

The Impact of Severe Acute Respiratory Syndrome on the Use of and Requirements for Filters in Canada

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To discuss the changes that have occurred in Canada related to filter use and regulation, it is necessary to set the stage with an overview of severe acute respiratory syndrome (SARS) spread (or containment) in Canada and to discuss the practical considerations and difficulties in applying filtration in different clinical settings. This article begins with a brief look at the epidemiology of SARS in Canada and then discusses barrier use and potential containment strategies that could be applied to the respiratory equipment and supportive procedures that have been implicated in the spread of SARS or other respiratory infections. The article ends with a discussion of how practice and regulations have changed in Canada since SARS and some suggestions on how practice or regulations could further improve.

Although a few SARS cases have been called “superspreaders” based on a disproportionately high rate of secondary spread, the typical rate of spread was only two to four cases per primary case. This rate of transmission indicates that, in general, the SARS coronavirus (SARS-CoV) is not as transmissible as most other respiratory pathogens [1]. This low rate of transmission, along with the fact that SARS generally was not contagious unless the host was symptomatic, significantly improved the ability to contain and control the outbreak. Future outbreaks of respiratory pathogens, such as the looming threat posed by the H5N1 avian influenza virus, would likely to present far greater challenges with much higher degrees of spread. Learning from the SARS experience in 2003 will be a fundamental step toward ensuring a timely, effective response to management of future outbreaks (or pandemic) of respiratory pathogens. The World Health Organization (WHO) lists three characteristics of an influenza pandemic:

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it occurs when a new influenza virus appears or emerges in the human population, it causes serious illness, and it spreads easily from person to person worldwide. At the time of writing, there have been 141 confirmed cases of H5N1 avian influenza in humans (laboratory-confirmed cases from Cambodia, Vietnam, Indonesia, Thailand, and China), with 73 deaths (52% case fatality) [2]. So far, all these cases can be traced to direct contact with infected poultry, and there is no evidence of sustained direct human-to-human transmission at this time. Vietnam, however, has just reported two laboratory-confirmed fatal cases in which the virus had mutated to high-level resistance against oseltamivir [3], the antiviral drug that is currently being stockpiled worldwide. With such early antiviral-drug resistance being demonstrated, it is likely that the world will need to rely more heavily on vaccination if an avian influenza outbreak occurs. Unfortunately, current estimates predict that it will take 3 to 6 months after a pandemic is declared for significant amounts of effective vaccine to be produced, and current global production capabilities fall far short of the expected demand during a pandemic. These factors create doubt as to whether it will be possible to treat a pandemic strain of avian influenza effectively and indicates that a strong focus on limiting transmission is paramount. It is clear that there is no better time to evaluate and re-evaluate the protective barriers and containment strategies used during SARS than while awaiting the next influenza pandemic.

Severe acute respiratory syndrome in Canada

On February 23, 2003, Canada imported the first of what would be five total imported SARS cases. Of these, the province of British Columbia imported three cases and had only one case of secondary spread for a total of four probable SARS cases. In contrast, the province of Ontario imported only two individuals infected with SARS leading to a total of 245 secondary cases. Two of Canada's imported SARS cases arrived before the March 12 WHO global alert regarding what would later be known as severe acute respiratory syndrome.

British Columbia was extremely fortunate on several fronts to have almost no secondary spread despite three imported cases. The combination of two outbreaks reported from Asia (avian influenza and a "mystery disease" of respiratory involvement) raised enough alarm among staff at the British Columbia Centre for Disease Control that several broadcast e-mails were sent out on February 20 informing doctors, infection-control specialists, and public health authorities to be alert for influenza-like symptoms in travelers returning from China [4]. Barely 1 week later, the first arrival to British Columbia with SARS was an Asian male Vancouver resident who had become infected in the Metropole Hotel in Hong Kong from a doctor who had been treating patients who had the "mystery disease" in Guangdong Province in China. The patient lived at home with his wife

but had no contact with any friends or family after becoming symptomatic on February 28. He did not visit a family doctor, so his first contact with the health care system was in the emergency department at Vancouver General Hospital, where he was quickly recognized as having an undiagnosed respiratory illness linked to a history of travel through Asia. He was immediately fitted with a mask and isolated according to the infection-control policy at the time. His symptoms progressed rapidly, and he was intubated within hours of arrival. He was placed on a ventilator with a built-in heated expiratory filter that was more than 99.97% effective in removing particles of the most penetrating particle size (MPPS). He subsequently was ventilated for about 2 months and survived the ordeal with no secondary spread of the disease.

The second and third imported cases in British Columbia were identified quickly as probable SARS cases because they presented well after the March 12 WHO global alert. The only secondary spread in British Columbia occurred when a nurse was infected after treating the province's second imported SARS patient. According to the Occupational Health and Safety Agency for Healthcare in British Columbia, the nurse who contracted SARS was practicing appropriate infection-control procedures but may not have been wearing any eye protection and may have contracted SARS through the intraocular route [5]. Overall, British Columbia survived SARS relatively unscathed, with no deaths and only one case of secondary infection.

With only two imported cases but almost 250 secondary cases in two waves, the Ontario experience with SARS was in sharp contrast to that of British Columbia. Ontario's first case, Mrs. K, was a 78-year-old resident of Toronto who also was infected in the Metropole Hotel in Hong Kong. Mrs. K returned to Toronto, became symptomatic on February 23, rapidly deteriorated, and died at home of a presumed heart attack on March 5 without having gone to hospital and with no diagnosis of a novel respiratory disease. On March 7, her 44-year-old son, Mr. T, presented at Scarborough Hospital Grace Division with high fever, cough, and shortness of breath but no travel history. He spent about 20 hours in an open observation ward in the emergency department where he was isolated from other patients only by a curtain. Respiratory medications were administered using a nebulized aerosol system, which may have facilitated spread of the SARS-CoV through the air-borne route, although it is possible spread occurred from direct contact with contaminated objects. On March 8, Mr. T was admitted to the ICU and intubated. At that time, his diagnosis was possible tuberculosis infection, so he was placed in respiratory isolation. In addition, his family was contacted and asked to isolate themselves at home. Several of Mr. T's family members subsequently became ill and were admitted into negative-pressure isolation rooms in four Toronto hospitals with no reported spread of disease.

While in the emergency department, Mr. T had infected two other patients. The first went on to suffer a confirmed myocardial infarction and

presented with a low-grade fever and small pulmonary infiltrates deemed inconsistent with SARS. Only routine infection-control precautions were implemented, and this patient was transferred to York Central Hospital, where a cluster of 50 cases developed before the hospital was closed.

A second patient, Mr. P, was also exposed to Mr. T in the Scarborough Hospital emergency department on March 7. Mr. P presented on March 16 with fever and respiratory symptoms, was rapidly isolated while in the emergency department, and then was transferred into isolation in the ICU. Three nurses who had cared for Mr. P in this short time were infected, as was the intubating physician in the ICU despite the use of full barriers including respirator, eye protection, gown, and gloves. Mr. P also had infected three other family members and his wife, who subsequently went on to infect seven visitors to the emergency department, six hospital staff, two patients, two paramedics, a firefighter, and a housekeeper.

By the end of March, all negative-pressure isolation rooms in Toronto were occupied with probable SARS patients, even though 10 members of the Scarborough hospital staff were in emergency departments requiring isolation, and even more were at home waiting to be assessed.

On April 12, a cluster was recognized in a Toronto religious community that seems to have originated from a large extended family visiting patients at Scarborough Hospital. A family physician who had been involved with treating this cluster also fell ill and was admitted to hospital under isolation. Several hours elapsed from his transfer until he was intubated, during which he spent some time receiving noninvasive positive-pressure ventilation (NIPPV). Nine health care workers in contact with this patient became ill, including six who were present during the intubation.

In the end, Canada claimed there were 251 total probable SARS cases of which 108 (43%) were health care workers. The median age was 49 years, and the overall mortality rate was 17% [6]. Although most SARS transmissions in Canada occurred while inadequate infection-control precautions were implemented (whether because of patient misdiagnosis, breaks in procedure, or other reasons), there were repeated instances in which health care workers fell ill despite apparent full use of appropriate barriers and recommended procedures. Canadian health authorities have documented at least two transmissions that involved health care workers wearing full barriers including N95 or higher masks, eye protection, gowns, and gloves [1]. Two other undiagnosed SARS cases were identified as the source of transmission for seven hospital staff members despite hospital-wide infection-control precautions in place. In a third case, infected staff members reportedly were compliant with infection-control precautions except for one break in technique in which a face-shield was accidentally dislodged [7]. Another 10 or 11 transmissions to health care workers were reported in lower-risk settings, such as low-risk SARS units or community hospitals, even though investigation of these cases suggested that transmission occurred while staff were wearing

recommended protective barriers and followed all recommended infection-control precautions [7].

With or without the use of adequate protective barriers, high-risk procedures such as intubation, bronchial suctioning, nebulized aerosol therapy, and NIPPV have been implicated in facilitating transmission to health care workers [8]. The number of reported cases in which SARS was transmitted despite apparent use of prescribed infection-control practices suggests several potential scenarios: the prescribed infection-control practices were either misunderstood or improperly implemented by the end-user, or the barriers and practices were inadequate to prevent transmission completely. Issues related to compliance and training pertaining to infection-control procedures and adequacy of protective barriers have been reviewed elsewhere [9] and are not covered here. Theoretical issues pertaining to the use of the N95 respirators are reviewed later in this article.

Personal protection versus control of the source (containment)

The spread of infectious disease requires three things: a source of microbial contamination, a susceptible host, and a mechanism to transport adequate numbers of viable microbes between the two. There are two different approaches in using barriers to minimize the risk of transmission. The first is to ensure through the use of barriers that caregivers, support staff, and visitors apply adequate personal protection to isolate themselves from a contaminated environment. The second is to create a barrier around the source itself to control contamination of the environment through containment.

Personal protection

The barriers used for personal protection (gowns, gloves, goggles, and other precautions) fall under the expertise of infection-control practitioners and are not described in detail here. Certain aspects of infection-control that relate to filtration seem to be less well understood across the spectrum of health care and are discussed in greater depth. The obvious assumption when employing protective barriers is that some component of the environment surrounding a source is contaminated with infectious microorganisms. The goal of personal protection is to apply correctly as many barriers as are deemed necessary to isolate oneself from the portion of the environment that is considered contaminated. Impermeable gowns and gloves are examples of direct physical barriers between the potentially susceptible host and the potentially contaminated object, which may be a patient's bed, nearby tables, medical instruments, or the infected patients themselves. Goggles, face-shields, and surgical masks are examples of barriers used to protect mucous membranes from contaminated droplets generated by splashes, coughing, sneezing, or other means. N95 or higher-rated respirators and powered

air-purifying respirators are examples of barriers used to minimize inhalation of infectious air-borne particles. Knowledge of the historical transmission routes for a given microorganism typically dictates the specific barriers used. In most cases, the route of spread is classified as one of the following: direct physical contact, droplet (close proximity), or air-borne. Although these routes are typically treated differently in terms of barriers used, some gray areas need to be recognized. Diseases that normally are spread by direct physical contact may be spread by droplets if a contaminated substance is "splashed" into the face of the susceptible host. In this case, the impermeable gowns and gloves typically worn as barriers against direct contact would not be adequate, and some sort of protection of the mucous membranes of the face would be needed. A second example of deviation from an accepted route of transmission is that of SARS-CoV itself, which generally was thought to be spread by direct physical contact or droplets. The cases from Amoy Gardens clearly show that air-borne spread was possible under the right circumstances [10]. These exceptions are highlighted here only to point out that the barriers needed for a specific microorganism can change in exceptional circumstances, and common sense must be used to predict potential risks in different situations.

Filtration for personal protection

Filtration for personal protection in health care made a great advance in June 1995 when the National Institute for Occupational Safety and Health (NIOSH) introduced a rating system to categorize the abilities of respirators to remove the most-difficult-to-filter particles from air [11]. The MPPS is discussed and defined elsewhere in this issue, but it is worthwhile revisiting the concept here. The MPPS is the particle size most likely to pass through a filter; larger particles are more likely to be captured because of their larger size and inertia, and smaller particles are more likely to be captured because of their tiny mass and subsequent Brownian motion. NIOSH respirators are rated at the MPPS, so that an N95 respirator will capture at least 95% of particles at the MPPS, an N99 respirator will capture at least 99% of particles at the MPPS, and an N100 respirator will capture at least 99.97% of particles at the MPPS. Particles larger or smaller than the MPPS will be captured with greater efficiency than the NIOSH rating of the respirator. A good example is the filtration of *Mycobacterium tuberculosis*. Even in its smallest (desiccated) form, *M tuberculosis* is significantly larger than the MPPS and is filtered more efficiently than the filter rating. Therefore N95 masks have been shown to be more than 99% efficient in capturing *M tuberculosis* and other bacteria of the same size and shape. It cannot be inferred, however, that an N95 mask is as effective a barrier against infectious particles closer to the MPPS, such as smaller spherical bacteria or viruses carried in droplets.

As mentioned earlier, several reported transmissions of SARS-CoV occurred despite proper procedures and barrier use. Although these

transmissions may have been the result of an unrecognized breakdown in procedure at some other level, there may also have been cases of the N95 standard being inadequate to protect against this particular viral threat. Viruses are so small that the greatest filtration threat is not an individual virus (which is relatively easy to filter because of Brownian motion), but a virus that is being transported in a particle at the MPPS. In exhaled breath there is a continuum of particle sizes from larger than 1000 μm to smaller than 0.1 μm , and it stands to reason that the larger the particle is at its time of origin, the more viruses it may carry. These particles begin to decrease in size because of evaporation as soon as they are expelled from an infected subject's respiratory tract. The water in the droplet evaporates, and the remaining particle becomes smaller while retaining the original number of viruses. At some point along this spectrum, there are virus-containing exhaled particles that have had just enough time to evaporate down to the MPPS at the exact instant that they pass through a protective respirator. An N95 mask has a 1 in 20 probability of allowing this particular particle to pass through. Given the potential for millions of particles to be generated by the patient during coughing, sneezing, or over the course of a specialized procedure such as intubation or bronchoscopy, it may be prudent to reconsider whether N95 respirators are adequate for microbial threats that can be transported in particles at the MPPS. Particles that pass through the respirator are inhaled deeply into the lungs. If these particles (mainly at the MPPS) remained static in size, they would deposit in the airways only about 15% of the time. These inhaled particles typically increase in size as they pass through the high relative humidity of the airways, however, increasing the probability of deposition in the airways.

At this time it seems that every health organization and governing body in North America (and perhaps in the entire developed world) accepts the N95 respirator as the mask of choice to guard against the air-borne spread of disease in a health care setting. To the author's knowledge, the majority of evidence for this acceptance has been based on the ability of the N95 to protect adequately against *M tuberculosis*, and not on the adequacy of protection against unknown and emerging viral threats that will, by their very nature, prove more difficult to filter than *M tuberculosis*. Ten years ago the respirator manufacturing industry had to step up its manufacturing process to create filter materials that would meet the new N95 standard set by NIOSH in 1995 [11] but would still be disposable and easy to use. To date, most, if not all, N99 and N100 respirators are the bulkier plastic models that look like gas masks and are not appropriately user-friendly for routine health care use. In this era of nanotechnology it is difficult to believe that industry would be overly challenged to create N99 or N100 respirators that are as user-friendly and as relatively nonimposing as the N95 respirators are today. Even though such filters are technologically possible, it is unlikely that the health care manufacturing industry will invest in this strategy until it has an external mandate to provide respirators with higher

levels of protection to health care facilities. Although there seems to be adequate evidence showing that N95 respirators are sufficient for protection against tuberculosis, there does not seem to be enough evidence to assume they will be adequately efficient when applied to emerging viral threats. In fact, if *M tuberculosis* had presented as a 0.3- μm spherical coccus (MPPS), instead of as a 1.0- μm long rod, the N95 standard might never have been accepted simply because it likely would have been shown to be an inadequate barrier. Is it wise to wait until a viral threat emerges in which the N95 mask is proven to be inadequate, or should the standard be raised to higher degrees of respiratory protection proactively?

Containment: control at the source

The preferred and most effective means of protecting workers is to prevent hazards entering their breathing zone in the first place.

NIOSH CFR, Title 42, Part 84 [11].

Containment can be seen as a continuum at many different levels. By limiting travel during an outbreak, infection can be contained in a geographic location. By quarantining a hospital, the source can be isolated from the surrounding community. By the use of a negative-pressure isolation rooms, the contaminated environment can be isolated from the rest of the health care facility. All these levels of containment have been addressed by provincial, national, and international organizations, as well as by local infection-control practitioners. Another form of containment, namely the containment of the microorganisms from the exhaled breath of infected subjects, was used only sporadically before or during SARS, is not as well understood by infection-control or health care professionals, and is far less standardized; nevertheless, it could make a great difference in a future outbreak of respiratory disease in which antiviral drugs are ineffective, vaccines are unavailable, and isolation rooms are in short supply.

In a future pandemic, health care facilities quickly will run out negative-pressure isolation rooms and then will run out of single-bed rooms that can be used for isolation purposes. Almost immediately, health care facilities will need to cohort suspected cases in shared rooms or, on a larger scale, in quarantined health care facilities. Depending on the scale of the outbreak, quarantining may require the use of nontraditional facilities such as sports complexes, hotels, or other similar facilities to become ad-hoc health care facilities. The difficulty with this approach is that patients who are falsely considered suspect will share space with those who actually are positive, thereby increasing the risk that falsely suspected cases will become infected as a result of attempts at large-scale containment. With adequate effort, planning, and study, it would be possible to implement containment on an individual basis to a degree that could significantly minimize the spread of infection through health care facilities, both from patient to patient and from patient to staff, visitors, or other persons.

The simplest example of individualized containment is placing a mask over the mouth and nose of an infected patient to limit the droplets being exhaled. This principle can also apply to filtration of exhaled gases before they exit the breathing system during mechanical ventilation. Filtration for containment is complicated by the great variety of equipment and methods used to provide respiratory care and therefore is discussed in more detail. Regardless of the level of individualized containment available during the next respiratory pandemic, it will be paramount that individuals visiting or providing care and support for these patients wear adequate personal protection at all times.

Filtration for containment

Filtration for containment of exhaled gases carries with it a host of complications based on the equipment and practices that are implemented routinely in respiratory care. The continuum of respiratory equipment is as great as the continuum of respiratory compromise during illness. Some ideas for providing some level of containment based on the different pieces of respiratory equipment required in different situations are discussed in the following sections. In a few cases there may not be a reasonable method to provide containment using current devices, but in all cases there are ways in which manufacturers can modify equipment to provide effective and user-friendly containment. The real value of such modifications or new devices may be demonstrated only during an epidemic or pandemic. Because most manufacturers are reluctant to invest in a device that may sell well only once every 50 years or so during a pandemic, sweeping regulation changes (similar to those promulgated in June 1995 by the NIOSH) undoubtedly will be necessary before such devices become available.

Containment for spontaneously breathing patients who have low oxygen requirements

The most basic example of respiratory containment would be a suspected patient who has no current need for ventilatory support or supplemental oxygen. In this situation, a sufficiently rated respirator placed on the face of the patient would be adequate to create a high level of containment. Attempts would need to be made to ensure the respirator had a good seal, because there is unlikely to be a way to fit-test the infected individual. Placing a surgical mask on an infected patient seems to be a reasonably common practice, even though the filtration efficiency of surgical masks for particles near MPPS often approaches 0% efficiency. Surgical masks capture most relatively large exhaled particles, especially those over about 5 μm , so they do provide some degree of containment against droplet-only spread; however, surgical masks should not be assumed to be effective against air-borne spread. To author's knowledge, there are no respirators currently designed to be applied long-term to infected individuals.

For the sake of added comfort during long-term use, several N99- and N100-rated respirators have one-way valves to allow unimpeded exhalation; only inspired potentially contaminated air is directed through the filter material. There are even some disposable N95-style respirators with similar one-way valve mechanisms. Designing a highly efficient respirator for use by the infected individual with a focus on long-term comfort and adequate facial seal would be a great step toward providing respiratory containment for such a case. The ability to adapt low-flow oxygen into such a respirator would give the added benefit of providing supplemental oxygen along with high levels of containment. The ability to add supplemental oxygen currently is not available but would be very beneficial, because it is extremely unlikely that an adequate facial seal can be obtained with any currently available respirator if the patient requires the use of nasal prongs or a simple oxygen mask to supplement inspired oxygen. Such a device potentially could replace nasal prongs and simple oxygen masks in an epidemic or pandemic. To make this device feasible for manufacturing, it probably would have to be a modular adaptation to an already manufactured device or a new dual-purpose device. An example might be a modular N95-style respirator designed for protecting the health care worker in which an oxygen inlet could be added if required and a one-way valve could be added (or reversed) to promote longer-term comfort and presumably higher compliance. When suspected cases need to be sequestered together, such a system might be effective in protecting the negative suspected cases from the positive suspected cases. Also, because the environment itself would be less contaminated, the use of such a system would decrease the consequences of the failure of the personal protection used by health care workers.

In practice, few containment strategies can provide 100% containment at all times, so the goal in this case is not necessarily to contain the pathogens completely but to minimize the risk to health care workers, families, and friends by significantly decreasing environmental contamination. For example, even though the patient may need to remove the mask to eat (in which case containment is lost for a brief period), the use of the system still will substantially minimize environmental contamination while the mask is worn and thus will decrease the probability that personal protective equipment worn by health care professionals will fail to be adequate.

Containment for spontaneously breathing patients who have high oxygen requirements

Containment faces different but still solvable challenges when higher levels of supplemental oxygen are required but ventilatory support still is not required. Historically, high levels of oxygen for spontaneously breathing individuals have been delivered by systems that simultaneously proportion air and oxygen to administer the proper oxygen concentration and aerosolize water to provide adequate humidity to the airways. The particulate water that these devices add to the inspired gas causes two problems in infection

control. The first problem is that these particles were implicated as potential carriers for the SARS-CoV when such systems were used on infected individuals. Because the water in these aerosolized droplets evaporates extremely quickly when exposed to room air at low or even moderately high levels of relative humidity, the potential for aerosolized humidity to promote spread of infection would probably be a threat only (1) in very close proximity to the source of the aerosol, (2) in rooms approaching 100% relative humidity, or (3) if the microorganism itself remains air-borne and viable long after the initial droplet has evaporated.

The second problem that this aerosolized humidity presents is that it will build up rapidly on the filter media of any nonheated filters that are used to purify exhaled gases. The resistance of most, if not all, filters increases quickly and dramatically when exposed to particulate water, even though molecular water passes right through them. This increase in resistance could easily cause a patient with a compromised respiratory system to go into respiratory failure.

For these two reasons, a previously seldom-used method using heated humidification was used for some SARS patients in Canada, and some, but not all, health care facilities seem to have switched exclusively to these systems after the SARS experience. The system abandons the use of aerosolized particulate water in favor of evaporated molecular water. To provide adequate molecular water, a heated humidifier typically is added to the inspiratory limb of these systems, and a heater wire also may be added to allow an elevated water content to be delivered to the patient. Such systems do not provide a direct transport mechanism for microorganisms and are easier to filter because the resistance of a filter is not as affected by molecular water. Filters currently used in this way are at room temperature, but the high-humidity gas passing through them is significantly warmer. This difference in temperature promotes condensation on the filter material itself and also leads to unacceptably high resistance through the filter, although not quite as quickly as occurs with particulate water.

These systems would benefit substantially from filters designed to maintain low resistance in the face of condensation (such as an orientation that promotes drainage of the condensate away from the filter material so water build-up is minimized), to minimize the condensation in the first place (either using a double-walled design that insulates the filter component from room temperature or externally heating the filter), or by a combination of these methods. The author knows of no currently available filter that performs these functions adequately, has an adequately high degree of filtration efficiency, and can be adapted easily into the system described previously.

Currently, these systems are designed and assembled out of various different spare parts by respiratory therapists or other health care professionals, and the author knows of no complete humidified high-oxygen delivery system on the market that performs all the functions required for infectious containment of these patients. There currently are no regulations,

guidelines, or recommendations on the use or design of such systems, even though they probably would have a large impact in decreasing the contamination of the surrounding environment when droplet or air-borne infections are present.

A second option is currently available for administering high oxygen levels with some degree of containment, but it involves ignoring the humidity deficit in the lungs. At least one device on the market delivers relatively high levels of oxygen with a reasonably tight facial seal (although this point has not been studied to the author's knowledge) and the ability to add an expiratory filter easily. A recent adaptation to this device even allows delivery of aerosolized medications, although it is not yet clear how quickly this adaptation would increase filter resistance. Unfortunately, adequate humidification through this device is not possible, so it should be reserved for short-term use or for situations in which the communal infection-control risk outstrips the individual's need for humidification (a difficult ethical issue). Ideally, however, similar devices that provide adequate humidification would become available.

Containment for mechanically ventilated patients

It seems fortuitous that high-level containment can be established most easily on the sickest (and possibly most contagious) sources of respiratory infection because of their requirement for invasive mechanical ventilation. Although the intubation procedure itself is a great risk (as discussed later), the cuffed tracheal tube offers the greatest ability to maintain a closed system because the system-to-patient interface is more reliably free of leaks. Once intubated, these individuals are connected to breathing systems that by their very nature are relatively free of leaks. Typically, inspired gas is directed to the patient through the inspiratory limb, and exhaled gas is directed through the expiratory limb. Humidity is provided either through heat and moisture exchangers, through heat and moisture exchanging filters (HMEFs), or through heated humidifier systems; aerosolized humidity is not commonly used, so the humidification system does not pose a risk of being a transport mechanism for microorganisms.

There are two main methods to provide high-level containment using these breathing systems: by placing adequately efficient filters on the inspiratory and expiratory limbs (Fig. 1) or by placing an adequately efficient filter between the patient's tracheal tube and the connection to the breathing system (Fig. 2). An acceptable variation may be to use an adequate scavenging system in place of an expiratory limb filter.

Highly efficient (N100 equivalent) filters often are placed between the ventilator and the inspiratory limb without risk of adding substantial breathing system resistance, because this portion of the system is not exposed to added humidity. This precaution is taken primarily to protect the internal parts of the ventilator from cross-contamination should retrograde flow occur in the inspiratory limb because of ventilator malfunction.

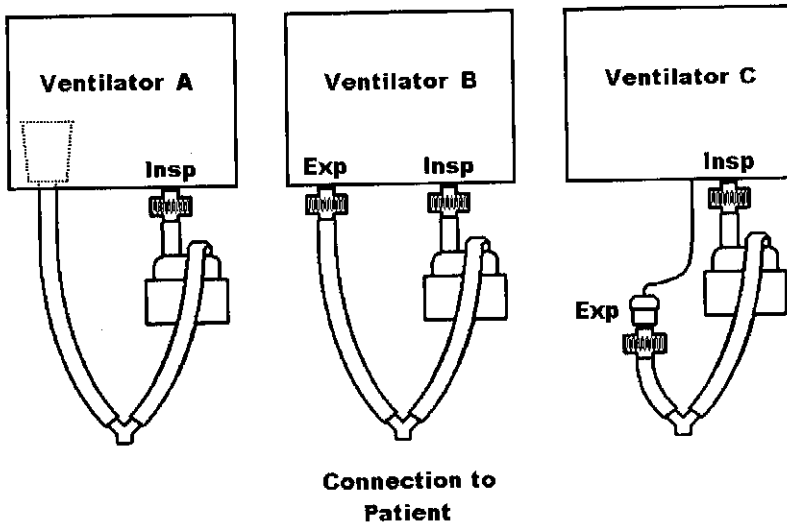


Fig. 1. Ventilators with active heated humidifier systems. These systems deliver heated, evaporated water to the airways at nearly 100% relative humidity and 37°C. Ventilator A has a built-in heated expiratory filter that typically does not require routine filter changes. Ventilator B requires the addition of a nonheated expiratory filter, which would require frequent changes as resistance builds up because of water condensation. In Ventilator C the expiratory valve is integrated into the breathing system itself, not into the ventilator housing. The breathing system may require modifications to allow the expiratory filter to be added into the system; because this filter would not be heated (with currently available equipment), it would require frequent routine changes as resistance builds up because of water condensation. Exp, expiratory; Insp, inspiratory.

If a filter is placed directly between the patient interface (in this case, a tracheal tube) and the breathing system, it generally is a specialized HMEF that has the added capability of providing recycled heat and humidity to the inspired gas. A few currently available HMEFs provide N100-equivalent filtration and at least 32-mg/L⁻¹ humidity; however, HMEFs need to be changed frequently (often every 12 hours) because they build up condensation and increase in resistance through prolonged use. Filtration between the patient interface and the breathing system is an easy method to add high-level containment to any ventilator breathing system but complicates the delivery of commonly used aerosolized respiratory medications, and multiple high-risk exposures are needed routinely to change the HMEF. Any procedure that requires breaking the ventilator circuit (eg, to obtain a sputum sample or to change a filter) probably should be considered a high-risk exposure because of the high-velocity flows of air (similar to the patient's coughing) that ventilators typically produce during disconnections. Such exposures should be as infrequent as possible, and probably the same personal protection should be used as during intubation or bronchoscopy.

Expiratory limb filters allow heated humidifiers to be used (if the moisture output of the HMEF is deemed inadequate) and allow delivery of aerosolized medications to the lungs without added technical difficulty. Heated expiratory filter housings are standard in approximately half the critical

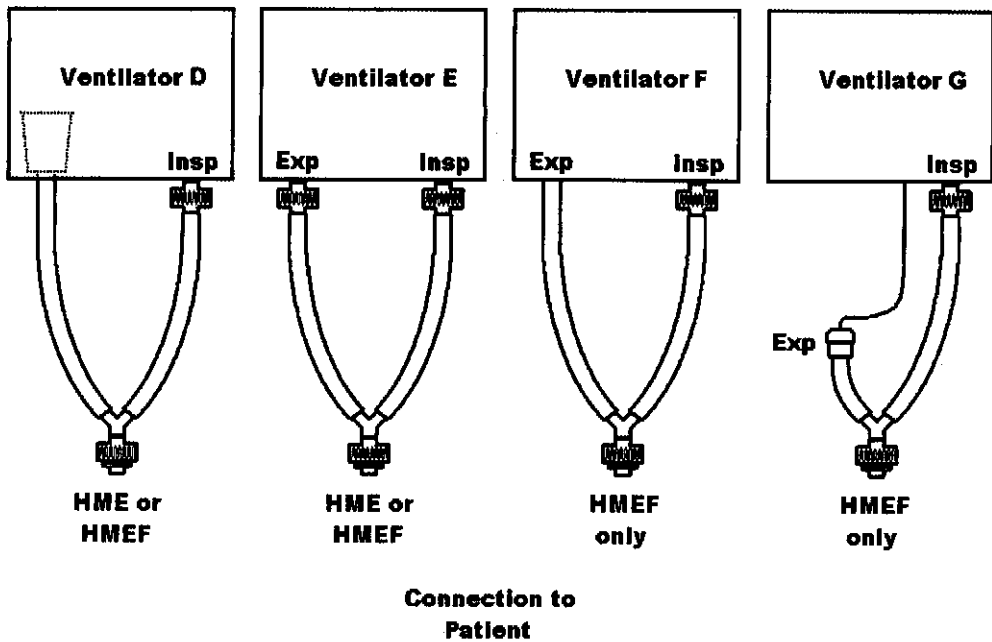


Fig. 2. Ventilators with passive heat and humidity systems. Ventilators D and E have expiratory filters, so the heat and moisture exchanger (HME) need not have adequate filtration capabilities. Ventilators F and G require heat and moisture exchanging filters (HMEFs) with adequate filtration capabilities because there is no expiratory filter in the system.

care ventilators on the North American market. Heating the filter housing eliminates condensation build-up in the filter itself and dramatically reduces the number of times that a health care professional is required to break the breathing system to change filters (potentially from two exposures per day per ventilator to no routine exposure at all). Although the use of sealed inline-suction devices (eliminating the need to break the ventilator breathing system to perform bronchial hygiene) was highly recommended as good infection-control practice both before and after the SARS experience, there was little or no emphasis on using filtration systems that also minimized the number of breathing system breaks. Clearly, the optimum solution is one that provides maximum containment but minimal exposures caused by breaks in the breathing system. Because only about half the critical care ventilators on the market come with this option, all other ventilator manufacturers would need to design heated housings for their ventilators (which is unlikely without standards or regulations to enforce the requirement), or add-on heated filter housings that could be used on any ventilator without a built-in heated housing would need to become available. Another potential solution would be for manufacturers of heated humidity systems simply to incorporate a heated filter into the heated expiratory limbs of currently available disposable breathing systems.

High-frequency oscillation is an alternative means of providing mechanical ventilation that has become increasingly popular in treating acute respiratory distress syndrome. During the SARS outbreak, the use of

high-frequency oscillation was implicated as a potential facilitator in several transmissions of the SARS CoV. Several devices that can perform high-frequency oscillation are available. The most commonly used device uses a proprietary ventilator breathing system that has one exhalation valve and two high-pressure dump valves built into the system. The breathing system is designed so that filtration of these valves is impossible, and scavenging of all three valves is impractical. The breathing system for this device could be redesigned easily to ensure that scavenging or filtration of all exhaled gas is possible and user friendly, but without standards or regulations to enforce such measures, this redesign is unlikely to happen before the next outbreak of airborne respiratory disease.

Similarly, NIPPV was implicated in facilitating transmission of the SARS-CoV. NIPPV is commonly used to decrease the need for intubation by providing some degree of mechanical support to the respiratory muscles through noninvasive means. Typically, some type of mask covering the nose, nose and mouth, or full face is used as the interface between patient and ventilator. As with the high frequency oscillator, NIPPV devices typically do not allow exhaled gases to be filtered or scavenged. Although it would be possible to redesign NIPPV breathing systems to enable filtration or scavenging of exhaled gases, it is unlikely that manufacturers will invest in such changes unless they become universally mandated. NIPPV poses another significant challenge that high-frequency oscillation typically does not. Although several noninvasive masks have made great strides in reducing leaks, it will not be possible to provide high-level containment with NIPPV until the breathing system is redesigned to allow scavenging or filtration and a leak-free interface is on the market. Recently there has been some success with the use of helmet-style interfaces for the delivery of NIPPV [12]. Such devices may provide a seal as effective as intubation with a tracheal tube and therefore perhaps can be adapted to provide levels of containment equivalent to invasive mechanical ventilation.

Containment for special procedures

Aerosol-generating procedures such as endotracheal intubation, nebulization (for humidity or medication delivery), bronchoscopy, and bronchial suction seem to have facilitated transmission of SARS-CoV during hospital care [1,13,14]. During the SARS outbreak, the WHO identified intubation, suction, and nebulized aerosol therapy as high-risk procedures. In Canada, the Ontario provincial government also included bronchoscopy as a high-risk procedure. Other special procedures are likely to pose similar threats and, to the author's knowledge, were not commonly recognized as high risk: changes of ventilator breathing system filters (or any other procedure that breaks the breathing system), extubation (removal of the tracheal tube), and pulmonary function testing.

The nature of these procedures may make containment impossible, so they should be avoided whenever possible and approached with extreme

caution (with appropriate, diligent use of barriers and hand-washing) when avoidance is not possible. When high-risk procedures are unavoidable, care should be taken to minimize staff exposure by the following means:

- Performing the procedure with the minimum possible number of staff
- Having the most skilled individual perform the procedure so there is higher likelihood of successful first attempts (especially important for intubations)
- Considering the use of high levels of sedation (or neuromuscular blockade) when possible to decrease coughing
- Using containment strategies as long as possible (eg, keeping an appropriate filtering mask on the patient as long as possible or ensuring bag/mask devices have appropriate filters)

Summary of current standards, guidelines, and regulations

Respirator purchasers and users expect and deserve to be able to select respirators with complete confidence that they will perform with a specific efficiency for a specific purpose. They rely on the NIOSH performance standards and certification program to assure them that they can have that confidence.

NIOSH CFR, Title 42, Part 84 [11].

The NIOSH statement above perfectly summarizes the purpose of regulating, certifying, and rating respirators. Before the introduction of the NIOSH rating system, respirators were as difficult to select with confidence as breathing system filters and pulmonary-function filters are today. A similar regulatory document is needed to ensure that purchasers and end-users are able to select breathing system filters and pulmonary-function filters with complete confidence that they will perform with specific efficiency for a specific purpose.

Unfortunately, the filtration of exhaled gases with breathing system filters is relatively unregulated and nonstandardized worldwide. The most commonly distributed data pertaining to the filtration effectiveness of breathing system filters continues to be based on inadequate and nonstandardized bacterial filtration efficiency and viral filtration efficiency test procedures. The use of such tests has led to the repeated use of the terms “bacterial filter” and “viral filter” in product literature, medical literature, and even in documents from Health Canada, the WHO, and the Centers for Disease Control and Prevention, even though there currently is no standard or regulation that describes the minimum effectiveness of a “bacterial” or “viral” filter.

In October 2003, the International Organization for Standardization (ISO) published ISO 23328-1:(2003), *Breathing System Filters for Anaesthetic and Respiratory Use—Part 1: Salt Test Method to Assess Filtration Performance* [15], to describe an appropriate test procedure for assessing

and comparing filtration efficiencies. This standard describes a test procedure similar to that used in rating NIOSH-approved respirators. Currently, however, ISO 23328-1 is voluntary in North America, and most filter manufacturers are continuing to use the bacterial filtration efficiency and viral filtration efficiency test data, which at first glance are far more impressive to both purchasers and end users of the products. Although this ISO standard was published after the SARS outbreak, it duplicates the European standard [16] that was written and adopted in 2001, before the SARS outbreak, so it is not likely that SARS was an influential factor in its adoption. Nonetheless, this standard is a step in the right direction, because informed filter purchasers can now demand to see data showing compliance with this ISO standard before making purchasing decisions on breathing system filters. This standard does not apply to pulmonary-function filters, for which there is no regulation or standardization at all. The current NIOSH rating system for respirators (N95, N99, and N100) would fit well with breathing system filters and pulmonary-function filters and would give a much clearer indication of the effectiveness of these devices than the current "bacteria/viral" designations.

In June 1995, the NIOSH rating system was adopted in North America for rating respirators through the Code of Federal Regulations CFR, Title 42, Part 84 [11], and the N95 became the standard respirator in health care for protection against *M tuberculosis* (and by default against all other airborne diseases). The N95 standard was a significant improvement over the respirators then available. To the author's knowledge, however, the N95 standard has not been proven to provide adequate protection against microbial threats that are closer to the MPPS or against microorganisms that are present in far higher concentrations in airway secretions than *M tuberculosis*. As discussed earlier in this article, the SARS-CoV and avian influenza H5N1 are theoretically much more likely to penetrate an N95 mask and are present in respiratory secretions in far greater numbers than *M tuberculosis*. These factors may have been reasons why transmissions of SARS-CoV occurred even when the recommended personal protection was used. It might be prudent to re-address current standards of respiratory protection in light of emerging viral threats such as SARS and avian influenza.

Lacking formal international standards or regulation, Canada's federal and provincial governments recommended adding "bacterial/viral filters" to ventilators during the SARS outbreak. To the author's knowledge, there are no federal guidelines or recommendations that demand the use of filters on breathing systems or in pulmonary function in a post-SARS era. The province of Ontario, however, has published the *Standard for all Ontario Health Care Facilities/Settings for High-Risk Respiratory Procedures under Non-Outbreak Conditions* [17] and the *Directive to All Ontario Health Care Facilities/Settings For High-Risk Aerosol-Generating Procedures Under Outbreak Conditions* [18], which defines high-risk procedures and treatments as anything with the potential to generate aerosolized droplets, including,

but not limited to, nebulized therapy, aerosol humidification, airway suctioning, sputum induction, endotracheal intubation, tracheostomy, bronchoscopy, tube or needle thoracostomy, open thoracotomy, bag-valve mask ventilation, noninvasive ventilation (continuous positive airway pressure, bilevel positive airway pressure), and ventilation using high frequency oscillation. Although these documents do not specifically mention filter changes, they do state that if the integrity of a closed breathing system is breached while caring for a patient who has febrile respiratory illness, staff in the room must use elevated personal protection, including N95 respirators. They also state that ventilators with built-in heated expiratory filter housings are preferred; if use of such ventilators is not possible, disposable filters must be placed on the expiratory limb of the breathing system. Although the authors used the term "hydrophobic submicron filter" (which is slightly more appropriate than "bacterial/viral filter"), there still is no recognized definition of the filtration efficiency that would be considered a "submicron filter" or test procedure that validate the designation.

Although no currently available data indicate how SARS may have affected the use of filters in Canada, it is clear that there is renewed awareness and interest in the issue of filtration of exhaled gases in health care facilities. It is hoped that concern will lead to the development of appropriate standards, guidelines, and equipment so that health care facilities are better prepared when the next outbreak emerges.

Preparedness

In February 2003, Canada (and much of the world) was largely unprepared for SARS. There was no known cure, and treatment consisted mainly of supportive therapy. Hope of recovery rested on the ability of the immune system of infected individuals to deal with the new virus. Canada's health care facilities sorely lacked trained infection-control practitioners, and in a matter of weeks every isolation room in infected areas was in use. The recommended personal protection strategies seemed to fail all too commonly, and respiratory devices that normally would have been used to treat these patients were implicated in fostering transmission. Canada—and the world—was extremely fortunate that SARS-CoV was considerably less transmissible than most other respiratory pathogens; otherwise, a pandemic might have been inevitable.

In reality, when the next pandemic or novel respiratory pathogen emerges, health care facilities again will scramble for effective therapies and will run out of isolation rooms. With adequate preparedness, however, improvements in personal protection and containment strategies can minimize transmission within health care facilities. Appropriate devices and methods for containment of exhaled gases will be available during a pandemic only if they are implemented into current practices in advance. N95 respirators should be assessed for their adequacy against emerging viral

pathogens, and, if necessary, a higher standard should be adopted quickly so manufacturers have time to adapt respirator design. Breathing system filters need an appropriate rating system so that purchasers can make appropriate decisions and end-users are protected. Appropriate standards and regulations need to be developed to force manufacturers to re-evaluate the design of respiratory equipment commonly used in the treatment of respiratory failure so that filtration or scavenging of exhaled gases is possible.

If governments and regulating bodies look at the financial impact and loss of life associated with SARS and then multiply that impact by thousands, they may realize what might happen if health care facilities choose not to become more prepared after the small warning that was SARS.

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