When the disposable mini-toga is used in conjunction with standard PPE, the donning, removal and disposal procedures each take approximately 30 to 45 seconds (see video demonstration at www.cmaj.ca). Because a paramedic can remove the device without assistance before driving, there is no risk of contaminating the driver's compartment and no reason for the paramedic's partner to leave the intubated patient unattended.

In conclusion, the "new normal" PPE standards are inadequate in the prehospital setting. In certain situations a PPS is the only means of achieving the balance between patient care and paramedic safety.

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References

1. Verbeek PR, Schwartz B, Burgess RJ. Should paramedics intubate patients with SARS-like symptoms? [editorial]. *CMAJ* 2003;169(4):299-300.
2. *Directive 03-11. Directive to all Ontario acute care hospitals for high-risk procedures.* Toronto: Ontario Ministry of Health and Long-Term Care; 2003 June 16. Available: www.health.gov.on.ca/english/providers/program/pubhealth/sars/docs/docs2/dir_acute_care_061603.pdf (accessed 2003 Oct 24).

[The authors respond:]

We are not surprised by the wide-ranging opinions expressed in response to our commentary.[1] The 2 physicians suggest that our level of concern for paramedic protection is unwarranted. Although our commentary did not clearly state that our position was in the context of a SARS outbreak as intended, we continue to feel that prehospital intubation of patients with SARS-like symptoms (SLS) in this circumstance poses an unacceptable risk to paramedics. During a SARS outbreak, all patients with SLS should be considered to have SARS until proven otherwise. Schabas' statements regarding ascertainment and the risk of intubation lack insight into the uniqueness of the prehospital environment where occupational and admission histories are frequently unavailable and intubation of a febrile, coughing patient is never straightforward. Moreover, he fails to recognize the evidence that all paramedics who contracted SARS did so by coming into contact with people who were neither hospital workers nor recent inpatients.[2] Interestingly, the situations in which Ovens prescribes risk-taking behaviour for paramedics are areas where efforts to reduce risk are ongoing. These include limitations on the use of lights and sirens and the introduction of safe catheters for intravenous initiation.[3,4]

We feel it is no more acceptable to expect underprotected paramedics to intubate patients with SLS during a SARS outbreak than to have underprotected paramedics enter a building with a suspected Sarin gas release. Would Ovens want to send paramedics headlong into the Sarin fog under the guise of an "occupational hazard"? Who would want to perform an awake intubation, on a patient with SLS lying on a landing between 2 staircases, without having access to the specialized protective equipment he calls for in a recent Canadian Association of Emergency Physicians position statement?[5]

Urszenyi construed our commentary to suggest that all situations requiring airway management pose an identical threat. Our premise is quite the opposite. In the end, the paramedic will make the final decision as to whether to intubate a patient with SLS. Our responsibility is to define potential risk, provide guidance and suggest alternatives. We do not feel it is appropriate for paramedics to be expected to "go it on their own."

We are unaware of any evidence that the "new normal" standard of PPE fails to protect paramedics, as asserted by Hutcheon. Nor are we personally aware of any paramedic who developed probable or suspect SARS once PPE was introduced for all patient encounters. Hutcheon's description of a powered helmet-style PPS is intriguing. We and many others consider this equipment to be necessary but not sufficient to create optimal circumstances for intubation of patients with SARS and SLS.[5,6]

Our recommendations are in no way a disservice to the bravery and commitment of paramedics. Instead they demonstrate that we consider paramedics to be "canaries in the mine" and at higher risk than most other health care workers. Emergency medical services administrators and medical directors understand this and are working to create guidelines that respect the primacy of the "principle of paramedic safety."[4] Our paramedics deserve no less.

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References

1. Verbeek PR, Schwartz B, Burgess RJ. Should paramedics intubate patients with SARS-like symptoms? [editorial]. *CMAJ* 2003;169(4):299-300.
2. Varia M, Wilson S, Sarwal S, McGeer A, Gournis E, Galanis E, et al. Investigation of a nosocomial outbreak of severe acute respiratory syndrome (SARS) in Toronto, Canada. *CMAJ* 2003;169(4):285-92.
3. Peate WF. Preventing needlesticks in emergency medical system workers. *J Occup Environ Med* 2001;43(6):554-7.
4. Kahn CA, Pirrallo RG, Kuhn EM. Characteristics of fatal ambulance crashes in the United States: an 11-year retrospective analysis. *Prehosp Emerg Care* 2001;5(3):261-9.
5. Ovens H, Thompson J, Lyver M, Murray MJ, Innes G, on behalf of the Canadian Association of Emergency Physicians (CAEP). Implications of the SARS outbreak for Canadian emergency departments [position statement]. *Can J Emerg Med* 2003:5(5);343-7.
6. Cooper A, Joglekar A, Adhikari N. A practical approach to airway management in patients with SARS. *CMAJ* 2003;169(8):785-7.

Revisiting Helsinki

Your editorial about the Helsinki Declaration[1] was probably the first indication of unequivocal support from a developed country for the developing countries' cry for justice, even if only (but hopefully just for the time being) in the arena of clinical trials.

As a researcher and concerned physician in Brazil, I agree with your evaluation of the crucial role of the Declaration of Helsinki in setting ethical standards for human research. In fact, its ethical framework has become a benchmark in this area and has become, on its own merits, a standard not just of the World Medical Association (WMA) but also for society as a whole.

While we researchers are generally privileged people, many research subjects are among the most vulnerable, living under conditions of deprivation and prone to exploitation. Many trials are performed in extremely poor regions of the world, with the questionable justification that these communities are in urgent need of answers to specific research questions. Such "specific questions" could undoubtedly be answered elsewhere. Furthermore, the vulnerability of these potential research subjects makes it almost impossible for meaningful informed consent to be obtained, and their extreme poverty makes it highly unlikely that the products of the research will be accessible to them. What people in developing countries really need is access to products that have been researched and developed and are in use elsewhere.

In addition to the opposition of the Argentinean and Brazilian medical associations to the changes in paragraph 30 (access to medical care) and the addition of notes of clarification, Brazil also opposed the confused and lax note of clarification to paragraph 29. This note was discussed in a *petit comité* meeting convened by the WMA in September 2001 but was defeated by representatives of the pharmaceutical industry and regulatory agencies and researchers from the United States.

The WMA postponed any modification or note of clarification to paragraph 30 and established a new working group for this discussion. Although this group is skewed in its representation, 2 of the 5 countries represented are from the developing world (Brazil and South Africa). Brazil's position is clear: any change in the Declaration of Helsinki should be made only if there are compelling reasons to do so. And in this unequal world, we argue that any modification should be in the direction of making the ethical obligations of providing adequate access to medical care even more stringent, to be applied to every trial involving a human being, wherever such a trial is performed.

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Reference

1. Dismantling the Helsinki Declaration [editorial]. *CMAJ* 2003;169(10):997.

Having represented the Canadian Medical Association (CMA) at the WMA meeting in Helsinki in September 2003, I must take issue with the allegations contained in your editorial and in a report on the debate surrounding paragraph 30 of the Helsinki Declaration.[1-2]

As I told your reporter, the CMA supports paragraph 30. It is unfortunate for you to suggest that the opponents of paragraph 30 were "abetted" by any silence on the part of the CMA. On the contrary, I personally intervened twice during the formal discussion at the WMA ethics committee in Helsinki to reiterate our support. Moreover, the CMA Secretary General and I intervened frequently and forcefully behind the scenes. That the CMA also supports the necessary efforts of the working group to build consensus behind paragraph 30 should not be misconstrued as weakening our traditional belief in our ethical obligation to help study participants obtain access to a treatment that has been proven beneficial upon completion of a clinical trial.

It is indeed unfortunate that the CMA's record on a matter of such importance has been needlessly called into question. I trust this sets the record straight.

Henry Haddad
Past President (2002/03)
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Ottawa, Ont.

References

1. Dismantling the Helsinki Declaration [editorial]. *CMAJ* 2003;169(10):997.
2. Helsinki Declaration revisited over concerns about human subjects. *CMAJ* 2003;169(10): 1066.

À titre de représentant de l'Association médicale canadienne à l'assemblée de l'Association médicale mondiale (AMM) à Helsinki en septembre dernier, je me dois de contester les allégations de votre éditorial et la représentation que vous faites du débat entourant le paragraphe 30 de la Déclaration d'Helsinki [1,2].

Ainsi que je l'ai expliqué à votre reporter, l'AMC appuie le paragraphe 30. Il est malheureux que vous ayez laissé entendre que l'opposition au paragraphe 30 aurait été «facilitée» par un silence de la part de l'AMC. Au contraire, je suis intervenu personnellement deux fois au cours des discussions officielles du comité d'éthique de l'AMM à Helsinki pour réitérer notre appui. De plus, le secrétaire général de l'AMC et moi-même sommes intervenus énergiquement en ce sens en coulisse, à de nombreuses reprises. Le fait que l'AMC appuie également les efforts du groupe de travail pour faire le consensus autour du paragraphe 30 ne devrait pas être faussement interprété comme un affaiblissement de la conviction que nous avons toujours eue de notre obligation éthique d'aider les personnes participant à des études à obtenir après l'essai clinique un traitement se révélant bénéfique.

Il est en vérité tout à fait malheureux que la position de l'AMC dans un dossier d'une telle importance ait été inutilement remise en question. J'espère que la présente lettre dissipera les doutes à cet égard.

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Référénces

1. Affaiblir la Déclaration d'Helsinki [éditorial]. *JAMC* 2003;169(10):999.
2. Helsinki Declaration revisited over concerns about human subjects. *JAMC* 2003;169(10):1066.