In its January 28, 2020 interim guidance report, the World Health Organization advised caution when handling contaminated oxygen equipment, "Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e. contact with contaminated oxygen tubing/interfaces)." (1)

Mary McGoldrick, MS, RN, CRNI, is a 25 year veteran in the field of infection prevention and control in homecare and hospice. An expert in her field, she has published many books on infection prevention and control including the "Home Care Infection Prevention and Control Program Manual." She, too, has cautioned medical practitioners on the handling of oxygen equipment, "The nasal cannula prongs often become contaminated when patients don't properly protect the cannula between uses (i.e., leaving the nasal cannula on the floor, furniture, bed linens, etc.). Then the patient puts the contaminated nasal cannula back in their nostrils and directly transfers potentially pathogenic organisms from these surfaces onto the mucous membranes inside their nasal passages, putting them at risk of developing a respiratory infection." (2)

In medical studies, the nasal cannula is considered a fomite - an object or material likely to carry infection. However, while experts and common sense dictate that one follows the World Health Organization and McGoldrick's advice at home and in medical settings, there are few studies of nosocomial transmission that specifically include nasal cannulas. A rare example is this MERS study (3), in which 16 fomites (ie, stethoscopes, bag valve masks, blood pressure cuffs, nasal prongs, pillows, and keyboards) were swabbed and 13 tested positive for MERS-CoV. Further, the study said their findings were "consistent with previous studies that demonstrated survival of MERS-CoV for 2 days on plastic and steel surfaces."

This result is concerning as most nasal cannulas are made from PVC material (4) and coronavirus has been found to persist in an infectious state on PVC for at least five days (5). Influenza A and B viruses also survive on nonporous surfaces, such as plastic for 24 to 48 hours (6).

Circumstantial evidence of the role of fomites like nasal cannulas in viral transmission is strong. "Currently, laboratory studies, epidemiological evidence, and disinfection intervention studies have generated strong indirect and circumstantial evidence that supports the involvement of fomites as a vehicle in respiratory and enteric virus transmission." (7)

Numerous examples exist:

- "RSV is spread by close contact with infectious respiratory secretions inoculated into the eyes or nose either via large droplets or from fomites." (8)
- "After a 10-second exposure, 70% of rhinovirus was transferred from donor to recipient hands in the 1978 study by Gwaltney et al. Also, Gwaltney et al. demonstrated that subjects with cold symptoms had rhinovirus on their hands, and the virus was recovered from 43% of the plastic tiles they touched. Contaminated hands frequently come into contact with portals of entry, and so the potential for viral infection from contaminated fomites and hands exists." (9)
- "Investigations of disease outbreaks and disinfection intervention studies have
 documented indoor surfaces as reservoirs for pathogenic viruses with potential spread of
 infectious disease. Epidemiological studies have also identified fomites as a potential
 vehicle for disease transmission. Hygiene and disinfection intervention studies have

demonstrated two concepts that support transmission of viral infection via fomites. First, proper cleaning of hands decreases respiratory and gastrointestinal illness. Second, disinfection of fomites can decrease surface contamination and may interrupt disease spread (norovirus, coronavirus, and rotavirus). In addition, laboratory evidence from studies by Ward et al. (rotaviruses) (Hendley et al rhinoviruses) support viral transmission via fomites. Disease transmission via contaminated fomites has been proven or is suspected for all 10 enteric and respiratory viruses reviewed." (10)

 "Once a fomite is contaminated, the transfer of infectious virus may readily occur between inanimate and animate objects, or vice versa, and between two separate fomites." (11)

Handwashing and gloves are not enough protection from contaminated fomites. For example, "...The benefits derived from wearing gloves are offset if the gloves are not changed after contact with an infected patient or with contaminated fomites." 1197 CDC MMWR report (12).

Studies have changed the perspective on viral transmission to include a more complex multifactorial model of disease spread and there is increasing evidence that contaminated fomites or surfaces play a key role in the spread of viral infections. This makes sense as before, during, and after illness, viruses are shed in large numbers in blood, feces, urine, saliva, and, most importantly for our thesis, nasal fluid. According to this article in "Applied and Environmental Microbiology," (13) "If viruses remain viable on surfaces long enough to come in contact with a host, the virus may only need to be present in small numbers to infect the host. After contact with the host is achieved, viruses can gain entry into the host systems through portals of entry or contact with the mouth, nasopharynx, and eyes." The authors go on to note,

"Yet, fundamental knowledge concerning the role of surfaces and objects in viral disease transmission is lacking, and further investigation is needed."

Clearly, when a majority of respiratory viruses are enveloped (parainfluenza virus, influenza virus, RSV, and coronavirus) and can survive on surfaces from hours to days (14) introducing them into the nasal cavity by a nasal cannula is dangerous. For example:

- "Our results clearly demonstrate that the unwitting actions by both patients and healthcare workers potentially induce viable virus contamination of the surface of various environments and medical devices (X-ray machines, thermometers) around MERS patients." (15)
- "Influenza virus and SARS-CoV may be shed into the environment and be transferred from environmental surfaces to the hands of patients and healthcare providers.
 Emerging data suggest that MERS-CoV also shares these properties. Once contaminated from the environment, hands can then initiate self-inoculation of mucous membranes of the nose, eyes or mouth. Mathematical and animal models, and intervention studies suggest that contact transmission is the most important route in some scenarios." (16)
- This 2016 study (17) looked at 20 previously published between 1998 and 2014. It found that, even after cleaning, the most common pathogens found in hospitals were MRSA, VRE and C. difficile on bed rails, tray tables, call buttons, and other hard surfaces. "Several studies suggest that SARS-CoV, MERS, CoV and influenza virus have the capacity to survive on dry surfaces for a sufficient duration to facilitate onward transmission." The study called out the role of mucus in transmission "adding mucus increased the survival time of influenza dried on bank notes from hours up to 17 days"

and "In order for the virus to initiate indirect contact transmission, inoculation or contact with mucous membranes must occur to transfer sufficient viruses. Nasal inoculation is a frequent route for establishing influenza and SARS infection."

 "Among patients with HAP (hospital-acquired pneumonia), 20% are due to viral pathogens. Respiratory viral infections, especially influenza and respiratory syncytial virus affect mainly immunocompromised patients and nosocomial transmission is common." (18)

MERS (another type of coronavirus) can be spread through surfaces such as bedsheets, bed rails, IV fluid hangers, up to 5 days after the last positive detection in respiratory specimens after the patients are recovered. These are surfaces upon which nasal cannulas are placed by medical personnel and nurses.

The results from this study (19) show that a relatively low concentration of enveloped respiratory viruses may retain infectivity on common hard surfaces for longer than previously thought and may present a real risk of infection to anyone who contacts a contaminated surface.

"Surface contamination has recently been found to be more significant than originally thought in the spread of many diseases. Symptoms of respiratory disease often result in continuous recontamination of surfaces which are then touched, and infectious virus particles may be transferred to facial mucosa...Coronavirus persists in an infectious state on common surface materials for several days...There is scant information on minimum infectious doses, but for many respiratory viruses, the minimum infectious dose is believed to be low, i.e., just a few virus particles."

It is entirely possible that nasal cannulas placed on any of the studied surfaces could directly or

indirectly infect a patient or medical staff, especially if only a few virus particles are needed to

cause an infection.

Studies have shown that patients using oxygen at home take their nasal cannulas off at least

25% of the time to take a break, eat, walk indoors, take or take a bath or shower. Another

common reason is social shame - patients don't want to use it in front of other people.

(20)(21)

In addition, in this overnight study (22) of 30 postoperative patients who used oxygen masks or

cannula, the oxygen source was removed by patients 9 out of 15 times overnight.

It's reasonable to assume patients in hospitals during the daytime reflect these behaviors as

well. It's unknown how many times a day a nurse or medical professional removes a nasal

cannula from a patient to give care, however, we can assume it is a considerable number of

interactions based on the number of visits to US Emergency Rooms for care during which

oxygen may be initiated (23):

-Chest pain (heart attack, pleurisy, pneumonia, hypertension: 4,346,349

-Acute upper respiratory infection: 2,504,641

-Unspecified asthma: 907,744

-Acute bronchitis: 831,156

Clearly, there is significant opportunity for nasal cannulas that are not protected by the Nasal

Cannula Cover to be placed on a contaminated surface and then put in a patients' nose while

giving care. The problem is magnified when, in addition to the numbers above, the number of surgeries conducted in the United State's 9,280 ambulatory surgical centers, the 1.4 million citizens in US nursing homes and 1.5 million people who use oxygen at home are added. Now include the overwhelming number of patients using oxygen delivered through nasal cannulas during a pandemic. Then consider that 5% of all nosocomial infections have been attributed to viruses, and this figure is likely to be an underestimate (24). The number of opportunities for pathogens to contact nasal cannulas on surfaces we have already shown to be contaminated with viruses and then re-inserted into a patient's nasal cavity or the potential for nasal cannulas to indirectly infect others when placed on beds, bed rails, IV poles and flow meters is beyond the scope of this report. In short, it is possible that improper nasal cannula storage causes patients to get infections and to give them to unsuspecting medical personnel and visitors.

This coronavirus study called contact infection via a fomite to face transmission a mode of transmission that is potentially "incredibly" important and "overlooked" and outlines how such a virus transmission could, and probably does, happen:

- "(i) Someone with coronavirus coughs, emitting large droplets containing the virus. Droplets settle on surfaces in the room, creating a thin film of coronavirus. The virus may be shed in nasal secretions as well, which could be transmitted to the environment.
- (ii) The virus persists on fomites in the environment. Human coronaviruses can survive on surfaces for up to about a week. It's unknown how long COVID-19 can survive in the environment, but it might be even longer (some animal coronaviruses can survive for weeks!).
- (iii) Someone else touches the contaminated surface hours or days later, transferring the virus to their hands.

(iv) If the hands touch a mucous membrane (eyes, nose, or mouth), this may transmit the infection." (25)

Substitute nasal cannula for hand or glove and you can begin to see the scope of the problem and why the Nasal Cannula Cover is needed. As we have shown, surfaces are contaminated with respiratory viruses and indirect or direct transmission of respiratory viruses through the nasal cannula is possible, if not probable. Respiratory viruses such as Influenza A, Influenza B, Asian Influenza Virus, RSV, parainfluenza virus, coronavirus, rhinovirus, and adenovirus remain viable on surfaces for several hours to several days. Given the number of people prescribed oxygen, It is not an exaggeration to say that a million times a day a nasal cannula is put down on a surface and then put back into a nasal cavity.

The infection prevention and control implications of the studies cited above and other studies readily available indicate the need for hand hygiene and personal protective equipment to provide protection from pathogens on surfaces in patients' rooms and their nasal cannulas and minimizes self-contamination of mucosal surfaces. The Nasal Cannula Cover provides an entirely new infection prevention concept and an advance that adds protection from nasal mucous secretions directly from a primary source: nasal cannulas. The Nasal Cannula Cover complements and enhances the protection of gloves, aprons and eye protection for medical personnel and infection control and cleaning efforts aimed at protecting patients from hospital-acquired infections.

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