNAaemia*') but "purified virus" confirmed by "*purification*" and "visualisation" using electron microscopy (White and Fenner, 1986 p9). This is key according to Ogenstad et al (2020) for "the correct determination of the real presence or absence of COVID-19 infection."

This may help to explain why the PHE is now reporting 'discordant results' (non-binary) where some people test alternatively 'positive' and then 'negative', with or without symptoms, according to investigative journalists at London's Daily Telegraph (Donnelly and Garner 2020). These PHE reports match other studies which show how the test is as far from binary (Li et al 2020) as a quantum, the cut-off is in reality totally arbitrary (Young et al 2020), discordant results occur continuously with the same patients (Cao et al 2020, Li et al 2020), and the quantity of RNA totally fails to correlate with illness severity (Young et al 2020).

British test guidance says the precautionary actions governing quality control of the RT-PCR should be expedited to get a definitive result (NHS England and NHS Improvement 2020 p8). This further helps to explain reports showing that people have been advised to return to work too early (false negatives), and vice-versa, people are similarly misadvised - to stay off work unnecessarily (false positives) (Donnelly and Gardner 2020).

Furthermore, the number testing RT-PCR positive (with or without antibodies) is reportedly inaccurate (Donnelly and Gardner 2020) and likely conflates false + true positives: false positives are those testing positive that never had the virus, and false negatives vice-versa. As the Georgia State US scientists openly admit: *"the accuracies of the tests are unknown"*. Coupled with these problems is the subjective way in which different definitions are made of how a positive test is arrived at (Bustin and Nolan 2017, Crowe 2020b). For example, in the 'HIV/AIDS' era this gave rise to a whole set of different generations of test methodologies engendering false and indeterminate results subsequently terrorising patients due to the uncertainty experienced (Corbett 2001, Corbett 2009). The evidence underpinning the accuracy of these 'novel Coronavirus' tests have been exhaustively summarised by David Crowe, an independent Canadian researcher, on the London website 'Lockdown Sceptics' (Crowe 2020c).

The Georgia State US scientists (Ogenstad et al 2020) show the downside of the *global rush to judgement* and the dangerous bypassing of the expected *precautionary principle* with regard to test

development. It points to the regulatory veneer of scientific certainty over testing versus the actuality of scientific uncertainty. The fast-tracking of tests together with the fear induced actions of the World Health Organisation and the profit-driven pharmaceutical industry have produced a confluence of interests. This is the background for the panic-driven collusion of the official health authorities - the U.S. Federal Drug Administration and their respective British counterparts (PHE/the British National Institute for Health And Care Excellence (NICE)). Together, under emergency instructions, these forces are rolling out these tests (accuracy 'unknown') onto a public who unquestionably believes them to be 'sound' and to be 'binary'. This is an appalling scientific disaster of enormous proportions, implications and ramifications.

Ogenstad et al (2020) are clearly admitting that no purified infectious 'novel Coronavirus' ('SARS-Cov-2') has ever been adequately demonstrated as coming from patients (e.g. see Huang et al 2020). The implication is that the 'novel Coronavirus' RNA/antibodies whose veracity are assumed by PHE/FDA may not actually prove to be 'viral' but could represent other phenomena. For example some scientists like Andrew Kaufman (Kaufman, 2020) suggest these may be 'exosomes', whilst others point to numerous confounding process artefacts (Schierwater et al 2009), or due to the laboratory 'quality processes' which appear remarkably open to errors and misinterpretation (Bustin and Nolan 2017). Until the proper research is suitably undertaken (and reproduced) regulators cannot scientifically claim that the tests are accurate.

The Pathology of Lockdown 'Science'

The 'science' underpinning this Lockdown is becoming more and more like the science underpinning Irving Langmuir's concept of '*pathological science*' (Langmuir 1953) with its '*claims of great accuracy*', now refuted (e.g. Imperial College London's 'model epidemic'). For example, the *fantastic over-reach* theories, contrary to human knowledge/experience, of this 'novel Coronavirus' that certain contagion occurs through the normal quotidian of '*touch*'; '*receiving holy communion*'; '*breathing*'; '*sitting on a park bench*'; '*attending funerals*'; '*CPR*'; '*non-invasive ventilation*'; and '*being present with hospitalised loved ones on their death beds*' etc. This *fauxdemic*'s '*high ratio of supporters to critics*' was *initially* rising but is now acknowledged as *falling*, as we see an emergent *Lockdown ennui* amongst politicians, scientists and the general population. All of these italicised characteristics of Langmuir's 'pathological science' are now arguably fulfilled in the case of this 'novel Coronavirus' and 'Covid-19'. This *fauxdemic*, by bizarrely turning the normal into the abnormal, is arguably looking like

another instance of pathological science, such as cold fusion theory. Many scientists have tried to rein in the zealotry of Imperial College London's epidemiology, but with little apparent success. For example, the work of Carl Heneghan and Tom Jefferson of Oxford University did not impact greatly in the media or with government even though they showed good evidence that this 'pandemic' is a *"…late seasonal effect in the Northern Hemisphere on the back of a mild ILI season."* ('ILI'=influenza-like illness)(Heneghan and Jefferson 2020).

Furthermore, daily snitch reports by the media show how the mystical spell cast by the pathological science can wear off, as all sections of society can *wake up* to the reality of what has been so zealously perpetrated in the name of 'epidemiological science'. This is the creation in the Western world of an inhuman dystopia of prospective mandatory screening, flawed testing and fast-tracked vaccination (akin to Communist China), from which all our *elected* 'Free World' politicians have failed to protect us.

The characteristics of this emerging dystopic order form the thematic of a further monograph in this *Coronahysteria* series.

British Scientific Credibility Compromised

What is not publicly admitted by PHE and is implicit in the above cited reports is PHE's failure to create testing capacity. This may be due to the rapid NHS public health changes which followed the Lansley NHS reorganisation (Health and Social Care Act 2012). It locally disaggregated services like PHE and exacerbated the existing NHS contract culture (Ham et al 2015). Those highly controversial reforms are now fatally impacting on test-kit purchasing and in-house test evaluation which is required on a UK-wide, and not a local ['home-brew'] scale and must impact similarly across both the NHS and commercial providers.

The marshalling of testing capacity in the UK is not happening quickly enough as the necessary infrastructure has changed from the 1980s when 'HIV' tests were the official panic. The infrastructure developed from the 1980s onward by Phillip Mortimer, and the now extinct Public Health Laboratory Service, created a truly innovative HIV testing strategy using in-house ELISA algorithms, thus dumping the more expensive/less accurate US ones (Corbett 2020). Such British innovation was arguably largely

due to Mortimer's creative scientific leadership of the PHLS (Corbett 2020). At the time of Lansley's NHS reorganisation, some very erudite and evidence-based warnings went almost entirely unheeded over the subsequent negative effects of the ensuing contract-culture (e.g. Pollock et al 2012).

Lack of Scientific Transparency and Public Accountability

What is very clear now is how our PHE experts seem much less transparent about these failures and the limitations of existing science, unlike their US colleagues (in the leaked report), who are basically calling for the scientific evidence for the existence of this 'novel Coronavirus'. A lot depends on this as the lockdown continues and civil liberties are severely curtailed (Corbett and Crowe 2020). Other independent researchers have already called for this sort of evidence (Crowe 2020) but their pleas have gone unheeded, or have been dismissed by officialdom just as was the work of The Perth Group (Papadopulos-Eleopulos et al 2012)(www.theperthgroup.com).

PHE and other national test regulators like the FDA must now urgently publish reproducible analyses on the 'proper' purification and visualisation of this 'novel Coronavirus' to underpin the proper gold standard for any associated testing.

CONCLUSION

Our respective test regulators, who in Britain are incapable of supplying the testing technology required for this government-imposed Lockdown, are practising what some call incomplete and erroneous science (OffGuardian 2020). They must be made fully accountable, and be required to address in the terms described in the opening of this monograph, this question:

Where is your evidence for the 'novel Coronavirus', 'SARS-CoV-2', and the accuracy of the tests?

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