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March 19, 2020 (updated March 31. 2020)

A Consideration of the Rationale Provided to Downgrade PPE Precautions for COVID-19

Given the many discussions over the last few weeks around the airborne transmission of the COVID-19 virus, we thought it would be appropriate to review the evidence for the case against airborne transmission. Using the rationale as the PHO published on their website: https://www.publichealthontario.ca/-/media/documents/ncov/wwksf-routes-transmission-mar-06-2020.pdf?la=en ("COVID-19 – What We Know So Far About... Routes of Transmission", March 6, 2020) we will consider the evidence to date for the following statements:

1. "WHO China Joint Mission on COVID-19 summarizing 75,465 cases indicates that airborne spread has not been reported"
2. "The absence of significant clusters in other settings *[outside of households]* suggests that the mode of COVID-19 transmission is not airborne." *[added explanation]*
3. "active follow-up of individuals exposed to first ten cases of COVID-19 in the United States describes secondary transmission only to close household contacts."
4. "Healthcare workers caring for COVID-19 patients in other jurisdictions, including British Columbia, have not acquired COVID-19 while using Droplet and Contact Precautions recommended in the province." (*citation is a newspaper article*)
5. "The lack of transmission to passengers seated nearby cases who have travelled on airplanes, does not support an airborne transmission route of COVID-19."
6. "In two studies conducting air sampling around confirmed cases, COVID-19 has not been detected."
7. RCT's (randomized control trials) comparing surgical masks to N95's have not proven additional protection under actual use conditions
8. N95's are uncomfortable and healthcare workers infect themselves when donning or doffing them via contact transmission

Rationale #1: WHO reports say there is no airborne transmission: Lisa Brosseau pointed out an insightful article in Wired (https://www.wired.com/story/they-say-coronavirus-isnt-airborne-but-its-definitely-borne-by-air/) that highlights some of the misunderstandings when it comes to the terms airborne transmission. For the infection control folks the term airborne transmission is reserved for diseases that are predominately transmitted by aerosol (small particles less than 5-10 microns in diameter that don't quickly settle out of the air like larger droplets do). The two main diseases

recognized as primarily being transmitted via the airborne path are measles and TB. These pathogens can remain in the air for long periods of time and ventilation systems can carry them to people who can get infected by inhaling them even if they aren't in the same room. It appears when the WHO says that the transmission of HCov-19 (the virus that causes COVID-19) is not airborne, they mean that it is not carried by air currents for distances beyond 2 meters and then infecting those inhaling these particles who are located further than 2 meters from the source. What the WHO report (Feb 28 2020) actually says is:

> "COVID-19 is transmitted via droplets and fomites during close unprotected contact between an infector and infectee. Airborne spread has not been reported for COVID-19 and it is not believed to be a major driver of transmission based on available evidence; however, it can be envisaged if certain aerosol-generating procedures are conducted in health care facilities." (page 8)

The Report recognizes that when it was written all the information is not yet in and that things could change – it seems the WHO document is much more tentative about its conclusions than the Canadian infection control people, who seem confident that the "jury is in".

The distinction between droplet and aerosol is sometimes defined by particle size. The dividing line in particle size is somewhat debatable but generally aerosols are defined as particles with a diameter of less than 5 micrometers (<5 μm) which can remain airborne for a significant period of time; and it is usually agreed that particles larger than 20 μm are considered droplets which usually settle out of the air within 1-2 meters of the source (the patient?). The "gray area" in between 5-20 μm is where there is some discussion and difference of opinion – it is the cross-over size between droplet and aerosol. Although the main principle is the smaller the particle the longer it stays in the air and the further it travels, however, air currents, traffic, relative humidity, ventilation design, etc., can also play a role in assisting or hindering these in between sized particles from travelling distance beyond 2 meters.

As the Wired article points out, the problem seems to be in the "all or nothing" definition of aerosol transmission. So we have three categories, and the tendency has been to pick a category (maybe two e.g. contact & droplet) and assign protective measures accordingly. However, as Mark Nicas & Rachael Jones so elegantly showed in their modelling paper (Nicas & Jones (2009) - Relative Contributions of Four Exposure Pathways to Influenza Infection Risk) a better way of looking at the problem of transmission is to assume that all infectious agents can theoretically be transmitted along all the pathways and that the job of researchers is to quantify what proportion of the transmission follows each path (e.g. as per Nicas & Jones (2009): 31% hand contact; 17% inhaled aerosol; 0.5% inhaled droplets; and 52% spray of droplets onto facial membranes under one set of assumptions, and 93% hand contact; 0.04% inhaled aerosol; 3.3% inhaled droplets; and 3.7% spray of droplets onto facial membranes under the opposite extreme assumptions). Thus, if we can apportion the amount of transmission along the different pathways, such information would help us design more appropriate protective strategies.

Unfortunately, such information may not available during the early stages of an outbreak, thus we are left with uncertainty as to what proportion of transmission follows which path. In fact, even when we are well past the outbreak, researchers are still arguing about the proportions of transmission along the different routes of exposure (e.g. the differences of opinion regarding the transmission of SARS, MERS and 2009 nH1N1). Mark Nicas' point in his letter to the editor (Nicas (2004) - SARS respiratory

protection JOEM letter) was that when we don't know the proportion of the transmission along the different paths, the best protective assumption is to assume the possibility of all paths of transmission. He goes on to say that if you assume the possibility of an aerosol exposure pathway then the appropriate level of personal respiratory protection is the PAPR because the N95 having a protection factor of 10 may well allow a sufficient dose of virus through in certain exposure conditions.

Samira Mubareka and her colleagues (from Toronto) have published a couple of papers (Mubareka, Astrakianakis, Scott, et al (2015) - Influenza virus emitted by naturally-infected hosts in a healthcare setting; and, Yip et al (2019) - Influenza virus RNA recovered from droplets and droplet nuclei emitted by adults in an acute care setting), measuring airborne virus in hospital settings. NIOSH has been doing this kind of work for at least 10 years (they loaned Samira their equipment for one of the studies). There is no scientific doubt that using air sampling and PCR you can measure and find virus RNA in the air in hospitals. The argument lodged against this sampling is that just detecting virus RNA is not equivalent to measuring viable virus – for instance you might be measuring pieces of broken viruses floating in the air which are no longer capable of infection or there may be insufficient viral material to cause an infection. This may well be true but no one so far has been able to tell us what percentage of the virus RNA detected in air samples belongs to non-viable viruses (is it 5% or 95% or ??). Again we're left with uncertainty, so what assumptions do we make in the face of this uncertainty.

Lisa Brosseau also recently published a viewpoint article which reviewed the nuances on aerosol particle generation and dispersion (http://www.cidrap.umn.edu/news-perspective/2020/03/commentary-covid-19-transmission-messages-should-hinge-science). There is also a very good TED talk on the topic by Lydia Bourouiba, Disease Transmission Scientist,(https://youtu.be/fJ1NN0HZWcQ) titled "How diseases and epidemics move through a breath of air".

In Hong Kong a group of researchers collected air samples for over two years and tracked the measurements against the regular flu seasonal activity on a university campus (Xie et al (2019) - Detection of Influenza and Other Respiratory Viruses in Air Sampled from a University Campus - A Longitudinal Study). They were able to track differences in airborne viral RNA with the flu season and actually the airborne levels of particular viruses spiked just before periods of increased flu activity in the population – thus suggesting that such measurements might be a proactive way of predicting flu activity. So, even though we don't know how much of the airborne virus RNA represents viable aerosol borne virus, the fact that airborne viral RNA correlates with flu activity (not just quantity but also the corresponding species of virus) suggests that airborne measurements correlate with population flu activity (even having possibilities of being a leading indicator).

The large number of papers on the measurement of airborne virus strongly suggest that this is a pathway not to be overlooked. In fact, the paper by Yin et al (2019 – which includes Allison McGeer, James Scott and Samira Mubareka, as co-authors describing research done in Toronto with the help of NIOSH (and published in the Journal of Occupational and Environmental Hygiene)) has the following few sentences on this topic:

> "The conventional paradigm is to classify respiratory pathogen transmission as droplet vs. airborne, with clear policies and procedures for each purported mode of transmission. Where there is doubt, both droplet and airborne precautions are generally employed. Large respiratory droplets are >10 μm in diameter and are involved in short-range (<2 m) droplet spread. Droplet nuclei are ≤5 μm and are responsible for short- or long-range (>2 m) airborne transmission;[15] these respirable particles are small enough to be inhaled into the alveoli. The relative contribution of each route to overall

> transmission of influenza is unknown, leading to debate regarding the important mode(s) of transmission and appropriate means of transmission prevention." (page 342)

The particular sentence that is pertinent to this discussion is: "Where there is doubt, both droplet and airborne precautions are generally employed."

The WHO in its updates (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/) have focussed on controlling coughing and sneezing emissions (droplets), however, NIOSH researchers have shown (Lindsley et al (2016) - Viable influenza A virus in airborne particles expelled during coughs versus exhalations) that while it is true that a cough expels more virus than talking and breathing, "Because individuals breathe much more often than they cough, these results suggest that breathing may generate more airborne infectious material than coughing over time." (page 404). The size of the particles collected were ≤ 10-15 µm.

There are also conjectures (Wu & Zha (Mar 12 2020), "Association of COVID-19 Disease Severity with Transmission Routes and Suggested Changes to Community Guidelines") that the virus can infect in three different locations and considered the implications:

> "We found that direct lung infection is the most lethal transmission route followed by bronchi infection. Transmissions by physical contacts, foods, and blood by low viral concentration (as expected in normal human activities) pose lower or much lower risks unless the infection is followed by subsequent lung exposures."

Thus, there is plenty of evidence from other viruses that airborne (<5 µm aerosol) transmission is likely (although the proportion in relation to contact and droplet is not agreed upon). Thus, to leave out the possibility of airborne transmission would seem counter to an evidence-based approach.

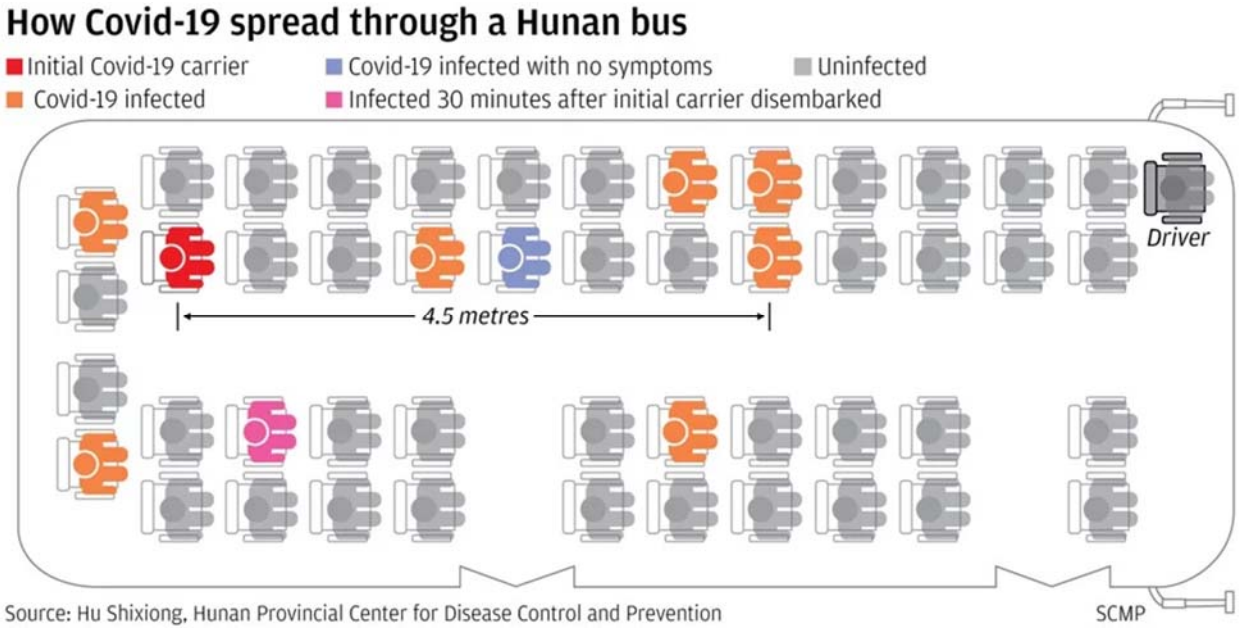
The H&S approach to uncertainty is to prepare for the worst case scenario and adjust your protective measures as the uncertainty diminishes. This was the argument at the Campbell Commission and Archie Campbell was quite clear that we're supposed to be using the H&S logic (i.e. the precautionary principle). So the issue comes down to evidence (or more likely "the lack of"). What we do have evidence of how this virus (or other previous outbreak viruses) are transmitted?

The evidence provided by the Public Health Ontario can be characterized as "proof by absence of evidence" – **rationale #2 – #5** all show that other routes of transmission could account for transmission and thus by default airborne transmission cannot account for the infections. This is a logical fallacy which is characterized as "Absence of evidence is not evidence of absence". This is most easily demonstrated with rationale #4 (the citing of a newspaper articles that says no healthcare worker had yet contracted COVID-19). The rationale being (as stated by the infection control people) since no healthcare worker had been infected the current level of protection (which included surgical masks) was obviously sufficient. However, since then at least 6 BC healthcare workers have contracted the virus, thus where does this leave the argument

Rationale #2 states: "The absence of significant clusters in other settings suggests that the mode of COVID-19 transmission is not airborne.", other settings being settings other than household settings. However, this begs the question how can we rule out any possibility that airborne transmission does not occur in households? Especially later on in the outbreak after people had been educated and adopted

droplet and contact precautions, would this not eliminate all transmission? The objection could be raised that if any transmission did occur among persons practicing droplet and contact precautions, then it must have been due to the fact that they didn't practice those precautions properly – but this is the classic "begging the question" fallacy – i.e. assuming your conclusion and fitting all the evidence to support it. The classic "other setting" was the Diamond Princess cruise ship docked in Japan. Rocklöv et al (Feb 24 2020) calculated the basic reproduction number R_0 (the number of new cases infected from an original case) for the outbreak on the ship ("COVID-19 outbreak on the Diamond Princess cruise ship: estimating the epidemic potential and effectiveness of public health countermeasures" (Feb 24 2020)), and derived an R_0 of 14.8 based on the data from January 21-25, 2020. After measures of isolation and protective practices and PPE were instituted the R_0 was reduced to 1.78. The question that demands answering is how can such a high rate of infection be explained by droplet and contact transmission only when the basic reproduction number in Wuhan was estimated to be around 4 – 5 (and in most of ther places seems to be 2-3 before interventions take effect)? Secondly, if under isolation and hygiene practices the R_0 is still above 1.0, how is the virus being transmitted? Again, the argument is given that obviously precautions were not strictly followed (again, begging the question).

Recently a detailed investigation was made of a series of infections which occurred on a long distance bus ride. Luo et al (Feb 17 2020 – "An epidemiological investigation of 2019 novel coronavirus diseases through aerosol-borne transmission by public transport" – *this paper has since been retracted but no reason given for the retraction*) showed how other passengers as far as 4.5 meters away from the index case were infected presumably through air transmission (all those who wore masks were not infected). The South China Morning Post (https://www.scmp.com/news/china/science/article/3074351/coronavirus-can-travel-twice-far-official-safe-distance-and-stay) provided an artist enhanced drawing of the paper's diagram of the bus and the locations of the index case and the subsequent cases:



This evidence challenges **rationale #5** which suggests that there hasn't been any evidence of airborne transmission in airplanes, however, a paper was recently published that investigated transmission

among airplane passangers and suggested the aerosol transmission was a possibility (Yang et al (Mar 30, 2020) “In-flight Transmission Cluster of COVID-19 - A Retrospective Case Series”).

This evidence, along with other lines of evidence seemed to have caused the National Health Commission of China to change the sixth version of the guidance for diagnosis and treatments for COVID-19 by stating that SARS-CoV-2 was transmitted through respiratory aspirates, droplets, contacts, and feces, and aerosols transmission. In one of their English translated materials (http://www.chinacdc.cn/en/COVID19/202002/P020200310326809462942.pdf) the National Health Commission states:

> “Once there are virus carriers, it is easy to cause human-to- human transmission, especially in crowded public places with poor air mobility, such as shopping malls, restaurants, cinemas, Internet cafes, KTV, stations, airports, docks and exhibition halls.” (page 1)

Rationale #3 is a classic example of jumping to conclusions too soon (the faulty generalization fallacy). Based on the first 10 cases found in the US, it is concluded that only household transmission occurs (and the underlying assumption is that household transmission excludes airborne transmission although this has not been proven). As of Mar 29, 2020 the CDC reports there are 122,653 cases in the US, and it will take a while to determine how the disease is being transmitted (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html). It seems rather brash to make a conclusion based on the first 10 US cases.

Finally, two studies are cited as proving that the virus has not been measured in air samples. A study by Ong et al (Mar 3, 2020, “Air, Surface Environmental, and Personal Protective Equipment Contamination by SARS-CoV-2 from a Symptomatic Patient”) took 10 air samples over two days and could not detect any virus present in the samples. The other paper by Cheng et al (Feb 17, 2020, “Escalating infection control response to the rapidly evolving epidemiology of the Coronavirus disease 2019 (COVID-19) due to SARS-CoV-2 in Hong Kong”) documents 8 air samples, all of which were negative for the virus RNA. Interestingly this paper by Cheng et al., also documents the precautions used by healthcare workers and it recommends using N95’s for “caring for suspected or confirmed SARS-CoV-2”, “triage station” and “aerosol generating procedures”. It rather ironic that the PHO uses this paper as rationale for downgrading the protection for healthcare workers PPE from N95’s to surgical masks for the first two of the three exposure categories.

Since that time, other papers have been published which document the measurement of HCov-19 viral RNA in air samples. Jiang et al (Mar 2, 2020 “Clinical Data on Hospital Environmental Hygiene Monitoring and Medical Staff Protection during the Coronavirus Disease 2019 Outbreak”) found viral RNA in 1 out of 27 air samples collected; and Liu et al (Mar 10, 2020 “Aerodynamic Characteristics and RNA Concentration of SARS-CoV-2 Aerosol in Wuhan Hospitals during COVID-19 Outbreak”) found viral RNA present in 14 out of 28 air samples taken in areas including patient areas, medical staff areas (PPE removal room, a worker change room, an medical staff office and a hospital dining room) and in public areas (hospital pharmacy, outside air outside the hospital and 2 department stores). An even more recent study by Santarpia et al (Mar 26 2020 “Transmission Potential of SARS-CoV-2 in Viral Shedding Observed at the University of Nebraska Medical Center”). They collected a total of 163 samples (surface and air) and found virus in well over half of all samples taken. The authors summarized their finds as follows:

> "Recent literature investigating human expired aerosol indicates that a significant fraction of human expired aerosol is less than 10 μm in diameter across all types of activity (e.g. breathing, talking, and coughing; (18) and that upper respiratory illness increases production of aerosol particles (less than 10 μm; (19)). Taken together these results suggest that virus expelled from infected individuals, including from those who are only mildly ill, may be transported by aerosol processes in their local environment, potentially even in the absence of cough or aerosol generating procedures. Further, a recent study of SARS-CoV-2 in aerosol and deposited on surfaces, indicates infectious aerosol may persist for several hours and on surfaces for as long as 2 days (20). Despite wide-spread environmental and limited SARS-CoV-2 aerosol contamination associated with hospitalized and mildly ill individuals, effective implementation of airborne isolation precautions including N95 filtering facepiece respirators and powered air purifying respirator use adequately protected health care workers, in the NQU and NBU facilities, preventing health care worker infections."

Similar to the classic "black swan" argument (the proposition that all swans are white is valid as long as every swan you observe is white, but it only takes seeing a single black swan to prove the argument wrong), the assertion that there has been no viral SARS-CoV2 detected in air samples has been definitively disproven.

Putting aside the arguments, a review of the evidence so far show that in particular circumstances (e.g. a long ride on a crowded bus, perhaps conditions on cruise ships, etc.) airborne transmission seems to have occurred and thus is possible (as the Chinese authorities have recognized and the CDC and European guidelines acknowledge as a possibility to be cautious of and the WHO indicated that they are reconsidering). It is unlikely in most circumstances that it is the predominate mode of transmission, however, to state that scientific evidence has definitively ruled out any airborne transmission is patently contrary to the evidence and thus is not an "evidence-based" conclusion. This virus is obviously not in the "league" of airborne transmission of pathogens such as TB and measles. A wiser approach would be to recognize that it may transmit along <u>all</u> paths and the specific conditions of the situation will dictate which will be predominate. Airborne transmission is unlikely to be the predominant path of infection under most conditions but may be under some conditions. Jiang et al (Mar 2, 2020 "Clinical Data on Hospital Environmental Hygiene Monitoring and Medical Staff Protection during the Coronavirus Disease 2019 Outbreak") point out that aerosol transmission may actual be a path to contact transmission with aerosols settling on surfaces (farther than 2 m away from the source).

Rationale #7: RCT's have not demonstrated the efficacy of N95's over surgical masks: Many evaluations of surgical masks compared to N95's were not able to show a difference in laboratory confirmed influenza (even though there have been significant differences in some studies in the rates of ILI diagnoses – which begs the question which is the "gold standard"? or, what are we trying to prevent?). The problem of the early studies (and likely some of the later ones) is N95's were new and HCW's weren't accustomed to wearing them. Many of the studies didn't measure compliance and often workers were not fit-tested (let alone adequately trained). Even in later studies, these problems of training and donning and doffing techniques have not been adequately evaluated making the interpretation of the studies problematic. You can "cherry pick" the studies to support (fallacy of incomplete evidence) which ever conclusion you wish to assume as your proposition (i.e. begging the question fallacy). The way around these biases is to do a systematic review (however, these have also been shown to be vulnerable to bias by manipulating their study selection criteria or methods).

I know of three systematic reviews, most of which have come to the conclusion that the evidence (for or against) is of poor quality, so that the bottom-line is, that whatever the conclusion, the evidence supporting it is a weak. There are also systematic reviews that compared wearing masks to hand washing and found that handwashing was superior to masks in preventing infections (such as the recent: Jefferson et al (March 30, 2020) "Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing - systematic review and meta-analysis") – should this be interpreted as support for getting rid of masks all together (after all, if it's only droplets, a full face shield should be sufficient, why include a mask?)? Or, does it mean we have some work to do regarding respiratory protection programs, training and practice, as Lisa Brosseau demonstrated in her published work?

There seems to be no uncertainty about the capability of the N95 to provide better protection as demonstrated in the lab, however, the issue seems to come down to the ability of HCW's to properly use the N95 to fully take advantage of its superior protective capabilities. The problem with the argument against N95's is somewhat clearer if you consider the analogous situation with ear plugs. The small yellow foam earplugs have an NRR of 30 dB yet many workers only get less than 15 dB protection because they don't insert them properly, and/or don't wear them all the time, etc. Does this imply that we may as well provide the old cotton ear plugs (NRR of 15 dB) since they get about the same protection? The analogy isn't perfect since noise is only a single pathway of exposure, whereas virus PPE masks also involve the contact pathway (hence the importance of donning and doffing techniques as we learned with Ebola).

I also think some of the protective measures took a step backwards with MERS. South Korea had the largest MERS outbreak outside of Saudi Arabia. The researchers who looked at the transmission of MERS virus during that outbreak concluded (Kim et al (2016) - Extensive viable MERS coronavirus contamination in air and surrounding environment in MERS isolation wards):

> "These findings are consistent with previous studies that demonstrated survival of MERS-CoV for 2 days on plastic and steel surfaces [13], survival of SARS-CoV for 3 days on various surfaces [16], and survival of human CoV for 6 days in air [17]. Therefore, the extensive environmental contaminations and prolonged environmental presence of MERS-CoV may partially explain why MERS is easily spread in healthcare settings." (page 368)

Despite these observations, the protocols for MERS exposure focus only on contact and droplet transmission.

The experience in China, Taiwan, Hong Kong and Singapore indicates that rather than degrading the level of protection during the crisis they increase the level of protection. They began with the SARS/MERS levels of protection and increased then to the plague/cholera levels of protection. It seems ironic that Ontario/Canada would be degrading the level of protection before the crisis hit us here – the opposite response as compared to the Chinese when they were in the midst of their crisis.

The other issue to remember when discussing the surgical mask vs. N95 is that, as Mark Nicas pointed out and as we learned with AGMP's during SARS and 2009 nH1N1, that N95's may not be sufficient. While PAPR's were new with 2009 nH1N1, by the time Ebola came around, they seem to be accepted and more importantly HCW knew how to use them and knew the importance of cleaning them. The other issue to keep in mind obviously is the hierarchy of controls. The surgical mask vs. N95 is taking so much focus that we're missing other opportunities for prevention.

The Airborne Infection Isolation Room (AIIR) is an example of technical innovations that are further up the hierarchy of controls. I believe the CDC mentions them in their protocols.

Finally, **rational #8** – the argument that N95's are uncomfortable and healthcare workers infect themselves when donning or doffing them via contact transmission. The implied suggestion is that because healthcare workers are incapable of safely donning and doffing the N95's or PAPR's, we should downgrade their protection to surgical masks. Again, as mentioned earlier, if healthcare workers are not getting the full benefit of the PPE they are using, why is this the case? Could it be poor design of the PPE, wrong type, inadequate fitting and training, lack of familiarity (practice), poor program support, stigma/attitudes, etc.? In health and safety outside of healthcare, we have struggled with these issues and worked to resolve them in various innovative ways. If this is a problem in healthcare, do we simply accept defeat and adjust practice to the lowest common denominator. Given the amount of financial resources devoted to protective equipment for healthcare workers, surely there should be an incentive to find better PPE solutions to fit the requirements of healthcare workers to care or and protect patients. Using the engineering design principles mentioned above, surely we can address this problem with a problem-solving approach rather than a fatalistic one.

And last but not least, the precautionary principle, which seems so misinterpreted that both sides of the argument now claim to be invoking the principle. In health and safety outside of healthcare the practical principle suggests if you are uncertain about the hazard you employ maximum protection until you have more information to base your decision on. We still are in uncertain times, the suggestion that we are now certain that air transmission does not occur is in contradiction with the studies and guidelines published to date and thus is not an evidence-based decision and does not reflect adherence to the precautionary principle suffers from logical fallacies.

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March 19, 2020 (updated March 31, 2020)