

# CHAPTER EIGHT: It's Not About the Mask

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## Introduction

One of the biggest bones of contention during SARS was the N95,<sup>887</sup> a respirator that protects much more than a surgical mask<sup>888</sup> and that was mandated for health workers caring for SARS patients.<sup>889</sup>

Although Ontario law since 1993 required that anyone using an N95 had to be properly trained and fit tested<sup>890</sup> to ensure proper protection, few hospitals complied with this law. Some medical experts even denied the very existence of this legal requirement.

Fit testing was the subject of official confusion and heated debate.

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887. Using highly efficient filtering materials, N95 respirators are one of the nine types of disposable particulate respirators that are independently tested and certified by the National Institute for Occupational Safety and Health in the United States, which is part of the Centers for Disease Control. "The N indicates that the respirator provides no protection against oils and the 95 indicates that it removes at least 95% of airborne particles during 'worst case' testing using a 'most-penetrating'-sized particle." (Yassi, Annalee MD, MSc, FRCPC et al., "Research Gaps in Protecting Health Workers from SARS," *Journal of Occupational and Environmental Medicine* DOI: 10.1097/01.jom.0000150207.18085.41) (Yassi et al, "Research Gaps in Protecting Health Workers from SARS").

888. In this chapter, *respirator* will refer to a respiratory protective device like the N95 that has been independently tested and certified. *Masks* will refer to any respiratory device like a surgical mask or the PCM 2000 that has not been independently tested and certified.

889. The N95 was sometimes required in other areas of hospital even when not caring for SARS patients. As noted below, the provincial directives for the use of the N95 changed throughout SARS and were not always clear or consistent.

890. Fit testing helps users select a respirator that best fits their faces and teaches them how to get a proper seal each time they use respirator, a procedure known as a *seal check*, and how to safely don and doff a respirator. A test verifies that the chosen respirator works properly. There are two types of tests. One is called a *qualitative fit test* and "relies on the user's subjective response to taste odour or irritation." The other is a *quantitative fit test* and "relies on an instrument to quantify the fit of a respirator." (Healthcare Health and Safety Association, *Respiratory Protection Programs* (2nd edition [Toronto: Healthcare Health and Safety Association, 2000]).

This chapter outlines how fit testing and the N95 became lightning rods for all the underlying problems of worker safety in health care.

## Respiratory Protection: A Fundamental Worker Safety Issue

The real problem during SARS was not the N95 respirator or fit testing but deep structural contradictions in worker safety in the health care system. This included both embedded resistance within the health care system to worker safety experts and to the Ministry of Labour and Ontario's failure to recognize, as an aspect of health worker safety, the precautionary principle that reasonable action to reduce risk, such as the use of a fitted N95 respirator, need not await scientific certainty.

There were two solitudes during SARS: infection control<sup>891</sup> and worker safety.

Infection control insisted that SARS was mostly spread by large droplets which do not travel far from an infectious person. Given that case, in their view, a surgical mask was sufficient to protect health workers in most situations. Worker safety experts said workers at risk should have the higher level of protection of an N95. They said not enough is known about how SARS is spread to rule out airborne transmission by much smaller particles, and besides, hospitals are dynamic places where unforeseen events and accidents can always happen. Infection control relied on its understanding of scientific research as it stood at the time. Worker safety experts relied on the precautionary principle that reasonable action to reduce risk should not await scientific certainty.<sup>892</sup>

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891. "Nosocomial infections, acquired by patients as a result of receiving health care, are under the purview of IC [Infection Control]" (Health Canada. *Prevention and control of occupational infections in health care: An Infection Control Guideline*. [Ottawa: Health Canada, 2002], p.2).

892. This is a good place to note that Dr. Sheela Basrur, Chief Medical Officer of Health, has taken steps to improve this situation. Only time will tell if these steps are effective. She notes in her letter of March 9, 2006, to Ms. Linda Haslam-Stroud, RN, President, Ontario Nurses' Association:

We recognize the need to ensure that the perspectives of occupational health and infection control receive consideration. In light of this, an occupational health physician is included in the membership of PIDAC and has been sitting on the committee since the inception of PIDAC in 2004. However, we see the importance in continuing to strengthen our links with the occupational health field and a physician delegate from the Ministry of Labour is now also sitting on PIDAC. This highlights our commitment to ensuring that occupational health and safety expertise is brought to the table during all PIDAC deliberations now and in the future. We are confident that building on this approach will assist in ensuring stronger linkages between occupational health and infection control on matters of science.

PIDAC refers to the Provincial Infections Diseases Advisory Committee.

A good illustration of their differences is the controversy over how far large droplets travel from an infectious person. Many infection control experts believe large droplets travel no more than one metre from the infectious person,<sup>893</sup> and they use this one-metre rule as a guide for what respiratory protection to wear. Worker safety experts are critical of this rule both on a scientific basis<sup>894</sup> and as a practical matter. They suggest that even if the one-metre rule could be proven scientifically, it is not realistic or safe in a workplace.

Dr. Diane Roscoe of Vancouver General said:

It is not an easy thing for health care workers to remember. This is a three-metre or this is a one-metre thing, and this is not. And what am I supposed to do.

As a result, said another expert at Vancouver General,

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893. To take one of many references, one respiratory protection manual says: "It has been a generally accepted infection control notion, based on epidemiological observations, that diseases spread by large droplets typically are not spread to others via the respiratory tract when more than 1 meter from the source" (Healthcare Health and Safety Association of Ontario, *Respiratory Protection Programs*, 2nd edition, p. 1).

894. See Bob Janssen, MSc, ROH, Senior Policy Analyst, "A Scientific Review – The Influenza Pandemic: Airborne vs. Non-Airborne Transmission and Considerations for Respiratory Protection" Vancouver: Policy & Research Division, WorkSafeBC, December 2005:

One should be aware of the effects of droplet evaporation and the resultant diminution in size of ejected droplets. A 30  $\mu\text{m}$  droplet dries to a 5  $\mu\text{m}$  droplet within seconds under normal indoor air conditions. This means that a large droplet, as it evaporates, will not settle to the ground but become a free-floating entity. This has implications for the 3 foot rule, the basis for infection control precautionary measures, since it is commonly believed that large droplets ejected upon sneezing or coughing will follow Stoke's Law and fall to ground within a 3 foot distance from the person's face. It is evident that it is commonly believed that the 3 foot rule is a division between an unsafe and safe distance.

There is no indication that the 3 foot rule takes into consideration the evaporation factor and the drift factor of airborne droplets, as discussed above. No scientific evidence is offered by WHO, DHHS-CDC, PCAH, or other medical authorities in explaining the rule. If large droplets quickly evaporate to free-floating small droplets, then the 3 foot rule applies only to droplets greater than about 50 – 100  $\mu\text{m}$  in diameter for which there is insufficient time chance for evaporation to take effect before they fall to the ground from a height of 5–6 feet. Free floating small droplets readily go beyond the 3 foot radius. Therefore, if the majority of ejected droplets following a sneeze are evaporated to a size that is free-floating after only seconds in air, the 3 foot rule becomes illogical and not particularly helpful from a disease transmission perspective.

We always start with the highest level of precaution ... We don't use droplet precautions in our hospital, never have, because we've always believed that droplets have been aerosolized so we only have one category, that's airborne, and you always start with the highest level of precaution and then as the clinical situation becomes clearer, you step back on your precautions – and we have found that the easiest for workers to understand rather to try to figure out when to wear a surgical, when to wear an N95, you know, how close am I to the patient, do I need to put on a mask – it's just simpler for them to remember that this patient's got respiratory symptoms, yes, put on an N95, do the appropriate precautions.

Dr. Elizabeth Bryce of Vancouver General said:

Even if you did determine [the distance from the patient] ... like poof, you know you are this distance, you put on a mask and presto, and you step back a foot and you no longer need a mask ... [health workers] are moving in and out of the “danger zone” for sure for droplets. They are in and out when they are in a room. And it is just simply easier for everyone and safer for them to put on some sort of respiratory protection when they step into the room ... You've got the patients moving around and the staff moving around. It is very hard to keep the spatial separation and just – we just feel it is safer too.

The point is not who is right and who is wrong about airborne transmission, nor is it how far large droplets travel. The point is not science, but safety. Scientific knowledge changes constantly. Yesterday's scientific dogma is today's discarded fable. When it comes to worker safety in hospitals, we should not be driven by the scientific dogma of yesterday or even by the scientific dogma of today. We should be driven by the precautionary principle that reasonable steps to reduce risk should not await scientific certainty.

The debate about respiratory protection and fit testing can be understood only in the context of the heavy burden of disease that fell on hospital workers, paramedics and others who worked in Ontario's health system during SARS. Two nurses and a doctor died from SARS. Almost half of those who contracted SARS in the health system were people who got the disease on the job.

**Table 1 – Probable and Suspect SARS Cases Contracted in Health Care Settings<sup>895</sup>**

	Phase 1	Phase 2	Total Number of Suspect and Probable Cases	Percentage of Total Number of Cases (375)
Health workers	118	51	169	45%
Patients	23	35	58	15%
Visitors	20	23	43	11%
Total	161	109	270	72%

Most of these workers were nurses whose jobs brought them into the closest and lengthiest contact with sick patients. And this does not show the full burden of SARS on nurses, paramedics and other health workers. Nurses sick with undetected SARS inadvertently brought illness, and in some cases death, home to their families.

Again and again nurses were told they were safe if they would only do what they were told by the health system. Again and again these scientific assurances, though well intentioned and issued in the best of good faith, turned out to be tragically wrong.

It is no wonder that nurses became alarmed when they saw their colleagues sicken and die. It is no wonder that they became angry when they saw such incidents recur again and again with no apparent improvement in their safety.

As SARS continued and more health workers fell ill, the resulting justified lack of confidence in health care safety systems fuelled a heated debate about the need for the N95 respirator and for the safety requirement that workers be fit tested and trained in its use.

Some infection control experts argued in good faith that the fit testing law was ill advised; that N95 respirators were not needed because SARS was droplet spread, not airborne; that the Provincial Operations Centre was wrong to require fitted N95s; and that nurses would be safe if they followed the advice of their employers instead of the safety procedures required by law.

Nurses pushed back with understandable heat, saying that hospitals should follow safety laws. Nurses took the reasonable position that if hospitals did not obey the law,

895. Dr. Colin D’Cunha, presentations, SARS Commission Public Hearings, September 29, 2003.

then the Ontario Department of Labour should fulfill its enforcement mandate and make them do so.

This is not the place to enter into that acrimonious debate. Nurses are angry, with good reason, that so many got sick and that safety laws were not respected or enforced. It must be noted that the experts who campaigned against the N95 and fit testing undoubtedly acted in good faith, doing what they believed was in the best interests of health workers and the health system. It would be too easy to personalize this debate and point out that some of those who most vociferously oppose the N95 and fit testing, and who were most disdainful of nurses and independent safety experts who prefer precaution, were the very people on whose watch nurses became sick despite the assurances that they were safe. Whenever someone presides over a system that fails and then leads a campaign against greater precaution, it is easy to forget that there are bigger issues at stake, more important things than arguing over who is right and who is wrong.

Scientific uncertainty and scientific debate can go on forever. We do not need a personalized debate or further recriminations. What we do need is a common-sense approach to worker safety in hospitals coupled with a measure of scientific humility in light of the terrible and sometime fatal failures in scientific advice and hospital safety systems during the SARS outbreak. What we need to do is to follow the precautionary approach that reasonable steps to reduce risk need not await scientific certainty. It is better to be safe than sorry.

The only way to make nurses and other health workers safe is to transcend the turf wars that hampered the fight against SARS. These turf wars continue even after SARS proved that hospital safety systems failed to protect workers.

On the one hand, some experts believe that in the face of a still relatively unknown disease like SARS, you can avoid a precautionary approach, start with the lesser protection of a surgical mask and ramp up to an N95 if and when it's needed.

On the other hand are independent safety experts like those in British Columbia, which stopped SARS in its tracks, like those from the Centers for Disease Control and NIOSH and like those from the Ontario Department of Labour say, who that experience dictates a common-sense precautionary approach, starting with a higher level of protection that is reduced as the clinical situation is clarified.

Until this precautionary principle is fully recognized, mandated and enforced in Ontario's hospitals, workers will continue to be at risk.

## Airborne and Droplet Transmission

At the heart of the mask debate is the question of airborne transmission. Is SARS spread mostly by large droplets? What is the risk of airborne transmission?

It is instructive to set the stage for the story of the N95 with a nutshell description of how SARS is transmitted from person to person.

Droplets from the breath of an infected person can contaminate surfaces and articles on which they land:

Viable organisms may survive long enough in droplets deposited on environmental surfaces to contaminate the hands of caregivers and then be further transmitted.<sup>896</sup>

Objects thus contaminated are called *fomites*. Fomite transmission occurs when an infectious droplet contaminates a fomite (the surface on which it lands) and is then spread by the hand of someone who touches it.<sup>897</sup>

A study of the Toronto outbreak looking at environmental contamination in SARS outbreak units detected SARS on frequently touched surfaces in rooms occupied by patients with SARS (including a bed table and television remote control) and in a nurses' station used by staff (on a medication refrigerator door).<sup>898</sup> SARS has been found to remain stable for 24 to 48 hours in urine, 36 hours on plastic surfaces, 72 hours on stainless steel and 96 hours on glass surfaces.<sup>899</sup>

Droplet transmission, the primary mechanism for the spread of SARS, occurs when

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896. Healthcare Health and Safety Association of Ontario, *Respiratory Protection Programs*, 2nd edition, p. 1.

897. Fomites have been defined as "objects, such as clothing, towels, and utensils that possibly harbor a disease agent and are capable of transmitting it" (U.S. Army Medical Research Institute of Infectious Diseases, *Medical Management of Biological Casualties Handbook*, 4th edition: U.S. Army Medical Research Institute of Infectious Diseases, 2001], p. A-5; and as "articles that convey infection to others because they have been contaminated by pathogenic organisms. Examples include handkerchief, drinking glass, door handle, clothing and toys." Last, John M. Last, *A Dictionary of Epidemiology*, p. 72.

898. T.F. Booth, B. Kournikakis, N. Bastien, et al., "Detection of airborne severe acute respiratory syndrome (SARS) coronavirus and environmental contamination in SARS outbreak units," *Journal of Infectious Diseases* 191 (2005):1472-77 (Booth et al, "Detection of airborne severe acute respiratory syndrome (SARS)).

899. World Health Organization, *Consensus Document on the Epidemiology of Severe Acute Respiratory Distress Syndrome* (Geneva: WHO, 2003), p.29.

large droplets are transmitted to a paramedic, nurse, doctor, visitor or family member from an infected person's respiratory tract by coughing, sneezing or even normal breathing.<sup>900</sup> They are too small to see but are heavy enough to fall quickly to the ground and can be breathed in by someone in close proximity to the infectious person. Close personal contact is thus required for droplet transmission.

At the smallest end of the scale are droplet nuclei, so tiny and light that, depending on the conditions, it is thought that they can remain suspended in the air for several hours,<sup>901</sup> and can also:

travel considerable distances in the air and may be readily inhaled into the lung.<sup>902</sup>

In some cases, it is believed that large droplets can themselves become droplet nuclei:

Larger droplets that are dispersed into fairly dry air can actually begin to “dry out” and become droplet nuclei.<sup>903</sup>

Diseases spread by droplet nuclei or evaporated droplets are generally considered to infect others through airborne transmission.

Airborne transmission, associated with diseases like measles, chickenpox and smallpox, occurs when droplet nuclei or evaporated droplets from an infected person remain suspended in the air. These nuclei or droplets may remain in the air for a long time and may also travel through the air to be inhaled a distance away by someone who had no contact with the infected person.<sup>904</sup>

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900. “Droplets are ejected from the respiratory tract during coughing, shouting, sneezing, talking, and normal breathing. The size and number of droplets produced is dependant on which of these methods generated the particles” (Dr. Annalee Yassi and Dr. Elizabeth Bryce, *Protecting the Faces of Health Workers: Knowledge Gaps and Research Priorities for Effective Protection Against Occupationally-Acquired Respiratory Infectious Diseases* [Occupational Health and Safety Agency for Healthcare in BC, April 30, 2004], p. 5.

901. Yassi et al, “Research Gaps in Protecting Health Workers from SARS”.

902. Yassi et al, “Research Gaps in Protecting Health Workers from SARS”.

903. Healthcare Health and Safety Association of Ontario, *Respiratory Protection Programs*, 2nd edition, 2005), p. 2.

904. “Airborne transmission: occurs by dissemination of either airborne droplet nuclei or evaporated droplets (sub micron particles) containing microorganisms that remain suspended in the air for long periods of time. These microorganisms can be widely dispersed by air currents and may be inhaled by persons even when standing a distance away from the source patient” Infection Control Standards Task Force, *Final Report* [Toronto: Infection Control Standards Task Force, December 2003], p. 5.



Research has shown that most viruses are spread through large droplets, only a few through airborne transmission:

... most viruses which cause respiratory and gastrointestinal disease in humans, must be contained in large droplets ... in order to survive outside the body and transmit disease from person-to-person. This includes such common respiratory pathogens as influenza, respiratory syncytial virus (RSV) parainfluenza viruses, the common coronaviruses and others. The notable exceptions are measles, varicella zoster virus (chickenpox) and smallpox[,] which apparently can survive in small diameter droplets or droplet nuclei and can be transmitted by air over long distances.<sup>905</sup>

Although believed to be spread mostly by large droplets, SARS is also transmitted when the droplets become aerosolized through medical procedures like intubation, bronchoscopy<sup>906</sup> or a type of assisted ventilation known as a BiPap, or bilevel positive airway pressure device.<sup>907</sup>

All these procedures and treatments were used during the SARS outbreak. Almost a quarter of SARS patients were intubated, a procedure that places a tube into the windpipe or trachea to open the airway for oxygen, medication or anesthesia. Because these aerosolizing events were so common in the treatment of SARS, it defies the evidence to dismiss it as simply a droplet-spread disease.

Some scientists say that a mere cough or sneeze can produce airborne viral particles. Dr. Annalee Yassi, one of the country's foremost occupational medical experts, said researchers now know that there is always an airborne component of a cough or a sneeze. A cough or a sneeze never produces just large droplets. She told the Commission:

There is unquestionably some airborne spread even if it's only when people are coughing or sneezing, never mind nebulized and ventilated

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905. Protecting the Faces of Health Workers, p. 16.

906. "Bronchoscopy is a test to view the airways and diagnose lung disease. It may also be used during the treatment of some lung conditions" (*MedLine Plus Medical Encyclopedia*, <http://www.nlm.nih.gov/medlineplus/ency/article/003857.htm>).

907. "Bilevel positive airway pressure (BiPAP) delivers a higher pressure on inspiration, helping the patient obtain a full breath, and a low pressure on expiration, allowing the patient to exhale easily. BiPAP is a common choice for neuromuscular disease" *Gale Encyclopedia of Surgery*, <http://www.answers.com/topic/mechanical-ventilation>.

and so on. It's always never purely droplet spread. It's droplet spread that's at least aerosolized in certain circumstances.

The jury is still out on the extent of airborne SARS. A strong current of scientific opinion suggests that the distinction between airborne and droplet transmission is not as clear-cut as some insisted during SARS. A recent study co-written by Dr. Allison McGeer of Mount Sinai concluded:

Accumulating evidence suggests that the distinction between droplet and airborne transmission may not be as clear-cut as previously thought.<sup>908</sup>

The Centers for Disease Control (CDC) agrees that airborne transmission of SARS cannot be ruled out and that N95 respirators should be used:

The transmission of SARS appears to occur predominantly by direct contact with infectious material, including dispersal of large respiratory droplets. However, it is also possible that SARS can be spread through the airborne route. Accordingly, CDC has recommended the use of N95 respirators, consistent with respiratory protection for airborne diseases, such as tuberculosis.<sup>909</sup>

The WHO takes the same position, that the risk of airborne transmission requires the use of the N95:

In view of the possibility of airborne transmission, current guidelines issued by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) state that health workers should wear N95 masks or higher-level protection during all contact with suspected SARS patients.<sup>910</sup>

A Health Canada December 2003 draft agreed with the CDC and WHO, although reluctantly, because it resisted the evidence of airborne transmission:

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908. Matthew P. Muller and Allison McGeer, "Febrile respiratory illness in the intensive care unit setting: an infection control perspective," *Current Opinion on Critical Care* 12 (2006):37-42.

909. Centes for Disease Control, *Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS* (Atlanta: CDC, May 3, 2005).

910. Derrick et al., "Protecting healthcare staff from severe acute respiratory syndrome: filtration capacity of multiple surgical masks," *Journal of Hospital Infection* 59 (2005): 365-68.

Currently, N95 respirators or equivalent are recommended by Health Canada, WHO and the CDC for the care of SARS patients even though the evidence shows that SARS is spread by droplet transmission.<sup>911</sup>

Since SARS, a considerable body of research and scientific opinion suggests it was wise to take a cautious approach and require the N95 respirator.

As one CDC expert told the Commission, in a hospital you never know when one of those aerosol-generated events will happen. That is one of the reasons why the CDC recommends routine airborne protection for SARS:

But in health care facilities, when you have people in, you just don't know sometimes when you're going to have an aerosol-generating procedure happen, and it could happen precipitously. And because of those issues and because of issues like this, we're going to continue to recommend airborne precautions.

Experts who opposed the use of the N95 and fit testing argued that because SARS is largely droplet-spread, the level of respiratory protection didn't matter, as long as health workers wore some kind of respiratory device. Even a surgical mask would do.<sup>912</sup>

It is not contested that a great deal of evidence points to the fact that SARS is usually spread by large respiratory droplets. The important word here is "usually." Highly contagious viruses spread by smaller aerosols have high reproduction numbers, or R0.<sup>913</sup> Measles has an R0 of 15. Experts expect that a person with measles could pass the disease to roughly 15 others at the start of an outbreak in the absence of prevention measures. SARS's R0 was about 3. A person with SARS could on average pass the disease to roughly three others at the start of an outbreak in the absence of prevention measures. There were, however, enough super-spreaders, people with a very high viral load who could spread SARS to more than 20 people in some cases,

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911. Health Canada, "Infection Control Precautions for Respiratory Infections Transmitted by Large Droplet and Contact Infection Control Guidance If There Is a SARS Outbreak Anywhere in the World, When an Individual Presents to a Healthcare Institution with a Respiratory Infection" (Ottawa: Health Canada, December 17, 2003).

912. SARS Commission Public Hearings, September 29, 2003.

913. The average number of people an infected person can be expected to pass the disease to at the start of an outbreak in the absence of prevention measures.

and super-spreading events like intubations, to prove that every case was not average and many were not.

The WHO consensus document on SARS said:

A basic reproduction number (R0) of approximately 3 is consistent with a disease spread by direct contact or larger virus-laden droplets that travel only a few meters rather than by lighter airborne particles. By contrast, if a disease is transmitted by aerosols, a single person can infect an entire room by coughing, as can happen with measles and influenza.<sup>914</sup>

On the worker safety side of the droplet vs. airborne transmission debate were those who took a more cautious approach. Yes, said experts who took this position, all signs point to the fact that SARS is usually spread by large droplets, but we don't know enough about the disease to rule out airborne transmission. With this uncertainty, they suggested, let's be cautious and use the N95.

The two sides were balanced well in the Naylor Report. First:

Given that SARS was being spread primarily via droplets, some informants questioned whether N95 masks were necessary.<sup>915</sup>

But then:

Others stressed that the disease should be treated as airborne until more information was available.<sup>916</sup>

A leader in the effort to contain SARS in Ontario told the Commission that, despite evidence that SARS was mostly spread by large droplets, he still supported a precautionary approach and the use of N95 respirators:

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914. WHO, *Consensus Document on the Epidemiology of Severe Acute Respiratory Syndrome (SARS)*, p. 12.

915. Naylor Report, p. 30.

916. Naylor Report, p. 30. The full quotation reads as follows:

A controversial directive was the requirement that health care workers wear fit tested N95 masks. Neither the fit testing (a complex operation requiring a subject to try various mask designs while a bitter-tasting gas circulates underneath a hood), nor the appropriateness of the N95 standard itself had been fully discussed by the SAC. Given that SARS was being spread primarily via droplets, some informants questioned whether N95 masks were necessary. Others stressed that the disease should be treated as airborne until more information was available.

There isn't enough data reported yet from the SARS outbreaks to really know. There's been some literature published to suggest that an N95 is no more effective with a SARS patient. Let's for argument's sake say, for a regular SARS patient not requiring a high-risk procedure, then a properly worn surgical mask [would be fine], and intuitively if it's droplet, that should be the case.

I'm not comfortable with that yet and I'm not sure why. Maybe it's because my colleagues got sick. Maybe it's because I know the backlash from the providers and the unions. I'd rather from a strategic point of view say let's just keep doing this until all the evidence is in, that we're able to evaluate it properly and then we can back off. I'd rather ... than say maybe we were wrong this time, let's go back to the N95.

Three years after the outbreak, one physician who caught SARS and strongly supports the use of N95 respirators told the Commission that we still don't know enough about SARS:

I mean there are still people who say they were just droplets and even surgical masks should stop the droplets. I am not sure how they got sick then. So it could be that there are things about SARS we don't know.

It was largely on the basis of Toronto's Sunnybrook disaster on April 13, when nine health workers caught SARS, that the CDC decided in favour of the precautionary approach and opted for airborne precautions.

One CDC expert told the Commission:

And it's largely because of this event here, the Toronto cluster – not only this event though: there's also clusters in Hong Kong and elsewhere where people have been wearing droplet-level precautions and still gotten sick.

Now, it's usually an aerosol-generating infection as far as I'm aware. It's always associated with some aerosol-generating procedure of some type. And in Hong Kong, it was the use of aerosized nebulized bronchodilator therapy medications and a bunch of medical students all got sick who were wearing masks.

When you look at the R0, it suggests it's probably not airborne, it's not airborne in the same sense as measles or anything like that. And when you look at epidemiologic links, people down the hallway, around the corner, they're not getting sick. But, in health care facilities, when you have people in, you just don't know sometimes when you're going to have an aerosol-generating procedure happen, and it could happen precipitously. And because of those issues and because of issues like this, we're going to continue to recommend airborne precautions.

Nothing brings home the point of airborne SARS risk better than the May 28 disaster at North York General, when workers caught SARS despite their use of the personal protective precautions they were told would keep them safe. As late as May 28, the lesson of airborne risk had not been learned. A scientific study of the incident said:

In this case, just as in previous cases, either contact, droplet, or airborne transmission might have occurred.<sup>917</sup>

The CDC reported this incident in its journal *Emerging Infectious Diseases*. The authors,<sup>918</sup> some of them well-known figures in the SARS outbreak, concluded that the mechanism of transmission of the virus from patient to worker could have been airborne rather than droplet:

Two explanations may account for the transmission observed in this case: 1) an unrecognized breach in contact and droplet precautions occurred, or 2) an airborne viral load was great enough to overwhelm the protection offered by droplet precautions, including non-fit tested N95 disposable respirators. If the last form of transmission was responsible, airborne virus may have been generated by the coughing patient before her cardiopulmonary arrest or due to a "cough-like" force produced by the airway pressures created during asynchronous chest compressions and ventilations using the bag-valve-mask ...

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917. M.D. Christian et al., "Possible SARS coronavirus transmission during cardiopulmonary resuscitation," *Emerging Infectious Diseases*, Vol. 10, No. 2, February 2004 (Christian et al, "Possible SARS Coronavirus Transmission").

918. Michael D. Christian, Mona Loutfy, Clifford McDonald, Kenneth F. Martinez, Mariana Ofner, Tom Wong, Tamara Wallington, Wayne L. Gold, Barbara Mederski, Karen Green, and Donald E. Low.

The final line of protection against occupational exposure is protection equipment. The use of N95 respirators offers a level of protection against airborne transmission of SARS. However, for any form of respiratory protection to perform at the level of its full potential, it must be properly fitted to provide an adequate seal. The N95 disposable respirators used by health workers in this instance were not fit tested to ensure an adequate seal. Thus the exact level of protection afforded by the N95 respirators for each person in this case is unknown. Nonetheless, a higher level of respiratory protection should be considered in environments with a potentially very high SARS-CoV load, *such as* that associated with aerosol-generating procedures. [emphasis added]<sup>919</sup>

Nothing could show better the scientific reasons for the N95 and for fit testing.

The body of evidence and scientific opinion about airborne SARS is too extensive to discuss in detail here. Reference is made below to evidence that the original transmission of SARS in the Metropole Hotel on February 21, 2003, to Toronto's index case and at least 15 others that may have been airborne,<sup>920</sup> to disasters in other countries (like Amoy Gardens in Hong Kong) and to evidence of airborne SARS in a Toronto hospital.

Because of this risk of airborne transmission, Ontario during SARS required workers with close patient contact and sometimes those in other areas of hospital to wear fitted N95 respirators to protect against the risk.

In the context of this risk, the following issues arise:

- N95 respirators and surgical masks
- Ministry of Labour approval
- SARS decision to require N95s
- Confusing directives during SARS
- Failure to train
- Ministry of Labour sidelined
- Confusion: N95 "equivalent"

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919. Christian et al, "Possible SARS Coronavirus Transmission".

920. WHO, *SARS: How a Global Epidemic Was Stopped* (Geneva: WHO, 2006), p. 8.

- Was the N95 necessary?
- Was fit testing necessary?

## The Difference Between an N95 Respirator and a Surgical Mask

While surgical masks<sup>921</sup> and their lower-standard cousins, procedure masks,<sup>922</sup> have long been used to safeguard health workers, they were originally intended primarily to protect patients.

One study said:

Surgical masks were developed to prevent the wearer's exhaled secretions from contaminating the operative field.<sup>923</sup>

Surgical masks, which must meet far less stringent regulatory standards than respirators,<sup>924</sup> are believed to offer the wearer some protection.<sup>925</sup> But this protection is

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921. "Surgical masks ... are of two main types: (1) flat-pleated or duck-billed in shape, conforming to the bridge of the nose with a flexible piece, affixed to the head with two ties and (2) pre-molded conforming to the bridge of the nose with a flexible piece, adhering to the head with a single elastic" National Academy of Sciences, *Reusability of Face Masks During an Influenza Pandemic* [Washington, DC: National Academy of Sciences, April 2006], p. 16).

922. "Procedure masks are flat/pleated or duck-billed in shape and fasten to the head with ear loops. All procedure masks have some degree of fluid resistance, but they are not required to meet the same standards as surgical masks" (National Academy of Sciences, *Reusability of Face Masks During an Influenza Pandemic*, p. 16).

923. Yassi et al, "Research Gaps in Protecting Health Workers from SARS".

924. The regulatory approval for surgical masks is far less stringent than that of independently certified N95 respirators There are no minimum standards or standardized testing methods for surgical mask filter efficiency. (WHO, *Avian Influenza, including Influenza A (H5N1), in Humans: WHO Interim Infection Control Guideline for Healthcare Facilities* [Geneva: WHO, February 9, 2006], p. 41).

The U.S. Food and Drug Administration, in approving surgical masks for sale, does not address the fit of the mask, or its effectiveness:

Food and Drug Administration's regulatory requirements do not address the fit of medical masks, which can make the total filtration efficiency of questionable value. Masks approved by the FDA for medical use are designed to be worn by an infected person, health worker or member of the public to reduce transfer of body fluids that may spread infection. (National Academy of Sciences, *Reusability of Face Masks During an Influenza Pandemic*, p. 32).



limited because a surgical mask doesn't create a tight seal around the mouth and nose of the wearer and always leaves gaps. As one study of respiratory protection explained:

The device is placed over the nose and mouth and held in place by straps placed behind the ears or around the head but more usually around the back of the head and neck. The device fits fairly loosely and a tight seal is not feasible where the outside edge of the mask meets the skin of the face. Most users in the healthcare industry tend to wear surgical masks rather loosely; considerable gaps are usually observed at the peripheral edges of the surgical mask along the cheeks, around the bridge of the nose and along the bottom edge of the mask below the chin.<sup>926</sup>

The problem with a surgical mask is that not all the air breathed in by a health worker passes through a surgical mask's filtering materials, regardless of the filtering quality of those materials. A recent study by the Institute of Medicine of the National Academies, whose authors included Dr. Allison McGeer of Toronto's Mount Sinai Hospital, said:

The loose fit of most medical masks [i.e., surgical and procedure masks] leaves gaps that could allow substantial contaminant leakage into and from the mask ... Medical masks may be used as barriers against disease transmission by fluids, especially blood, and some large droplets, and they are designed to prevent release to the environment of large droplets generated by the wearer. They are not designed or approved for the

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Standard surgical masks are considered a Class II device by the US federal Food and Drug Administration (FDA) which require pre-market sales approval. This means that to obtain approval as an item for sale, the manufacturer must demonstrate to the satisfaction of the FDA that the new device is substantially equivalent to similar masks currently on the market. There is no specific requirement to prove that the existing masks are effective and there is no standard test or set of data required supporting the assertion of equivalence. Nor does the FDA conduct or sponsor testing of surgical masks. Yassi and Bryce, *Protecting the Faces of Health Workers*, p. 17).

925. Health Canada's *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare* says: "Masks are also worn to protect the HCW from acquisition of infections transmitted by large droplets. Surgical masks are considered adequate for this purpose. It appears logical to use a mask when within 1 metre of a coughing patient" (Vol. 25S4, July 1999, p. 27).

926. Yassi et al, "Research Gaps in Protecting Health Workers from SARS".

purpose of protecting the wearer against entry of infectious aerosolized particles potentially surrounding the wearer and his mask.<sup>927</sup>

A Toronto physician who was involved in treating SARS patients said:

The trouble with ordinary surgical masks are you lick them and you stick your nose in them and they have big holes in the outside part and so forth. Let's face it, they're a joke. But surgeons use them to this very day. They're cheap and they're comfortable. We still use them. Surgical masks protect mainly the patient.

Studies have shown that surgical masks, because of their inability to create a tight seal, are less effective against smaller droplets and droplet nuclei than N95 respirators. Even wearing as many as five surgical masks does not raise their ability to filter out smaller airborne particles to the level of an N95 respirator.<sup>928</sup>

Designed to create a tight seal around the mouth and nose of the wearer, an N95 respirator provides a far higher level of protection to the wearer than surgical masks. Respirators rely:

on the breathing action of the user to draw air through the filtering medium. On inhalation a negative pressure is created as the air is drawn through the medium. Respirators of this type are considered tight fitting because they rely on a good seal between the user's face and the respirator itself in order to work properly.<sup>929</sup>

As one U.S. expert explained to the Commission, masks and respirators are designed for different purposes:

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927. National Academy of Sciences, *Reusability of Face Masks During an Influenza Pandemic*, p. 32.

928. A recent study that examined whether wearing as many as five surgical masks was sufficient protection from the SARS virus concluded: "Our data confirm previous findings that the filtration of submicron-sized airborne particles by a single surgical mask is minimal ... Although greater filtration was afforded by multiple masks, with an approximate doubling in the filtration factor when five masks were worn compared with a single mask, the absolute filtration factor remained low and well below the minimum fit factor of 100 required for a respirator" Derrick et al., "Protecting healthcare staff from severe acute respiratory syndrome," 365–68).

929. Healthcare Health and Safety Association of Ontario, *Respiratory Protection Programs*, 2nd Edition, p. 11.

Masks are meant to protect something else, e.g., a surgical field, or someone else from getting whatever the wearer of the mask may have. They are not designed to protect the wearer of the mask from whatever is floating around in the air. Respirators, on the other hand, are designed to protect the wearer and that's one of the reasons why they need to be form-fitted.

## Ministry of Labour Approval

The N95 is part of a family of nine respirators introduced in July 1995 under a new NIOSH standard known as 42 CFR Part 84.<sup>930</sup>

NIOSH, the National Institute for Occupational Safety and Health, is part of the Centers for Disease Control and Prevention, the U.S. agency responsible for worker safety research, standards, evaluation and education.

Because there is no Canadian agency that tests and certifies respirators, the Ministry of Labour, in regulating workplace safety, often relies on NIOSH. A ministry official said this was the case with NIOSH's new respirator standards:

And we essentially accepted these new [NIOSH respirator] approvals and – and we basically said these are the respirators that we want to see used.

The ministry began to phase in the new standards in 1995. The phase-in period expired in May 1999, after which only new NIOSH-tested respirators would be approved for use. As the phase-in period was expiring, the Ministry of Labour advised:

It is Ministry of Labour policy to continue to accept both the new approved respirators under Part 84 and the old respirators for dusts, mists and fumes, approved under the old Part 11, up until May 10, 1999, as long as the old respirators are in good physical condition and are appropriate for the type and concentration of an airborne contaminant.

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930. National Institute for Occupational Health and Safety, "NIOSH change will save healthcare industry millions," news release, August 25, 1995.

After May 10, 1999, Inspectors will issue orders under clause 25(2)(h) of the *Occupational Health and Safety Act* to require the new respirators or filters.<sup>931</sup>

Clause 25(2)(h) of the Act requires that an employer:

take every precaution reasonable in the circumstances for the protection of a worker.

This change in the ministry's respirator standards was also reflected in the Policy and Procedures Manual of the ministry's Operations Division. Section 10.17 of the manual, dated April 1, 2000, said:

In issuing orders for new non-powered air purifying filter/respirators the following wording is suggested:

“Pursuant to section 25(2)(h) of the OSHA, the employer shall ensure that respirators used in the workplace meet the current standards to ensure the workers wearing air purifying particulate respirators for exposure (i.e. state hazard i.e., asbestos, welding fume, lead, silica, etc.) in the (state area or location) are adequately protected.”

The narrative of the report can provide explanatory material such as:

“It is a reasonable precaution to provide respirators approved to the new NIOSH standard referred to as 42 CFR 84 since these new filters are tested to new and more demanding testing requirements than those tested under the old NIOSH approval system. The new testing provides better evidence of the filters' ability to remove airborne particulates and thus the workers will receive better protection from the particulates.”

Before SARS, N95 respirators were not widely used in most Toronto hospitals. Some did stock N95 respirators for use in treating tuberculosis patients. At some other hospitals, however, health workers treating TB cases used respirators that the hospitals felt were equivalent to an N95 even though they were not independently tested and certified. (The issue of equivalency is discussed below.)

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931. Ontario Ministry of Labour, “Ministry updates respirator policy for NIOSH approved particulate respirators,” January 18, 1999.

Regardless of what type of respirator their hospitals stocked, most health workers interviewed by the Commission said that before SARS they had never seen an N95 respirator, had never used one and had not been trained in its use either at school or on the job.

## The Decision to Require N95s

On the evening of March 26, just hours after the provincial emergency was declared, a critical meeting was held at the Provincial Operations Centre (POC). With the outbreak gathering momentum, the men and women who led the fight against SARS decided what measures, including respiratory protection, were needed to contain the new disease.

The atmosphere among the attendees, who included Drs. Jim Young, Colin D'Cunha and Sheela Basrur, was understandably tense. One participant recalled the mounting concern over the worsening situation:

I got paged late Wednesday night and asked if I would come down to the emergency centre because they were going to, now the province was involved. People were very upset that things, we were hearing stories now not only about people coming back to Scarborough Grace Hospital unwell but people were arriving in other emergency departments around the city sick, so it was no longer confined to Scarborough Grace Hospital but now patients were showing up at Scarborough General, at North York, at Centenary, and so things were kind of ... we did not have a handle on what was going on.

SARS was spreading so fast that it overwhelmed efforts to trace the contacts of SARS patients and find out where the infection was coming from and where it was going. No one knew how far it had spread in Toronto. No one knew where it was spreading. Dr. Don Low said:

We recognized that we had lost control, that we were not able to identify patients.<sup>932</sup>

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932. Interview with Dr. Donald Low in *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science 2* (2004) (Dr. Low – Biosecurity and Bioterrorism Interview).

Amid this uncertainty, it was clearly evident from the devastating outbreak at Scarborough Grace that health workers were terribly vulnerable to the new disease and that the health care system had failed thus far to protect them.

As Table 2 below indicates, of the initial 128 SARS cases at Scarborough Grace, 47, or 37 per cent, were staff at the hospital, and seven, or 6 per cent, were non-hospital health workers, including EMS personnel. At least eight members of health workers' households were also infected. The disturbing bottom line: of the 128 cases, 62, or 48 per cent, were either staff at the hospital, other health care workers or members of health workers' households.<sup>933</sup>

**Table 2 – SARS Cases at Scarborough Grace Hospital<sup>934</sup>**

<b>Contact Setting</b>	<b>Number</b>	<b>Percentage of Total Cases (128)</b>
Hospital – Staff	47	18%
Patients	18	37%
Visitors	14	14%
Other health workers	7	6%
Close contacts	38	30%
Total number of health workers and members of their households	62	48%

If health workers were this vulnerable, no one appeared to be safe.

The fact that SARS had infected so many health workers led those trying to contain the Scarborough Grace outbreak to conclude that more protection was needed. Heightened precautions implemented at Scarborough Grace in late March included the requirement that all health workers use N95 respirators:

Following the initial investigation, contact and droplet precautions were implemented for all patients in ICU on March 22, and the ICU and

933. Varia et al., "Investigation of a nosocomial outbreak of (SARS)"

934. Varia et al., "Investigation of a nosocomial outbreak of (SARS)"

emergency department were closed on March 23. On March 24, following the identification of staff and patient cases not linked to the ICU or emergency department, the hospital was closed to admissions, outpatient clinics were closed, and discharged patients were placed into quarantine at home for 10 days. Along with an increased emphasis on hand-washing, additional precautions, including the use of gowns, gloves, N95 or equivalent masks, and eye protection, were implemented for all patient care, and single or negative-pressure rooms were used for all febrile patients. Dedicated equipment was used for all patients, and patients were restricted to their rooms except for medically necessary tests. Staff wore N95 masks at all times in the hospital.<sup>935</sup>

In the face of a new, unknown disease, and mindful of the experience of Scarborough Grace, provincial officials decided on March 26 that affected health workers outside of Scarborough Grace also needed the higher protection of N95 respirators.

Dr. James Young told the SARS Commission public hearings that the decision was taken from a precautionary approach:

We chose, for means of protection, to use the N95 mask. We believed from the beginning that it was droplet-spread, but we believed, until we were more certain, that we should use the more protective N95 mask.<sup>936</sup>

One expert told the Commission that officials decided to err on the side of caution:

Even then we started talking N95. If I remember correctly that Wednesday night, we started because we did not know how this thing was transmitted and we assumed the worst, which is the right thing to do, and that's why N95s. Either that night or the next, the decision was made to buy every N95 in North America. We bought out the market by the weekend.

Dr. Low said:

In the early days, that's what kept me awake at night: the thought that we would always be remembered as the epicentre for a new endemic disease

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935. Varia et al., "Investigation of a nosocomial outbreak of SARS"

936. SARS Commission Public Hearings, September 3, 2003.

which eventually would find its way across North America. But early on, we didn't know how it was transmitted. We couldn't say that it wasn't airborne-transmitted. And therefore we assumed the worst and made the decision. We were going to require that everybody in the city wear an N95 mask in a health care facility.<sup>937</sup>

## N95s Were Hard to Wear

It quickly became evident that health workers would have a difficult time doing their jobs while using an N95.

Respirators were uncomfortable to wear, restricted human interaction (an important part of patient care) and added significantly to health workers' workloads. One study of the experience of health workers during SARS said:

Wearing a mask was the precaution most frequently cited as most bothersome ... The most commonly cited difficulty with the mask was physical discomfort (92.9% [1588/1710] of respondents).<sup>938</sup>

The ONA survey found:

Over 70% of respondents experienced some side effects from the use of PPE [personal protective equipment], including: headaches, shortness of breath, facial rash, fatigue, dizziness, and others.<sup>939</sup>

The ONA and OPSEU told the Commission public hearings that wearing N95 respirators for a long time caused fatigue, probably because of reduced oxygen intake.

One health worker told the Commission:

We had it on for our whole 12-hour shift, right? We changed our masks, our gloves, our gowns, everything, but you were donned, except on break time, in this, and the thirst and the fatigue was phenomenal that we went

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937. Dr. Low Biosecurity and Bioterrorism Interview.

938. L. Nickell et al., "Psychosocial effect of SARS on hospital staff: survey of a large tertiary institution," *CMAJ* 170 (2004): 793-98.

939. Hay Group, "Nurses' Perspective on the Outbreak of SARS in Toronto" (March 2006), p. 10.



through. We were so tired and so listless.

Another health worker said:

Question: So it was very hot?

Answer: It was very uncomfortable and I remember we had a cardiac arrest and I ended up being the one that was doing the chest compressions and I had never been so hot in my entire life, thinking, how did I manage to get this job?

A third health worker simply said:

I was very uncomfortable in it – you can't breathe through these fibre-glassy things.

The ONA and OPSEU told the Commission public hearings that pregnant workers especially noted fatigue because their breathing was already restricted by the pressure from the growing fetus:

The mask restricts breathing and increased carbon dioxide levels. The mask restricts successful exhalation because, as you exhale, the air containing carbon dioxide is trapped in the mask and then you breathe it in again.<sup>940</sup>

The Registered Nurses Association of Ontario told the Commission:

Nurses complained about a constant burning irritation of the throat, tightness in the upper chest, headaches, allergic skin reactions, swollen lips and tongue, dizziness, lethargy, sleep disorders and the exacerbation of other health problems such as asthma. Some nurses reported that they could taste and feel the fibres from the mask and were concerned about long-term implications of prolonged mask use.<sup>941</sup>

During and after SARS, some experts in and out of government used the discomfort of wearing an N95 as an argument against a precautionary approach.

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940. SARS Commission Public Hearings, November 17, 2003.

941. SARS Commission Public Hearings, November 17, 2003.

In the words of one health workers' union, these experts argued that "personal protective equipment is uncomfortable and difficult to put on" and that this was a reason not to use respirators. Representatives of health workers say their members accept the discomforts of wearing N95 respirators if it means they are protected. As one union stated:

A day in the life of a health care worker is replete with all varieties of discomfort. While health care workers (like all workers) would prefer not to wear respirators, they are prepared to adjust to discomfort when necessary to make the very air they breathe safe for themselves and safe to pass on to patients and family. Firefighters, steelworkers, chemical workers and others have for decades routinely crouched in cramped, confined spaces for hours at a time, dragged down by much heavier respiratory protection than the N95 respirators ... Given information and training about hazards and the need for respiratory protection, all workers tolerate the discomfort.<sup>942</sup>

It is hard to argue with the union's point of view.

## **N95 Respirators and POC Directives**

Comfortable to wear or not, the N95 respirator, with its recognizable, face-hugging shape and its frequent media use to illustrate the outbreak, came to symbolize the battle to contain SARS.

For health workers, along with being the source of much discomfort, the N95 respirator was also the subject of a great deal of confusion over who should wear an N95, where it should be worn and how it should be properly used.

Unclear directives were a significant cause of this uncertainty.

Issued by the POC, directives were meant to ensure that measures to contain the outbreak were based on the best expert advice and were consistently applied. While there is no doubt that directives on N95 respirators were at times confusing, those who prepared the directives made a remarkable effort under pressure. From a standing

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942. ONA letter to Premier McGuinty, December 15, 2005.

start they helped to create a system that in the end stopped SARS. The wonder is not that there were problems with the directives. The wonder is that these dedicated men and women were able to produce from nothing a system that did the job.

When the March 26 decision was made to mandate the use of N95 respirators, for example, experts like Dr. Low stayed up late into the night to craft appropriate directives. Dr. Low recalled:

That night we sat down and came up with policies and procedures that we sent to all the hospitals the next morning.<sup>943</sup>

Directives on N95 respirators were at times confusing because of the massive systemic weaknesses that hampered efforts and capabilities. Those preparing the directives did the best they could under difficult circumstances with insufficient resources, infrastructure and planning. One expert involved in preparing directives recalled:

Whatever information we had, we then issued new orders and directives as to how we thought hospitals should react. And the kinds of questions that were thrown at us, when the volume I likened to taking a shower in Niagara Falls. It was colossal, and we had to set rules as to how many people were allowed in to interrupt us ... We were so short of infectious disease human intellectual resources, that the people who were in Toronto were either quarantined or were themselves struggling with maintaining their own hospitals.

Regardless of the reasons for the directives' failings, reality is that on many occasions the directives did not provide sufficient advice to health workers, their supervisors or their employers.

Consider the first hospital directive issued by the POC on March 27. It required only staff in emergency departments and clinics to wear N95 respirators:

All staff in GTA [Greater Toronto Area] and Simcoe County hospital emergency departments and clinics to wear protective clothing (gloves, gown, eye protection and mask – N95 or equivalent).

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943. Dr. Low Biosecurity and Bioterrorism Interview.

Yet, as ONA and OPSEU noted in their joint submission to the SARS Commission, workers in the rest of the hospital were not required to take any special precautions:

This distinction between what protection was recommended for which groups of workers in the same facilities arose again and again throughout the crisis. Both unions were constantly trying to establish which areas were required to wear what personal protective equipment (PPE) and why.<sup>944</sup>

Problems with the March 27 directives appeared to have been addressed in the next few days, when two new directives extended the use of respirators to all health workers in affected facilities. On March 29, 2003, a POC directive to acute care hospitals in the GTA and Simcoe County required the wearing of an N95 respirator or equivalent by “all staff when in any part of the hospital,” “for hospital staff who are required to visit a patient care unit” and “for direct patient contact.” And on March 31, 2003, the requirement was extended to long-term care facilities in a directive that said:

All GTA/Simcoe County staff must invoke gown, glove, N95 mask (or equivalent), and eye protection precautions and cohort nursing protocols, whether or not they have identified possible SARS patients.

In a matter of days, new directives had a different message.

Directives on April 1, 2003, and April 3, 2003, appeared to require health workers to wear N95 respirators only in SARS patients’ rooms and for direct contact with any patient in intensive/critical care units or emergency departments.

ONA and OPSEU noted in their joint submission to the SARS Commission:

One example of such a change is found in two consecutive Directives for Acute Hospitals. The March 29 Directive for All Acute Hospitals in the GTA/Simcoe County required that “All staff when in any part of the hospital ... Use an N95 (or equivalent) mask (ensure mask is fit tested).” The April 1 and 3, 2003 Directives to All Ontario Acute Care Hospitals (which replaced the March 29 Directive above, and others) required staff to wear an N95 mask in SARS patients’ rooms, and for direct

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944. OPSEU/ONA Joint Report on Health & Safety Matters Arising from SARS, November 2003, pp. 4-5 (ONA/OPSEU Joint Report).

contact with any patient in Intensive/Critical Care Units or Emergency Departments.<sup>945</sup>

The April 1, 2003, POC directive to all Ontario acute care hospitals said:

All HCWs and staff entering the room of a SARS patient in ANY location ...

Use an N95 mask

—

For direct contact with any patient in Intensive/Critical Care Units or Emergency Departments HCWs must ...

Use an N95 mask

—

Patients with suspected or probable SARS must be placed in single isolation rooms, or cohorted with other SARS patients and treated using contact, and respiratory precautions. N95 masks, or equivalent, must be worn by anyone entering the room.

The April 3, 2003, POC directive to all Ontario acute care hospitals said:

All HCWs and staff entering the room of a SARS patient in ANY location ...

Use an N95 mask

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For direct contact with any patient in Intensive/Critical Care Units or Emergency Departments HCWs must ...

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945. OPSEU/ONA Joint Report, p. 8.

Use an N95 mask

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Patients with suspected or probable SARS must be placed in single isolation rooms, or cohorted with other SARS patients and treated using contact, and respiratory precautions. N95 masks, or equivalent, must be worn by anyone entering the room.

Health workers undoubtedly felt like yo-yos, told one thing one day, another the next, by the people who, acting in good faith, were supposed to keep them safe in a dangerous workplace.

The ONA and OPSEU noted in their joint submission that the confusion caused by the directives helped to undermine the confidence of health workers in the system that was supposed to protect them:

If workers throughout a facility are required to wear certain personal protective equipment (PPE) one day, and the next day only workers in the Emergency department are required to wear this PPE, and there is no explanation or rationale offered, it is difficult to be confident that every precaution is being taken to protect the health of our members.<sup>946</sup>

The uncertainty over who should wear an N95 and where they should wear them was exacerbated by the fact that the N95 was a completely new piece of protective equipment for most health workers.

An Ontario Nurses' Association (ONA) survey of its members<sup>947</sup> found:

Only 5% of respondents had been fit tested and/or trained and instructed in the care, use and limitations of PPE (personal protective equipment) before SARS.<sup>948</sup>

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946. OPSEU/ONA Joint Report, pp. 7-8.

947. The independent Hay Group summarized the survey's results for the Commission. The complete Hay Group report is available in Volume 2 of the Commission's final report.

948. Hay Group, "Nurses' Perspective on the Outbreak of SARS in Toronto" (March 2006), p. 8.

Since so few health workers had been taught how to properly use this new piece of protective equipment before SARS, health workers and their employers and supervisors were particularly reliant on the guidance of POC directives.

The directives were not only confusing, but during the early part of the outbreak they also lacked sufficient detail. For the first month and a half of the outbreak, the POC directives failed to explain in sufficient detail how to properly apply and remove an N95 respirator.

As the ONA and OPSEU said in their joint submission:

On April 20, for the first time detailed direction was given on matters such as ... procedures such as applying personal protective equipment, removing personal protective equipment ...

These directives offer the first concrete evidence that the POC had begun to recognize that employers, supervisors and workers did not understand how to implement the previous Directives. It is surprising that in an acute hospital setting accustomed to caring for patients with infectious diseases, that such detail was necessary.<sup>949</sup>

Directives issued on April 20, 2003, detailed procedures for applying and removing personal protective equipment.<sup>950</sup> Directives issued a few days later, on April 24, 2006, provided more detailed instructions.<sup>951</sup>

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949. OPSEU/ONA Joint Report, pp. 10-11.

950. Procedure for removing protective equipment on exit from the room:

While still inside the room:

- Remove gloves
- Remove gown (discard in linen hamper in a manner that minimizes air disturbance)
- Decontaminate hands with alcohol hand wash; do NOT use patient bathroom to wash hands
- Leave room, bag specimens, etc.

After leaving the room:

- Use alcohol hand wash again
- Remove face shield/fluid shield and discard
- Remove N95 mask. Remove hair cover
- Use alcohol hand wash again
- Put on new hair cover, N95 mask and gown
- At least once per hour, wash hands at nearest hand washing sink to remove residue from alcohol hand wash and reduce skin irritation

But by then, more than six weeks into the outbreak, dozens and dozens of health workers and members of their households had already contracted SARS, including two who were to die from it.

Confusing directives hindered the ability of health workers to protect themselves. Confusing directives hindered the ability of their employers and supervisors to know exactly what respiratory protections were needed to protect their employees. And confusing directives undermined the faith of health workers, their employers and their supervisors in the recommendations of those in charge of the fight to contain SARS.

An important lesson from SARS is that during a public health emergency, directives on respirator protective equipment need to be clear and complete. They need to be

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951. Routine procedure for applying personal protective equipment prior to entering patient room:

- Wash hands (do NOT use patient washroom to wash hands)
- Put on a disposable hair cover
- Put on a face shield. Use either a surgical mask with attached face shield (“fluid shield”) over the N95 mask or a full-face plastic shield.
- Put on 2 pairs of gloves

While in the patient room:

- Remove first pair of gloves after providing direct patient care
- Keep second pair of gloves on for remainder of stay in the room

Routine Procedure for removing protective equipment on exit from the room:

While still inside the room:

- Specimens to be placed in a clean specimen bag using a two person transfer method
- Remove second pair of gloves
- Remove gown (discard in linen hamper in a manner that minimizes air disturbance)
- Use alcohol hand rinse; do NOT use patient bathroom to wash hands

Just prior to leaving or immediately after leaving the room:

- Use alcohol hand rinse again
- Remove face shield/fluid shield and discard
- Remove N95 mask and discard
- Remove hair cover and discard
- Use alcohol hand rinse again
- Put on new N95 mask or equivalent and gown
- At least once per hour, wash hands at nearest hand washing sink (but NOT in a patient washroom) to remove residue from alcohol hand wash and reduce skin irritation



developed before the emergency strikes and not made up from scratch after it begins. They need to be developed in concert with all workplace parties to ensure that they are accurate, are consistent with worker safety laws and best practices, can be understood and will work.

## Lack of Training

It was bad enough that directives, at least during the first part of the outbreak, often lacked sufficiently detailed information. What made things worse was the lack of training.

The ONA members' survey found that 44 per cent of respondents felt that during the SARS outbreak there either was not enough training on the proper use of personal protective equipment or they didn't know.<sup>952</sup>

Many health workers interviewed by the Commission were not taught how to use N95 respirators when first required to use them. Often they were not properly taught until they were fit tested, which typically happened only long after the outbreak.

The following are representative of health workers' comments to the Commission:

Question:           And did anybody ever show you how to use it properly? Was there any training?

Answer:             No. I just looked at the box and put it on the way the box said to put it on.

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I really did not receive any formal training on the use of the equipment. You were pretty well [told] there's equipment there, you figure out yourself how to put it on. And certainly the missing piece with me was that I didn't have any formal training in how to remove it properly.

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952. Hay Group, "Nurses' Perspective on the Outbreak of SARS in Toronto" (March 2006), p. 9.

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Answer: There were no instructions on the memo [provided by the employer] for how to put on an N95 mask. Actually, I didn't know there was a way to put it on until after.

Question: And I guess you didn't know that there was a way to take it off?

Answer: Right. The memos did say in what order to take your gear off, like one set of gloves and then the next, but it didn't say specifically how.

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Question: Were you – at some point were you fitted for your mask?

Answer: Yes, I was.

Question: When was that, in the fall ... Was it after the second outbreak, or after the hospital shut down?

Answer: After the hospital shut down.

Question: And prior to your fitting, when you started wearing the N95 mask, did anyone give you training and education on how to properly apply the mask and how to make sure you get a proper seal?

Answer: No

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But what we didn't have was – the first day [was] anybody [who] taught us how to really put those masks on. So we didn't know whether we were putting them on properly or not.

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Question: Did you get training on how to properly don the equipment, how to properly remove the equipment, how to properly put your masks on. Did you get any of that in the first part of SARS?

Answer: No.

—

Question: So, you just go in and get a mask and you're expected to figure out how to use it properly and that's the complete extent of the training of the personal protection equipment, really?

Answer: Until, yes.

Question: Until the fit test?

Answer: Well, no. Because I guess somebody shows you once, you start talking to people and they tell you, fit it here and somebody else you work with has been already been shown.

Question: Right. But was there a formal [training] – like someone come around that [provided formal instruction]?

Answer: No, there's a little pamphlet that came in the box of them when you got the first ones that basically told you what to do.

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Question: And had you at that point [i.e., during the SARS outbreak] been given any instructions on how to properly wear a mask?

Answer: No.

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Question: And were you given any in-service training on how to properly put the equipment on and take it off?

Answer: Oh, not till far, far later. Months after.

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Question: You had said that you were not fit tested prior to that.

Answer: No.

Question: But you have been since?

Answer: Yes.

Question: And did someone show you [during the fit testing process] the proper way to put on that respirator, that mask?

Answer: Yes.

Question: During SARS, prior to you being fit tested, were you shown how to put it on?

Answer: No.

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Question: How did you know how to put that N95 on initially?

Answer: It's from colleagues.

Question: Prior to the fit testing taking place, did anybody ever give you training on how to properly apply your mask, how to get a proper seal.

Answer: Training? I don't remember any training.

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Answer: We weren't given an official in-service until the middle of the second SARS.

Question: And who did that for you?

Answer: You know what, I'm not really sure. Someone in regards to the education, like the nurse educator and stuff. We thought it was kind of ridiculous because, you know, at this point, we'd been through the first SARS and halfway through the second.

In cases where health workers were taught to use N95 respirators during SARS, health workers on day shifts in some cases appeared to have a greater chance of getting trained than their colleagues on nights.

One nurse said:

Professional practice leader came – it was the second day – came up to the unit, and they had signs, and it showed you the appropriate way to don and take off your garb, which we put outside the rooms. I said to her, this is great that we have this, but the staff's coming on at 7:30 [in the evening], are you going to be able to come back and explain all this to them? And she said to me, oh no, can't you do that?

Another nurse had a similar experience:

Question: So, there wasn't an educator that came on the unit and [provided formal training]?

Answer: That's my big issue. There is no education except for Monday to Friday. Basically 9:00 to 5:00, sometimes in the evening. So, if you do permanent night shift you have absolutely no education for off-hours.

Question: Mostly occurred Monday to Friday during the day shifts?

Answer: Yes. And I brought it up over and over. Nursing is

24/7. They need to be accommodating, especially when most of the staff are nurses, for night shifts, somebody needs to be coming in at nights for in-services and education, and it just doesn't happen.

Less attention also appeared to have been paid to training medical residents and fellows. One physician told the Commission:

There were no training sessions for the residents or the fellows. I think there were training sessions for the nurses and I think there were for the staff physicians, but there weren't for the residents and the fellows, which is – the reason for that is because resident and fellows rotate between hospitals and it is harder for the infection control service to capture them, but at the same time, it is a bit of a deficiency because residents and fellows have a lot of hands-on with patients.

As an indication of the consequences of poor training, some health workers told the Commission they were not told a good seal could be jeopardized by facial hair or by inserting something between the skin and the respirator.

An occupational safety consultant told the Commission that respirators work properly only if there is direct contact between the face and the respirator:

What the intent is, you need to have a proper seal. And what is a proper seal? A proper seal is there can be nothing such as beard growth, or beard or, you know, even face deformities fall into this. You've got to be able to have skin-surface-to-respirator contact. So as long as you've got that contact and it allows you to feel the negative pressure within your respirator, then there's absolutely no reason why it wouldn't be safe.

One health worker with a beard who caught SARS despite his unfitted N95 had never been told that the N95 required a tight fit around the face. When asked if he had been given any instructions, he said no:

Answer: No, I was never given any instructions.

Question: Did you get that when you were fit tested?

Answer: Yes.

Question: And was there anything that you learned that you weren't doing at the time or ...?

Answer: Yes. In regards to ensuring a seal between the mask and the face. I was not doing that at the time in 2003.

A respiratory protection manual said:

Facial hair can prevent a good seal between the skin and the respirator. Therefore, employees required to wear tight fitting respirators should be required to be clean-shaven where the respirator seals to the face unless there is a specific medical or religious reason for facial hair. In these cases, the employee can be reassigned to a position that does not require the use of a tight fitting respirator.<sup>953</sup>

Another health worker who caught SARS more than two months into the outbreak placed facial tissue between her skin and her N95 because of an allergic reaction to the respirator. She told the Commission:

Question: Do you know who you contracted SARS from?

Answer: I'm assuming it was [names patient].

Question: And you recall wearing a mask with her.

Answer: I had to shove Kleenex in it so it wouldn't touch my skin because I had an allergy to it. So I was wearing a mask, but I doubt it was in any way effective.

A hospital assistant who caught SARS in late May 2003 wore a surgical mask under his N95 respirator, unaware that inserting something between the respirator and the face can prevent a tight seal.

Question: But with this particular patient, you said you had on two masks.

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953. Healthcare Health and Safety Association of Ontario, *Respiratory Protection Programs*, 2nd edition, p. 31.

- Answer: Two masks.
- Question: Which one did you put on first?
- Answer: First I put that one [surgical mask] and the second one I put that [N95].
- Question: Indicating the surgical mask first and then the one that sticks out [N95]. Do you know what the second one was? Do you know what kind of mask that was?
- Answer: They are two colours, one was white [surgical mask], one was grey like this [N95] ... but I was using only white because it's a little bit bigger and it would fit over my nose.
- Question: Now, have you ever been fit tested for an N95 respirator?
- Answer: No, I don't remember that ...
- Question: And did anyone show you how to put on that top mask [N95]?
- Answer: Yeah, the nurse told me that you have to put like this first [surgical mask] and then comes this [N95] and put it on. Or she will put it on for me because I was very attached with that nurse up to now.
- Question: Prior to SARS, were there occasions where you would wear two masks?
- Answer: If it is very serious, the patient. Otherwise it is usual we put the mask on like that.
- Question: And would you always wear the surgical mask and then the other mask [N95] over the top?
- Answer: Not always. When the patient is very serious and if they were ... the patient was, then we wear two. Otherwise my one mask is fine.



To send a man like this into SARS without training does not reflect well on the way the health care system protected its workers.

Another health worker also told the Commission that she wore a surgical mask underneath her N95 until she found out that that ruined the seal. Luckily, she did not contract SARS.

Lack of training underlay most problems. Very few hospitals had a respiratory training program to ensure that workers when called upon to use the N95 were properly trained and fitted as required by law. Respirators can become hazards if not worn properly and can spread infection if not removed properly after contact with a sick patient.

Once SARS struck there was little time to correct years of neglect and bring training up to speed. But even then more could have been done to ensure that hospitals knew about the training and fit-testing requirements and did their best to train up quickly and efficiently.

An important lesson from SARS is that safety training needs to be in place before emergency strikes. Once an emergency strikes, the emergency response and directives should include a requirement for whatever training is urgently needed to protect responders.

## Ministry of Labour and Respiratory Protection

No safety device will protect a worker if he or she does not know how to use it properly. A medical study has noted:

Previous efforts to improve infection control in the hospital and elsewhere have demonstrated that the efficacy of an intervention does not guarantee its success. The best respirator or medical mask will do little to protect the individual who refuses to wear it or who does not use it correctly.<sup>954</sup>

To ensure protection, Ontario law requires employers to train and supervise workers in the proper use of safety equipment.

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954. National Academy of Sciences, *Reusability of Face Masks During an Influenza Pandemic*, pp. 39-40.

Section 10 of Ontario Regulation 67/93 requires:

10. (1) A worker who is required by his or her employer or by this Regulation to wear or use any protective clothing, equipment or device shall be instructed and trained in its care, use and limitations before wearing or using it for the first time and at regular intervals thereafter and the worker shall participate in such instruction and training.
- (2) Personal protective equipment that is to be provided, worn or used shall,
  - (a) be properly used and maintained;
  - (b) be a proper fit;
  - (c) be inspected for damage or deterioration; and
  - (d) be stored in a convenient, clean and sanitary location when not in use. O. Reg. 67/93, s. 10.

Section 27 (1) of the Occupational Health and Safety Act requires:

27. (1) A supervisor shall ensure that a worker,
  - (a) works in the manner and with the protective devices, measures and procedures required by this Act and the regulations; and
  - (b) uses or wears the equipment, protective devices or clothing that the worker's employer requires to be used or worn.

During SARS, the health workers who wore a surgical mask underneath their respirator, stuffed facial tissue underneath their respirator or wore the respirator over a beard cannot be faulted. They had not been trained, as required by law, on the proper use of respirators. None of their supervisors, as required by law, appeared to notice that respirators were not worn properly. That so many health workers were not properly trained, supervised or equipped reflects a deep systemic problem in the health care sector. Before and during SARS, much of the health care sector were unaware of the personal protective equipment requirements of Ontario work safety laws.

As a senior health administrator with significant experience in other sectors told the Commission:

I can draw the conclusion from my 30-odd years of working in various industries, and I think that hospitals would be less aware of occupational health and safety at that time [i.e., during SARS] than what I found in other industries.

If there was a general lack of awareness of worker safety regulations among hospitals, provincial officials did little to remind them of hospitals' legal obligations during much of the outbreak.

The March 29, 2003,<sup>955</sup> and March 31, 2003,<sup>956</sup> directives contained nonspecific references to fit testing (i.e., "ensure mask is fit tested," and "masks must be fitted appropriately"), but these were insufficient for a health care system that was largely unaware of both fit testing and the fact that it was a legal requirement. It was not until May 13,

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955. The March 29, 2003, POC directive to GTA and Simcoe County hospitals said:

*For all staff when in any part of the hospital ...*

Use an N95 (or equivalent) mask (ensure mask is fit tested)

*For hospital staff who are required to visit a patient care unit ...*

Use an N95 mask (ensure mask is fit tested)

*For direct patient contact ...*

Use an N95 mask (ensure mask is fit tested)

956. The March 31, 2003, POC directive to GTA and Simcoe County long-term care facilities said:

All GTA/Simcoe County staff must invoke gown, glove, N95 mask (or equivalent), and eye protection precautions and cohort nursing protocols, whether or not they have identified possible SARS patients ...

Note: N95 masks must be fitted appropriately

POC directives to GTA and Simcoe County community care access centres:

Full protocol precautions for staff

Invoke gown, glove, N95 mask (or equivalent), and eye protection precautions and cohort nursing protocols, whether or not they have identified possible SARS patients.

Masks and gowns may be reused but must be changed:

- Following contact with a SARS patient
- When wet or soiled

N95 masks must be fitted appropriately

2003, that the POC first issued directives<sup>957</sup> explicitly reminded health care institutions of their legal duties regarding N95 respirators and other personal protective equipment. All six directives issued that day contained the following language:

Personal protective equipment must be properly used and maintained consistent with the Occupational Health and Safety Act Reg. 67/93 s.10. N95 or equivalent masks must be qualitatively fit tested to ensure maximum effectiveness. (See NIOSH website at [www.cdc.gov/niosh](http://www.cdc.gov/niosh) - Publication No.99-143).

These requirements had been in place as a feature of Ontario safety law since 1993, but many hospitals officials told the Commission they become aware of this only on May 13, 2003.

Provincial labour officials also did too little to ensure that worker safety regulations were enforced.

As noted elsewhere in this report, despite the large number of health workers who got SARS, the Ministry of Labour was largely on the sidelines. Reminders to employers of their worker safety obligations were not issued until late in the outbreak, and the Ministry of Labour, unlike its counterpart in B.C., did little during most of the SARS outbreak to ensure that employers were aware of and were meeting their statutory duties.

The Ministry of Labour conducted no proactive inspections of SARS hospitals in March 2003. During that month, nearly half of the SARS cases in the initial outbreak at Scarborough Grace were either health workers or members of their households, and six health workers at Mount Sinai also caught SARS.

Despite the events at Scarborough Grace and Mount Sinai in March 2003, the Ministry of Labour conducted no proactive inspections of health care settings with SARS patients in April 2003. Yet, during that month, the list of health workers contracting SARS grew. Affected hospitals included Mount Sinai, York Central, Sunnybrook and North York General.

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957. On May 13, 2003, the POC issued six directives: Directive to Ontario Healthcare Providers in Community Settings and Community Healthcare Agencies (Excluding Community Care Access Centres); Directive to all Community Care Access Centres; Directive to all Ontario Non-Acute Care Facilities; Directives to all Ontario Acute Care Facilities; Directives to all Ontario Acute Care Hospitals for High-Risk Procedures Involving SARS Patients Critical Care Areas; Directives to all Ontario Prehospital Care Providers and Ambulance Communications Services.

Nor did the Ministry of Labour conduct proactive inspections in May 2003, when the second phase of the outbreak began. None was undertaken until June 12, 2003, in the face of a growing number of health worker complaints and work refusals. By that time virtually all 51 health workers<sup>958</sup> who caught SARS during the second phase of the outbreak had become infected.

It cannot be proven that health workers caught SARS because of unclear and confusing directives, because they were not trained or because the Ministry of Labour did not enforce worker safety regulations.

But SARS did demonstrate the importance of meticulous attention to worker safety measures. As one study found:

Experience from Hong Kong suggested that infection among “protected” health workers was related to how well the precautionary measures were used. In a case control survey, they found no infection in staff using complete precautionary measures, whereas infected staff had omitted at least one of the precautionary measures.<sup>959</sup>

A key lesson from SARS is that while health workers needed to pay meticulous attention to their respiratory protection, the lack of clear directives, the lack of training and the lack of enforcement found during SARS made that task difficult and sometimes impossible.

No hospital or nursing home can be totally safe. They cannot even begin to be safe if workers are not properly trained and supervised in their use of safety equipment and if the government does not enforce its own safety laws.

## Confusion over N95 Equivalent Respirators

It should have been crystal clear to health workers what type of respirator would protect them against SARS. Instead, as the ONA nurses' survey found, this was often not the case:

53% of respondents experienced confusion about which masks would provide the necessary protection.<sup>960</sup>

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958. Dr. Colin D'Cunha, presentation to the SARS Commission Public Hearings, September 29, 2003.

959. Philip W. H. Peng et al., “Infection control and anesthesia: lessons learned from the Toronto SARS outbreak,” *Canadian Journal of Anesthesia* 10 (2003) 984-97.

960. Hay Group, “Nurses' Perspective on the Outbreak of SARS in Toronto” (March 2006), p. 6.

Part of this uncertainty was because instead of specifying that only N95 respirators were to be used, the directives required N95 or equivalent respirators. The term “equivalent” was open to interpretation.

To worker safety experts like Dr. Gabor Lantos, the term “equivalent” was puzzling. Dr. Lantos told the SARS Commission:

They are still talking about N95 masks or equivalent. As an engineer, I don't know what an equivalent is. It's either an N95 or it's better.<sup>961</sup>

Many in the health system interpreted “equivalent” to mean masks with the same manufacturer's specifications as an N95 but which had not been independently tested and certified. One such device was the PCM 2000 mask. (As noted above, we will use the term *respirator* to describe only respiratory protective devices that have been independently tested and certified.)

A health worker who got SARS told the Commission that his hospital haphazardly provided a variety of respiratory protective devices, including N95s and PCM 2000s, without differentiating between them:

Question: ... do you have a sense of what different kinds of respirators and masks were potentially used?

Answer: There were for sure many N95 masks but also duckbill masks [i.e., PCM 2000] as well and, unfortunately, it seems very haphazard what in fact is put outside each individual patient's room. The little trolleys and dollies outside every room, and it's really, as I say, an assortment of equipment but not always standardized ...

This doctor noted the problem:

Question: What do you understand to be the difference between an N95 respirator and other forms, such as duckbilled or surgical mask?

Answer: Okay, so my understanding was that the N95 mask had been certified to filter out 95 per cent of the aerosol

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961. SARS Commission Public Hearings, November 18, 2003.

particles. The duckbill mask [i.e., the PCM 2000] is one step below that but better than the ordinary surgical mask and in, with tuberculosis for instance, if the patient wears a duckbill mask and the health practitioner wears a duckbill mask, the risk of transmission is almost zero. What is not known is with a viral infection whether the duckbill mask offers any protection or not. I must say at the time, my recollection is that [his health care institution] said, yeah, use the N95, but it wasn't like no, but the fact that there were duckbill masks available suggests that, you know, that may be good enough. You don't have to have an N95.

During SARS, there was a wide divergence of opinion over what constituted an N95-equivalent respirator.

On one side were Health Canada, the Ministry of Health and Long-Term Care and experts at some major Toronto teaching hospitals who believed that an N95-equivalent respirator did not need to be independently tested and certified.

This was Health Canada's position:

4. Health Canada recommends wearing an N95 mask or equivalent. What does "equivalent" mean?

It should be noted that NIOSH is an American agency, and there is no equivalent agency in Canada which certifies masks for industrial use. N95 masks have been tested and certified by NIOSH. For more information on NIOSH, testing and certification, visit <http://www.cdc.gov/niosh/homepage.html>

Health Canada recognizes that many institutions and other health settings may not use N95 masks that are NIOSH approved, and considers masks fulfilling the following requirements as the "equivalent" to NIOSH certified N95 masks:

- Filter particles one micron in size or smaller
- Have a 95% filter efficiency
- Provide a tight facial seal (less than 10% leak).

5. Are N95 masks considered an "equivalent" to the TB masks?

Yes, NIOSH approved N95 respirators/masks or equivalent meet and exceed the TB mask criteria.

If your health care facility masks meet the filter and fit criteria of #4 (above), they can be considered equivalent to TB masks.<sup>962</sup>

An April 11, 2003, document prepared by the Ministry of Health and Long-Term Care and entitled “Questions and Answers” took a similar position:

Q3. Are the PCM 2000, P-95 and R-95 masks equivalent to the N95 mask?

A3. Yes.<sup>963</sup>

An article by Toronto experts in the *Canadian Journal of Anesthesia* contained in a footnote the following description for a PCM 2000 mask:

N95-equivalent mask ...<sup>964</sup>

An article published in a British medical journal in June 2003 and written by three experts at a major Toronto teaching hospital also appears to suggest that the PCM 2000 is equivalent to an N95:

As a result of the transmission of SARS to health workers, N95 (or equivalent) masks are currently mandatory in Toronto for all medical personnel. They fulfill the filtering efficiency criteria of the National Institute for Occupational Safety and Health (NIOSH) N95 standard by protecting against droplet and airborne transmission of 95% of particles greater than 0.3 microns in size. These masks will offer a high degree of protection against the contact and droplet spread of the coronavirus. The N95 masks should be fit tested using an appropriate “fit test kit” according to the manufacturer’s instructions. The PCM 2000 Tuberculosis masks meet the N95 filtration criteria and fit the majority of wearers adequately. They do not require routine fit testing. N95 masks can be worn continuously for 8 h whereas PCM 2000 masks can only be worn continuously for 4 h.<sup>965</sup>

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962. Health Canada, “Infection Control Guidance for Respirators (Masks) Worn by Health Workers – Frequently Asked Questions – Severe Acute Respiratory Syndrome (SARS),” revised 2003-06-05.

963. [http://www.health.gov.on.ca/english/providers/program/pubhealth/sars/docs/qa\\_041103.pdf](http://www.health.gov.on.ca/english/providers/program/pubhealth/sars/docs/qa_041103.pdf)

964. “Intubation of SARS patients: infection and perspectives of health workers,” *Canadian Journal of Anesthesia* 53 (2006).

965. “Anaesthesia and SARS,” *British Journal of Anaesthesia*, 90 (2003).



Experts at another major teaching Toronto hospital took a similar position, suggesting that PCM 2000 masks, even though they were not NIOSH approved, were the equivalent of N95s because they had the same technical specifications. One expert at this hospital told the SARS Commission:

... because we didn't know what we were dealing with, so we went with an N95-equivalent mask, which had been our mask for TB ... for decades. The brand is PCM 2000 masks, and they're N95-equivalent. They're not NIOSH-approved masks, but they have the same filtration ... The manufacturer would tell us what filtration the mask has ...

This infection control expert noted that PCM 2000 masks met Health Canada's guidance:

We were confident in them, and they were widely used across Canada, and Health Canada had no problems with those masks.

The Ministry of Labour took a very different position on what was equivalent to an N95. It told the Commission that it accepted the term "equivalent" in directives because this allowed health workers to also use the protection of higher-rated NIOSH-approved respirators like the N99 or N100.<sup>966</sup>

One ministry official told the Commission:

Now, if somebody uses an N99 or an N100, they are equivalent and would provide even higher protection.

This approach was reflected in a document that the Ministry of Labour prepared for its staff, which appears to have been issued in early April:

Problem: Refusal to work with or serve a patient, client or inmate with possible SARS and symptoms e.g. fever, cough, history of travel or contact with confirmed SARS case, in healthcare setting or in corrections facilities.

Solution: Health care facilities and corrections facilities must implement the infection control measures required by MOHLTC and public health units. These include gloves, gowns, **N95 or better respirators**, eye protection, hand-washing facilities, plus the appropriate training and respirator fit testing.<sup>967</sup> [emphasis added]

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966. The minimum efficiency of each tested filter is to be greater than or equal to 99.97% for N100 filters and 99% for N99 filters.

967. Document entitled "SARS Scenarios" which was attached to a copy of the Ministry of Labour's SARS protocol which it provided to the SARS Commission in the course of its submission at the public hearings.

Ministry of Labour officials told the Commission that they would have preferred to have seen the phrase “N95 or better” in the directives. But the directives continued to refer to “N95 or equivalent.”

The Ministry of Labour said it would not, without appropriate independent testing, accept the manufacturer’s specifications as being sufficient proof that a respirator was equivalent to one certified by NIOSH.

During SARS, the Ministry of Labour was asked whether a European-approved respirator was an N95 equivalent. At the time, there was concern about supplies of N95 respirators and officials wondered if there might be appropriate substitutes in Europe. A Ministry of Labour official consulted with NIOSH, learned that the European test was less rigorous than NIOSH’s and was told NIOSH would accept the European respirator only if it passed its own tests.

This official told the SARS Commission:

So the question is: Is that equivalent?

Now, certainly at the Ministry of Labour, we don’t have a laboratory that’s testing respirators, approving respirators. We don’t have people that are doing the research and so we’re going to rely on NIOSH.

And if NIOSH had said to us their professional opinion is it is equivalent, then we would have considered making a statement to say we’ve done some research, we consulted with an expert in the field and we have concluded that, you know, it is equivalent or it is adequate.

And NIOSH was being very, very careful. And the position that NIOSH was taking is that the efficiency is not the same and certainly the European respirator was less efficient.

Now the only way NIOSH would be willing to make a comment would be if [the manufacturer] would submit their respirator to NIOSH, have it go through the N95 approval testing and if it met the criteria then they would be issued, I guess, approval as an N95.

The debate over what was an equivalent respirator continued after SARS.

On March 3, 2004, one Toronto hospital wrote to the Ministry of Labour after it had issued an order requiring the hospital to provide health workers with NIOSH-approved respirators, and not the PCM 2000:

Further to our discussion, our Infection Prevention and Control department wanted to get clarification on the MOL order regarding change to “N95 or better” in our policies.

- Can you indicate the specific regulation or standard that is the basis for the MOL requirement that N95 is the minimum protection and other masks without the N95 under the NIOSH criteria are not acceptable e.g. PCM 2000
- Can you provide the evidence that supports the MOL's requirement

On March 23, 2004, the Ministry responded:

The inspector's order gives the regulatory requirement. The contravention is of the compliance order issued.

The CSA Standard Z94.4-02 Selection, Use and Care of Respirators G4.3.1, page 67, indicates there are three filter efficiencies for non-powered particulate removing respirators (95%, 99% and 99.97%) and one efficiency for powered air-purifying respirators (99.97%). A P100 respirator has better filter efficiency than an N95 and is acceptable for use. A powered air-purifying respirator with a 99.97% efficient filter also has better filter efficiency than a N95.

The CSA Standard Z94.4-02 Selection, Use and Care of Respirators 2.1, page 1, indicates an accepted respirator to be a respirator tested and certified by procedures established at testing and certification agencies recognized by the authority having jurisdiction. The Ministry of Labour, as that authority, recognizes NIOSH testing and certification. The N95 respirator or respirator with better filter efficiency must be tested and certified by NIOSH.

There are several reasons the Ministry of Labour recognizes NIOSH testing and certification:

1. Assurance that the respirator/filter has met a recognized standard of efficiency.
2. Assurance of consistent quality since manufacturers of NIOSH approved respirators must submit to NIOSH a quality assurance plan.
3. Assurance that in the event of a serious problem being identified NIOSH has the power to issue a stop sale order to the manufacturer.
4. For respirators that are not approved by a recognized testing and certification agency such as NIOSH, the Ministry does not have the same assurance of quality and performance.

While undoubtedly acting in the best of good faith and with the best of intentions, it is surprising that so many experts took the position during and after SARS that a PCM 2000 is equivalent to an N95. In an age when independent testing is the norm in so many product areas, from the crash worthiness of automobiles to the safety of household appliances, it seems remarkable that anyone in charge of health worker safety would be content to rely solely on the manufacturer's specifications without independent certification.

By not providing NIOSH-certified and -tested respirators, employers accepted a lower standard of protection. Regrettably, they also appeared to place greater reliance on advice from Health Canada, a federal agency with no jurisdiction over Ontario workplaces, than on the higher standards of protection required by the provincial ministry in charge of worker safety in Ontario.

An important lesson from SARS is that in any health emergency, the Ministry of Labour must be actively engaged from the start to ensure adherence to safety standards and to ensure that there is no confusion in the workplaces over what equipment is required to protect workers.

## Evidence of Airborne Transmission

During SARS, there were multiple episodes of transmission that could not be readily explained by droplet spread alone, and there were episodes and situations where airborne transmission appears to have been involved in transmission.

In the Amoy Gardens housing complex in Hong Kong, cases appeared rapidly in several different apartment buildings in manner atypical of contact or droplet transmission.<sup>968</sup>

Spread to health workers in Toronto during aerosol-generating procedures, including endotracheal tube intubation or bronchoscopy,<sup>969</sup> is another example where airborne transmission has been invoked during nosocomial spread.

The pattern of spread of SARS associated with sick patients travelling on aircraft suggests that airborne transmission could have occurred during the flights.<sup>970</sup>

Another example is the super-spreader event at the Hotel Metropole, when at least 16 people, including the index cases in Toronto, Vancouver, Singapore, Hanoi and Hong Kong, were infected in February 2003.

According to the World Health Organization:

Professor LJJ's infected body fluids must have been aerosolized, as indicated by the traces on the inlet of the elevator lobby fan. Anyone who stepped out of the 9th floor lift [i.e. elevator] shortly after the event would have been exposed, while those who walked past room 911 [i.e.,

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968. I.T.S. Yu, Y. Li, T.W. Wong, et. al., "Evidence of airborne transmission of the severe acute respiratory syndrome," *New England Journal of Medicine* 350 (2004): 1731-390 (Evidence of airborne transmission of SARS Article).

969. M. Ofner, M. Lem, S. Sarwal, M. Vearncombe, A. Simor, "Cluster of severe acute respiratory syndrome cases among protected health-care workers" – Toronto, Canada, April 2003," *MMWR* 52 (2003): 433-436; D.C. Scales, k. Green, A.K. Chan, S.M. Poutanen, D. Foster, et. al., "Illness in intensive care staff after brief exposure to severe acute respiratory distress syndrome," *Emerging Infectious Diseases* 9 (2003): 1205-10.

970. W.H. Seto, D. Tsang, R.W. Yung, et. al., "Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of SARS," *Lancet* 361 (2003): 1519-20 (Seto et al, "Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of SARS")

the index patient's room] may have been at risk for a longer period. Presumably, by morning there was no longer any viable virus, or else staff had quickly disinfected the area without becoming exposed. It certainly appears that only those who were on the 9th floor that night were at risk. Thus, the "miracle" of none of the hotel staff getting SARS could simply have been due to their not having been exposed to the virus.

The rooms in the hotel, atypically, were pressurized; so infected aerosols could not have entered from the corridor. The WHO team dismissed theories that the virus was transmitted through elevators, door handles, or handrails. "In this hotel, these are unlikely scenarios," the report [by the WHO team of Health Canada experts] said, "because other guests would have made similar contacts, and indeed, staff would have had intense exposure risk. Staff who served the subject floor did not get infected."

The contamination occurred in the corridor of one wing of one floor, and never moved up or down the building or endangered people inside their rooms.<sup>971</sup>

The single most dramatic spread of SARS was the Amoy Gardens outbreak. More than 300 people in four separate Hong Kong buildings caught SARS. Airborne spread was at first dismissed as the likely transmission mechanism as opposed to:

person-to-person spread, contamination of communal facilities (such as elevators) and thus indirect contact transmission, and problems with sewage disposal resulting in fecal-oral transmission.

A later study<sup>972</sup> suggests airborne transmission as the likeliest explanation. This research says it is likely that the exhaust fan in bathroom of the index cases drew aerosols (generated by coughing or flushing virus-laden stool in toilets) from the bathroom into common building airshafts. These aerosols would rise with the warm humidified air currents and be transmitted to the residents in upper levels of the apartment complex. Natural wind currents likely then permitted the spread to other buildings as the contaminated air plume left the building of the index case. This

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971. WHO, *SARS: How a Global Epidemic Was Stopped* (Geneva: WHO, 2006), pp. 147-48.

972. Evidence of Airborne Transmission of SARS Article.

theory is supported in a mathematical model. On this basis, airborne transmission appears to provide the single best mechanism explaining the varied attack rates in the different floors and buildings within the Amoy Gardens complex.

Some experts regard this as a landmark study because it provides a fresh perspective on the droplet-versus-airborne debate. They suggest the initial Amoy Gardens investigation did not seriously consider airborne transmission because of the current bias in favour of the large-droplet theory.<sup>973</sup>

Noting that research into airborne transmission has been neglected, some researchers suggest SARS provides an opportunity to critically re-evaluate how respiratory diseases are spread:<sup>974</sup>

The SARS epidemic provides an opportunity for the critical reevaluation of the aerosol transmission of communicable respiratory diseases. Prevailing thought has focused on determining whether an infectious agent has “true” airborne transmission. We find it more useful to classify the aerosol transmission of diseases as obligate, preferential, or opportunistic, on the basis of the agent’s capacity to be transmitted and to induce disease through fine-particle aerosols and other routes ...

There are probably many diseases with opportunistically airborne transmission – infections that naturally cause disease through other routes

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973. “In the official investigation, airborne transmission was not seriously considered, because the current paradigm, as initially described by Charles Chapin in 1910, supports the belief that most communicable respiratory infections are transmitted by means of large droplets over short distances or through contact with contaminated surfaces” (Chad J. Roy and Donald K. Milton, “Airborne transmission of communicable infection – the elusive pathway,” *New England Journal of Medicine* 350 [April 22, 2004], [www.nejm.org](http://www.nejm.org)) (Roy, and Milton, “Airborne transmission of communicable infection – the elusive pathway”)

974. Roy, and Milton, “Airborne transmission of communicable infection — the elusive pathway”:

What underlies the low repute of airborne transmission today? First, the two diseases whose aerosol transmission is most widely acknowledged, measles and tuberculosis, have been largely controlled through vaccination or drug therapy. As a result, the impetus to understand the aerobiology of infectious diseases has faded. Second, contamination of water, surfaces, and large-droplet sprays can be easily detected. It is difficult, however, to detect contaminated air, because infectious aerosols are usually extremely dilute, and it is hard to collect and culture fine particles. The only clear proof that any communicable disease is naturally transmitted by aerosol came from the famous experiment by William Wells, Richard Riley, and Cretyl Mills in the 1950s, which required years of continual exposure of a large colony of guinea pigs to a clinical ward filled with patients who had active tuberculosis.

(e.g., the gastrointestinal tract) but that can also initiate infection through the distal lung and may use fine-particle aerosols as an efficient means of propagating in favorable environments. For all three classes of diseases that are communicable through aerosols, the agent must be capable of initiating infection, with some reasonable probability, by means of a small dose delivered to the lung in a single airborne particle.

The current analysis of the outbreak at Amoy Gardens suggests that SARS has at least opportunistically airborne transmission.<sup>975</sup>

Two more recent studies also suggest the possibility of airborne spread in hospital wards. One examined a nosocomial outbreak in a Hong Kong hospital.<sup>976</sup> The other detected the presence of the SARS virus in the air in the room of a SARS patient in Toronto:

Severe acute respiratory syndrome (SARS) is characterized by a risk of nosocomial transmission; however, the risk of airborne transmission of SARS is unknown. During the Toronto outbreaks of SARS, we investigated environmental contamination in SARS units, by employing novel air sampling and conventional surface swabbing. Two polymerase chain reaction (PCR)-positive air samples were obtained from a room occupied by a patient with SARS, indicating the presence of the virus in the air of the room. In addition, several PCR-positive swab samples were recovered from frequently touched surfaces in rooms occupied by patients with SARS (a bed table and a television remote control) and in a nurses' station used by staff (a medication refrigerator door). These data provide the first experimental confirmation of viral aerosol generation by a patient with SARS, indicating the possibility of airborne droplet transmission, which emphasizes the need for adequate respiratory protection, as well as for strict surface hygiene practices.<sup>977</sup>

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975. Roy, and Milton, "Airborne transmission of communicable infection — the elusive pathway."

976. "The analysis of the temporal-spatial spread of SARS from the index case patient to other inpatients in the ward suggested that airborne spread through virus-laden aerosols possibly played an important role. Unlike other reports of airborne outbreaks, we were unable to document the existence of the infective agent in aerosols. Such documentation was simply impossible in early March 2003, when the infective agent was yet to be identified. SARS was unlikely a communicable disease with obligate airborne transmission, such as tuberculosis, but there was evidence to suggest that SARS could have at least opportunistic airborne transmission under special circumstances when virus-laden aerosols could be generated" (I.T.S. Yu et al., "Temporal-spatial analysis of severe acute respiratory syndrome among hospital inpatients," *Clinical Infectious Diseases* 191 (2005):1472-77.

977. Booth et al., "Detection of airborne severe acute respiratory syndrome (SARS), 1472-77.



An editorial that accompanied the article noted:

Airborne transmission of the severe acute respiratory syndrome (SARS) coronavirus (CoV) has been the favored explanation for its transmission on an aircraft and appeared to explain a large community outbreak of SARS in the Amoy Gardens in Hong Kong. The article by Booth et al. in this issue of the *Journal of Infectious Diseases* suggests that airborne dissemination of SARS-CoV may also occur in the health-care setting. A patient with SARS who was breathing quietly but coughing occasionally in a hospital room contaminated the surrounding air with SARS-CoV, as shown by experiments conducted during the SARS outbreak in Canada in early 2003.

Several viruses and other pathogens, such as *Mycobacterium tuberculosis*, have been shown to be transmitted by airborne dissemination. However, the possibility of airborne dissemination of SARS-CoV has been controversial. The important work by Booth et al. has shown beyond doubt that SARS-CoV aerosol generation can occur from a patient with SARS ...

Because none of the SARS-CoV cultures were found to be positive and host infection was not involved, the authors rightly avoided drawing a conclusion of airborne *transmission* of SARS-CoV. Definitive proof of transmission will need to come from experiments similar to those performed by Riley et al. in the 1950s, which involved exposure of guinea pigs to air shared by patients with active pulmonary tuberculosis. In vitro viral culture tests may not be sensitive enough for this purpose. However, if SARS-CoV is naturally airborne (produced by breathing and coughing), as was shown by Booth et al., then there is sufficient concern that it can be transmitted successfully by air ...<sup>978</sup>

## Were N95 Respirators More Protective than Surgical Masks?

Despite the evidence of airborne SARS, and despite the fact the N95 was specified by Ontario and the CDC and the WHO for protection against SARS, doubts remained that these safety precautions had been proved necessary beyond a scientific doubt.

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978. Tommy R. Tong, "Airborne severe acute respiratory syndrome coronavirus and its implications," *Journal of Infectious Diseases* 191 (2005).

Health Canada said:

International SARS studies have not shown a difference in efficacy between surgical masks and N95 respirators in preventing transmission of the SARS coronavirus. Recommendations will be reviewed as further evidence emerges.<sup>979</sup>

Two studies of how health workers got SARS, one by a Hong Kong team led by Dr. W. Seto<sup>980</sup> and another in Toronto led by Dr. Mark Loeb,<sup>981</sup> suggest no substantial benefit to wearing a surgical mask over an N95 respirator.

Citing those studies, one expert told the SARS Commission:

You have to go back to the early days. So there's some stuff from Hong Kong that were published in *The Lancet* in May. And there is some data out of the Scarborough Grace hospital from, particularly, in their intensive care unit from very early in the outbreak before they realized what they were dealing with. And it looks at nurses in the ICU there and what personal protective equipment they used and whether they were protected or infected. The things that fall out of that as being statistically significant are if you put on a mask consistently, and it did not matter much if it was an N95 mask or surgical mask, and did some hand hygiene consistently, and there is similar kind of data from Hong Kong.

Despite the opinion of this expert and others, there is no consensus on the conclusions that can be drawn from these two studies.

A Vancouver team of researchers who conducted a major study on respiratory protection commissioned by the Ontario Hospital Association's Change Foundation acknowledged the importance of these two studies, but also pointed to their shortcomings:

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979. Health Canada, "Infection Control Precautions for Respiratory Infections Transmitted by Large Droplet and Contact Infection Control Guidance If There Is a SARS Outbreak Anywhere in the World, When an Individual Presents to a Healthcare Institution with a Respiratory Infection," December 17, 2003.

980. Seto et. al., "Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of SARS".

981. M. Loeb, A. McGeer, B. Henry, et. al., "SARS among critical care nurses, Toronto," *Emerging Infectious Disease* 10 (2004): 251-55.

Seto and colleagues showed that wearing any mask was protective against SARS in a case-control study of 13 HCWs [health care workers] who developed SARS and 241 controls who did not. Regularly wearing gowns was protective in univariate analyses, but only mask (surgical or N95) use was significant in the multivariate analysis.

The conclusions from this study must be viewed with caution because of the small number of cases and because the study excluded HCWs from one hospital with a large outbreak where exposure to aerosolizing procedures was likely.

In another study, Loeb et al. constructed a retrospective cohort of 43 intensive-care unit nurses from Toronto. Eight of the 32 nurses who had direct contact with a patient with SARS later developed SARS themselves. Regular use of N95 respirators and surgical masks was associated with protection from SARS when compared with irregular or no mask or respirator use ... There was a trend toward increased protection from the N95 respirators in comparison with surgical masks, but this was not statistically significant. Again, the number of cases limited the power of this study.<sup>982</sup>

Experts who questioned the value of N95 respirators over surgical masks also pointed to the fact that SARS was controlled in Vietnam without their use:

Although a great deal of attention was focused on the need for N95 respirators or even respiratory protection with higher protection factors, it is also worth noting that in Vietnam, N95 respirators were not available until the third week of the outbreak. However, this did not prevent Hanoi from becoming the first affected jurisdiction to effectively control SARS; masks and barriers with spatial separation were thought to be the key control factors.<sup>983</sup>

Vietnam did indeed control SARS despite an initial lack of N95 respirators. But as Table 3 indicates, Vietnam also had the highest percentage of health workers among its SARS cases.

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982. Yassi et al., "Research gaps in protecting health workers from SARS."

983. Yassi et al., "Research gaps in protecting health workers from SARS."

**Table 3 – Comparison of Percentage of Health Workers Who Got SARS in Ontario and in Other Jurisdictions<sup>984</sup>**

<b>Jurisdiction</b>	<b>Number of HCWs Who Caught SARS</b>	<b>HCW Cases as Percentage of Total Cases</b>
Vietnam	36	57%
Ontario	169	45%
Singapore	97	41%
Hong Kong	386	22%
Taiwan	68	20%
China	1,002	19%

The fact that N95s were not used at first in Vietnam, where 57 per cent of those who got SARS were health workers, hardly supports those who campaign against the N95.

The debate over whether N95 respirators were really necessary for routine patient care is actually two separate debates. The first is whether it was the right decision to require the N95 in late March 2003, during the difficult early days of the outbreak. The second is whether, in hindsight and with the benefit of all the scientific research to date, the decision can be seen in a different light.

It is difficult to fault the early decision to require the use of N95 respirators. The officials who led the response to SARS were taking a prudent approach in the face of a mysterious new disease. As Dr. James Young told the SARS Commission public hearings:

... we were dealing with an outbreak where we did not know for sure that it was a virus, we did not know for certainty what virus it was, we did not know what symptoms and what order of symptoms SARS presented with.

We had a vague idea that some of the symptoms might include fever and cough. We did not, for example, for some period of time, realize that

984. WHO SARS Summary, July 31, 2003; Ontario data is from the Presentation of Dr. Colin D’Cunha, SARS Commission Public Hearings, Sept. 29, 2003.

about 30 per cent of patients also could produce – present with diarrhea. We did not know how long it incubated for. We did not know with certainty whether it was droplet-spread or whether it was airborne. We did not know when it was infectious. We did not have a diagnostic test for it and still do not have an accurate diagnostic test. We had no way of preventing it, we had no vaccine and we had no treatment.

What we had was an illness with many unknowns and virtually no knowns.<sup>985</sup>

Knowledge about SARS was slow in coming, whether it was about how it spread or how far it had in fact spread.

Dr. Young told the SARS Commission's public hearings:

... it's not like a forest fire which, in and by itself, can be difficult enough to control, but if I want to know the size of a forest fire, I can get above the forest fire, see where it is and build a barrier so that the forest fire does not jump over that barrier, and even if it does, I may be able to have a series of smaller fires I can put out.

The theory in controlling something like SARS is the same, but the difficulty and the problem is, I have no idea where it is. I only know where it was 10 days ago and I have to not only catch up that 10 days, I must get further ahead.<sup>986</sup>

To take Dr. Young's analogy further, if you don't know where an outbreak currently is, you don't know in real time if it's expanding or contracting. You also don't know in real time whether your current containment efforts, including levels of respiratory protection, are working.

Under these circumstances, and in view of the initial scientific uncertainty over SARS, provincial officials cannot be faulted for taking a better-safe-than-sorry approach to worker safety and respiratory protections by mandating the use of N95 respirators.

Now, with the benefit of post-SARS scientific research and the arguments of those

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985. SARS Commission Public Hearings, September 30, 2003.

986. SARS Commission Public Hearings, September 30, 2003.

who opposed in good faith the use of the N95, can this decision still be questioned in hindsight?

Much remains unknown about SARS and about our understanding of how respiratory infections are spread. Research since the outbreak has shed some light on SARS and its mechanisms of transmission. The research shows how little was known during the outbreak and how much remains unknown even now about this new disease.

As noted above, knowledge about how SARS is transmitted has evolved significantly since the outbreak. Some recent studies suggest that it may be spread by airborne transmission. These studies lend further weight to taking a prudent precautionary approach to the protection of health workers against a new disease whose method of transmission is not fully understood.

In addition to all the research that suggests a risk from airborne transmission, there is another important reason to remain cautious about how SARS is transmitted and thus to require a higher level of protection than just a surgical mask.

One senior occupational medical expert suggested that the high number of health workers who got SARS is itself reason enough to use higher levels of respiratory protection:

Clearly the high morbidity and mortality associated with SARS – that's another reason to utilize the N95. A lot of literature dealing with SARS tends to talk about contact and droplet transmission. There are some reports about Vietnam and about how they only wore surgical masks. So it's still controversial in the literature about what would be appropriate from a transmission basis. However, there is reason to recommend airborne precautions and N95 due to the high morbidity and mortality associated with this disease.

Dr. Annalee Yassi told the Commission there was very little downside to using a higher level of protection:

Even if we don't have strong evidence that the transmission of infection would have been different had there not been N95s, we do know that N95s do protect better than surgical masks. There was really no downside, other than some trivial cost factor. It is trivial in the bigger picture when you look at the billions and billions of dollars spent on the outbreak. The extra little cost of an N95 versus a surgical mask is more than made up for by the

better degree of protection that it provides ... If health workers felt more protected wearing an N95 when someone is coughing and sneezing, then why not. It was the right decision then and it still is the right decision.

Although scientific research into SARS transmission continues, it appears that the initial dogmatic statements dismissing the possibility of airborne transmission were premature. SARS demonstrated the importance of taking precautionary approach to transmission of a new respiratory disease and to requiring the best system of respiratory protection for hospital workers.

Setting aside the ongoing droplet-versus-airborne debate, the Commission heard other compelling arguments favouring a precautionary approach requiring higher levels of respiratory protection.

A number of witnesses remarked that unforeseen events and accidents happen in hospitals that might inadvertently generate aerosolized particles. Experts note that even if SARS is primarily droplet-spread, no one knows when an incident might happen in a hospital to cause the inadvertent generation of aerosols.

One CDC expert said:

... when you look at the R0 it suggests it's probably not airborne in the same sense of measles or anything like that. When you look at epidemiologic links, people down the hallway, around the corner, they're not getting sick. But in health care facilities, when you have people in, you just don't know sometimes when you're going to have an aerosol-generating procedure happen and it could happen precipitously, and because of those issues and because of issues like this, we're going to continue to recommend airborne precautions.

Nora Maher, an occupational hygienist with the Occupational Health Clinics for Ontario Workers, told the SARS Commission's public hearings:

In determining how to control a hazardous exposure, it is important to take into account the chance of human error. No worker wants to make a mistake; no one sets out to undertake a task with more risks than necessary. The best controls will be those that have a failsafe or backup mechanism built in and to evaluate.<sup>987</sup>

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987. SARS Commission Public Hearings, November 17, 2003.

## Opposition to Fit Testing

Fit testing<sup>988</sup> was the most contentious safety issue during SARS.

Nurses and their unions were quite properly angry that hospitals were ignorant of the long-standing 1993 legal requirement for fit testing:<sup>989</sup>

- One prominent hospital infection control director insisted in a June 2003 memo to health workers that “Canadian regulations have never required fit testing in the healthcare setting.” Nothing could have been more untrue. While no one questions the good faith of this person, there is something profoundly wrong with a system in which a person in this position can be so utterly wrong about worker safety in hospitals.
- An article by some Canadian experts in the *British Medical Journal* made the same point: “Fit testing had never been required in the Canadian health care setting.”<sup>990</sup>

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988. Fit testing helps users select a respirator that best fits their faces and teaches them how to get a proper seal each time they use respirator, a procedure known as a *seal check*, and how to safely don and doff a respirator. A test verifies that the chosen respirator works properly. There are two types of tests. One is called a *qualitative fit test* and “relies on the user’s subjective response to taste odour or irritation.” The other is a *quantitative fit test* and “relies on an instrument to quantify the fit of a respirator” (Healthcare Health and Safety Association, *Respiratory Protection Programs*).

989. Section 10 of the Ontario Regulation 67/93 requires:

10. (1) A worker who is required by his or her employer or by this Regulation to wear or use any protective clothing, equipment or device shall be instructed and trained in its care, use and limitations before wearing or using it for the first time and at regular intervals thereafter and the worker shall participate in such instruction and training.

(2) Personal protective equipment that is to be provided, worn or used shall,

(a) be properly used and maintained;

(b) be a proper fit;

(c) be inspected for damage or deterioration; and

(d) be stored in a convenient, clean and sanitary location when not in use. O. Reg. 67/93, s. 10.

990. Sue Lim, Tom Closson, Gillian Howard, and Michael Gardam, “Effects of outbreak policies: collateral damage: the unforeseen effects of emergency outbreak policies,” *Lancet Infect Dis* 4 (2004): 697-703.



- Health Canada also seemed unaware of this Ontario requirement. A Canada Communicable Diseases Report on the April 13, 2003, intubation at Sunnybrook said: “In addition, at the time these exposures occurred, fit testing was not recommended by Canadian public health authorities; such testing has been mandated in the United States since 1972.”<sup>991</sup>

Officials at a number of hospitals told the Commission that they only become aware of the legal requirement of fit testing when the May 13, 2003, directives<sup>992</sup> were issued.

As a result, fit testing did not begin in most hospitals until May 2003. Most health workers who used N95 respirators were not fit tested until June 2003. Not surprisingly, the proper fit of a respirator was a problem for many health workers. The ONA survey found:

50% of respondents experienced problems with the masks not fitting properly, and 8% were told to return to work without a properly fitting mask.<sup>993</sup>

Unions were angry that so many health workers had to go through SARS without being fit tested as required by law.

ONA and OPSEU said in their joint presentation at the public hearings:

Finally, fit testing began, sporadically due to union complaints and a nurse's June 6th work refusal. The Ministry of Labour ordered that the

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991. Health Canada, “Cluster of severe acute respiratory syndrome cases among protected health care workers – Toronto, April 2003,” Canada Communicable Diseases Report volume 29-11, June 1, 2003.

992. All six directives issued that day contained the following language:

Personal protective equipment must be properly used and maintained

consistent with the *Occupational Health and Safety Act* Reg. 67/93 s.10. N95

or equivalent masks must be qualitatively fit tested to ensure maximum effectiveness. (See NIOSH website at [www.cdc.gov/niosh](http://www.cdc.gov/niosh) -Publication No.99-143.)

993. Hay Group, “Nurses’ Perspective on the Outbreak of SARS in Toronto” (March 2006), p. 10.

nurse be fit tested before being required to work in a workplace that required respiratory protection.<sup>994</sup>

Fit testing was a hot-button issue for the health system, but for different reasons. Many in the health care system questioned the scientific basis for fit testing and were angry at the logistical challenge of a procedure that, in their view, had limited value.

One prominent infection control practitioner said:

We want to point out that fit testing of masks, or the lack of fit testing of masks in Canada, we believe to be a red herring and was not part of the reason for transmission of the SARS virus.

The Ontario Medical Association told the SARS Commission public hearings:

At the time when mask fit testing was first proposed, we followed the directive but we did ask for the scientific evidence that this fit testing would make a difference.

In our own comprehensive literature search, we have not found any evidence to support mask fit testing as it is being proposed in Ontario. In fact, we have been instructed during the current planning of this massive project not to ask for the evidence.<sup>995</sup>

An infection control practitioner told the Commission in a confidential interview:

I think people in Canada did not see that this was a really big issue, the fit testing of the N95 masks, and I think a lot of experts in Canada still do not believe that it is a big issue. It may be a big issue in industry, where you are wearing N95 or N99, N100 masks for chemicals, where you are dealing with vaporized chemicals; that is probably or certainly is a whole different level of protection you require. But a lot of experts still believe that for biologic agents, there is not good evidence that you need to go through all of this; extra protection that is offered through the fit testing is not necessary for biologic agents.

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994. SARS Commission Public Hearings, November 17, 2003, p. 13.

995. SARS Commission Public Hearings, September 29, 2003, pp. 47-48.

Part of employers' frustration over fit testing was that it meant they would have to carry many different types of respirators, at a time when there was much concern over respirator shortages. As was noted in the second interim report, getting enough supplies of N95 respirators was a widespread problem during SARS.

The Ministry of Health and Long-Term Care noted the problem of masks during its presentation to the Commission at public hearings:

The lack of a domestic mask supplier and an insufficient inventory of masks to deal with the infection protocols as the emergency progressed was also problematic.<sup>996</sup>

An article in *The Lancet* by some Toronto experts describes the particular challenge of getting enough masks:

... submicronfiltering masks (e.g., N95 masks) were in variable supply, because before SARS such masks were used only for patients with airborne infections and hence most facilities would have only kept a limited supply. With 211 hospitals in Ontario alone requiring these supplies, Canadian suppliers rapidly ran out of stock. There was no pre-existing supply stock-pile, and our mask supplies were obtained from foreign manufacturers. Because SARS was a worldwide threat, there was great difficulty in acquiring masks from other countries, since foreign governments understandably wanted to keep such supplies for their own citizens.<sup>997</sup>

St. Michael's Hospital said at the public hearings:

Supplies were particularly problematic as there is not enough masks available in the system for optimal safety. After fit testing having supplied the right type of mask for the right staff member complicated the issue. The requirement for mask fit testing was a significant challenge. St. Michael's Hospital went to great lengths to comply with provincial directives with respect to fit testing.<sup>998</sup>

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996. SARS Commission Public Hearings September 30.

997. Sue Lim, Tom Closson, Gillian Howard, and Michael Gardam. "Collateral damage: the unforeseen effects of emergency outbreak policies. *Lancet Infectious Dis.* 2004;4(11): 697-703"

998. SARS Commission Public Hearings, September 30 2003.

Some experts argued during SARS that fit testing was not necessary because it was sufficient to teach users to perform a seal check.

An infection control expert who argues against the N95 and against fit testing told the SARS Commission in a confidential interview that a seal check is a good substitute for a fit test:

An N95 mask, the more important thing is the design of the mask rather than the fit testing. A well-designed N95 mask applied properly so the person knows to fit it around his face and does the test for the seal has a 93 per cent effective seal in terms of protection.

... if you fit test it, you could get that up to 95 per cent and that is a marginal difference, so the issue around fit testing these masks, to say that was a large issue in the middle of this outbreak I think was a huge mistake, and a huge disservice to those people taking care of the patients.

On the particular issue of whether a seal check is a substitute for a fit test, recent research indicates that “a seal check should not be used as a surrogate fit test.”<sup>999</sup>

On the overall value of fit testing, a study by the Institute of Medicine concluded:

By contrast, the ability of an individual wearer to obtain good face piece fits is far more varied and is a function of the facial dimensions of the wearer, the training received by users to ensure that the device is properly placed on the face each time the respirator is donned, and how closely the

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999. “Guidelines issued by the Centers for Disease Control and Prevention and the World Health Organization state that health workers should wear N95 masks or higher-level protection during all contact with suspected cases of severe acute respiratory syndrome. Before use, the manufacturer recommends performing a user seal check to ensure that the mask is fitted correctly. This study aimed to test the ability of the user seal check to detect poorly fitting masks. This study is a retrospective review of a mask-fitting programme carried out in the intensive care unit of the Prince of Wales Hospital in Hong Kong. In this programme, all staff were tested with two types of N95 mask and one type of N100 mask. The results of the documented user seal check were then compared with the formal fit-test results from a PortaCount. Using a PortaCount reading of 100 as the criterion for a correctly fitted mask, the user seal check wrongly indicated that the mask fitted on 18-31% of occasions, and wrongly indicated that it did not fit on 21-40% of occasions. These data indicate that the user seal check should not be used as a surrogate fit test. Its usefulness as a pre-use test must also be questioned.” J.L. Derrick, Y.F. Chan, C.D. Gomersall, S.F. Lui “Predictive value of the user seal check in determining half-face respirator fit,” *J Hosp Infect.* 59 (2005): 152-55.

device matches the size and shape of the wearer's face. Coffey et al. (2004) have demonstrated that subjects who wear most N95 filtering face pieces without prior fit testing fail to achieve the expected levels of protection, and that persons passing a qualitative or quantitative fit test will achieve the expected level of protection (Coffey et al., 2004).<sup>1000</sup>

One expert who campaigned heavily against the N95 and fit testing went so far as to say that because we got through SARS without fit testing, we therefore did not need fit testing:

We got through SARS I and managed it, controlled it, without fit testing for the N95 masks.

The logic of this confident assertion is not immediately apparent. Ontario certainly managed to get through SARS I without fit testing, but almost half of those who got SARS were health workers. The fact that we got through SARS without fit testing in an outbreak where 169 health workers caught it on the job is no argument against the evidence that fit testing provides a better level of protection.

Some who campaigned against the N95 and fit testing distorted the debate by setting up a straw man to knock down. They suggested inaccurately that the N95 and fit testing had been held up as the magic bullet against SARS. No one ever said the N95 and fit testing were magic bullets.

No one ever said that fit testing "is the answer." Yet those who campaigned against fit testing did so on the inaccurate basis that those in favour of fit testing said it was the answer. One hospital expert who wrongly insisted that no Ontario law required fit testing put it like this:

In SARS, both myself and many of my colleagues believe that fit testing is not the answer to protecting health workers.<sup>1001</sup>

To the Commission's knowledge, no expert in worker safety suggested that the N95 respirator or fit testing were the be-all and end-all to containing SARS. No expert in worker safety believed the N95 respirator or fit testing could, or should, be singled out as ends in themselves.

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1000. Institute of Medicine of the National Academies, "Reusability of facemasks during an influenza pandemic: facing the flu: report brief" (April 2006), <http://222.nap.edu>.

1001. Michael Gardam, Fit testing memo, June 2003.

These attacks on the N95 and fit testing, this focus on one component only of the hierarchy of safety controls so absent from Ontario hospitals during SARS, is just one more piece of evidence that the health system during SARS lacked a basic understanding of worker safety principles.

Safety experts regarded N95 respirators and fit testing not as magic bullets but as simply one part of a respiratory protection system that should include:

- A hazard assessment of the workplace
- The selection of appropriate respiratory protection based on the hazard assessment
- Health assessment and ongoing surveillance of respirator users
- Fit testing
- Initial and ongoing training and education<sup>1002</sup>

Perhaps the most important respiratory protective lesson from SARS is the importance of focusing not just on one protective component, whether it's the N95 respirator or fit testing. To return to the title of this chapter, it's not about the mask; and it's not about fit testing. It's about a whole system of safety controls in which the respirator and other personal protective equipment are simply the last component, the final line of defence.

That bigger safety system, of which the respirator is just one small part, is known as the hierarchy of controls. It is a fundamental principle of the worker safety discipline of occupational hygiene.<sup>1003</sup> Among these controls, personal protective equipment is the last line of defence, not the first:

... all available options for controlling the hazard should be put into place and that when these controls are not possible or not sufficient to control the risk, personal protective equipment such as respirators should be implemented. The hierarchy of controls is as follows:

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1002. Healthcare Health and Safety Association, *Respiratory Protection Programs*, pp. 15-16.

1003. Occupational hygiene, which is often called industrial hygiene in the U.S., is defined as follows: "The science and art of anticipating, recognizing, evaluating, and controlling chemical, physical, biological, ergonomic hazards that are in or originate from the workplace" (Salvatore R. DiNardi and William E. Luttrell, *Glossary of Occupational Hygiene Terms*, [Fairfax, VA: American Industrial Hygiene Association, 2000], p. 106).

1. Engineering controls
2. Administrative controls
3. Work practices
4. Personal protective equipment.

These controls are meant to address hazards through control at the source of a hazard, along the path between the worker and the hazard and lastly, at the worker.

Controls that are implemented at the source should be put into place first. These include using engineering controls such as enclosing the hazard or using local exhaust ventilation. An isolation room with negative pressure ventilation is an example of an engineering control aimed at the source of the hazard.

Controls that are implemented along the path should be put in place next. These include general exhaust ventilation or the use of shielding or barriers.

Administrative control and workplace practice controls are also critical. These controls include such program components as processes to ensure early recognition and appropriate placement of patients who are infectious, surveillance for detection of outbreaks, adequate cleaning and disinfection of patient care equipment and the environment and education programs for health care workers about identifying and managing risk.

If, after implementing controls at the source and along the path does not eliminate the worker's risk of exposure, then controls at the worker can be put in place. These include the use of personal protective equipment such as respirators and eye protection.

The essential point from the hierarchy of controls is that employers should not rely exclusively on personal protective equipment (PPE) to protect workers. All other means of control should be used to protect workers and PPE used only when other controls have not eliminated or reduced the hazard significantly.<sup>1004</sup>

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1004. Healthcare Health and Safety Association of Ontario, *A Guideline for the Development and Implementation of a Respiratory Protection Program for the Prevention of Occupational Infections in Health and Community Care Workplaces – Final Draft*, (Toronto July 23, 2003), p. 11.

Worker safety principles like the hierarchy of controls are not new. They had been developed long before SARS. Worker safety experts knew how to use these systems, these processes, these procedures and this equipment to protect nurses and other health workers.

As Health Canada noted in a worker safety manual issued in 2002, close cooperation between worker safety and infection control is essential for the safe operation of a health care facility. Health Canada's *Prevention and Control of Occupational Infections in Health Care* says:

A component of the [worker safety] program relates specifically to infection control and must be planned and delivered in collaboration with the Infection Control (IC) program of the workplace ... This document supports the close collaboration of OH personnel with those responsible for the IC program ... It notes the essential collaboration of both groups working together where responsibilities overlap, especially in the management of outbreaks.<sup>1005</sup>

Tragically, this knowledge was not used during SARS. This expertise was ignored.

As one hospital said in its submission to the Commission:

It was interesting to note that an occupational hygienist was part of the CDC team called in to help review how SARS was being spread; earlier recognition and utilization of local professional resources (e.g. through the Canadian Registration Board of Occupational Hygienists, the University of Toronto graduate program in occupational hygiene, etc.), may have helped contain the problem much sooner.

It is time for Ontario to stop the turf wars and remove the barriers that prevented the use of this expertise during SARS to protect health workers.

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1005. Health Canada. *Prevention and Control of Occupational Infections in Health Care: An Infection Control Guideline* (Ottawa: Health Canada, 2002), p. 1.



## Progress Since SARS

Some experts who campaigned during SARS against fit testing have come to accept that any worker required to wear an N95 respirator should be fit tested as required by law.

One infection control expert who opposed fit testing said after SARS:

... if you need an N95 mask, it should be fit tested and that's one issue, and I don't think anybody's going to argue with that anymore.

A senior Ministry of Labour official who bore the brunt of the hospital establishment's opposition to fit testing told the Commission that the climate has changed:

I think they have moved on. Now the question you get nowadays is when should you use the N95? One doesn't have the same resistance to fit testing. The big question is when do we need N95s.

Part of the change of heart may be due to the large number of post-SARS studies in support of fit testing.

Representatives of health workers, however, have detected continuing resistance to fit testing. They have:

... participated in many government round tables that have discussed personal protective equipment during a response to an outbreak. We have been told the science of respirator fit testing is not perfect, and thus fit testing does not guarantee that a respirator will be completely effective in protecting against airborne hazards. While this seems to be news to the MOHLTC, the occupational health and safety community has long been well aware of this. The response of safety professionals and researchers is to strive to improve fit testing, not abandon it.<sup>1006</sup>

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1006. Letter from ONA to Premier McGuinty, December 15, 2005.

As noted earlier, the current Chief Medical Officer of Health has taken steps to try to bridge the wide gulf separating infection control and worker safety. However, only time will tell whether her efforts will bear fruit.<sup>1007</sup>

## Conclusion

Those in charge of the system that failed to protect health workers during SARS undoubtedly acted in good faith. But during most of the outbreak they were regrettably unaware of their occupational safety obligations under Ontario law. They were unaware until reminded late in the outbreak that when health workers have to use N95 respirators, employers must ensure that the respirators fit properly and that health workers are trained in their limitations and safe use. This has been Ontario law since 1993.

The Ministry of Labour may have acted in good faith, but it did little until late in the SARS outbreak to proactively inspect health care workplaces to ensure that health workers were using the appropriate respiratory protection and were properly trained in its use. The absence of the Ministry of Labour was especially significant because the health care system had little experience or expertise in N95 respirators or the respiratory protection programs necessary to ensure that N95s safely provide their intended level of protection.

The fact that about 45 per cent of all SARS cases were health workers demonstrates how badly respiratory protection and other worker safety issues were handled.

The primary role of occupational health and safety laws, regulations and systems is solely to protect workers in many workplaces.

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1007. Dr. Sheela Basrur notes in her letter of March 9, 2006, to Ms. Linda Haslam-Stroud, RN, President, Ontario Nurses' Association:

We recognize the need to ensure that the perspectives of occupational health and infection control receive consideration. In light of this, an occupational health physician is included in the membership of PIDAC and has been sitting on the committee since the inception of PIDAC in 2004. However, we see the importance in continuing to strengthen our links with the occupational health field and a physician delegate from the Ministry of Labour is now also sitting on PIDAC. This highlights our commitment to ensuring that occupational health and safety expertise is brought to the table during all PIDAC deliberations now and in the future. We are confident that building on this approach will assist in ensuring stronger linkages between occupational health and infection control on matters of science.

In health care settings, occupational health and safety protections perform a double duty, safeguarding workers while also shielding patients and visitors.

As the Ontario Nurses' Association and the Ontario Public Service Employees Union told the Commission in their joint submission:

Workplace health and safety is important in any workplace, but in a healthcare environment it's doubly important. If workers are not protected from health and safety hazards, patients and the public are not protected either. It's that simple.<sup>1008</sup>

Scientific knowledge changes constantly. Yesterday's scientific dogma is today's discarded fable. When it comes to worker safety in health care, we should not be driven by scientific dogma. We should be driven by the precautionary principle that reasonable steps to reduce risk should not await scientific certainty.

Until this precautionary principle is fully recognized, mandated and enforced in our health care system, nurses and doctors and other health workers will continue to be at risk from new infections like SARS.

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1008. SARS Commission Public Hearings, November 17, 2003.