

Personal Protective Equipment for Filovirus Epidemics: A Call for Better Evidence

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Personal protective equipment (PPE) is an important part of worker protection during filovirus outbreaks. The need to protect against a highly virulent fluid-borne pathogen in the tropical environment imposes a heat stress on the wearer that is itself a safety risk. No evidence supports the choice of PPE employed in recent outbreaks, and standard testing procedures employed by the protective garment industry do not well simulate filovirus exposure. Further research is needed to determine the appropriate PPE for filoviruses and the heat stress that it imposes.

Keywords. Ebola; heat stress disorders; hemorrhagic fever; protective clothing.

The filovirus is the archetypal biohazard. A small infectious dose causes highly lethal disease for which there is currently no specifically effective treatment. A high death toll among healthcare workers who care for patients with Ebola and Marburg virus diseases is a fearful hallmark of filovirus outbreaks. Healthcare worker protection is one of the principal objectives of the international response to filovirus outbreaks.

The most visible means of worker protection is the use of personal protective equipment (PPE), the material covering the face, head, and body to protect the wearer from filovirus infection. However, this equipment alone is insufficient, and must be accompanied by other interventions, such as training staff on safe work practices, engineering a safe working environment in Ebola treatment units, and employment of administrative controls such

as limiting shift lengths and restricting access. Nevertheless, PPE is a critical part of keeping those who care for Ebola and Marburg patients from becoming infected themselves.

In past outbreaks, PPE was usually put together using materials commonly available in outbreak-prone countries, much of which came from the operating theater: surgical scrubs, gowns, head coverings, masks, and gloves. These items were supplemented by rubber Wellington boots, a rubber apron, a second pair of gloves, and eye protection (either glasses or goggles). This configuration was formalized in the Centers for Disease Control and Prevention's (CDC's) "Infection Control for Viral Haemorrhagic Fevers in the African Health Care Setting" [1].

In subsequent outbreaks coveralls were added, as wearers sought more complete coverage. The garments became more resistant, changing from the material used in surgical gowns to uncoated polyethylene fabric and then to coated polyethylene. Polyethylene fabric hoods that fully covered the head and neck became favored over surgical head covering. Surgical masks were abandoned in favor of masks that did not lie flat against the face. Most of these changes were made because of the presumption of increased security, but there was no empirical basis for the changes other than that granted by the EN 14126 certification [2] of the coated polyethylene material.

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This progression presents a problem. The need to protect the healthcare worker from contaminated fluids has led to them being wrapped in material that allows very little gas exchange. This impairs evaporative cooling, which is a nontrivial matter in the tropical environment where filovirus outbreaks occur, so that most workers can only tolerate around 40 minutes in their PPE. The potential adverse effects from overheating include cognitive impairment and loss of situational awareness, as well as changes in postural stability, which in a high-risk environment can be a significant danger to the wearer. The accompanying potential for severe dehydration, heat illness, and heat stroke aggravates this situation. Moreover, many facilities treating Ebola patients are ill-equipped to treat heat illness or heat stroke (which has a 90% mortality rate if untreated).

The time that healthcare workers can tolerate PPE limits the total contact time between healthcare workers and their patients. This puts constraints on how intensively patients with Ebola and Marburg virus disease can be cared for [3].

As most of the PPE elements are single-use, wearing them for only 40 minutes at a time results in a significant consumption of material. Ebola and Marburg outbreaks usually take place in remote resource-limited settings, and the PPE material must be shipped from high-income countries to the outbreak zone. The high rate of consumption increases the purchase and shipping costs, while adding to the significant logistical problems of distribution to remote areas.

Unfortunately, the evidence base for making informed decisions about appropriate PPE is very thin. A PubMed search using the terms “personal protective equipment” and “Ebola” yields 9 items, none of which provide evidence for guidance, and many of which highlight the aforementioned problems of the PPE in use during the West African Ebola outbreak of 2014.

THE MEETING

To try to address these concerns with PPE, Médecins Sans Frontières convened a meeting on 3 April 2014, at the Galveston National Laboratory in Galveston, Texas. Representatives were present from the CDC Viral Special Pathogens Branch, the World Health Organization, the National Institutes of Health’s Integrated Research Facilities at Frederick, Maryland and Rocky Mountain Laboratories at Hamilton, Montana the Galveston National Laboratory, the Public Health Agency of Canada’s Special Pathogens Unit, the PPE divisions of DuPont, 3M, and Microgard, and the CDC National Institute for Occupational Safety and Health. This meeting brought together, for the first time, experts in the virology of filoviruses, worker protection and protective equipment, epidemiologists, and outbreak response agencies. Their deliberations are summarized here.

The presumed portal of entry for filovirus disease in the occupational setting is exposure of the mucus membranes of the eyes, nose, and mouth to the virus. Intact skin is assumed to be

an effective barrier, although this can be bypassed by sharp penetrating injury or disruption of its integrity.

Given this, the consideration of PPE was taken up in two parts: protection from the neck down and from the neck up. Protection below the neck involves the garments that cause most of the heat stress. Protection from the neck up involves the highest risk of virus reaching the portals of entry.

Below the neck, the protection afforded by intact skin and gravity drawing fluids away from the mucus membranes leave, as the chief risk, the deposition of viral particles onto the skin or clothes that could subsequently be translocated to the mucus membranes. The primary role of gowns, coveralls, and aprons is to prevent deposition of the virus on the skin or clothes on the assumption that they prevent viral penetration. There is no evidence that any material does this.

Most commercially available garments that are engineered to provide resistance to infectious fluids have their resistance measured by their ability to prevent passage of a tracer bacteriophage, Phi X 174, in a synthetic blood medium under varying degrees of pressure. The tests that employ this bacteriophage are ISO 16604, which is a test method comprising part of the aforementioned European standard EN 14126, and the similar ASTM F1671 [4]. Phi X 174 is a nonenveloped DNA virus 27 nm in diameter, whose physical characteristics are rather different from filoviruses, which are lipid-enveloped, thread-like forms 80× approximately 800 nm [5]. As filoviruses are much larger than Phi X 174, materials passing the standard tests for protection from fluid-borne infectious agents may well be more resistant than is needed for protection from filoviruses. As higher degrees of resistance correlate with decreasing gas permeability, setting too high a standard comes at a cost of decreased evaporative cooling.

It may be that protection with material passing the ISO 16604 or ASTM F1671 is unnecessary. Healthcare worker deaths in past outbreaks were stopped with the introduction of PPE that used available surgical gowns that did not meet these standards [6]. This may be the result of either the available materials being sufficiently resistant or of any virus penetrating this material being inactivated or removed before it could be transferred to the healthcare worker’s mucus membranes.

A material that was not guaranteed to prevent filovirus penetration could still be employed, provided that the wearer’s skin were intact and that the wearer changed clothing and engaged in a skin decontamination procedure after doffing their PPE. This would prevent any deposited virus from becoming an infection risk. This assumes that the worker does not have skin microbreaks of which they are unaware.

The priority above the neck is the protection of the eyes, nose, and mouth. Protective measures must first account for direct entry of virus, such as from coughed droplets or contaminated hands. However, protection must also account for indirect entry, such as the movement of contaminated material deposited

onto the face or carried there by the hands, which may be drawn by gravity to the eyes or mouth when the wearer is perspiring.

Some PPE configurations have allowed for the skin of the head or neck to be exposed, while others offered complete coverage. The risk of infectious material migrating the short distance to the mucus membranes was considered high by most attendees.

The decontamination procedures that might allow for tolerance of deposition of infectious material on intact skin below the neck do not apply above the neck. Infectious material may migrate in running perspiration to a mucus membrane prior to decontamination. Hair is not easily decontaminated by simple decontamination procedures, such as wiping with disinfectant or soap. More thorough decontamination procedures, such as a shower, may cause infectious material to run toward mucus membranes. As such, complete coverage above the neck with impermeable protection is advisable.

Above-neck PPE included facial protection that allowed for maximum visibility of the face while still providing complete coverage. This would allow better interaction between clinical staff and the patient. If a nonenclosed face shield is employed, it should be supplemented by a mask to cover the mouth and nose from unconscious movements of the hands to the face. Furthermore, the skin of the lower face should be disinfected after PPE removal to account for any infectious material deposited by unconscious hand movements.

A fully enclosed solution that would prevent touching of the face while still permitting full visibility of the face would require ventilation to prevent fogging of the face shield. Powered air purifying respirators have been employed in deployed field laboratories during filovirus outbreaks, but their suitability and practicality in the clinical environment has not yet been assessed.

CONCLUSIONS

The limited evidence for the effectiveness of PPE used in filovirus outbreaks has led to choices being made with little empiric support. This weak evidence base prevented the attendees of the meeting from making strong recommendations with regard to the choice of protective equipment. Rather, the recommendations were to improve the evidence base.

As a first step, it was agreed that the materials currently in use for protective gowns, coveralls, and hoods should undergo testing in a Biosafety Level 4 (BSL-4) laboratory to demonstrate their resistance to filovirus using standard (ISO 16604/ASTM F1671) methodology. The most gas-permeable material that prevented filovirus penetration under these test circumstances would be a suitable option for PPE use.

Tolerance for the use of protective material that has not been shown to be resistant to filovirus penetration is based on the assumption that intact skin is an effective barrier. As there is no evidence for this, it was agreed that this assumption should be tested in a nonhuman primate study in a BSL-4 laboratory. Furthermore,

a strategy would be needed to effectively monitor skin condition to prevent infection via nonintact skin, which could potentially result from insect bites, sunburn, shaving nicks, dermatitis (including disinfectant-related dermatitis), and so forth.

Because the principle danger imposed by PPE was its potential for inducing heat illness, it was agreed that current PPE configurations should be tested in an environment simulating the temperature and humidity of the typical outbreak environment to determine the length of time they could be safely worn under normal working conditions. In addition, standardized test methods designed to quantify breathability of garment fabrics, such as ISO 11092 [7], could be useful.

These three investigations would establish an improved evidence base for selecting PPE for use in filovirus epidemics that would provide sufficient protection from the virus while minimizing the risk of heat illness in the wearer. Given the unprecedented scope of the current Ebola epidemic, and the need for the most effective PPE, the proposed research must be a very high priority.

Notes

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