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Public Administration and Constitutional Affairs Committee
Data Transparency and Accountability: Covid 19

Executive Summary

The way in which data regarding the COVID-19 epidemic is presented to the UK media and wider public is critical to providing protection against the effects of the SARS-CoV-2 virus whilst balancing this against the severe harm that mitigation measures undoubtedly cause. As an academic clinical laboratory scientist with over 30 years in the NHS and clinical research, I address four key areas where I feel I have the expertise to comment (linked to Terms of Reference items 1, 3, 4 and 6):

1. Evidence associated with the utility of the PCR test used for the detection of SARS-CoV-2.
2. The policy on use of face coverings on public transport and in retail outlets.
3. The way in which data were interpreted and communicated to the public and via the media. This also includes; (i) transparency in areas where there was insufficient available evidence and, (ii) the absence of comparable reference data for other conditions, such as non-COVID-19 infections as well as other causes of illness/injury with which to provide context regarding risk.
4. Understanding among journalists and parliamentarians to enable informed and accurate presentation and interpretation of data for the public.

In section 1, I describe the critical importance of defining a 'case' and illustrate how the government has used this term to imply an individual with infections virus, when it actually refers to the number of positive PCR tests. I highlight the importance of missed 'cases' at the height of the epidemic, and the major impact of false positives since June when the incidence has continued to be low relative to the number of tests. I discuss in some detail issues around the testing process and wider, rarely mentioned, sources of variability which would contribute to incorrect test results. I describe how even most healthcare professionals, including doctors, have limited understanding of the concept of variability in test results.

In section 2, I outline sone of our work on the effectiveness of face coverings in retail outlets and on public transport and highlight how this is predicated on 'correct use' in the correct circumstances. I show how the introduction of this policy, at a time when the R value was low, was ineffective, reducing the death rate by less than 3 per week. I comment on how this policy has major negative impacts, including on mental health, with very limited, if any, benefit.

In section 3, I discuss the metrics used by the government, and how the focus on 'cases' creates a false impression of risk. I describe how lack of reference to other metrics such as (i) total test numbers, (ii) false positives/missed cases, (iii) COVID-19-related hospital admissions & deaths, (iv) non-COVID-19-related harms, (v) excess deaths (versus the 5-year average) and, (vi) comparison with all-cause mortality & other causes of death gives a

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misleading picture of the risk posted by SARS-CoV-2. I describe that COVID-19 is the 24th most common cause of death (assuming that SARS-CoV-2 was a significant contributor in all of these deaths) and is at least 10-fold less common as a cause of death than influenza/pneumonia. I also make reference to the absence of evidence on a causal relationship between implementation of various policies and changes in 'case' numbers or other metrics, and the contrast with recent data indicating that lockdown *per se* has had little positive impact, if any.

In section 4, I comment on the complex, technical nature of much of this work, and the challenges this poses for non-experts, including parliamentarians, media and the wider public, as exemplified by Matt Hancock's inability to provide the correct definition of a false positive in an interview with Talk Radio in September.

Following the main body of the evidence, in section 5, I present a **series of recommendations on how data transparency and accountability could be improved** in order to give the public and media a more balanced and evidence-based view of the current situation.

I then finish with a conclusion which states my grave concerns around how the data has been presented to date and the lack of accountability, with reference to the damage done to date and to follow over many years to come. I state my support for the Great Barrington Declaration which, while imperfect in some areas, provides a more constructive framework for a much-needed Public Health-led approach to supporting and protecting the vulnerable whilst freeing the majority to return to normality.

PERSONAL CREDENTIALS

I am currently Professor of Clinical Biochemistry at Keele University, but my prior career history is also of relevance to this subject. Up until the end of March 2020, I spent the previous 34 years as a registered NHS Clinical Scientist based in a large Clinical Biochemistry Laboratory, and clinical academic with protected time for clinical research. Prior to retiring from the NHS in March, I was Clinical Lead for the Clinical Biochemistry Department at the University Hospitals of North Midlands, Research and Innovation Director for the Trust and Honorary Professor of Clinical Biochemistry at Keele University.

I have published over 200 scientific/clinical peer-reviewed papers, including numerous papers involving tens of thousands of polymerase chain reaction (PCR) analyses, as well as a range of other genetic and epigenetic tests. More recently, my research has also focused on the correct use of laboratory tests in the diagnosis and monitoring of a range of conditions, and its impact on patient outcomes. As Clinical Lead, I was responsible for the clinical oversight of a large clinical laboratory, including ensuring that over 200 different tests were fit for purpose (including the impact of false positives and negatives on informing clinical decisions).

Both my clinical and academic roles are dependent on accurate interpretation of large and complex sources of data and understanding when evidence is insufficient to reach key decisions, in the interests of patient safety.

In the last few months, I have utilised these skills, in collaboration with colleagues, to write a clinical paper exploring the effectiveness of face coverings on infections, hospital admissions and deaths from COVID-19.

I therefore feel that I have the necessary expertise to provide comment to the inquiry.

Areas to be addressed

Given the above expertise, my comments will focus on four key areas:

1. Evidence associated with the utility of the PCR test used for the detection of SARS-CoV-2 (Terms of Reference items 1, 3, 4 and 6).
2. The policy on use of face coverings on public transport and in retail outlets (Terms of Reference items 1, 3, 4 and 6).
3. The way in which data were interpreted and communicated to the public and via the media. This also includes; (i) transparency in areas where there was insufficient available evidence and, (ii) the absence of comparable reference data for other conditions, such as non-COVID-19 infections as well as other causes of illness/injury with which to provide context regarding risk (Terms of Reference items 1, 3, 4 and 6).
4. Understanding among journalists and parliamentarians to enable informed and accurate presentation and interpretation of data for the public (Terms of Reference item 6).

1. EVIDENCE ASSOCIATED WITH THE UTILITY OF THE PCR TEST USED FOR THE DETECTION OF SARS-COV-2

Throughout the epidemic, great emphasis has been placed on the change in numbers of 'cases', both in terms of determining policy to mitigate risk and in the way in which risk was portrayed to the media and wider public. Hence, a clear understanding of the data that goes to define a 'case' is critical to correct interpretation of the data. In this context, there are three key questions:

1.1. What is a 'case'?

While there is debate as to whether number of 'cases' is the most informative metric in monitoring disease progress (see section 3 below), **the underlying basis for the definition of a 'case' has been based entirely on the presence of a positive diagnostic test** (antigen test using a swab sample). In the communications by both the government spokespersons (including the Chief Medical Officer and Chief Scientific Advisor), and in the media, **the term 'case' has almost always been used to imply a person who has active and transmissible SARS-CoV-2 virus. There is no evidence that equates these two**; indeed, no informed clinical scientist would accept this.

This interchangeability of someone with a positive PCR test as representing someone with infectious COVID-19 is potentially extremely misleading. This, along with the rhetoric and tone used at press conferences and in other government-led communiques (and hence re-iterated by the media), has the danger of presenting a significant and potentially damaging over-exaggeration of risk.

At no point has it been made clear in government communications that a positive test does not equate to an infectious 'case', or that figures presented have been in any way adjusted to account for this difference. It is clear that some infectious cases will have been missed, either through lack of testing (especially early in the epidemic) or due to false negative tests (see section 1.2 below). Similarly, some people presented as infectious cases on the basis of a positive test will not be infectious (e.g. false positive tests; see 1.2).

In each of the above two scenarios, the reliance on test results to define 'case' numbers is misleading. The relative numbers of people in these scenarios will potentially have a major impact on the correct way to interpret data on the progress of the epidemic. However, while the importance of these scenarios would have been clearly known to all NHS Clinical Laboratory Scientists, it was not apparent in communications from the DHSC or government ministers/advisors that the views of this group of staff, with such unique and invaluable expertise, was taken into consideration. Furthermore, **given the critical importance of the proportion of missed cases, false negatives and false positives, the studies to elucidate these key parameters were not commissioned.**

An additional factor in the definition of a 'case' is the need to acknowledge that **not all true positives are infectious cases**. Indeed, as discussed below, at very low viral load, shedding of virions (virus particles) is low and hence not all individuals with live virus in their respiratory tract will pose the same risk in terms of transmission. This has also not been acknowledged in government communications.

1.2. How 'accurate' is the test at defining a 'case'?

No clinical laboratory test is 100% 'accurate' (defined in correct Clinical Laboratory Medicine terms as the number of true positives + true negatives divided by the total number of tests).

This is linked to two components which contribute to the total variation used in assessing test performance:

- Biological variation: the variability due to factors such as daily changes in the analyte being measured within a given individual.
- Analytical variation: this includes:
    - pre-analytical variation, such as site of sampling (e.g. nasal, throat), sample transport conditions and timing, and pre-test processing.
    - analytical variation, such as variation in the effectiveness of the test itself. In the context of this document, variation between the different commercial assays is also relevant.
    - post-analytical variation, such as the generation of the result report and its accurate transmission to the person who requested the test.

These factors mean that **a significant proportion of tests will give incorrect results**. In some cases, serial samples from the same person may give different results. For example, two sample may be taken from the same individual on the same day and vary because of:

a. what time of day the sample was taken

b. what the person had eaten/drunk immediately before the test
c. the part of the mouth or nose that the swab was taken from
d. the way in which the sample was labelled
e. they way in which the sample was handled
f. the sample transport temperature and time it took to get the sample to the laboratory
g. the accuracy of the data entry on receipt of the sample by the laboratory (was the sample booked in under the correct name?)
h. the skill of the Biomedical Scientists (assuming they are actually trained, Health & Care Professions Council-registered NHS Biomedical Scientists in the first place) in handling the sample
i. the performance of the Internal Quality Control (IQC) and External Quality Assurance (EQA) within the laboratory for that assay (assuming the laboratory testing facility follows the correct IQC and EQA procedures) to ensure that the assay is performing adequately
j. the variability, sensitivity and specificity of the test itself
k. the clarity and accuracy of the results report (e.g. is the correct result assigned to the correct patient sample)
l. the systems to ensure that the correct results report reaches the healthcare professional who requested the test
m. the ability of the healthcare professional to interpret the report (assuming that the healthcare professional in this case is adequately trained)

These will be discussed in more detail below.

1.2.1. Test performance. **Much of the discussion around false positive and negative rates for SARS-CoV-2 testing in the government and media communications, and even clinical and scientific arenas has focused only on item 'j' in the above list**. I will therefore address this first; I have referred to this as 'test false positive/negative' rates.

Estimates of test false positive and false negative rates have been provided by several groups (usually in the range of 0.5-2.5%) and it is not my intention here to argue for one level or another. The key issue is that they are highly likely to be critical in providing a correct interpretation of the 'case' data; resulting in (i) under-estimates of true positives in times of high COVID-19 prevalence (such as April 2020 in the UK), or (ii) under-estimates in the proportion of cases that are false positives in times when prevalence is low (i.e. from June 2020 onwards).

Health Data Research UK (HDRU) state: '*Even with an almost perfect test, the lower the prevalence of infection, the higher will be the proportion of false positive results among all the positive results*.'[2]. HDRUK provide a very useful tool for assessing the impact of various test performances on proportion of false positives and negatives (see footnote[1]). They go on to provide an example of the impact of test performance on proportion of tests that are false positive:

[2] Health Data Research UK. Testing for coronavirus (SARS-CoV-2) infection in populations where active infection is very uncommon: the problem of false positives. https://www.hdruk.ac.uk/projects/false-positives/

'With an infection prevalence of 0.05% or 1 in 2,000 (the average community prevalence in the UK in early August) and very optimistic test performance measures (sensitivity of 80% and specificity 99.9%), ***the chance of a positive result being truly positive will be only 29% with one test****. This increases to almost 100% if a second test is also positive*[3]*. However, the* ***percentage of positive results that are truly positive can fall to unacceptably low levels when infection is very uncommon in the population and test specificity is less than excellent****.'*[1]

This illustrates the major importance of understanding and correctly interpreting the impact of false positive rates, using very optimistic estimates of true assay performance.

1.2.2. Test stringency and cycle number. PCR tests detect virus by amplifying its genetic material (in the case of SARS-CoV-2, this is RNA) over a number of cycles of the reaction. At each cycle, the number of copies of the target genetic material approximately double. Therefore, for most routinely used clinical assays, 25 cycles are sufficient to enable detection of the target genetic material. **Use of over 30 cycles risks amplification of either very low levels of virus genetic material and/or detection of genetic material that is not from the target virus genetic material** (e.g. from other common coronaviruses other than SARS-CoV-2). This has been investigated in a Systematic review by Jefferson et al[4]. Non-specific amplification can also occur if the 'stringency' of the reaction is not sufficiently high. This can be affected by small changes in the temperatures used in the PCR, or by slight differences in the balance of reagents in the PCR mixture itself. This stringency affect will be exaggerated by use of very high cycle numbers.

Many PCR methods used in the detection of SARS-CoV-2 use over 35 cycles, **meaning that the risk of false positive results is higher if the reaction conditions are not extremely well controlled**. While this is more likely to be the case in the hands of well-trained Biomedical Scientists who are operating under the quality standards offered by UKAS ISO15189 accreditation (see section 1.2.3 below), there is a significantly higher risk in insufficiently trained hands where quality control and assurance are not as strictly maintained, such as in those areas where non-NHS facilities have been used (including commercial providers).

1.2.3. Other sources of variability. These are based on sources other than those in item 'j' from the list above. **These other potential causes of incorrect results have been almost universally ignored in the context of COVID-19**. UK

[3] Note: this is only likely if the methodology of the second test is different to that used in the first. Furthermore, some causes of false positives will be missed even by this approach.

[4] Jefferson et al. Viral cultures for COVID-19 infectivity assessment. Systematic review. https://www.medrxiv.org/content/10.1101/2020.08.04.20167932v4

Clinical laboratories are regularly subject to rigorous inspection by the United Kingdom Accreditation Service (UKAS; under the ISO15189 standards) to ensure that systems and processes, facilities, training, etc are of the highest standard to ensure patient safety. The demand for huge increases in additional capacity to provide sample collection and testing facilities has required use of services outside the usual NHS Clinical Laboratories, raising serious questions about the quality of the testing (and hence increased risk incorrect test results). No studies have explored the impact of these other causes of variability on risk of incorrect results, though repeat testing would reduce this risk significantly. **This has therefore not been adequately addressed and represents a further risk to the correct interpretation of the data presented to the public**.

1.2.4. Causes of false positive test results. Here it is worth mentioning some of the potential causes of false positive test results that are incorrectly assumed to be infectious cases:

i. Remnants of dead virus genetic material from past infections. The extreme sensitivity of the PCR assay, particularly at high cycle numbers and/or low stringency (discussed above), will detect genetic material from inactive virus.

ii. Low levels of active virus below the level that is likely to correspond with viral shedding. The sensitivity of the assays detect virus at very low levels were viral load is insufficient to cause clinically significant shedding.

iii. Cross-reactivity with other viruses with similar genetic sequence. Evidence from an External Quality Assurance schemes study by Matheeussen et al[5], where samples were sent blind to over 500 European laboratories, showed that, not only did **some samples give positive results in negative samples with no virus in at all, but that they also detected SARS-CoV-2 in samples that only contained genetic material from other common coronaviruses** (e.g. HCoV-NL63 and HCoV-OC43) in 3% of cases. They **assessed over 20 different PCR methods and the percentage of correct results ranged from 90.3% to over 99%,** illustrating that not all methods perform the same.

1.2.5. Challenges for non-specialists. The difficulty in non-clinical laboratory staff correctly understanding and interpreting the impact of false positives was illustrated when Matt Hancock was interviewed on Talk Radio by Julia Hartley-Brewer on the 18th September 2020. Here he insisted that false positives were expressed as a percentage of the number of *positive tests* rather than the *total number of tests*. This makes a huge difference; if 200,000 tests are performed each day and 2000 people test positive, a false positive rate of 1% by Mr Hancock's calculation would mean that 20 of these would be false positives.

[5] Matheeussen V, Corman VM, Donoso Mantke O, et al. International external quality assessment for SARS-CoV-2 molecular detection and survey on clinical laboratory preparedness during the COVID-19 pandemic, April/May 2020. Euro Surveill. 2020;25(27):2001223.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7364759

This would understandably not be perceived as a major problem of testing. Unfortunately, his definition was incorrect. The correct interpretation would be that 1% of the 200,000 would be false positives; a figure somewhat larger at 2000 (i.e. all of the positive test results would be false positives. As you can see, **this makes a huge difference to how the data is interpreted and illustrates the crucial need to understand what the actual false positive rate is, and/or to re-test all positive tests using alternative methodology**. The key decision makers are clearly not understanding this (the alternative is worse still; they do understand it but are not disclosing this to the public).

1.3. How well understood is the performance of the test in defining a 'case'?

The challenge here is that **parliamentarians, media correspondents and <u>even most doctors</u> do not truly understand the potential impact of variability on the test result**. Virtually all doctors and non-laboratory-based healthcare professionals automatically assume that the test result is correct and use it to treat the patient (and so they should – it's their job). There is very little likelihood that parliamentarians, media correspondents and members of the public will understand the impact of these factors on the data that is presented. **This therefore means that almost everybody involved in making decisions around the testing is mis-informed in this respect and therefore liable to misinterpret the data in a way that is misleading to the public**.

A further complication is around the potential introduction of these 15-30 minute on-the-spot tests (referred to as *point-of care* or *near patient testing* in clinical laboratory circles). Almost exclusively, the performance of this type of test modality is worse than clinical laboratory testing and rarely subject to the rigour of UKAS inspection or external quality assurance. However, under normal circumstances where such testing is used, it is adequate for the purposes of clinical care. It is not used where the level of performance required is of the level that will be needed for mass testing for COVID-19. Hence, **the mere suggestion of Operation Moonshot is ludicrous to any Laboratory Healthcare Scientist**. The announcement of this programme, with its vast spending, illustrates clearly the lack of understanding by the government and, from the lack of informed challenge, by the wider parliamentary body and media. **This should never have reached the point of announcement as a viable option**.

It should be mentioned that some reports have suggested that the 'accuracy' of some rapid tests has been suggested to be superior to PCR-based testing. However, the other sources of variability (other than item 'j') become more important here. All trained NHS clinical laboratory professionals ill recognise that performance of 'near patient' testing modalities by untrained staff with little concept of External Quality Assurance and the impact of variability, is almost certain to result in higher risk of incorrect results. This would need careful independent assessment before widespread introduction, and inspection by UKAS under the ISO 15189 standards).

2. THE POLICY ON USE OF FACE COVERINGS ON PUBLIC TRANSPORT AND IN RETAIL OUTLETS

The issue of face coverings has been a topic of significant debate across the UK, and indeed the world in general, with many governments and the WHO changing their views almost overnight. The logic behind their use appears on the surface to be logical, and has generally been accepted by the public as a seemingly sensible thing to do in an attempt to reduce transmission of the virus. However, the evidence, and effectiveness and timeliness of the implementation of mandatory face coverings on public transport (15th July) and in retail outlets (24th July), as well as more recently in pubs and restaurants, remains deeply questionable.

There are three areas warranting further consideration in this regard:

i. The filtering characteristics and efficacy of face coverings
ii. The estimated population impacts of widespread community use of face coverings
iii. The sociological considerations for policies concerning the wearing of face coverings

These are addressed in our recently submitted paper to the International Journal of Clinical Practice[6] (currently awaiting response from the journal to a submitted revised version with minor corrections).

2.1. The filtering characteristics and efficacy of face coverings

A number of studies have examined the filtering efficiencies of various types of face coverings. **Most of these are conducted in carefully-controlled laboratory environments for short periods**. For example, experimental data obtained in such a carefully-controlled settings by van der Sande et al suggested that home-made face coverings offered around 29-78% protection against aerosol transmission over short periods, while surgical masks provided 50-91% protection.[7] The evidence from real-world population settings is, however, severely lacking. Thus, **prolonged mask use outside a laboratory context is likely to give results than are significantly lower and more variable than these estimates**. Despite this lack of real-world data, widespread mass use of face coverings, including bandanas and scarves, has been advocated in UK government guidance as beneficial. This indicates a lack of clear evidence and an absence of honesty and transparency in the rationale for implementing this policy.

2.2. The estimated population impacts of widespread community use of face coverings

The policy on mandatory use of face coverings on public transport and in retail outlets was based on government guidance that stated: '*The best available scientific evidence is that, when used correctly, wearing a face-covering may reduce the spread of coronavirus droplets in certain circumstances, helping to protect others.'*

There are two key phrases here which are causes for concern: '*when used corre*ctly' and '*in certain circumstances'*. **It is clear that in real-world circumstances, people do not**

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[6] Stedman et al. Modelling the impact of the mandatory use of face coverings on public transport and in retail outlets in the UK on COVID-19-related infections, hospital admissions and mortality. Intl J Clin Pract. https://doi.org/10.22541/au.159985977.79629376

[7] van der Sande M, Teunis P, Sabel R. Professional and home-made face masks reduce exposure to respiratory infections among the general population. PLoS One. 2008;3:e2618.

use face masks '*correctly*'; any casual walk along a UK high street will provide clear evidence of that.

Secondly, under what '*certain circumstances'* would their proper use reduce the spread of infection? In our paper, we estimated the impact of the introduction of this policy, which coincided with a time when, by ONS figures, the R value was less than 1. We showed that:

2.2.1. Based on data from the United Kingdom Time Use Survey and the relative risk of different activities, **public transport and retail outlets comprised only 7% of the overall infection risk, irrespective of the use of face coverings**, suggesting that these areas were not the most appropriate activities in which to mandate face coverings in the first place.

2.2.2. Using conservative estimates based on ONS data, we calculated that **the nationwide mandating of face coverings would only prevent 0.6 deaths per day** (assuming all deaths were cases where COVID-19 was the actual cause of death; some estimates suggest that around a third have COVID-19 on the death certificate, but where this was not a contributory factor to the death). This also assumes that all tests were true positives. Hence, this policy is likely to have prevented, at most, around 3 deaths per week. Using ONS data[8], this compares with a total weekly death rate of around 9000/week (5-year average), around 1400 of which were linked to influenza/pneumonia.

2.2.3. **We also raise the question of the timeliness of the introduction of these policies, when the quoted R value was below one and the impact of any face covering policy would be at its least effective**. It should be noted here that the R value itself may be inaccurate due to the false positive/negative rates as discussed above.

Most studies regarding face coverings in the literature focus on the effectiveness of face coverings in the healthcare setting. To quote a recent paper in the British Medical Journal by Prof Greenhalgh's group (Professor of Primary Care Sciences, University of Oxford); '***Almost all randomised controlled trials of face coverings have been done in healthcare facilities and addressed their efficacy in protecting the wearer from infection, not as source control. But drawing on the same evidence base for healthcare facilities and community settings has limitations***.'[9] This is illustrated by Chu et al who performed a systematic review and meta-analysis of 172 observational studies across 16 countries and six continents, on three precautionary measures, including the use of face coverings.[10] They suggested that face masks have value in reducing the spread of infection. However, in the assessment of face masks, only three (n=725; examining the SARS virus in China and Vietnam) were from non-

[8] Office for National Statistics. Deaths registered weekly in England and Wales, provisional: week ending 25 September 2020. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending25september2020

[9] van der Westhuizen HM, Kotze K, Tonkin-Crine S, Gobat N, Greenhalgh T. Face coverings for covid-19: from medical intervention to social practice. BMJ. 2020 Aug 19;370:m3021. https://www.bmj.com/content/370/bmj.m3021

[10] Chu DK, Akl EA, Duda S, et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet. 2020;395:1973-1987.

healthcare settings. Many studies on their use in a community setting rely on the change in cases in relation to the timing of their implementation. For example, the only study we identified that examined the introduction of face coverings on public transport and in retail outlets, examined the association between introduction of face coverings in a specific region of Germany relative to when they were introduced in other comparator regions.[11] While this study suggested that 'face masks reduce the daily growth rate of reported infections by around 40%', the design of the study means that it is difficult to assign the observed effect to the introduction of compulsory face coverings in a causal fashion. Hence, this provides little direct evidence of the benefit of mandating mass use of face coverings in a community setting.

It can therefore appear that such a policy could be portrayed to the public in a manner that demonstrates that the government is doing 'something' but has insufficient relevant scientific evidence to underpin its mass use in a community context. This is true for many measures (such as the recent introduction of curfews and face coverings in pubs and restaurants, where evidence is non-existent).

In my view, **face coverings should be limited to at-risk groups, and focus on the use of high-quality medical masks (at least N95 specification and above), as used in healthcare settings, as a means of protecting the vulnerable.**

2.3. The sociological considerations for policies concerning the wearing of face coverings

There appears to have been no consideration on providing evidence on the other consequences of this policy. **These unintended consequences of introduction of the mandatory mass use of face coverings are stark and yet have not been addressed**. These include a number of elements, including:

2.3.1. Mental health impacts. The development of a fear-led culture that over-exaggerates the public's perception of risk has significant implications for mental health. Wearing of face coverings may provide a degree of short-term reassurance to people with some types of mental health challenge,[12] whilst others may perceive the increased use of face coverings as heightening their sense of threat and insecurity.[13] While it may be argued that use of face coverings provides some element of safety to those with underlying concerns about the risk, **there is a real danger of damaging the mental health of many of these people in the long term, by reinforcing messages of health anxiety, OCD, paranoia, etc.**

In my experience, I have seen the severely damaging effects of this policy, such that some individuals will not now enter shops/bars/restaurants, or use public

[11] Mitze T, Kosfeld R, Rode J, Wälde K. Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Method Approach. http://ftp.iza.org/dp13319.pdf.

[12] Szczesniak D, Ciulkowicz M, Maciaszek J, et al. Psychopathological responses and face mask restrictions during the COVID-19 outbreak: Results from a nationwide survey. Brain Behav Immun. 2020;87:161-162.

[13] MIND. Mask anxiety, face coverings and mental health. https://www.mind.org.uk/information-support/coronavirus/mask-anxiety-face-coverings-and-mental-health/ .

transport because of the trauma associated with seeing widespread use of face coverings. This group suffer in silence because their voice is not heard. **This leads to a sense of isolation and disempowerment; such factors have not been considered at all in evidence collection, and certainly not discussed at press briefings**.

2.3.2. Economic impacts. It was intended that introduction of this policy would facilitate economic boost by giving the public confidence to use public transport and retail outlets. As the requirement to wear face coverings may increase anxiety in some people, this may indeed result in a reluctance to utilise public transport and/or visit retail outlets. This may, therefore, reduce the time spent on these activities. While it is also possible that the use of face coverings may increase the confidence of other people, it is difficult to say whether this will negate the above effect. Certainly, public transport usage[14] and retail footfall[15] does not appear to have returned to pre-epidemic levels.

3. THE WAY IN WHICH DATA WERE INTERPRETED AND COMMUNICATED TO THE PUBLIC AND VIA THE MEDIA.

A major concern is the metrics used to define the progress of the epidemic (and define its end), and the way in which these were presented in a fashion that creates an atmosphere of fear amongst the public. Whilst the rationale for this appears to be to use fear to make the public conform to the implemented measures, this fear-driven, 'stick'-based approach is not at all helpful. Below are a number of areas where, in my view, the metrics used and data presented was not transparent or unbiased.

3.1. Use of 'cases' as the primary metric

As discussed in section 1 above, it is important to reiterate that the use of the term 'case' actually refers to PCR positive tests, and includes false positives and potentially duplicate tests in the same patient. However, there are other factors that are of concern in this regard, with reference to the way that data is used in media briefings. These include:

3.1.1. The absence of reference to total test numbers. As the volume of testing rises, the probability of detecting cases rises. **At the height of the epidemic in the UK in April, advice, if people had symptoms, was to self-isolate; testing was neither recommended, nor widely available.** Hence, many 'cases' with positive tests (true and false) were not detected. Hence, the peak presented in many graphs in press briefings still implies that it reached around 10,000 cases per day. This will be a gross underestimate and can give seriously misleading information to the public. The true figure, according to *post hoc* calculations, is more likely to **be nearer 100,000 positive per day if the testing levels were**

[14] Department of Transport. Transport use during the coronavirus (COVID-19) pandemic. https://www.gov.uk/government/statistics/transport-use-during-the-coronavirus-covid-19-pandemic

[15] Office for National Statistics. Coronavirus and the latest indicators for the UK economy and society: 8 October 2020. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronavirustheukeconomyandsocietyfasterindicators/8october2020#footfall

equivalent to those seen now. This would give a more balanced perspective of the number of 'cases' seen now relative to in April. Hence, **data would benefit from being expressed as positive tests per 10,000 tests performed**, though even this would need caveats around the type of people being tested, as pillar 1 and 2 will have different proportions who are likely to test positive, with asymptomatic community cases having a high risk of false positives (low pre-test probability).

3.1.2. The absence of reference to deaths, or to hospital admissions. While the focus in press briefings has been on the number of positive tests, **there has been little discussion of hospital admissions, or more importantly COVID-related deaths**. In April, deaths were more likely, due both to the tendency of the virus to target the vulnerable, and as a result of lack of effective medical interventions (drugs, ventilators, etc). This is no longer the case, yet deaths are rarely used in press briefings, and **there appears to be no allowance made for the significantly lower conversion rate from 'case' to death now**.

3.1.3. The absence of reference to excess deaths. Related to section 3.2 and 3.3 below, the interpretation of COVID-related deaths needs to be placed in the context of excess deaths relative to all-cause mortality. Data indicates that this has been around the 5-year average since June.[16] This is important to give the public a more balanced perspective of the relative impact of COVID versus other causes of death (including the excess non-COVID deaths linked to the effect of lockdown and COVID mitigation measures). As things stand, there appears to be an over-emphasis on COVID-related deaths without context to other causes of mortality and harm. This is discussed in more detail below.

3.2. Lack of contextual comparison

To date, the way in which COVID-associated data has been interpreted poses a significant risk of mis-representing the true situation if presented out of context of other causes of hospital admission or death. For example, **Office for National Statistics data has shown that the relative incidence of influenza/pneumonia-associated deaths as being 10-14x that for COVID-19** (see footnote [15] below). This would give the public a more balanced context of the relative risk of COVID-19 with respect to other common conditions. The importance of this is illustrated by the observation that recently, **COVID-19 was listed as the 24th most common cause of death**[17] (assuming all COVID-19-associated deaths were those where SARS-CoV-2 was actually a contributor to cause of death, as opposed to being coincidental but not causative). **Data presentation relative to COVID-19 therefore needs to be done alongside other common causes of death.**

3.3. Lack of data on non-COVID harms

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[16] Office for National Statistics. Deaths registered weekly in England and Wales, provisional: week ending 25 September 2020.
https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending25september2020

[17] Office for National Statistics. Monthly mortality analysis, England and Wales: August 2020.
https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/monthlymortalityanalysisenglandandwales/august2020#leading-causes-of-death-registered-in-august-2020

The other key comparators that are essential for balanced interpretation of the data are the non-COVID harms (including deaths) that are caused by mitigation measures, such as delayed diagnosis of cancer, increased cardiovascular disease, increased suicides, deteriorated mental health, health impacts of increased deprivation due to the economic down-turn (especially as the most deprived have suffered disproportionately during lockdown restrictions). There is no doubt that these are significant. Indeed, the recent letter from 66 GPs to the Secretary of State for Health[18] regarding their feeling that **non-COVID-related harms have been outweighing the supposed benefits of government mitigation policies for a number of months** highlights this. There is overwhelming evidence that lockdown and associated COVID-19 'mitigation' measures introduced by the government have caused major harm and suffering, and will continue to do for many years.

3.4. The absence of evidence to confirm a causal relationship between measures and impact on progression of the epidemic

A further aspect regarding the presentation of data which is potentially misleading is the assumption often used that introduction of mitigation measures 'cause' changes in number of 'cases', when there is rarely any possibility of proving any causal relationship. In many cases, the change in 'cases' numbers is assumed to be because of the implementation of measures (such as face coverings as discussed above) when there is no real causal data to underpin this argument. However, it is still presented as though this is the case to the public, most of whom cannot possibly have the expertise to realise that there is a lack of causality.

Indeed, if anything, the data on timings between implementation of measures and changes in cases points away from implying that measures have much if any impact. For example, **there is increasing data showing that lockdown measures *per se* have had little positive (and yet much negative) impact**.[19]

4. UNDERSTANDING AMONG JOURNALISTS AND PARLIAMENTARIANS TO ENABLE INFORMED AND ACCURATE PRESENTATION AND INTERPRETATION OF DATA FOR THE PUBLIC

Given the points discussed above, much of which are technical in nature and require a significant level of scientific and/or clinical expertise, **it is hardly surprising that most parliamentarians, media representatives and certainly members of the public, will not have the necessary capability to correctly interpret the complex data around the progression of the epidemic and the effectiveness, or otherwise, of mitigation measures.** Furthermore, their understanding of the need for evidence-based approaches, rather than those that appear to make logical sense at a superficial level, will not be easily differentiated.

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[18] https://www.gponline.com/gps-urge-government-consider-indirect-covid-19-harms-lockdown-decisions/article/1696300

[19] National Review. Stats Hold a Surprise: Lockdowns May Have Had Little Effect on COVID-19 Spread.4 Oct 2020. https://www.nationalreview.com/2020/10/stats-hold-a-surprise-lockdowns-may-have-had-little-effect-on-covid-19-spread/

The example listed in section 1.2.5 regarding Matt Hancock's interview on Talk Radio is just one example of this.

5. RECOMMENDATIONS

In light of the evidence presented above, I would suggest the following changes to the way in which the data is being presented to the media and general public:

5.1. Case definition

5.1.1. Replace the use of the term 'case' to 'positive test'.

5.2. Testing

5.2.1. Correct all graphics and discussion around 'cases' to account for the number of missed positive tests during the height of the epidemic in March/April/May due to reduced levels of testing.

5.2.2. Similarly, correct the graphics and discussion to express positive tests per 10,000 tests performed, thereby correcting data for total test numbers.

5.2.3. Include in all graphics and discussion on positive tests an error estimate to illustrate the impact of false positive tests. While debate remains around the exact level of this, the government should present alternatives of the impact of false positives at 0.5%, 1% and 2%. They should be honest where uncertainly lies and evidence needs to be collected regarding this exact value.

5.3. Face coverings & other mitigation measures

5.3.1. Provide robust and independently-validated scientific evidence that underpins any measures being proposed, ensuring that this has the support of the entire House of Commons, so as to ensure proper accountability. This evidence should be presented at all press briefings.

5.3.2. Where evidence does not exist, or is contradictory, be responsive and honest enough to change the policy rapidly so as to minimise the indirect and significant harms caused by these measures.

5.3.3. Ensure that measures are independently evaluated as a medical intervention using the same criteria as used by NICE prior to implementation.

5.3.4. Resist the temptation to implement knee-jerk reactions, which has often used the need to act quickly as an excuse for poor policy. Where this has been already put in place, be honest with the public and change it quickly. This will give much more respect than is currently the case.

5.4. Correct metrics

5.4.1. Include graphs showing the number of hospital admissions and COVID-19-related deaths, correcting to include only those deaths where COVID-19 was a significant contributory factor in the cause of death, rather than just where COVID-19 was mentioned on death certificates, or where the person tested positive but this was coincidental.

5.4.2. Ensure than this is presented in the context of total, all-cause mortality, alongside the top 5 other causes of death/admission and with influenza/pneumonia (with deaths per week) as comparators to ensure a balanced context is presented.

5.4.3. Present data on the non-COVID-associated harms alongside the impact of COVID, giving them equal billing. As well as the current and future non-COVID health-related harms (including deaths), such as from increased cardiovascular events and delayed diagnoses, this should include economic and mental health impacts, the latter of which has been wholly inadequate in its focus by the government over the last 7 months.

5.5. Understanding

5.5.1. Provide easy to understand training modules for the key aspects discussed above so that the non-expert can understand some of the key terminologies, and make these readily available though widespread advertising campaigns on the same scale, but with greater clarity, as those used to portray the current key messages.

6. IN CONCLUSION

It is now clear to me that the public has been grossly mislead during the last 7 months, particularly since June when most measures could have relaxed without significant negative impact regarding COVID, whilst reducing significantly the major harms due to the lockdown measures. The Coronavirus Bill has resulted in minimal, if any accountability, for the measures implemented, so that the Prime Minister can implement non-evidence-based measures with impunity. These will result in severe damage to the health and wealth of UK people for many years to come.

I have always supported a more focused approach aimed at protecting the genuinely vulnerable, whilst allowing the vast majority of the population to go about their daily lives as normal. **Whilst I understand that during April and May, this was a fluid situation with little data, this could have been changed by June to a complete return to normal for the majority of people, but with a much greater emphasis on supporting and protecting the vulnerable. In this regard, I wholeheartedly support the Great Barrington Declaration[20] ,** which focuses on this more targeted approach. While the detail may require some further discussion, the **principle of release of mass measures to focus on protecting the vulnerable (as is the case for influenza and other public health concerns) is well within the UK's Public Health England remit**.

October 2020

[20] Great Barrington Declaration https://gbdeclaration.org/ At the time of writing, this included over 12,000 signatories from experts (including myself) and 112,000 members of the public. The growth in signatories is showing a true pandemic growth!