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'?

Author:

Kevin P. Corbett MSc PhD Independent Research Consultant KPC Research & Consultancy Ltd London, England, Great Britain. kpcresearch@btinternet.com

CONTENTS

KEY ARGUMENTS	3
WHERE IS THE EVIDENCE?	4
No Gold Standard, No Fulfilment of Koch's Postulates	4
Britain Is Using Flawed Tests	4
The Pathology of Lockdown 'Science'	7
British Scientific Credibility Compromised	8
Lack of Scientific Transparency and Public Accountability	9
CONCLUSION	9
REFERENCES	10

How to cite this monograph:

Corbett K (2020) Monograph One. Where is the Evidence For The Existence of The 'novel Coronavirus', SARS-CoV-2? The Coronahysteria Series:'SARS-CoV-2', the 'novel Coronavirus'. London, KPC Research and Consultancy Limited. April 2020. ISBN 978-1-5272-6214-0.

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.

If the 'novel Coronavirus' is proven to exist, regulators must then publish evidence showing how this 'novel Coronavirus' fulfils Koch's postulates before it can be assumed that it causes the 'new' disease recently termed 'Covid-19'.

WHERE IS THE EVIDENCE?

No Gold Standard, No Fulfilment of Koch's Postulates

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). This must be followed by proof that any proven viral agent fulfils Koch's postulates for causation of this 'new' disease called 'Covid-19' which is currently lacking (e.g. Zhu et al 2020).

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:

"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). Even then, after what Ogenstad et al (2020) term "the correct determination of the real presence or absence of COVID-19 infection" [SARS-CoV-2, 'novel Coronavirus'] these conjectured 'viral' particles must be rigorously proven to cause the disease through strict criteria called Koch's postulates (University of Maryland 2020), which have <u>never</u> been fulfilled for the 'novel Coronavirus' (Zhu et al 2020, Crowe 2020a).

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 cutoff 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 1998). Such British innovation was arguably largely due to Mortimer's creative scientific leadership of the PHLS (Corbett 1998). 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 Papadopulos-Eleopulos et al.

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 existence of the 'novel Coronavirus', 'SARS-CoV-2'?

REFERENCES

Bustin S Nolan T (2017) Talking the talk, but not walking the walk: RT-qPCR as a paradigm for the lack of reproducibility in molecular research. European Journal of Clinical Investigation: August 10 https://doi.org/10.1111/eci.12801

Cao S, Wu A, Li J et al.(2020) Recurrent recurrence of positive SARS-CoV-2 RNA in a COVID-19 patient, April 15, PREPRINT (Version 1) available at Research Square. https://doi.org/10.21203/rs.3.rs-23197/v1

Corbett K (2018) The Regulation of British HIV Testing, 1985-2003. London, KPC Research and Consultancy Ltd. www.kevinpcorbett.com

Corbett, K (2001) Contesting AIDS/HIV: the lay reception of biomedical knowledge. Unpublished PhD thesis, London South Bank University. https://lispac.lsbu.ac.uk/record=b1015575~S1

Corbett, K (2009) "You've got it, you may have it, you haven't got it": multiplicity, heterogeneity, and the unintended consequences of HIV-related tests. Science, Technology and Human Values, 34 (1), pp. 102-125. ISSN 0162-2439. http://dx.doi.org/doi:10.1177/0162243907310376

Corbett K, Crowe D (2020) Problems with current UK government lockdown policy. Journal of Advanced Nursing *interactive*. https://journalofadvancednursing.blogspot.com/2020/04/problems-with-current-uk-government.html

Crowe D (2020a) Flaws in Coronavirus Pandemic Theory. https://theinfectiousmyth.com/book/CoronavirusPanic.pdf

Crowe D (2020b) The Infectious Myth - Simplifying RT-PC.R. The Infectious Myth, April 21. https://theinfectiousmyth.com/coronavirus/RT-PCR_Test_Issues.php

Crowe D (2020c) The Incredible and Scary Truth about COVID-19 Tests. London, Lockdown Sceptics April 26 https://lockdownsceptics.org/the-incredible-and-scary-truth-about-covid-19-tests-2/

Donnelly L, Gardner B (2020) Revealed: NHS staff given flawed coronavirus tests Leaked memo exposes farce as Covid-19 results are less reliable than first thought because of 'degraded' performance. April 21. London. https://www.telegraph.co.uk/news/2020/04/21/public-health-england-admits-coronavirus-tests-used-send-nhs/

Griner PF, Mayewski RJ, Mushlin AI (1981) Selection and interpretation of diagnostic tests and procedures. Annals of Internal Medicine 94:559-563.

Ham C, Baird C, Gregory S, Jabbal J, Alderwick H (2015) The NHS under the coalition government. London, King's Fund. https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/the-nhs-under-the-coalition-government-part-one-nhs-reform.pdf

Health and Social Care Act (2012) Health and Social Care Act. London, Her Majesty's Government http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

Heneghan C, Jefferson T (2020) COVID-19 deaths compared with "Swine Flu". Oxford University and The Centre for Evidence-Based Medicine develops, promotes and disseminates better evidence for healthcare. April 9, https://www.cebm.net/covid-19/covid-19-deaths-compared-with-swine-flu/

Huang C et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet. 2020 Jan 24. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30183-5/fulltext

Kaufman A (2020) Dr. Andrew Kaufman: Is COVID-19 an Exosome? https://hipegalaxy.com/covid19/dr-andrew-kaufman-is-covid-19-an-exosome/

Kuhn, Thomas S. (2012). The Structure of Scientific Revolutions. 50th anniversary. Ian Hacking (intro.) (4th ed.). University of Chicago Press.

Langmuir I (1953) Pathological Science. Colloquium at The Knolls Research Laboratory Niskayuna, New York City, New York, December 18, 1953. Transcribed and edited by R. N. Hall. https://www.cs.princeton.edu/~ken/Langmuir/langmuir.htm

Li, Y, Yao, L, Li, J, et al. (2020) Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19. Journal of Medical Virology, 1– 6. https://doi.org/10.1002/jmv.25786

NHS England and NHS Improvement (2020) Guidance and standard operating procedure COVID-19 virus testing in NHS laboratories. London, NHS England and NHS Improvement. https://www.england.nhs.uk/coronavirus/publication/guidance-and-standard-operating-procedure-covid-19-virus-testing-in-nhs-laboratories/

OffGuardian (2020) 12 Experts Questioning the Coronavirus Panic. https://off-quardian.org/2020/03/24/12-experts-questioning-the-coronavirus-panic/

Ogenstad S, Peace K, Liu L (2020) Accurate COVID-19 Testing in Clinical Trials. Unpublished paper submitted to Journal of Bioharmaceutical Statistics.

Papadopulos-Eleopulos, E et al.(2012) HIV – A virus like no other. Posted at the Perth Group website July 12th. www.theperthgroup.com/HIV/TPGVirusLikeNoOther.pdf

Pollock A, Macfarlane A, Godden S (2012) Dismantling the signposts to public health? NHS data under the Health and Social Care Act 2012. https://www.bmj.com/content/344/bmj.e2364

Roche (2020) Covid-19 Factsheet. Cobas®-SARS-CoV-2. Fact Sheet. Roche Molecular Systems Inc., Pleasanton, California. https://www.fda.gov/media/136047/download

Schierwater B, Metzler D, Kr€uger K, Streit B (2009) The effects of nested primer binding sites on the reproducibility of PCR: mathematical modeling and computer simulation studies. Journal of Computational Biology 3, 235–51.

Smyth C, Kennedy D, Kenber B (2020). "Britain has millions of coronavirus antibody tests, but they don't work" London April 6. https://www.thetimes.co.uk/article/britain-has-millions-of-coronavirus-antibody-tests-but-they-don-t-work-j7kb55g89

University of Maryland (2020) Koch's Postulates to Identify the Causative Agent of an Infectious Disease. http://science.umd.edu/classroom/bsci424/BSCI223WebSiteFiles/KochsPostulates.htm

White DO, Fenner FJ. (1986) Medical Virology. San Diego, Academic Press.

Young BE et al. Epidemiologic Features and Clinical Course of Patients Infected With SARSCoV-2 in Singapore. JAMA. 2020 March 3. https://jamanetwork.com/journals/jama/fullarticle/2762688

Zhu N et al. (2020) A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl Journal of Medicine. January 14. https://www.nejm.org/doi/full/10.1056/NEJMoa2001017

DESIGNED AND PUBLISHED IN APRIL 2020 KPC RESEARCH AND CONSULTANCY LIMITED

An independent research and management consultancy owned and directed by Kevin P Corbett.

ABOUTH THE AUTHOR

Kevin P Corbett completed both undergraduate and postgraduate training in Art at the University of Reading (1979) and The Slade School of Fine Art, University College London (1981). Kevin qualified as a Registered Nurse in 1986 becoming part of the commissioned staff for Broderip Ward at The Middlesex Hospital, London, Britain's first purpose-built HIV/AIDS unit, opened by Princess Diana in 1987. Postgraduate nursing research followed at King's College London (1987-1989) into improving metred dose inhalation through patient training in the physiology of the inhaled route. This won support from the Stimulating Progress fund of London's North East Thames Regional Health Authority and *Vitalograph* Ltd (UK). Doctoral research (1995-2001) focused on patients' indeterminate experiences of the tests used in HIV/AIDS, the ELISA, Western blot and PCR tests. Kevin has more than thirty years' experience in gaining £150k+ in research funds for leading and participating as principal and coinstigator. He is a qualified nurse educator who has worked in university education, research and public health at Kingston/St.George's University of London, University and Middlesex University. Kevin also has experience in acute clinical, forensic and community nursing with over one hundred research outputs in peer-reviewed, patient-reviewed and citizen science publications. Current research and consultancy is focused on human physiology, visual art and citizen participation in science and technology.

ACKNOWELDGEMENTS

KPC Research and Consultancy Limited gratefully acknowledge the valuable feedback received from all of the reviewers during preparation of the manuscript revision prior to publication. Monograph design by KPC Research and Consultancy Limited.

Kevin P. Corbett has asserted his right under the Copyright, Designs and Patent Act, 1988, to be identified as the Author of this Work. All rights reserved

© Kevin P. Corbett

ISBN 978-1-5272-6214-0

Designed and Printed in Great Britain KPC Research and Consultancy Ltd kpcresearch@btinternet.com www.kevinpcorbett.com

