

# Why Face Masks Don't Work: A Revealing Review

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*Yesterday's Scientific Dogma is Today's Discarded Fable*

## Introduction

The above quotation is ascribed to Justice Archie Campbell author of Canada's SARS Commission Final Report. **1** It is a stark reminder that scientific knowledge is constantly changing as new discoveries contradict established beliefs. For at least three decades a face mask has been deemed an essential component of the personal protective equipment worn by dental personnel. A current article, "Face Mask Performance: Are You Protected" gives the impression that masks are capable of providing an acceptable level of protection from airborne pathogens. **2** Studies of recent diseases such as Severe Acute Respiratory Syndrome (SARS), Middle Eastern Respiratory Syndrome (MERS) and the Ebola Crisis combined with those of seasonal influenza and drug resistant tuberculosis have promoted a better understanding of how respiratory diseases are transmitted. Concurrently, with this appreciation, there have been a number of clinical investigations into the efficacy of protective devices such as face masks. This article will describe how the findings of such studies lead to a rethinking of the benefits of wearing a mask during the practice of dentistry. It will begin by describing new concepts relating to infection control especially personal protective equipment (PPE).

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## Trends in Infection Control

For the past three decades there has been minimal opposition to what have become seemingly established and accepted infection control recommendations. In 2009, infection control specialist Dr. D. Diekema questioned the validity of these by asking what actual, front-line hospital-based infection control experiences were available to such authoritative organization as the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Association (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). **3** In the same year, while commenting on guidelines for face masks, Dr. M. Rupp of the Society for Healthcare Epidemiology of America noted that some of the practices relating to infection control that have been in place for decades, "haven't been subjected to the same strenuous investigation that, for instance, a new medicine might be subjected." **4** He opined that perhaps it is the relative cheapness and apparent safety of face masks that has prevented them from undergoing the extensive studies that should be required for any quality improvement device. **4** More recently, Dr. R. MacIntyre, a prolific investigator of face masks, has forcefully stated that the historical reliance on theoretical assumptions for recommending PPEs should be replaced by rigorously acquired clinical data. **5** She noted that most studies on face masks have been based on laboratory simulated tests which quite simply have limited clinical applicability as they cannot account for such human factors as compliance, coughing and talking. **5**

Covering the nose and mouth for infection control started in the early 1900s when the German physician Carl Flugge discovered that exhaled droplets could transmit tuberculosis. **4** The science regarding the

aerosol transmission of infectious diseases has, for years, been based on what is now appreciated to be “very outmoded research and an overly simplistic interpretation of the data.” <sup>6</sup> Modern studies are employing sensitive instruments and interpretative techniques to better understand the size and distribution of potentially infectious aerosol particles. <sup>6</sup> Such knowledge is paramount to appreciating the limitations of face masks. Nevertheless, it is the historical understanding of droplet and airborne transmission that has driven the longstanding and continuing tradition of mask wearing among health professionals. In 2014, the nursing profession was implored to “stop using practice interventions that are based on tradition” but instead adopt protocols that are based on critical evaluations of the available evidence. <sup>7</sup>

A December 2015 article in the National Post seems to ascribe to Dr. Gardam, Director of Infection Prevention and Control, Toronto University Health Network the quote, “I need to choose which stupid, arbitrary infection control rules I’m going to push.” <sup>8</sup> In a communication with the author, Dr. Gardam explained that this was not a personal belief but that it did reflect the views of some infection control practitioners. In her 2014 article, “Germs and the Pseudoscience of Quality Improvement”, Dr. K Sibert, an anaesthetist with an interest in infection control, is of the opinion that many infection control rules are indeed arbitrary, not justified by the available evidence or subjected to controlled follow-up studies, but are devised, often under pressure, to give the appearance of doing something. <sup>9</sup>

The above illustrate the developing concerns that many infection control measures have been adopted with minimal supporting evidence. To address this fault, the authors of a 2007 New England Journal of Medicine (NEJM) article eloquently argue that all safety and quality improvement recommendations must be subjected to the same rigorous testing as would any new clinical intervention. <sup>10</sup> Dr. R. MacIntyre, a proponent of this trend in infection control, has used her research findings to boldly state that, “it would not seem justifiable to ask healthcare workers to wear surgical masks.” <sup>4</sup> To understand this conclusion it is necessary to appreciate the current concepts relating to airborne transmissions.

### **Airborne Transmissions**

Early studies of airborne transmissions were hampered by the fact that the investigators were not able to detect small particles (less than 5 microns) near an infectious person. <sup>6</sup> Thus, they assumed that it was the exposure of the face, eyes and nose to large particles (greater than 5 microns) or “droplets” that transmitted the respiratory condition to a person in close proximity to the host. <sup>6</sup> This became known as “droplet infection”, and 5 microns or greater became established as the size of large particles and the traditional belief that such particles could, in theory, be trapped by a face mask. <sup>5</sup> The early researchers concluded that since only large particles were detected near an infectious person any small particles would be transmitted via air currents, dispersed over long distances, remain infective over time and might be inhaled by persons who never had any close contact with the host. <sup>11</sup> This became known as “airborne transmission” against which a face mask would be of little use. <sup>5</sup>

Through the use of highly sensitive instruments it is now appreciated that the aerosols transmitted from the respiratory tract due to coughing, sneezing, talking, exhalation and certain medical and dental procedures produce respiratory particles that range from the very small (less than 5 microns) to the very large (greater than a 100 microns) and that all of these particles are capable of being inhaled by persons close to the source. <sup>6, 11</sup> This means that respiratory aerosols potentially contain bacteria averaging in size from 1-10 microns and viruses ranging in size from 0.004 to 0.1 microns. <sup>12</sup> It is also acknowledged that upon their emission large “droplets” will undergo evaporation producing a concentration of readily inhalable small particles surrounding the aerosol source. <sup>6</sup>

The historical terms “droplet infection” and “airborne transmission” defined the routes of infection based on particle size. Current knowledge suggests that these are redundant descriptions since aerosols contain a wide distribution of particle sizes and that they ought to be replaced by the term, “aerosol transmissible.” <sup>4, 5</sup> Aerosol transmission has been defined as “person –to – person transmission of pathogens through air by means of inhalation of infectious particles.” <sup>26</sup> In addition, it is appreciated that the physics associated with the production of the aerosols imparts energy to microbial suspensions facilitating their inhalation.

Traditionally face masks have been recommended to protect the mouth and nose from the “droplet” route of infection, presumably because they will prevent the inhalation of relatively large particles. <sup>11</sup> Their efficacy must be re-examined in light of the fact that aerosols contain particles many times smaller than 5 microns. Prior to this examination, it is pertinent to review the defence mechanism of the respiratory tract.

### **Respiratory System Defences**

Comprehensive details on the defence mechanisms of the respiratory tract will not be discussed. Instead readers are reminded that; coughing, sneezing, nasal hairs, respiratory tract cilia, mucous producing lining cells and the phagocytic activity of alveolar macrophages provide protection against inhaled foreign bodies including fungi, bacteria and viruses. <sup>13</sup> Indeed, the pathogen laden aerosols produced by everyday talking and eating would have the potential to cause significant disease if it were not for these effective respiratory tract defences.

These defences contradict the recently published belief that dentally produced aerosols, “enter unprotected bronchioles and alveoli.” <sup>2</sup> A pertinent demonstration of the respiratory tract’s ability to resist disease is the finding that- compared to controls- dentists had significantly elevated levels of antibodies to influenza A and B and the respiratory syncytial virus. <sup>14</sup> Thus, while dentists had greater than normal exposure to these aerosol transmissible pathogens, their potential to cause disease was resisted by respiratory immunologic responses. Interestingly, the wearing of masks and eye glasses did not lessen the production of antibodies, thus reducing their significance as personal protective barriers. <sup>14</sup> Another example of the effectiveness of respiratory defences is that although exposed to more aerosol transmissible pathogens than the general population, Tokyo dentists have a significantly lower risk of dying from pneumonia and bronchitis. <sup>15</sup> The ability of a face mask to prevent the infectious risk potentially inherent in sprays of blood and saliva reaching the wearers mouth and nose is questionable since, before the advent of mask use, dentists were no more likely to die of infectious diseases than the general population. <sup>16</sup>

The respiratory tract has efficient defence mechanisms. Unless face masks have the ability to either enhance or lessen the need for such natural defences, their use as protection against airborne pathogens must be questioned.

### **Face Masks**

*History:* Cloth or cotton gauze masks have been used since the late 19th century to protect sterile fields from spit and mucous generated by the wearer. <sup>5,17,18</sup> A secondary function was to protect the mouth and nose of the wearer from the sprays and splashes of blood and body fluids created during surgery. <sup>17</sup> As noted above, in the early 20th century masks were used to trap infectious “droplets” expelled by the wearer thus possibly reducing disease transmission to others. <sup>18</sup> Since the mid-20th century until to-day, face masks have been increasingly used for entirely the opposite function: that is to prevent the wearer from inhaling respiratory pathogens. <sup>5,20,21</sup> Indeed, most current dental infection control recommendations insist that a face mask be worn, “as a key component of personal protection against airborne pathogens”. <sup>2</sup>

Literature reviews have confirmed that wearing a mask during surgery has no impact whatsoever on wound infection rates during clean surgery. <sup>22,23,24,25,26</sup> A recent 2014 report states categorically that no clinical trials have ever shown that wearing a mask prevents contamination of surgical sites. <sup>26</sup> With their original purpose being highly questionable it should be no surprise that the ability of face masks to act as respiratory protective devices is now the subject of intense scrutiny. <sup>27</sup> Appreciating the reasons for this, requires an understanding of the structure, fit and filtering capacity of face masks.

*Structure and Fit:* Disposable face masks usually consist of three to four layers of flat non-woven mats of fine fibres separated by one or two polypropylene barrier layers which act as filters capable of trapping material greater than 1 micron in diameter. <sup>18,24,28</sup> Masks are placed over the nose and mouth and secured by straps usually placed behind the head and neck. <sup>21</sup> No matter how well a mask conforms to the shape of a person’s face, it is not designed to create an air tight seal around the face. Masks will always fit fairly loosely with considerable gaps along the cheeks, around the bridge of the nose and along

the bottom edge of the mask below the chin. **21** These gaps do not provide adequate protection as they permit the passage of air and aerosols when the wearer inhales. **11,17** It is important to appreciate that if masks contained filters capable of trapping viruses, the peripheral gaps around the masks would continue to permit the inhalation of unfiltered air and aerosols. **11**

*Filtering Capacity:* The filters in masks do not act as sieves by trapping particles greater than a specific size while allowing smaller particles to pass through. **18** Instead the dynamics of aerosolized particles and their molecular attraction to filter fibres are such that at a certain range of sizes both large and small particles will penetrate through a face mask. **18** Accordingly, it should be no surprise that a study of eight brands of face masks found that they did not filter out 20-100% of particles varying in size from 0.1 to 4.0 microns. **21** Another investigation showed penetration ranges from 5-100% when masks were challenged with relatively large 1.0 micron particles. **29** A further study found that masks were incapable of filtering out 80-85% of particles varying in size from 0.3 to 2.0 microns. **30** A 2008 investigation identified the poor filtering performance of dental masks. **27** It should be concluded from these and similar studies that the filter material of face masks does not retain or filter out viruses or other submicron particles. **11,31** When this understanding is combined with the poor fit of masks, it is readily appreciated that neither the filter performance nor the facial fit characteristics of face masks qualify them as being devices which protect against respiratory infections. **27** Despite this determination the performance of masks against certain criteria has been used to justify their effectiveness.<sup>2</sup> Accordingly, it is appropriate to review the limitations of these performance standards.

*Performance Standards:* Face masks are not subject to any regulations. **11** The USA Federal Food and Drug Administration (FDA) classifies face masks as Class II devices. To obtain the necessary approval to sell masks all that a manufacturer need do is satisfy the FDA that any new device is substantially the same as any mask currently available for sale. **21** As ironically noted by the Occupational Health and Safety Agency for Healthcare in BC, "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." **21** Although the FDA recommends two filter efficiency tests; particulate filtration efficiency (PFE) and bacterial filtration efficiency (BFE) it does not stipulate a minimum level of filter performance for these tests. **27** The PFE test is a basis for comparing the efficiency of face masks when exposed to aerosol particle sizes between 0.1 and 5.0 microns. The test does not assess the effectiveness of a mask in preventing the ingress of potentially harmful particles nor can it be used to characterize the protective nature of a mask. **32** The BFE test is a measure of a mask's ability to provide protection from large particles expelled by the wearer. It does not provide an assessment of a mask's ability to protect the wearer. **17** Although these tests are conducted under the auspices of the American Society of Testing and Materials (ASTM) and often produce filtration efficiencies in the range of 95-98 %, they are not a measure of a masks ability to protect against respiratory pathogens. Failure to appreciate the limitations of these tests combined with a reliance on the high filtration efficiencies reported by the manufacturers has, according to Healthcare in BC, "created an environment in which health care workers think they are more protected than they actually are." **21** For dental personnel the protection sought is mainly from treatment induced aerosols.

### **Dental Aerosols**

For approximately 40 years it has been known that dental restorative and especially ultrasonic scaling procedures produce aerosols containing not only blood and saliva but potentially pathogenic organisms. **33** The source of these organisms could be the oral cavities of patients and/or dental unit water lines. **34** Assessing the source and pathogenicity of these organisms has proven elusive as it is extremely difficult to culture bacteria especially anaerobes and viruses from dental aerosols. **34** Although there is no substantiated proof that dental aerosols are an infection control risk, it is a reasonable assumption that if pathogenic microbes are present at the treatment site they will become aerosolized and prone to inhalation by the clinician which a face mask will not prevent. As shown by the study of UK dentists, the inhalation resulted in the formation of appropriate antibodies to respiratory pathogens without overt signs and symptoms of respiratory distress. **14** This occurred whether masks were or were not worn. In a 2008 article, Dr. S. Harrel, of the Baylor College of Dentistry, is of the opinion that because there is a lack of epidemiologically detectable disease from the use of ultrasonic scalers, dental aerosols appear to have a

low potential for transmitting disease but should not be ignored as a risk for disease transmission. <sup>34</sup> The most effective measures for reducing disease transmission from dental aerosols are pre-procedural rinses with mouthwashes such as chlorhexidine, large diameter high volume evacuators, and rubber dam whenever possible. <sup>33</sup> Face masks are not useful for this purpose, and Dr. Harrel believes that dental personnel have placed too great a reliance on their efficacy. <sup>34</sup> Perhaps this has occurred because dental regulatory agencies have failed to appreciate the increasing evidence on face mask inadequacies.

### **The Inadequacies**

Between 2004 and 2016 at least a dozen research or review articles have been published on the inadequacies of face masks. <sup>5,6,11,17,19,20,21,25,26,27,28,31</sup> All agree that the poor facial fit and limited filtration characteristics of face masks make them unable to prevent the wearer inhaling airborne particles. In their well-referenced 2011 article on respiratory protection for healthcare workers, Drs. Harriman and Brosseau conclude that, “facemasks will not protect against the inhalation of aerosols.” <sup>11</sup> Following their 2015 literature review, Dr. Zhou and colleagues stated, “There is a lack of substantiated evidence to support claims that facemasks protect either patient or surgeon from infectious contamination.” <sup>25</sup> In the same year Dr. R. MacIntyre noted that randomized controlled trials of facemasks failed to prove their efficacy. <sup>5</sup> In August 2016 responding to a question on the protection from facemasks the Canadian Centre for Occupational Health and Safety replied:

- The filter material of surgical masks does not retain or filter out submicron particles;
- Surgical masks are not designed to eliminate air leakage around the edges;
- Surgical masks do not protect the wearer from inhaling small particles that can remain airborne for long periods of time. <sup>31</sup>

In 2015, Dr. Leonie Walker, Principal Researcher of the New Zealand Nurses Organization succinctly described- within a historical context – the inadequacies of facemasks, “Health care workers have long relied heavily on surgical masks to provide protection against influenza and other infections. Yet there are no convincing scientific data that support the effectiveness of masks for respiratory protection. The masks we use are not designed for such purposes, and when tested, they have proved to vary widely in filtration capability, allowing penetration of aerosol particles ranging from four to 90%.” <sup>35</sup>

Face masks do not satisfy the criteria for effectiveness as described by Drs. Landefeld and Shojania in their NEJM article, “The Tension between Needing to Improve Care and Knowing How to Do It. <sup>10</sup> The authors declare that, “...recommending or mandating the widespread adoption of interventions to improve quality or safety requires rigorous testing to determine whether, how, and where the intervention is effective...” They stress the critical nature of this concept because, “...a number of widely promulgated interventions are likely to be wholly ineffective, even if they do not harm patients.” <sup>10</sup> A significant inadequacy of face masks is that they were mandated as an intervention based on an assumption rather than on appropriate testing.

### **Conclusions**

The primary reason for mandating the wearing of face masks is to protect dental personnel from airborne pathogens. This review has established that face masks are incapable of providing such a level of protection. Unless the Centers for Disease Control and Prevention, national and provincial dental associations and regulatory agencies publically admit this fact, they will be guilty of perpetuating a myth which will be a disservice to the dental profession and its patients. It would be beneficial if, as a consequence of the review, all present infection control recommendations were subjected to the same rigorous testing as any new clinical intervention. Professional associations and governing bodies must ensure the clinical efficacy of quality improvement procedures prior to them being mandated. It is heartening to know that such a trend is gaining a momentum which might reveal the inadequacies of other long held dental infection control assumptions. Surely, the hallmark of a mature profession is one which permits new evidence to trump established beliefs. In 1910, Dr. C. Chapin, a public health pioneer, summarized this idea by stating, “We should not be ashamed to change our methods; rather, we should be ashamed not to do so.” <sup>36</sup> Until this occurs, as this review has revealed, dentists have nothing to fear by unmasking. **OH**

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