Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers in Tropical Climates

World Health Organization

Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers* in Tropical Climates

*Ebola, Marburg and other hemorrhagic fevers that share similar human-to-human transmission characteristics

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Acronyms

AAMI	Association of the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
AC	WHO Advisory Committees for Innovative Personal Protective Equipment
AC-WG	WG AC working group
ANSI	American National Standards Institute
ASTM	American Society of Testing Materials International
BS EN	European Standard that is published in United Kingdom
DIN EN	European Standard is published in Germany by German Standards Institute
EBOV	Ebola virus
EN	European Standard-European Norm
ETU	Ebola treatment unit
EVD	Ebola virus disease
HW	Health worker
HW-F	Health worker at the frontline
IPC	Infection prevention and control
ISO	International Organization for Standardization
MSF	Médecins sans Frontières (Doctors without Borders)
N95	Respirator, blocks at least 95% of 0.3 micron test particles
NFPA	National Fire Protection Association
OSH	Occupational safety and health
PAPR	Powered air purifying respirator
PPE	Personal protective equipment
PPC	Preferred product characteristics
R&D	Research and development
RSV	Respiratory Syncytial Virus
SARS	Severe Acute Respiratory Syndrome
TPP	Target product profile
WHO	World Health Organization

Definitions

Health worker at the frontline (HW-F): Clinical health workers tending to Ebola virus disease (EVD) patients and non-clinical staff performing heavy duty services such as transporting symptomatic patients, care-setting cleaning, environment decontamination and removal of deceased for respectful disposition. Together, these workers are at the highest risk of exposure and thus are defined as health workers at the frontline (HW-F). Health worker (HW) is a more generalized term for those personnel who also will use PPE but are not necessarily in direct patient contact or performing high risk activities.

Ebola treatment unit (ETU)s: Treatment units set up for EVD patients, with sections divided into increasing degree of illness from triage to suspect (holding) to confirmed zones (treatment).

Low and middle income countries: As defined using the World Bank country classification.

Preferred product characteristics (PPC): A PPC profile describes the preferred criteria for a product or suite of products that meet the intended unmet public health need in a priority disease area and is structured to drive innovation towards meeting the need. PPC addresses research and development (R&D) therefore its parameters are not static and will be reviewed and updated periodically to meet the public health demand.

Standard precautions: Set of infection control practices used to prevent transmission of diseases and should be applied in a constant basis with all patients, regardless of diagnosis- in all practices and at all times. Standard precautions include: hand hygiene, use of PPE based on risk assessment, prevention of needle-stick or sharps injuries, safe waste management, cleaning, disinfection and sterilization; where applicable, of the equipment, linen used and the patient care environment. This is to protect from contact with blood, body fluids, non-intact skin (including rashes), and mucous membranes.

Target product profile (TPP): May contain similar parameters as PPC and includes a set of desired minimally acceptable technical specifications in addition to preferred criteria. TPP is a technical document detailing specific requirements.

Technical specifications: Refers to the existing local, national, regional and international sets of standards, testing methods and quality control systems for which all individual PPE elements are reviewed or tested before they can be made available in their respective markets. The manufacturers and normative entities take the responsibility to ensure product performance and reliability. Detailed explanations are in Figure 1 in Appendix 3.

Tropical climate: Tropical zones dominated by abundant rainfall with a temperature range of >200 C-380 C and >75-95% humidity. This includes tropical rainforest, monsoon and savanna climate zones (i.e. “hot, humid” conditions).

Work period: Little is known about the ideal amount of time a HW-F can wear PPE and safely provide care for a patient or carry out heavy duty work. This period includes the time needed for donning and doffing PPE. The literature indicates that given existing knowledge about disease transmission, an appropriate period may be between 40 minutes and 4 hours. Beyond this time, the HW-F may become subject to discomfort and be more likely to misuse PPE, thereby increasing the chance of disease transmission. For this reason, we define a work period as being between 40 minutes and 4 hours, subject to IPC protocol.

Intended target

Key explanations and concepts are presented here to guide the reader when viewing this document.

Intended target for this PPC document: Although this document is addressing the unmet public health need for protective PPE for the HW-F when responding to Ebola virus (EBOV) infections, the principles of this guidance may also be applied to other filovirus infections such as Marburg virus. The document may also have applications for other diseases that share human-to-human transmission characteristics which pose a similar risk to the health worker (see explanation in *Definitions*) (Table 1).

Table 1. The target use populations, setting and intended use of this PPC document

Target population, setting and use	
Primary target use population	Heath workers on the frontline providing patient care and heavy duty services in basic facilities under hot, humid conditions.
Secondary target use population	Health workers who will use PPE for protection from high risk exposure in advanced equipped medical facilities.
Target use setting	Health facilities and community environments where health workers on the frontline are at risk of exposure to virus shedding by patients or dead bodies.
Intended use	To serve as a guide for health workers, industry, engineers, innovators, medical and scientific researchers and others, the opportunity to re-think, energize and innovate for a better PPE system to protect the health worker.

Use of evidence from Severe Acute Respiratory Syndrome (SARS) and Respiratory Syncytial Virus (RSV) studies: This document focuses on evidence research from EBOV publications combined with generalized information from SARS and RSV infections studies. SARS and RSV can be transmitted through mucous membrane contacts via airborne or aerosolized virus. EVD is primarily transmitted through contact of infectious virus with mucous membranes. EBOV has not been proven to be transmitted by aerosol, despite animal studies designed to study this route[1,2].

Technical specifications for PPE are comprised of a complex set of product characteristics, standards and methods with most of the specifications applying to an individual PPE element or category (Figure 1, Appendix 3), which are used for procurement. Many of the existing standards apply to conditions relevant to the characteristics described in this document but none specifically addresses a *full PPE ensemble* that is when different components are utilized together. Because there is scant technical data