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"Too little too late" - The epitaph for SAGE and advisory groups concerning COVID-19 .

Summary

This information predominantly relates to evidence available in March around use of face masks in the general population; divided into sections: background , evidence for general use of masks , preventing spread, medical press articles, modelling, risk in community and need for better quality masks, public health information and compliance, conclusion and recommendation for the future. Two incidental areas are mentioned concerning SAGE'S decision making ability concerning anosmia and the statement made twice that efforts to completely suppress the virus would lead to a second wave. For each section relevant questions that should be asked are in red with supplementary information in blue.

Introduction

I am submitting evidence primarily in relation to the scientific evidence for the use of face masks in the general population. However, I will touch on other areas of concern as a result of reading the published minutes of SAGE.

I write with a background of 34 years of clinical experience working as an ENT surgeon, having worked with the clinical risk of viruses such as hepatitis, HIV, swine flu , SARS and prion CJD , including laser surgery where is a risk of papilloma virus infection, requiring FFP3 masks with a 0.1 micron filtration. I was extremely concerned by the policy produced in relation to general non-use of masks from the beginning of March which seemed to defy logic and have published two papers on why the general population should be wearing masks, both forwarded to the Dept. of Health and Scottish government, one at the beginning of April and the other at the beginning of May. The WHO also need to be strongly criticised for contradicting its own 2019 document concerning influenza which states regarding influenza ,'Face masks worn by asymptomatic people are conditionally recommended in severe epidemics or pandemics, to reduce transmission in the community.' The government could take comfort in that they were broadly following WHO guidelines concerning masks in the population, however, this was not 'following the science.'

Reference - WHO Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza . 2019. Licence: CC BY-NC-SA 3.0 IGO. https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf

In the UK compulsory face covering in public transport was only from 15th June which is three months later than needed.

SAGE did not advise all precautions and measures to protect the British population .

In the minutes there is very little evidence of scientific discussion in the meetings for a policy that is described as, 'following the science.

From the minutes of SAGE meetings on two occasions, the 13th March and repeated again on 19th, a point was made which is of concern:

' SAGE was unanimous that measures seeking to completely suppress spread of Covid19 will cause a second peak. SAGE advises that it is a near certainty that countries such as China, where heavy suppression is underway, will experience a second peak once measures are relaxed.'

This implies that the directions from SAGE were such that not all possible measures to reduce COVID-19 infections in the UK were considered or advised.

Question 1 - What evidence is there that completely suppressing Covid-19 would cause a second wave and did this underly the low key approach to supressing Covid-19 in the UK ?

Question 2 - From a policy of not fully suppressing Covid-19 how was the risk of excess deaths calculated as a trade-off compared to the theoretical possibility of a second wave

If the numbers are kept low any second wave would be controlled more easily with general use of masks , social distancing and test and trace .

There has been no evidence of a second wave and particularly in Hong Kong , a country which has relied on social distancing and masks avoiding lock down , with 7 million population there have been 4 deaths which had not changed until the end of June .

In the Spanish Flu pandemic 1918-19 which spread extensively throughout the world , although there were some attempts at measures such as social distancing, the virus spread more or less unchecked and unsuppressed but there were 3 waves .

Question 3 - Did the statement/conclusion concerning theoretical risk of a second wave by too much suppression lead to the bizarre policy statement that Covid-19 would be allowed to spread throughout the population with an estimated 80% of the population being infected and resultant herd immunity ?

The only concern seemed to be of reducing the peak , spreading the cases over a more prolonged period so that the health service could cope . With a 1 % mortality this would mean approximately 500,000 deaths. Was this policy acceptable ?

Question 4 – Relating to lack of suppression, was this related to the fact that 1000's of people were allowed to return from endemic areas in Italy largely unchecked ? Should all those returning from endemic areas at border control have been supplied with masks and asked to self-isolate for two weeks ?

ANOSMIA - evidence of SAGE's inability to reach timely decisions

The first point is that the evidence shows that SAGE under guidance from NERVTAG appears to have significant shortfalls in relation to making decisions.

Regarding anosmia ENT-UK informed the Public Health England that this is a prevalent symptom on 24th of March. The ENT-UK position paper advised that people with anosmia should self-isolate. Anosmia in absence of rhinological disease is extremely rare . The evidence is that no practical action was taken other than 'looking into it ,' for two months giving the appearance of an academic exercise.

Chief Scientific Adviser Sir Patrick Vallance admitted at the briefing on Monday 30th March that "Loss of taste and smell is something that can happen with other respiratory viruses as well. It does seem to be a feature of this from what people are reporting and it is obviously something that people should take into account as they think about their symptoms." We would argue that there is now enough evidence to take this symptom much more seriously.

Professor Van Tam : 18th May

'And that's why we have taken our time in this country because we wanted to do that, again, painstaking and very careful analysis before we jumped to any conclusions. And even if it was obvious that anosmia was part of this, we wanted to be sure that adding it to cough and fever, as opposed to just listing it, adding it in formerly into our definition, was the right thing to do. And based on advice from NERVTAG, we have made that decision.'

Question 4 - Why was SAGE's decision making so slow and were they aware of the urgency?

This 2 month delay is with the backdrop of 600 to 1000 people dying per day .

It does appear that the advisory committees were overburdened by scientists and academics when decisions were needed often without any existing evidence base or protocols.

Question 5 - Should there have been more full-time actively acute practising clinicians such as intensive care specialists, infectious disease consultants and clinical virologists in SAGE/NERVTAG ?

Face Masks

Background

It important to be clear that masks work and are highly effective, otherwise they would not be used in hospitals and hazardous environments such as those dealing with biological or neurotoxic agents, noting that a respirator is simply a more advanced form of mask. Masks will act at the three aspects of transmission to greater or lesser degree for aerosol or airborne

particles, all will reduce larger droplets, which in turn reduces contamination of fomites that subsequently might be touched leading to infection .

Concerning aerosol spread, this is a case for better quality masks, in reality there is not a strict cut off between droplet spread and fine airborne aerosol particles which has been known since Wells's classic paper from 1934 that showed that many of smaller droplets evaporate before falling and become airborne droplet nuclei. Some individuals produce high amounts of aerosol when speaking and also breathing (which may account for super-spreading). The 2 meters distancing is based on how far larger droplets can spread and will have some effect on airborne reduction but is more limited in enclosed areas.

SAGE 28th January minutes . Reasonable Worst-Case Scenario (RWCS) 24. There are a number of scenarios that this outbreak could follow, depending on virulence and transmissibility. 25. The current RWCS is similar to an influenza pandemic where no vaccine or specific treatment is available. 26. The RWCS for the UK should be based on a reproductive number of 2.5 (middle of current estimates) and should assume that some of those who have returned from China are infectious. 27. SAGE also agreed that the UK RWCS should be based on pandemic influenza planning.

For other beta corona viruses, SARS and MERS there were multiple cases subsequently found to be caused by aerosol spread, which is also the case with other respiratory viruses such as influenza. In view of this it is reasonable to make inferences from available literature and applying this to a Covid-19 together with new information such as that showing the wide distribution of virus in infected patients' rooms meaning airborne spread is likely, of which a preprint was published in March.

Santarpia J L, Rivera D N, Hererra V, et al. Transmission Potential of SARS-CoV-2 in Viral Shedding Observed at the University of Nebraska Medical Centre. (accessed 2020). preprint from the University of Nebraska Medical Center.https://www.medrxiv.org/content/10.1101/2020.03.23.20039446v1.full.pdf

It is true that there is a lack of good studies concerning public wearing of masks in epidemics and more especially pandemics. Limitations occur such as trial design, and variation in types of mask. Most studies concerning community wearing of have encountered problems making results inconclusive including the few randomised controlled trials (RCT's), often only addressing spread in the home setting or in residencies such as student halls, not surprisingly with compliance problems. One study crucially found a significant benefit for those that were compliant. The overall finding is that on balance the evidence is in favour of a benefit from public wearing of masks, and was the conclusion in of the Public Health England review 2011 and a similar review by the Dept. of Health 2013, that there is evidence with good compliance in efficacy in health care setting and in the community. Masks in the community were not recommended, however, which presumably is related to compliance and cost effectiveness but noting this is in relation to an influenza epidemic situation. The studies analysed were only behavioural and did not consider the substantial laboratory studies on efficacy. In fact, there was substantially more evidence for use of masks than lockdown in February.

Importantly there are differences between Covid-19 and seasonal influenza in relation to mask wearing :

1. Although rapid spread of Covid-19 (SARS-CoV-2 virus) is similar to other respiratory viruses and influenza main point is that the R number unchecked was 3 to 3.5 .

Estimating the Reproductive Number and the Outbreak Size of COVID-19 in Korea Epidemiol Health 2020;42:e2020011. doi: 10.4178/epih.e2020011. Epub 2020 Mar12

2. The mortality rate for seasonal influenza is 0.001 % and for Covid-19 from initial reports, was 1 to 3% which is 1000 to 3000 times more .

3. Compliance is affected by many factors and can be increased significantly when the individual perception of risk increases , also guided by communicating an effective public health message .

Sim S W, Moey K S, Tan N C. The use of facemasks to prevent respiratory infection: a literature review in the context of the Health Belief Model. Singapore Med J. 2014;55(3):160–167. doi:10.11622/smedj.2014037

Evidence for masks in community

Successful strategies in other countries

Comparing London: 9m population with 6000 cases by May (1 in 1,500) to Hong Kong: 7.4m population 4 cases (1 in 1.85 million), just under 1000 times less.

The minutes show consideration of evidence from China for social distancing and lockdown being effective but there is no mention of masks .

Sage minutes. 25th February. Measures to limit spread 9. Interventions should seek to contain, delay, and reduce the peak incidence of cases, in that order. Consideration of what is publicly perceived to work is essential in any decisions. 10. SAGE discussed a paper modelling four non-pharmaceutical interventions: university and school closures, home isolation, household quarantine and social distancing, including use of interventions in combination. 11. All measures require implementation for a significant duration in order to be effective. 12. Evidence from social distancing and school closures implemented in Hong Kong, Wuhan and Singapore indicates that these measures can reduce the Covid-19 reproduction number to approximately 1 (a 50-60% reduction). Reduced spread in the UK through a combination of these measures was assessed to be realistic. 13. Any combination of measures would slow but not halt an epidemic.

Question 6 - What is the evidence for statement 13 if using all the measures used in East Asia ?

There is no evidence to separate an individual component from a successful strategy . The policy of the countries with best control involves masks or facial coverings and these countries have strikingly lower rates of infection particularly with early introduction. A confounding factor may be time to lockdown but Hong Kong , Taiwan avoided lockdown.

Question 6 - What evidence is there for taking masks out of a successful strategy implemented in East Asian countries ?

General use of masks should be implemented before lockdown and would also be a more cost effective strategy. One immediate problem apparent is that there was no provision by stockpiling of masks for public use. The most effective time for introducing mask wearing is before the exponential rise, reducing new cases sufficiently so that contact tracing can work and is not overwhelmed.

If use of masks shortened lockdown by only a few days, the cost of providing a supply to most of the population would be cost effective.

Approximate Cost of 1 week of UK Lockdown v Masks

Cost lockdown - 10.4% fall in UK GDP Feb to April 2020
UK GDP 2019 £2.21 trillion
Weekly fall UK GDP during lockdown (2.21 x 10.4)/ 52 x100 = £4420 million
Cost of 5 surgical masks £0.5x 5 for 60 million population plus £1 distribution = £210 million

Preventing spread

Super-spreaders may be related to individuals that produce large amounts of aerosol when breathing up to 10,000 particles per litre. Asymptomatic spread of infection was known from work available online in mid-February and published in March .

Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV2)March 2020 Science 368(6490):eabb3221 DOI: 10.1126/science.abb3221

On the 13th Feb. SAGE concluded that neither travel restrictions within the UK nor prevention of mass gatherings would be effective in limiting transmission.

Patient 31 in S. Korea was identified on the 16th of February infecting over 100 people at a mass gathering .

On the 5th March SAGE agreed there is no evidence to suggest that banning very large gatherings would reduce transmission.

Many institutions stopped mass gatherings before government advice .

Super-spreaders and asymptomatic spread are additional factors mandating the general use of masks early on.

Media coverage

On the 9th April BMJ editorials concerning mask use and cloth masks as alternative including the paper by Professor Greenhalgh et al. mentioning the precautionary principle .

Greenhalgh G , Schmid M B , Czypionka T, Face masks for the public during the covid-19 crisis BMJ 2020; 369 doi: https://doi.org/10.1136/bmj.m1435 (April 2020) Cited as: BMJ 2020;369:m1435.

Question 7 - Why was the first consideration of masks by SAGE not until 14th April and only after SAGE policy being questioned in the medical press ?

The precautionary principle is when there is an inadequate evidence base for making a decision but the decision to do nothing risks considerable harm.

A similar situation would be crossing a road. There is no high level evidence that keeping your eyes open is beneficial but there are anecdotal reports of people not looking being knocked down. Do you need a high level evidenced study to conclude you are better crossing a road with your eyes open compared to being closed when there is no disadvantage from keeping your eyes open and it is easy to do ?

Concerning masks there is no proven disadvantage . The only valid point is that deaf people will not be able to lip read but needs to be put in the context of risk to life .

Hand hygiene issues, such as touching the mask with unclean hands, means public educational information is needed and similarly advice on fitting (which has been lacking in the UK) . Concerning other proposed disadvantages such as increase in risky behavior, there is no evidence of this in countries that have high mask usage. The argument is similar to the compulsory wearing of seat belts where there is no evidence of increased risky driving behaviour.

There are some individuals with respiratory disease that would find using a mask difficult but the more people using masks will provide more protection for them and if necessary powered respirators are available. Lazzarino's proposed increased respiratory rate secondary to CO2 retention from the mask causing increased dispersal of respiratory particles to those

unable to wear mask, for instance with COPD, can be disproved by taking a person with COPD and no mask and respiratory rate of 12 litres/min, together with an infectious person wearing an FFP3 mask the respiratory rate would have to increase more than 4 times to be more infectious than normal breathing and no mask. A mask would not be tolerated for long if causing a fourfold increase in respiratory rate.

One misquoted study shows cloth masks allow more infections compared to medical masks in the healthcare setting and that cloth masks were worse than the control group but as most of the control group used medical masks there is no study showing that cloth masks are worse than no mask. (A cluster randomised trial of cloth masks compared with medical masks in healthcare workers C Raina MacIntyre 2015 BMJ Volume 5, Issue 4).

As viruses cannot multiply on a mask there is no exposure situation where wearing a mask can be worse than not wearing one, although it does make sense to keep the mask clean and dry to maintain efficiency and prevent bacterial or fungal colonisation.

Protection against eye risk is not a case against masks. Eye risk is considerably lower compared to inhalation, taking the surface area of the lungs (the size of a tennis court) to the surface area of the eyes. Eye contamination is more likely when close to someone from droplets and in this situation a minimum of everyone using a basic mask and hand hygiene, similar to precautions needed in commercial food preparation, will help to reduce eye contamination risk.

Higher efficiency masks can be more difficult to tolerate for long periods especially in humid environments, however, surgical masks are easy to wear for long periods and the combined effect of everyone wearing one giving a 17 times reduction in infection risk is not insignificant.

Barr, G.D. (2020). A simple model to show the relative risk of viral aerosol infection and the benefit of wearing masks in different settings with implications for Covid-19 . *medRxiv*.

Modelling

The models published by the Dept. of Health did not mention masks .

Tracht's model showed that for Influenza, N95 masks at 50% compliance would give over 30% reduction in cases . Early intervention before the exponential rise is more beneficial and at this juncture the effect of general mask wearing would be even more marked. This together with other measures such as social distancing can keep numbers low enough to allow contact tracing and isolation to work. It is possible with 70% compliance and good quality masks 50% or more cases could be avoided.

Tracht model 29. Tracht S M , Del Valle S Y , Hyman J M . Mathematical Modelling of the Effectiveness of Facemasks in Reducing the Spread of Novel Influenza A (H1N1) PLoS One. 2010; 5(2): e9018. doi: 10.1371/journal.pone.0009018

Mniszewski S M, Del Valle S Y, Priedhorsky R, et al. Understanding the Impact of Face Mask Usage Through Epidemic Simulation of Large Social Networks. Theories and Simulations of Complex Social Systems 2013;52:97-115. Published 2013 Oct 27. doi:10.1007/978-3-642-39149-1_8

Question 8 - Why did the modelling used not include use of masks ?

Argument for better quality masks for public use

SARS and MERS were found to spread by aerosol transmission, both the government advisors and the WHO acknowledged that there is an aerosol risk in hospitals. The virus is the same within and without hospitals, if aerosol spread can happen in hospital it can happen anywhere ; there is simply a higher concentration of risk in certain situations.

As the virus is the same there is no reason a mask should be effective in hospitals but not in the community. 45000+ people did not die simply because they did not wash their hands, but each one was in a situation exposed to significant risk.

Question 9 - How many could have been saved by others and themselves wearing masks ?

Early introduction is likely to have saved somewhere between 1000 and 22000 deaths, with better quality masks being nearer the higher range .

In the absence of good quality masks being available for the general public cloth masks or facial coverings are a second best, however, the latter are low cost without disadvantage although their limitations need to be emphasised.

Public Health information and compliance

The first advert in Scotland mentioning face coverings was on the 5th June noting Scotland has generally been ahead of the rest of the UK in relation to masks.

The public health information appeared weak from the start. In answer to repeated questions from journalists about general mask wearing the reply was consistently that the public do not need masks . There are some that would take this to mean Covid-19 can only be contracted by poor hand hygiene.

Compliance has been a problem in western countries even as far back as the Spanish Flu pandemic on the other hand masks have developed significantly since then. The health belief model shows perception of risk of death and to health are important factors in compliance and also when livelihood becomes affected.

In Hong Kong during the SARS epidemic the public mask usage was around 65% , but for asymptomatic individuals as low as 21.5% for H1N1 [41] rising to over 95% for Covid-19 .

A strong and consistent public health message is needed such as the campaign in Czechia, with visual media messages, " I protect you, you protect me," also introducing the compulsory public wearing of masks in March. This compares to the USA and UK where for weeks even after the exponential rise in cases and hospitals being overwhelmed the official message was that masks were not needed. Not surprisingly this has to led to a relatively low compliance.

Protection by face masks against influenza A(H1N1)pdm09 virus on trans-Pacific passenger aircraft, 2009. Emerg Infect Dis. 2013;19 (9) :1403-1410. doi:10.3201/eid1909.121765

Question 10 - Why were masks not advised on public transport or anywhere social distancing was not possible, including care homes and other confined areas at the start of lockdown?

Images were seen on national news of key workers crammed into the London underground or buses and shops with queues of people not distanced. Care homes are a prime example of close contact with carers needing protection and other high risk situations such as cleaners of toilets . This would explain the prolonged peak of Covid-19 cases in the UK with little fall in the number of daily new cases for 6 to 7 weeks despite lockdown.

In addition to a strong public health campaign provision of masks for the general population is also a way of increasing compliance.

Question 11 - What advice was followed to have no stockpiles of masks for the general population?

Conclusion

The default position given the evidence available in February should have been that masks in the general population should be advised unless evidence appears to the contrary, which has not been the case.

Question 12 - Face coverings or cloth masks although less effective are easy to implement and a risk free alternative. Why were facial coverings advised on public transport only from the 15th June and not the beginning of March when the same evidence was available ?

Future

Encouraging mask use such as in influenza epidemics for public transport, in shops and care homes could reduce morbidity and loss to the economy from sickness absence .

Stockpiles of surgical masks for the population are necessary for epidemics or pandemics with significant morbidity or mortality and need to be implemented early on. Logistically this could be achieved by gradually building up a national stockpile which supplies the Health Care Sector's needs with the amount used each year being replenished. Manufacturers extending the shelf life to 7 years or longer from 5 years would aid this. In addition, this could be supplemented by encouraging as many people to have good quality

masks in their households once supplies are back to normal, through efficient and sustained public health information, similar to advice on smoke alarms. This at first might seem excessive, but if carried out correctly could be done in a cost efficient manner. Any reluctance can be countered with the “What if “ question , what if the next pandemic has a 90% mortality ?

G Barr July 2020