



# Applying the precautionary principle to personal protective equipment (PPE) guidance during the COVID-19 pandemic: did we learn the lessons of SARS?

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## Background

On 24 March 2020, the World Health Organization warned that the “chronic global shortage of personal protective gear is among the most urgent threats to virus containment efforts” in the current coronavirus disease (COVID-19) pandemic.<sup>1</sup> In response, actions have been taken by agencies and institutions to conserve current supplies while attempting to procure more personal protective equipment (PPE). Conservation strategies often feature recommendations that suggest limiting higher-level PPE (e.g., N95 masks) to certain clinical situations. This guidance is not supported by reliable data, as uncertainty around severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) transmission mechanisms persist. In clinical decision-making, we rely on the principles of evidence-based medicine (EBM); it is the process by which we generate guidance and set standards for care using high-quality evidence. The current pandemic is challenging this hallmark of medical science, as the evidence required to support recommendations on patient care, healthcare worker protection, and resource use is limited, subject to uncertainty, and is constantly evolving.<sup>2</sup> We are dealing with a disease where the sensitivity of diagnostic testing is variable, the symptoms may be vague, the clinical course following infection can be unpredictable, the timing and method of transmission is contested, and a vaccine or treatment is unavailable. That said, during a healthcare

crisis, policy makers cannot wait for scientific certainty to make decisions.<sup>3</sup> Rather they require alternative approaches to dealing with uncertainty and mitigating risk in decision-making. In this paper, we aim to support decision-makers by examining areas of uncertainty regarding COVID-19, reviewing lessons from previous pandemics (including SARS), and outlining how the precautionary principle can be employed in developing guidance around PPE until more robust scientific evidence becomes available.

## COVID-19: What we do and do not know

SARS-CoV-2 is the  $\beta$ -coronavirus responsible for the worldwide COVID-19 pandemic.<sup>4</sup> Two other  $\beta$ -coronavirus infections—SARS-CoV in 2002–2003 and Middle East Respiratory Syndrome (MERS-CoV) in 2012—have caused severe respiratory syndromes in humans and resulted in global spread of disease.<sup>5</sup> Much of our working knowledge of SARS-CoV-2 behaviour and transmission has been inferred from experiences with these earlier viruses. Even so, differences between the viruses and gaps in understanding left over from the previous pandemics are contributing to uncertainty in our approach to the management of COVID-19.

During the SARS outbreak, most infectious patients were symptomatic, so it was relatively clear to healthcare workers who the high-risk patients were.<sup>6</sup> Conversely, evidence from early in the COVID-19 pandemic suggests that the majority of community infections result from contact with a subclinical yet contagious case.<sup>7–9</sup> Infected hosts who are not showing symptoms can have high viral loads and transmit virus with high efficiency, occasionally becoming super-spreaders of disease.<sup>10</sup> When viral transmission from patients exhibiting no symptoms is plausible, PPE choices become challenging, and rely

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heavily on accurate patient risk stratification. Estimation of the prevalence and contagiousness of subclinical COVID-19 infections is critical for understanding the overall threat to healthcare workers. Although COVID-19 tests are now commercially available, there is limited evidence on their clinical sensitivity, so the false negative rate with real-world use is uncertain.<sup>11</sup>

Transmission of coronaviruses is thought to occur primarily by contact and droplet routes, but there is evidence of airborne transmission with COVID-19 as there was with SARS and MERS.<sup>7,12-17</sup> Aerosol-generating medical procedures (AGMP) amplify typical transmission routes for respiratory viruses and can create the conditions necessary for airborne transmission.<sup>14</sup> Distinguishing a medical procedure as an AGMP is important as it informs guidance regarding appropriate PPE use for healthcare workers. Evidence outlining which medical procedures can act as AGMPs is limited, and largely based on observational studies undertaken during the SARS pandemic.<sup>18-20</sup> In a meta-analysis of these studies, tracheal intubation, tracheotomy, non-invasive ventilation, and manual ventilation were identified as AGMPs.<sup>19</sup> Other procedures, including surgical interventions, were not significantly associated with viral transmission. Although many of these procedures are known to create environmental contamination by droplets and aerosols, there were too few observations documented during SARS to generate sufficient data for analysis.<sup>19</sup> When observing for adverse events that are uncommon but plausible, there needs to be caution about drawing meaningful conclusions from a limited number of trials, especially when few or none of the events of interest have been recorded.<sup>21</sup> Interpreting “no evidence of harm” as “evidence of no harm” could place patients and healthcare workers at significant risk.<sup>22</sup> This is an obvious concern as we try to apply conclusions from the SARS experience, with just over 8,000 cases, to the current COVID-19 pandemic, with cases now numbering greater than 10,000,000 (29 June 2020).<sup>23</sup> Acknowledging the limited strength of any conclusions that might have been drawn from that experience and the uncertainty that persists is important in the current pandemic.

In the face of global shortages of PPE, difficult decisions must be made about how, where, and to whom supplies should be allocated. When the evidence regarding the risk of transmission from any given patient or procedure is weak or non-existent, the indications for appropriate PPE use, which form the basis of these decisions, will be marked by uncertainty. Under these conditions, conflicting guidance from different authorities may arise.<sup>24</sup> This was seen during the SARS pandemic, and examples can now be found with COVID-19.<sup>25-29</sup> Conflicting recommendations can lead to loss of trust in organizational leadership and

anxiety among healthcare workers.<sup>30</sup> This is especially the case when guidance suggests constraining PPE use to safeguard supplies. Healthcare workers may be left with the impression that supply conservation is a priority over protecting providers.<sup>31</sup> In the absence of reliable evidence, how can organizations generate guidance around AGMPs and PPE use to allow for the safe provision of care to patients with COVID-19, while ensuring that the risks to healthcare workers are kept to a minimum?

### Dealing with uncertainty

*Decision theory* is the study of how choices should be made under uncertain conditions. It is an alternative to EBM in the evaluation healthcare when relevant randomized-controlled trials are underpowered or do not exist. While EBM may focus on an objective primary outcome, decision theory considers the totality of outcomes in pragmatic decision-making, incorporating more subjective measures of cause-and-effect, including prior beliefs, observational evidence, and expert opinion about current best practice.<sup>32</sup> A decision theory model involves a decision problem, a set of possible choices or actions, and their associated consequences or outcomes. Decision-makers use fundamental knowledge about their environment to assign probabilities to different outcomes occurring based on the actions they take, and they attach utility (value) to these outcomes, which allows alternatives to be ranked. They then choose the action that maximizes their expected utility based on the model.<sup>33</sup>

The advantages of using a decision theory approach to decision-making are that it calls for a clear statement of the problem, applies information to a coherent framework, and offers a transparent and repeatable analysis for generating an expected course of action.<sup>34</sup> Nevertheless, for many events of interest in a pandemic, we do not have enough information to generate probabilities, nor is it likely that there exist probabilities to summarize all the relevant information for decision-making. This presents a normative challenge to decision theory; in cases where your decision framework cannot be neatly summarized by known probabilities, how *should* you rank your alternatives? The *precautionary principle* is a concept that complements utility as a normative criterion for choice.<sup>35</sup>

The precautionary principle was first referenced internationally in policymaking in the 1992 *Rio Declaration on Environment and Development* to describe a proactive approach to risk mitigation in the face of serious and irreversible threats to the environment amid scientific uncertainty.<sup>22</sup> It captures the idea that if a threat is sufficiently severe, intervention may be considered legitimate, even where the supporting evidence is

incomplete or speculative and the economic costs are high.<sup>22</sup> The principle has since featured prominently in two judicial inquiries into significant events in Canadian healthcare. The first was the *Royal Commission of Inquiry on the Blood System in Canada*.<sup>36</sup> Justice Krever, Commissioner of the Inquiry, stated: “When there is reasonable evidence of an impending threat to public health, it is inappropriate to require proof of causation beyond a reasonable doubt before taking steps to avert the threat”.<sup>36</sup> In the context of pandemic policy, the *Commission to Investigate the Introduction and Spread of SARS in Ontario* (The SARS Commission) also cited the precautionary principle as perhaps the most important lesson to come from the SARS experience; it formed the basis of many of the Commission’s recommendations.<sup>3</sup>

The SARS Commission was chaired by Justice Campbell who was appointed by the Ministry of Health and Long-Term Care in Ontario, one of the regions hardest hit by the SARS pandemic and where 44% of infections were among healthcare workers. Justice Campbell concluded that there was a profound lack of awareness of worker safety and best practices within the health system, and a systemic failure to apply the precautionary principle to limit risks to healthcare workers.<sup>3</sup> The report recommended that the precautionary principle “be expressly adopted as a guiding principle in health, public health, and worker safety systems”. Campbell also advised that, in any future infectious disease crisis, the precautionary principle should be used to guide the development of worker safety policies, practices, and guidelines; that “communication to staff reflect a precautionary approach, that it is better to err on the side of caution when dealing with a little understood new disease”; and that “the health concerns of healthcare workers be taken seriously and in the spirit of the precautionary principle healthcare workers be made to feel safe, even if this means continuing with heightened levels of precautions.”<sup>3</sup>

### An approach to decision-making in a pandemic

Guidance on PPE and procedure risk should consider access to care, healthcare worker protection, and supply conservation. Policies must avoid underutilization of PPE and minimize overutilization, as the former may harm healthcare workers and the latter jeopardizes future stock and is associated with both economic and environmental costs. Policy development should begin by fully evaluating the available evidence and degree of uncertainty, reviewing the risk-management options, and should involve (as much as possible) all interested parties in the decision-making process.<sup>22</sup> To achieve these objectives, we propose a

pandemic approach to decision-making that borrows from concepts arising from the precautionary principle.

Experiences from SARS taught healthcare organizations that, in times of crisis, “where guidance is incomplete, consequences uncertain, and information constantly changing, where hour-by-hour decisions involve life and death, fairness is more important, rather than less”.<sup>37</sup> It was recognized that ignoring the moral dimension in decision-making led to loss of public trust, low morale among hospital staff, confusion about roles and responsibilities, and misinformation.<sup>38</sup> To mitigate unintended collateral damage in a public health crisis, Thompson *et al.* proposed a set of ethical principles to be used in decision-making.<sup>30</sup> These principles included accountability, inclusiveness, openness and transparency, and reasonableness and responsiveness. The same measures can easily be applied to a COVID-19 decision-making framework.

Accountability requires that mechanisms be put in place to ensure that ethical decision-making is sustained throughout the pandemic on the part of the leaders responsible for the care of healthcare workers, and on the part of healthcare workers taking care of patients. Inclusiveness calls for explicit consideration of stakeholder interests in decisions, and opportunities for stakeholder engagement during the decision-making and review process. Formation of a working group with a clear and actionable mandate to generate guidance at an institutional level speaks to these first two principles. The group should be composed of organizational leadership, content experts, managers, and frontline workers, to ensure that relevant evidence, interests, and institutional understanding are represented in discussions, and that ethical values of accountability and inclusiveness are addressed. We have learned from previous pandemics that failing to involve frontline staff in decision-making can lead to a lack of trust in leadership and negatively impact institutional morale.<sup>39</sup> Although the exact makeup of a working group may evolve as the pandemic progresses, the establishment of a decision group at the earliest opportunity is essential, as the scope and complexity of issues will likely go beyond the purview of any single decision-maker.

Openness and transparency call for a clear communication plan to disseminate decisions and requires that decisions should also be open to scrutiny.<sup>30</sup> There should be an accessible forum through which frontline healthcare workers can voice concerns with decisions regarding their safety. Reasonableness implies that decisions should be based on evidence where they can be, but that principles and values are also integrated into the decision-making process.<sup>30</sup> In keeping with the precautionary principle, reasonable recommendations around PPE use would start with advising a higher level

of protection that is reduced as the clinical situation is clarified.<sup>38</sup> Additionally, latitude should be afforded to healthcare workers to use their own clinical judgement. This belief is in line with the directive published by the Chief Medical Officer of Health of Ontario which states that: “If a healthcare worker determines, based on a [point-of-care risk assessment], and based on their professional and clinical judgement, that health and safety measures may be required in the delivery of care to the patient, then the public hospital must provide that worker with access to the appropriate health and safety control measures, including an N95 respirator.”<sup>40</sup> Scarcity of PPE is not a valid reason to limit PPE access to healthcare workers. Infected healthcare workers represent a “triple threat” in pandemic control. They serve as vectors for disease transmission, reduce the capacity of an already overwhelmed system, and add further strain by becoming patients themselves.<sup>41</sup> Rather than compromising the safety of healthcare workers to address issues of scarcity, there should be a focus on developing and implementing solutions for sustainable and resource-conscious PPE use that do not limit access to PPE. These may include deferring elective procedures and non-urgent care in high-risk patients, investigating approaches to decontamination and reclamation of used PPE, employing alternative barriers to aerosolization, substituting AGMPs with regional anesthesia when appropriate, and ensuring PPE effectiveness when airborne precautions are needed by providing adequate training and support in donning and doffing.<sup>42,43</sup>

Finally, responsiveness necessitates that there must be structured opportunities to revisit and revise decisions as new information emerges.<sup>30</sup> Changes to sensitivity and specificity in screening and testing may clarify what we know about patient risk, new evidence may be generated on AGMPs, PPE supply may change, and institutions may broaden access to care as lockdowns end. Changes to any of these factors that form the basis of a decision problem could warrant a review of the decision and a change in guidance. Working groups should have a structured formal process for examining new evidence and re-evaluating decisions at reasonable and frequent intervals to ensure the ethical principle of responsiveness. Any changes to recommendations should be clearly communicated to all stakeholders with explanations as to what prompted reconsideration of earlier decisions and why new guidance is considered to be more appropriate.

## Conclusions

In Canada, the initial wave of COVID-19 was largely concentrated in long-term care facilities. While healthcare workers in those environments have dealt with a significant

burden of disease in their ranks, community spread in most areas of the country has been relatively low, and in acute care settings, workers have faced a much lower prevalence of disease than was initially predicted. This likely has more to do with public health measures, such as social distancing and self-isolation, than PPE. Nevertheless, as regulatory interventions are lifted, we can anticipate an increase in community transmission and should remain vigilant regarding personal protective measures. It is the unfortunate likelihood that many of the uncertainties currently recognized around COVID-19 will persist and only be clarified after the resolution of the pandemic. All things considered, if there was a take-away lesson from previous pandemics it would be this: the point is not science, but safety. The precautionary principle should be applied by hospital leadership in their approach to pandemic decision-making and healthcare worker safety. PPE shortages should not be an excuse for healthcare workers not to have access to the maximum level of protection. Until robust scientific evidence becomes available, guidance around PPE use should *first, do no harm*.

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