Preferred Product Characteristics for Personal Protective Equipment for the Healthcare Worker on the Frontline Responding to Ebola Virus and Haemorrhagic Fever Outbreaks in Tropical Climate

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DRAFT FOR COMMENTS

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49 SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF THE PREFERRED
50 PRODUCT CHARACTERISTICS DRAFT DOCUMENT FOR PERSONAL PROTECTIVE
51 EQUIPMENT FOR HEALTHCARE WORKERS ON THE FRONTLINE RESPONDING TO
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A Guideline Development Group meeting was convened in Geneva, Switzerland to review the critical situation in the West African countries fighting Ebola infections and share situational updates. Personal protective equipment delivered and worn by healthcare workers taking care of Ebola patients were faced with confusing PPE elements that were not designed to fit together to provide the necessary protection while trying to work under extreme stress and heat. An effort was made to strike a balance for safety and best provision of care under those conditions. Critically needed was a rapid advice guidance to provide PPE use recommendations coupled with technical specifications for the PPE being purchased and received as donations	October 2014
WHO Rapid Advice Guideline for personal protective equipment in the context of filovirus disease outbreak response was published. A set of 12 recommendations and a list of technical specifications were included in the guidance. The guidance also highlighted the need for better review based on evidence as many practices in the field were put forward based on best advice and need.	October 2014
Consultation on innovative personal protective equipment, review on available and short-term PPE solutions for response. Determine the needs of healthcare professionals, logistician and procurement specialists. Geneva, Switzerland	March 2015
Evidence for innovative personal protective equipment workshop. The purpose of the workshop was to: (1) review current knowledge on transmission of high-threat pathogens, in particular Ebola and other viral haemorrhagic fever viruses, (2) review the knowledge and lessons learned in the field on the benefits and harms of various PPE approaches for high threat pathogens and, (3) to discuss the need for a target product profile or a preferred product characteristics for PPE for high-threat pathogens. An outcome of this workshop was to recommend the formation of Technical Advisory Committee to review evidence, form expert recommendations for a PPE system suited for the healthcare worker on the frontline. Geneva, Switzerland	October 2016
Formation of the Technical Advisory Committee (TAC) for Innovative PPE for Health Workers Responding to Ebola Outbreaks in Tropical Climate. The TAC included four groups: (1) Ebola virus research-laboratory evidence, (2) Infection Prevention Control and Occupational Health, (3) Technical Specifications, Logistics and Procurement, and (4) PPE users (Ebola outbreak).	November 2016
Committee working towards reviewing evidence, identifying gaps and developing descriptions for PPE system suited for hot, humid weather. Decision was taken to develop a Preferred Product Characteristics document for PPE to be worn by healthcare workers on the frontline responding to Ebola and viral haemorrhagic fever outbreaks.	December 2016-April 2017
Workshop to define the characteristics for innovative PPE, Geneva, Switzerland.	May 2017

The Members of the Committee met, in a special closed session during the 3rd WHO Global Forum on Medical Devices, in Geneva, to review and discuss evidence, anecdotal observations, technical specifications, logistics and procurement challenges. The members also identified gaps in knowledge and the lack of harmonized standards, testing methods and the donning and doffing of PPE. A list of 10 characteristics were finalized for the PPC.	
Drafting of the PPC document, refining the information tables, by member of the Advisory Committee working together on collating and analyzing the information for the 10 characteristics and reviewing additional materials for reports, manuscripts and surveys to complement the PPC.	June – August 2017
Developed the plan for the review of the draft PPC characteristics	August 2017
Posting of the working document on the WHO website for public consultation	September 2017
Compilation and review of comments received by Advisory Committee	September 2017
Final draft review and approval by Advisory Committee	October 2017
Approval process for final PPC release	October 2017
Follow up actions, as needed	On-going

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1. Introduction

a. Background

The 2013-16 epidemic of Ebola virus disease (EVD) in West Africa was the largest on record with over 28,500 cases and at least 11,000 deaths[1]. Included among the many unique and tragic elements of the epidemic was the high number of infected health workers (over 900 cases and 500 deaths) working on the frontline. In addition, three cases, one fatal, occurred in health workers caring for EVD patients in high-resource settings (United States and Spain).

A preliminary World Health Organization (WHO) report summarized the impact of the Ebola epidemic on the health workforce of Guinea, Liberia and Sierra Leone[2]. WHO investigated the causes of the infections and analyzed infection outcomes in health workers. The report defined the "health worker" as including clinical staff and all those who worked in health services such as drivers, cleaners, burial teams and community-based workers during the epidemic. They were the workers on the frontline, putting themselves at the greatest risk of exposure to infection, so in this document they are characterized as healthcare workers at the frontline (HCW-F). A finding of this WHO report was that HCW-Fs were between 21 and 32 times more likely to be infected with Ebola than people in the general adult population of the three countries. This high number of HCW-F led to the speculation that the Makona variant of Ebola virus transmitted during the West Africa epidemic was more infectious than other Ebola viruses. However, published investigations[3][4][5]have not provided confirmation of this hypothesis. Neither has it been easy to identify modes of infection for the vast majority of HCW-F EVD cases. Discrete recognizable exposure events, such as needle sticks and blood splashes to mucous membranes, rarely led to HCW-F getting infected by the Ebola virus. A strong suspicion of the source of EVD among health workers pointed to the procedures for doffing contaminated personal protective equipment (PPE).

Health worker infections can be prevented. WHO demonstrated that by working with its partners and ministries of health reducing infection of the HCW-Fs from 12% in July 2014 to 1% in February 2015 by establishing rigorous infection prevention control (IPC) and occupational health and safety strategies. The many styles of "PPE products" and inconsistent donning and doffing practices in multiple Ebola treatment areas led to constant confusion and inappropriate implementation of IPC in the health-based settings. Much of the PPE was donated to the WHO, but there was no consistent standard applied and for some of the PPE materials sent, there were no quality control assessment of the materials. A rapid advice guideline with technical specifications was published by WHO to try and ensure product consistency being used in the response[6]. The PPE used was stifling and appeared ghost-like in tropical heat leading to anecdotal recounting of horrific instances of HCW-Fs carrying out their duties under adverse and risky conditions. PPE should be a part of an infection prevention strategy and never should be

[1] World Health Organization. Ebola situation report March 2016. http://apps.who.int/ebola/current-situation/ebola-situation-report-30-march-2016

[2] World Health Organization. Health worker Ebola infections in Guinea, Liberia and Sierra Leone. May 2015. http://www.who.int/hrh/documents/21may2015_web_final.pdf

[3] Park et. al. 2015. Ebola virus epidemiology, transmission and evolution during seven months in Sierra Leone. Cell 161:1516-1526.

[4] De La Vega et al. 2015. Ebolavirus evolution: past and present. Plos Path 11☹11). Doi:10.1371/journal.ppat1005221.

[5] Gire et. al. 2014. Genomic surveillance elucidates Ebola virus origin and transmission during the 2014 outbreak. Science 345:1369-1372.

[6] World Health Organization. Personal protective equipment in the context of filovirus disease outbreak response. October 2014. http://www.who.int/csr/resources/publications/ebola/ppe-guideline/en/

considered the only answer to prevent HCW-F infections, it is, however, a point where innovative design, use of bio-engineering techniques and harmonized practices can lead to a safer, more comfortable and less threatening presentation of the HCW-F while working to save lives and prevent further spread of Ebola virus or other viral haemorrhagic fevers and high threat pathogens (herein referred to only as Ebola).

b. Aim of this guidance

This preferred characteristics document aims to provide guidance for industry, health workers, bio-engineers, innovators, medical and scientific researchers and others, the opportunity to re-think, energize and innovate for a better PPE system for the HCW-F responding to Ebola virus outbreak in tropical climate. WHO would like to believe that products following this PPC guidance will result in a PPE system that will increase likelihood of safety and comfort and meets a most important public health need in low and middle income countries (LMICs).

c. Objectives of this guidance

i. Provide a review and summary of current evidence on protective effects of PPE, applicable standards and identify the knowledge gaps related to safety, comfort and disposal of PPE.

ii. Stimulate stakeholders to innovate, collaborate, design, engineer and plan for a PPE system that will reduce the heat, stress and comfort. This can be modified from current PPE already on the market or be a part of a re-imagined PPE system.

iii. Develop a PPE system whose parts are intentionally designed with ergonomic human design factors to fit and allow for harmonized procedures for donning and doffing PPE, standardize the regulatory components with attendant appropriate testing of the PPE and remove confusion at the user's level.

d. Scope of this guidance

This PPC document addresses very targeted specific needs for the HCW-F working under hot, humid conditions in low and medium resource countries. It is not meant to be used in clinics, hospitals and communities where better health care resources are available. Though it is hoped that innovations emanating from the characteristics presented here could be also adopted in other healthcare situations. The purpose is to ensure harmonization in design and use to avoid confusion and increased risk of infections.

e. Definitions and acronyms

<u>Terms relating to personal protective equipment</u>

ETU, Ebola treatment units

HCW, healthcare worker including not only clinical staff, but all those who work in health services, including drivers, cleaners, burial teams and community-based workers.

HCW-F, healthcare workers as define above but who are working on the frontlines where Ebola virus and other haemorrhagic fever or high threat pathogen transmission and outbreaks occur. Also can be described as frontline workers

IPC, infection prevention and control

PPE, personal protection equipment worn by HCW-F while treating Ebola patients and other viral haemorrhagic fevers or high threat pathogens.

Acronyms relating to technical standards and regulations

AAMI: Association of the Advancement of Medical Instrumentation
AATCC: American Association of Textile Chemists and Colorists
ANSI: American National Standards Institute
ASTM: American Society of Testing and Materials International
BS EN: European Standard that is published in United Kingdom
DIN EN: European Standard is published in Germany by German Standards Institute
EN: European Standard- European Norm
ISO: International Organization for Standardization
NFPA: National Fire Protection Association

Annex A provides a description of the relationships of the standards and regulations (page 39)

2. Preferred Product Characteristics

a. What is a preferred product characteristics (PPCs) guidance?

PPCs profiles describe the desired features of a product or suite of products that meets the intended unmet public health need in a priority disease area. PPC is designed to be a high-level guidance addressing some of those unmet needs by outlining preferences for a product not yet developed (see WHO Research and Development Blueprint[7], R & D Blueprint). WHO has identified the desirability of a newly-imagined innovative PPE for protecting HCW-F while responding to Ebola virus outbreaks in hot, humid working conditions.

The PPC is also known as a Target Product Profile. A technical guidance may also be issued in the future alongside a PPC that describes the technical characteristics of a product in development with specific details. PPCs focus on desired features at a higher-level with a global health community perspective. PPCs are intended to be developed by WHO while the technical guidance may be developed by any party and ideally be informed by the PPCs. PPCs may include features that currently do not exist but can be innovatively engineered to be incorporated into products for priority diseases, specially affecting LMICs.

b. How was the WHO PPCs document developed?

Development of this PPC document adheres to the WHO recommended process beginning with consultations, working groups, followed by the formation of advisory committees with the goal to produce a draft PPC for open comment, adjudication of the comments, then the drafting and final review of the document prior to publication. The historical accounting of the process of the WHO effort for this PPE process is described on page 2~~2~~.

The WHO Technical Advisory Committee for Innovative PPE (Committee) undertook a thorough review and reading of available evidence and applicable standards. The Committee focused on: (1) Ebola virus laboratory research, (2) infection practices and control/occupational health, (3) technical specifications and logistics and procurement issues, and (4) PPE users from the field, specifically the HCW-F who participated in the Ebola response in Guinea, Liberia and Sierra Leone. The Committee consulted and received advice from subject matter experts, field

[7] World Health Organization. Research and development blueprint. June 2016. http://www.who.int/blueprint/en/

health workers, administrators and regulatory bodies. The Committee deliberated on the evidence, analyzed the information and identified knowledge gaps and unmet needs.

c. The Committee then drafted the PPCs now offered for open comment (Table 1).

Table 1. Preferred Product Characteristics for a re-imagined, innovative PPE system for healthcare workers at the frontline responding to Ebola virus disease outbreaks:

	Preferred Product Characteristics
1	Reduce the steps to donning and doffing to achieve simple, easy-to-follow,[SJ2] and intuitive protocols
2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a healthcare worker at the frontline the necessary time to execute emergency exit protocols
3	Minimize the number of junctions (interfaces) where PPE elements connect. Design all junctions to be comfortable and leak-proof
4	Provide a PPE design with no-fog visibility to the face and the range of vision to be as broad as possible
5	Design head and neck protection to keep the mucous membrane areas (eyes, nose, and mouth) protected throughout the working period
6	Design PPE elements to allow for clear communications (speaking, hearing, and visibility)
7	Use human factors design to assure PPE are ergonomically functional while keeping the HCW-F dry for the duration of the working period
8	Design PPE elements intended for reuse to be resistant to corrosive effects of the disinfectant. Function and integrity should be maintained after multiple disinfection procedures
9	Use materials for PPE elements that do not generate toxicity when disposed in the environment nor generate large volumes of residual waste
10	Assure packaging and storage conditions keep items intact and protective. Both the inner and the outer packaging should maintain their integrity under high humidity and high ambient temperatures

d. Information tables

There are 10 preferred characteristics. Each characteristic is explained in its own table. Each table contains three sections: (1) Evidence (published or anecdotal), (2) Applicable standards, and (3) Gaps in knowledge.

The purpose of the tables is to serve as an information tool for the reviewer while considering that characteristic. It gives the results of structured research and studies and can include statements and observations as anecdotal evidence. This is because structured and planned research on many of the characteristics are few, of poor quality or do not exist.

There are no standards or regulations that directly apply to each of the characteristics, only partial application may be inferred or used. There is a lack of coherence of standards for PPE, countries and regions adopt their own and though some are very similar, others differ. This difference attests to the difficulties for PPE manufacturers when bringing PPE products to the market across countries and regions. These differences makes it challenging for procurement as different types of PPE elements and uniform quality control cannot be applied. Some characteristics have many standards while none exists for others.

The lack of credible sound scientific evidence and standards that do not fully meet the need of the characteristic mean that there exist substantial knowledge gaps between desired protective effects, standards and practices. WHO, following the strategies outlined in the R&D Blueprint, and for the purpose of this PPC would like to encourage industry, public health agencies, academic institutions and regulatory bodies find opportunities to collaborate/coordinate to develop the knowledge and to seek dynamic new innovations that is cost effective, environmentally-friendly and serve to protect the healthcare worker at the frontlines.

e. The reviewers, their roles and how to read and make comments

For the PPC open comment period, WHO aims to reach as broad an engagement of relevant stakeholders for input, this includes UN agencies, Ministry of Health, clinical professionals, scientific organizations and societies, non-governmental aid organizations, public health practitioners, logisticians, procurement specialists, filovirus research experts, regulators, standards development organizations, aid development agencies, PPE industry, bio-engineers, designers, -innovators, PPE users and more. The Committees will read and deliberate on the received comments to refine the product profile which then will be reviewed, edited and published online by WHO. The PPC document will be updated at regular intervals to include new findings and evidence.

i. How to review and offer comments for this PPC during the open comment period

<u>Languages used for the review</u>

Comments may be submitted in English or in French. Communication with the Committees can be in English or French. The draft PPC and the supporting tables and annexes are in English.

<u>Collecting the comments</u>

WHO is collecting the information through a template format. The template table for comments is found at the link on the webpage.

Reviewers are also asked to rate their comment as High (strongly disagree or error that must be corrected), Medium (improves clarity) and Low (minor changes).

Transparency and privacy

WHO requests that reviewers provide their name, contact information. This information will not be shared publically but is requested so that a communications channel can be established if the Committees need to ask for clarification or additional questions. The channel can also allow the reviewer to receive a personal feedback.

What is the role of a reviewer?

WHO recognizes that reviewers may not have input to all the 10 characteristics but encourages the reviewer to examine them all and then provide comments to those most relevant to the reviewer's expertise.

The PPC administrator (identified on the cover page) will monitor day-to-day activities through the web-site link and reply to queries posted through the generic electronic email box on the web-link.

After reviewers have provided comments, what can be expected?

Every received comment and input will be reviewed and considered by the Committees. WHO intends to compile and share the comments without attribution (no names or contact information will be made public unless permission is given by the reviewer to WHO).

The Committees will aim to finalize the PPC document for publication through the WHO publication process in the shortest time possible.

311
312 Table 2. Preferred Product Characteristic: Reduce the steps to donning and doffing to
313 achieve simple, easy-to-follow, and intuitive protocols.
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Characteristic 1	Reduce the steps to donning and doffing to achieve simple, easy-to-follow, and intuitive protocols
Donning and doffing PPE	PPE design should allow for doffing in a manner that allows simple, easy-to-follow, and intuitive protocols to minimize the risk for self-contamination. This might be by reducing the steps, but it might simply be the same number of steps but less risky ones.
Evidence	Self-contamination and errors are common when donning and doffing PPE worn for protection against filovirus exposure. A standard operating procedure for donning and doffing is necessary and must include a checklist that can be used to guide the health worker at the HCW-F through the steps for each process. For the doffing process, the protocol must include a buddy, or a dedicated person stationed at the doffing area. The dedicated person must have clearly delineated duties in the protocol, and must ensure that the HCW-F does not deviate from protocol while doffing. Guo *et. al.* found that when subjects used an individually-accustomed removal method (IARM) vs. a Centers for Disease Control and Prevention (CDC) removal method for doffing PPE, the IARM doffing method resulted in significantly greater instances of environmental and small body contamination.[8] Casalino *et. al.* assessed the difference in the errors made while donning and doffing using a conventional monitored system, and a reinforced system that included a specialist reading each step aloud from the protocol. This study found that reinforced training reduced errors compared to standard training.[9] End users of PPE state that the lack of standardization among donning and doffing guides from different organizations leads to confusion in the field. Creating one protocol for HCW-F caring for filovirus disease patients (in tropical climates) would streamline the donning and doffing processes, ensure compliance with recognized standards, and reduce the risk of disease transmission.
Applicable	The CDC, European CDC, Médecins Sans Frontières, and World Health

[8] Guo YP et al. Environment and body contamination: A comparison of two different removal methods in three types of personal protective clothing. *Am J Infect Contr*. 2014; 42(4): e39-45.
[9] Casalino E et al. Personal protective equipment for the Ebola virus disease: A comparison of 2 training programs. *Am J Infect Contr*. 2015; 43(12): 1281-1287.

Characteristic 1	Reduce the steps to donning and doffing to achieve simple, easy-to-follow, and intuitive protocols
standards	Organization all have published guidelines for donning and doffing filovirus disease PPE.[10] The CDC, ECDC protocols do include the role of a dedicated buddy. While all protocols include instructions on donning and doffing recommended PPE, there is ***significant variation*** in the order of steps between each organization's protocols.
Gaps in knowledge	There is conflicting information about the appropriate order in which a HCW-F should don and doff PPE. There is also little agreement on the exact roles and responsibilities of a buddy, including where this buddy should be situated with respect to the HCW-F. Innovative design of the doffing area might include telemetric monitoring in lieu of a buddy person. There is a lack of a harmonized standard for human factors testing of PPE to determine the use error when donning, using and doffing

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[10] Médecins Sans Frontières, Informal Chapter on Infection Control for PPE, 2014; World Health Organization, "Clinical Management of Patients with Viral Haemorrhagic Fever: a Pocket Guide for Front-line Health Workers. Interim Emergency Guidance or West Africa," 2016; 120-126; Centers for Disease Control and Prevention, "Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE," 2015, https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html; European Center for Disease Prevention and Control, "Safe Use of Personal Protective Equipment in the Treatment of Infectious Diseases of High Consequence," Stockholm: ECDC; 2014.

317
318 Table 3. Preferred Product Characteristic: Make the protective features of the PPE in the
319 front effective for the duration of the working period and protective effects of the PPE in the
320 back should permit a frontline worker the necessary time to execute emergency exit protocols
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Characteristic 2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a frontline worker the necessary time to execute emergency exit protocols
PPE front and PPE back	PPE should prevent the HCW-F's mucous membrane areas, face and skin from becoming contaminated with the body fluids of infected patients. The liquid resistance feature of the front of the PPE, preferably covering 180°, must be effective for the duration of the working period, as PPE provides a necessary barrier between the HCW-F and contaminated fluids. Occupational health studies define the working period as lasting for 4 hours. Emergency exit period should be at least 2 times longer than the time it takes to execute the doffing procedure
Evidence	Cloud *et. al*. conducted a survey of 1,354 infection control professionals.[11] 45% (n=609) reported encountering tears or punctures in isolation gowns during wear, 31% (n=501) reported rips or holes during wear, and 8% (n=108) reported that fabric was worn out during wear. This is particularly significant, as Jefferson's Cochrane review found that wearing a surgical gown was associated with a 77% risk reduction (OR=0.23, 95% CI 0.14-0.37) in the transmission of respiratory viruses to HCW-F.[12] There is concern, however, that the protective effect of gowns was confounded, and likely related to other PPE or IPC practice. Kilinc-Balci *et. al* .reported that nine of the twenty two single-use isolation gowns currently available on the market do not meet the AAMI PB70 liquid barrier penetration classification requirements at the level specified by the manufacturer.[13] Studies point out the need for improved processes surrounding activities such as premarket testing and post-market evaluation of gowns according to standardized test methods by third party laboratories.

[11] Cloud R et al. Isolation gown use, performance, and potential compliance issues identified by infection control professionals [APIC abstract 7-075]. Am J Infect Contr. 2012; 40: e31-176.
[12] Jefferson T et al. Physical interventions to interrupt or reduce the spread of respiratory viruses (review). *Cochrane Database Syst Rev*. 2010; 1: No: CD006207.
[13] Kilinc-Balci, F. Selcen, Julian Nwoko, and Todd Hillam. "Evaluation of the Performance of Isolation Gowns." *American Journal of Infection Control* 43.6 (2015): S44.

Characteristic 2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a frontline worker the necessary time to execute emergency exit protocols
	There is a need to refine PPE protocols. With full PPE (a hazmat suit and a powered air purifying respirator, Kang *et. al.* found that the donning process took an average of 7.55 minutes (range: 5.2-13.47 minutes) and the doffing process took 4.06 minutes (range: 3.08-5.63 minutes).[14] A significant difference (p=0.0488) was noted when comparing contamination versus speed of doffing with simple PPE sets: obvious levels of contamination (45.39 seconds average doffing time) versus minor levels of contamination (55.46 seconds average doffing time). The results of this study emphasize the need for simplifying and clarifying PPE protocols. Nikiforuk *et. al.* used phosphate-buffered saline to replicate perspiration and possible penetration of Ebola virus through saturated PPE following use for 30 minutes in 30-50% relative humidity.[15] Surrogate Ebola virus particles were recovered both saturated N95 respirators and surgical masks, meaning that liquid stress and saturation compromise the protection of these PPE. Existing standards are therefore not protective enough under conditions of heat and humidity, and must be examined and redefined.
Applicable standards	**There are different standards that apply to the different properties of the PPE:** **Performance Requirements and Classification Standards** **EN 13795** European Standard for Surgical Drapes, Gowns and Clean Air Suits **ANSI/AAMI PB70** Liquid barrier performance and classification of protective apparel and drapes in health care facilities **EN 14126:2003**: Protective clothing. Performance requirements and tests methods for protective clothing against infective agents: Protective clothing, Re-usable, Infective materials, Biological hazards, Health and welfare facilities, Hospital equipment, Health and safety requirements, Safety measures, Performance, Performance testing **NFPA 1999**: "Standard on protective clothing for emergency medical operations"

[14]Kang J et al. Use of personal protective equipment among health care personnel: Results of clinical observations and simulations. *Am J Infect Contr*. 2017; 17(23).

[15] Nikiforuk AM et al. Challenge of liquid stressed protective materials and environmental persistence of Ebola virus. *Sci Rep*. 2017; 7: 4388; Supplementary information: doi:10.1038/s41598-017-04137-2.

Characteristic 2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a frontline worker the necessary time to execute emergency exit protocols
	Liquid and Viral Penetration Resistance Testing Standards **ISO 16603:2004** Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood **ISO 16604:2004** Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage **ASTM F1670** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood **ASTM F1671** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System **EN 20811** Determination of Resistance To Water Penetration—Hydrostatic Pressure Test **EN ISO 22610** Test method to determine the resistance to wet bacterial penetration **EN ISO 22612** Test method for resistance to dry microbial penetration **AATCC 42** Water Resistance: Impact Penetration Test **AATCC 127** Water Resistance: Hydrostatic Pressure Test **Durability Testing Standards** **ASTM D 5034** Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) **ASTM D5587** Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure **ASTM D5733** Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure **ASTM D1683** Standard Test Method for Failure in Sewn Seams of Woven Fabrics **ISO 13934-1**: Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method
Gaps in knowledge	Little is known about how protective gowns and coveralls are after they become damp or wet. There is a lack of understanding about micro-perforations, how frequently they can occur, and how often PPE should be changed as a result. There is also little agreement about whether a gown or a coverall is the best PPE, and whether an apron must or must not be used in conjunction.

Characteristic 2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a frontline worker the necessary time to execute emergency exit protocols
	Manufacturers, bioengineers and designers should examine the different types of fabric and nanomaterials that may allow for better breathability, strength and liquid repellence. Fabrics may also be produced to have virucidal/bactericidal properties. Research and testing considerations are needed to determine if innovations in this area can be yield desired outcome. There is a lack of a harmonized standard for minimum performance requirements for health care PPE used against biological agents. There are several differences between ANSI/AAMI PB70 and EN 13795 surgical gown classifications. Because the test methods and performance requirements cannot be compared directly, it is difficult to assign equivalency between surgical gowns classified according to EN 13795 and ANSI/AAMI PB70. Similarly, for coveralls it is difficult to compare test methods and performance specifications used in different countries. In Europe, the EN 14126 standard typically is used to evaluate and classify coveralls used to protect from infectious agents and EN 13795 is used to evaluate and classify surgical gowns. Unlike surgical or isolation gowns (ANSI/AAMI PB70), there is no widely used classification standard in the United States. Coveralls with materials and seams tested against ASTM 1671 are specified in NFPA 1999. However, while originally designed for pre-hospital healthcare workers, NFPA 1999 could be used for hospital-based healthcare workers as well. The lack of harmonized standards and performance requirements make the PPE selection process more cumbersome.[16] In addition there is standard defining the minimum performance criteria for aprons, hoods, and boots/boot covers, or interfaces (e.g., leakage at glove/body suit interface). Other needs with the current test methods are also listed below: Lack of test surrogates that are representative of current pathogen characteristics

[16] Balci, F. Selcen Kilinc. "Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use." *American journal of infection control* 44.1 (2016): 104-111.

Characteristic 2	Make the protective features of the PPE in the front effective for the duration of the working period and protective effects of the PPE in the back should permit a frontline worker the necessary time to execute emergency exit protocols
	• Phi-X174 surrogate may not be representative of Ebola virus Generally, only material is tested. Seams and conjunctions should be also tested. Only new products are tested, used products are not tested, i.e. effect of the mechanical stress to the PPE is not tested/simulated. Only 60 minutes duration is used for ASTM F1670/1671 tests, effect of the duration of exposure is not tested. Limited information on representative pressure type and levels for healthcare worker PPE • Only hydrostatic pressure was used in the viral/liquid penetration tests, no mechanical pressure is applied (which may be more common in medical activities, such as leaning, kneeling)[17] Limited representative pathogen mediums (blood, vomit, liquid faeces, sweat, etc.) • The surface tension (42 dynes/cm) and the viscosity of the synthetic blood used in the penetration tests (ISO 16603 and ASTM F1670) may not be applicable for the other body fluids which may be more common during Ebola (vomit, diarrhea) • There are surface tension issues (instability) reported with synthetic blood which is used for the ASTM F1670 synthetic blood test. • The surface tension of water is much higher compared to the surface tension of the most of the body fluids. Therefore water resistance tests used for testing textiles (EN 20811, AATCC 42 and AATCC 127) may not simulate the conditions of actual use. Finally, inconsistencies of the testing protocols between labs make the comparison of the manufacturer data of PPE items more difficult.

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[17] Jaques, Peter A., et al. "Evaluation of gowns and coveralls used by medical personnel working with Ebola patients against simulated bodily fluids using an Elbow Lean Test." *Journal of occupational and environmental hygiene* 13.11 (2016): 881-893.

Table 4. Preferred Product Characteristic: Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof

Characteristic 3	Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof
Junction of PPE elements	There is little evidence[18][19][20][21][22] in the literature that supports this parameter, but there are anecdotal opinions from PPE users that leaky junctions could create greater risks and complicate donning and doffing procedures.
Evidence	PPE elements (clothing, glove, respirators, etc.) are produced by different manufacturers and are not considered to function together as a system or not necessarily manufactured to function with other PPE elements. Currently, in healthcare settings, most of the elements of healthcare worker PPE ensembles are selected/purchased/packaged/ used separately without considering their interoperability.
Applicable standards	Most (if not all) of the methods used for continuous regions could be used for discontinuous regions like seams, zippers, etc. **Performance Requirements and Classification Standards** **EN 13795** European Standard for Surgical Drapes, Gowns and Clean Air Suits **ANSI/AAMI PB70** Liquid barrier performance and classification of protective apparel and drapes in health care facilities **EN 14126:2003**: Protective clothing. Performance requirements and tests methods for protective clothing against infective agents: Protective clothing, Re-usable, Infective materials, Biological hazards, Health and welfare facilities, Hospital equipment, Health and safety requirements, Safety measures, Performance, Performance testing **NFPA 1999:** "Standard on protective clothing for emergency medical operations" **Liquid and Viral Penetration Resistance Testing Standards**

[18] Fernandez M, Del Castillo JL, Nieto MJ. Surgical Gown's Cuff Modification to Prevent Surgical Contamination. *Journal of maxillofacial and oral surgery.* 2015;14(2):474-475.

[19] Edlich RF, Wind TC, Hill LG, Thacker JG. Creating another barrier to the transmission of bloodborne operative infections with a new glove gauntlet. *Journal of long-term effects of medical implants.* 2003;13(2):97-101.

[20] Fernández M, Del Castillo J, Nieto M. Surgical Gown's Cuff Modification to Prevent Surgical Contamination. *Journal of maxillofacial and oral surgery.* 2015;14(2):474-475.

[21] Meyer KK, Beck WC. Gown-glove interface: a possible solution to the danger zone. *Infection Control.* 1995;16(08):488-490.

[22] Fraser J, Young S, Valentine K, Probst N, Spangehl M. The Gown-glove Interface Is a Source of Contamination: A Comparative Study. *Clin Orthop Relat Res.* 2015;473(7):2291-2297.

Characteristic 3	Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof
	ISO 16603:2004 Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood **ISO 16604:2004** Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage **ASTM F1670** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood **ASTM F1671** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System **DINEN 20811** Determination of Resistance To Water Penetration— Hydrostatic Pressure Test **EN ISO 22610** Test method to determine the resistance to wet bacterial penetration **EN ISO 22612** Test method for resistance to dry microbial penetration **AATCC 42** Water Resistance: Impact Penetration Test **AATCC 127** Water Resistance: Hydrostatic Pressure Test **Durability Testing Standards** **ASTM D1683** Standard Test Method for Failure in Sewn Seams of Woven Fabrics **ISO 13934-1**: Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method
Gaps in knowledge	Remarkable effort has been employed to develop new materials or manufacturing techniques in order to improve barrier protection and quality of each PPE element, little attention has been paid to the interfaces and interoperability of PPE. Particularly, the interface between the sleeve of the clothing and the glove, or in the elements of face and head protection, which areas of concern as blood or body fluids can flow through the protective system worn by healthcare workers. Research is needed to understand how to best protect the HCW-F while using the minimum number of PPE items to minimize connecting junctions. Studies can also focus on the most protective yet comfortable material for PPE, to ensure that the protective effects do not hinder the ability of the HCW-F to wear the PPE for the duration of the working period. Further research is necessary to understand how

Characteristic 3	Minimize the number of junctions where PPE elements connect. Design all junctions to be comfortable and leak-proof
	PPE materials and junctions handle liquid and stress testing, especially under conditions of high heat and humidity. Generally, only material is tested for liquid penetration, viral penetration, or strength. Seams and conjunctions should be also tested and data should be reported by manufacturers. Furthermore, there is a need for globally developed standard which is specifically designed for healthcare PPE and healthcare worker tasks and evaluates the fluid leakage at the interfaces (e.g., fluid leakage through glove and protective clothing interface).

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Table 5. Preferred Product Characteristic: Provide a PPE design with no-fog visibility to the face and the range of vision to be 180^0 in the front or as broad as possible

Characteristic 4	Provide a PPE design with no-fog visibility to the face and the range of vision to be 180^0 in the front or as broad as possible
Field of vision and no fogging	PPE worn for protection against Ebola virus often is used in hot, humid, tropical climates. End users of PPE report that given these working conditions, facial and eye protection fogs easily. Fogging can obstruct the healthcare frontline workers' (HCW-F) field of vision, and impair his or her ability to safely provide care while using PPE.
Evidence	Current PPE elements for protecting eyes and head are to be fog and scratch resistant (for resusable protection) with adjustable band to secure firmly so as not to become loose during clinical activity and may be re-usable. Reusability depends on having appropriate arrangements for decontamination. HCW-Fs reported constant fog and sweat interference while performing clinical and heavy duty tasks every day. Anecdotal evidence: There are limited scientific data that describe the impact on safety and care of fog and diminished visibility. PPE users have opined that powered air purifying respirators (PAPRs) can avert eyewear fogging, and because of this additional benefit, PAPRs may therefore be preferred over N95 respirators. PAPRs are used in the field laboratory setting where working conditions are confined and controlled but difficult to use widely in treatment units because of their cost and power support needs.
Applicable standards	Quality compliant with EU standard directive 86/686/EEC, EN 166/2002 - ANSI/ISEA Z87.1-2010
Gaps in knowledge	More research is needed to understand the exact climate conditions that cause eyewear to fog, the benefits imparted by no-fog PPE, and the difficulty in manufacturing such PPE.

337
338 Table 6. Preferred Product Characteristic: Design head and neck protection to keep the
339 mucous membrane areas protected throughout the working period
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Characteristic 5	Design head and neck protection to keep the mucous membrane areas protected throughout the working period
Mucous membrane protection	PPE must protect the face, as well as the mucous membranes of the mouth, nose, ears, and eyes, from contact with infectious agents and contamination from splashes. PPE should also protect the healthcare frontline worker (HCW-F) against inadvertently touching, and therefore possibly contaminating/self-contaminating, the face or head with their hands.
Evidence	There is limited evidence about how well head and neck PPE protects the HCW-F against filovirus disease infection, but several studies have evaluated how well masks and respirators (with or without face shields) protect against respiratory viruses. In 2016, Verbeek *et. al.* combined six studies in a meta-analysis and reported a beneficial effect of consistent mask/respirator use during the Severe Acute Respiratory Syndrome (SARS), epidemic. The benefit was evident both in a fixed effect [OR=0.28, 95% CI (0.17-0.46)] and in a random effects meta-analysis model [OR=0.27, 95% CI (0.13-0.53)].[23] There is evidence that N95 respirators and medical masks protect the HCW-F from infection with diseases like SARS. Teleman *et. al.* found that use of N95 respirators were strongly protective against infection [OR=0.1, 95% CI (0.02-0.09)], and Nishiura *et. al.* found that surgical masks were significantly protective against infection with SARS.[24] Moreover, Jefferson's 2010 Cochrane review found that wearing an N95 respirator was associated with a 99% risk reduction in transmission of respiratory viruses [OR=0.09, 95% CI (0.03-0.30)].[25] Anecdotal evidence suggests that 90% of HCW-F's risk for infection

[23] Verbeek JH et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. *Cochrane Database Syst Rev*. 2016; 4: CD011621.

[24] Teleman MD et al. Factors associated with transmission of severe acute respiratory syndrome among health-care workers in Singapore. *Epidem Infect*. 2004; 132(5): 797-803; Nishiura H et al. Rapid awareness and transmission of severe acute respiratory syndrome in Hanoi French Hospital, Vietnam. *Am J Trop Med Hyg*. 2005; 73(1): 17-25.

[25] Jefferson T et al. Physical interventions to interrupt or reduce the spread of respiratory viruses (review). *Cochrane Database Syst Rev.* 2010: 1:CD006207.

Characteristic 5	Design head and neck protection to keep the mucous membrane areas protected throughout the working period
	may be around the mucous membranes and exposure from to the head and neck area. This is a strongly held belief from those who have treated Ebola patients in Ebola treatment units.
Applicable standards	Most of the test methods available for protective gowns could be used for measuring the mucous membrane (head and neck) protective effects; **ASTM F1862 / F1862M - 17** Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) **ISO 22609**: Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected) **ISO/TS 16976-8:** Respiratory protective devices — Human factors — Part 8: Ergonomic factors **NFPA 1999**: "Standard on protective clothing for emergency medical operations" **ISO 16603:2004** Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood **ISO 16604:2004** Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage **ASTM F1670** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood **EN 20811** Determination of Resistance To Water Penetration— Hydrostatic Pressure Test **EN ISO 22610** Test method to determine the resistance to wet bacterial penetration **EN ISO 22612** Test method for resistance to dry microbial penetration **AATCC 42** Water Resistance: Impact Penetration Test **AATCC 127** Water Resistance: Hydrostatic Pressure Test
Gaps in knowledge	There is little consensus about the optimal combination, composition, re-usability, and amount of PPE to best protect mucous membranes. There is a lack of standards for minimum performance criteria for hoods (head covering) and for testing the non-continuous regions of PPE (for neck). Innovative design and smart bioengineering might be able to define an optimal style that effectively protects the wearer.

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342
343 Table 7. Preferred Product Characteristic: Design PPE to allow for clear communications
344 (speaking, hearing, and visibility)
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Characteristic 6	Design PPE to allow for clear communications (speaking, hearing and visibility)
Communication	Health workers attending to Ebola patients and wearing full-covered PPE could not communicate with patients and co-workers, use stethoscope, take notes nor hear clearly.
Evidence	Bistafa and Bradley[26] suggest the reverberation time that maximizes speech intelligibility should be between 0.4 and 0.5 seconds and that background noise should be 20 dB would be acceptable[1] Anecdotal evidence offered: There was very poor ability to communicate with both patients and colleagues due to 1) fogging of the face shield, 2) thickness / layering of the mask and face shield combined and 3) the covering of the recipients ears by PPE. In addition, the masks often became foggy giving the wearer the feeling of limited or poor oxygen exchange. Often a PPE wearer would minimize speaking due to the difficulties in breathing. Another anecdotal evidence was the ghost-like appearance of the frontline worker to the patient and the community in addition to the muffled audio and speaking. This engendered fear and mistrust thus impairing ability to render services and increased risk to the worker.
Applicable standards	**ISO 9921**: Ergonomics — Assessment of speech communication
Gaps in knowledge	Research is needed to incorporate innovative design, use of alternate materials and communication equipment. These features could improve the ability to communicate (visual, audible and verbal), while maintaining safety of the frontline worker needs research and thereby increasing the efficacy and ease of team work and of clinical management of EVD patients.

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[26] Bistafa SR, Bradley JS: Reverberation time and maximum background-noise level for classrooms from a comparative study of speech intelligibility metrics. *The Journal of the Acoustical Society of America* 2000, **107**(2):861-875.

Table 8. Preferred Product Characteristic: Ensure that the PPE is designed with consideration of human factors, such as comfort and heat strain

Characteristic 7	Preferred Characteristic
Discomfort and heat strain	Ensure that the PPE is designed with consideration of human factors, such as comfort and heat strain. Frontline workers must be able to use PPE comfortably and safely for the duration of the work period, even in hot, humid weather conditions.
Evidence	Current filovirus disease PPE is associated with discomfort and heat strain after extended use, or regular use while performing physical activities. Occupational health experts define a working period as 4 hours. During the Ebola epidemic, PPE users, especially in the Ebola Treatment Unit highest risk zones, lasted on the average about 45 minutes in full PPE. PPE design should include consideration of human factors, such as ergonomics (fit, comfort, and compatibility with other PPE). For PPE to be the most effective at preventing disease transmission to the frontline workers, it is essential that it be both comfortable and durable in tropical climates. Using a sweating thermal manikin in a simulation study, Potter *et. al.* proposed time of work/rest in an hour based on modeled body temperatures using high level protection PPE (as used by Médicin Sans Frontière) at varying levels for metabolic equivalent of tasks (MET).[27] A HCW-F that performs heavy tasks in high-level PPE requires 30 minutes of rest for every 30 minutes of activity to minimize discomfort and physical stress. In a simulated study, Coca *et. al.* found that compared with medical scrubs and boots only, PPE used during filovirus disease exposure results in significantly more heat stress and less comfort ($p<0.05$) after just one hour of use in ambient environment (32˚ C, 92% resting heartrate) at a typical HCW-F work rate of 3 MET.[28]

[27] Potter AW et al. Ebola response: Modeling the risk of heat stress form personal protective clothing. *PLoS One*. 2015; 10(11): e0143461.

[28] Coca A et al. Physiological and subjective evaluation of PPE using a sweating thermal manikin. *Extrem Physiol Med*. 2015; 4(S1): A27.

Characteristic 7	Preferred Characteristic
	Grillet *et. al.* analyzed the impact of Ebola PPE on intensive care unit (ICU) procedures.[29] They found that physical demand was higher with Ebola PPE as compared to standard protection for nasogastric tube placement [median = 2.5, IQ range (0.9-5.2) vs. median = 0.6, IQ range (0.4-0.9)], and central venous catheter insertion median = 3.6, IQ range (1.8-13.4) vs. median = 1.2, IQ range (0.4-2.5)], but not for orotracheal intubation. The Heat Strain Decision Aid (HSDA), originally developed to address United States Army needs, uses information on individual characteristics, physical activity, clothing biophysics, and environmental conditions to mathematically predict core temperature rise over time. The rise in core temperature can be used to estimate maximum safe work times, optimal work-rest cycles, water requirements, and the likelihood of heat casualties.[5] There is also some degree of uncertainty about the thermal effects of PPE. Grélot *et. al.* found only a slight rise in body temperature and limited heat strain in HCW-F that wore Ebola PPE for a mean duration of 65.7 minutes.[30]
Applicable standards	**Material Testing:** **ASTM D 737** Standard Test Method for Air Permeability of Textile Fabrics **ASTM F1868** Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate **ASTM D3776** Standard Test Methods for Mass Per Unit Area (Weight) of Fabric **ASTM D1777** Standard Test Method for Thickness of Textile Materials **ISO 11092** Textiles – Physiological effects – Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test) **ASTM E96-80** Standard Test Methods for Water Vapor Transmission of Materials **AATCC 195** Liquid Moisture Management Properties of Textile Fabrics **ASTM F1249** Standard Test Method for Water Vapor Transmission

[29] Grillet G et al. Intensive care medical procedures are more complicated, more stressful, and less comfortable with Ebola personal protective equipment: A simulation study. *J Infect*. 2017; 74(6): 618-620.
[30] Grélot et al. Moderate thermal strain in healthcare workers wearing personal protective equipment during treatment and care activities in the context of the 2014 Ebola virus disease outbreak. *J Infect Dis*. 2015; 213)9): 1462-1465.
[5] Potter et al. Mathematical prediction of core body temperature from environment, activity, and clothing: The heat strain decision aid (HSDA). *J Thermal Bio.* 2017; 64: 78-85.

Characteristic 7	Preferred Characteristic
	Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor **AATCC 197** Vertical Wicking of Textiles **AATCC 198** Horizontal Wicking of Textiles **AATCC 199** Drying Time of Textiles: Moisture Analyzer Method **AATCC 200** Drying Rate of Textiles at their Absorbent Capacity: Air Flow Method **AATCC 201** Drying Rate of Fabrics: Heated Plate Method **AATCC 204** Water Vapor Transmission of Textiles **ISO/TS 16976-8:** Respiratory protective devices —Human factors — Part 8: Ergonomic factors **ISO 11092**: Textiles — Physiological effects —Measurement of thermal and water vapour resistance under steady-state conditions (sweating guarded hotplate test) **ISO 15496**: Textiles - Measurement of water vapour permeability of textiles for the purpose of quality control **ISO 9237**: Textiles -- Determination of the permeability of fabrics to air **ISO 15831**: Clothing — Physiological effects — Measurement of thermal insulation by means of a thermal manikin **AAMI TIR51:2014**: Human factors engineering – Guidance for contextual inquiry **ANSI/AAMI HE75:2009/(R)2013**: Human factors engineering – Design of medical devices **ANSI/AAMI/IEC 62366-1:2015:** Medical devices – Part 1: Application of usability engineering to medical devices American National Standard **Manikin Testing:** **ASTM F2370-05** Standard Test Method for Measuring the Evaporative Resistance of Clothing Using a Sweating Manikin **ASTM F 1291-05** Standard Test Method for Measuring the Thermal Insulation of Clothing Using a Heated Manikin **ISO 15831**: Clothing — Physiological effects — Measurement of thermal insulation by means of a thermal manikin **Human Subject Testing:** **ASTM F 2668** Standard Practice for Determining the Physiological Responses of the Wearer to Protective Clothing Ensembles
Gaps in knowledge	Persons developing PPE need information about the amount of time a HCW-F can remain in high-level PPE in tropical climates. More research is needed to understand the thermal effects of PPE, as well as an appropriate work-to-rest ratio for HCW-F using PPE in hot, humid conditions.

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356 Table 9. Preferred Product Characteristic: Design PPE elements intended for reuse to be
357 resistant to corrosive effects of the disinfectant
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Characteristic 8	Design PPE elements intended for reuse to be resistant to corrosive effects of the disinfectant
Reusable PPE elements	Function and integrity should be maintained after multiple disinfection procedures.
Evidence	Disinfection is a part of universal precautions for infection prevention and control, as viruses can persist on fomites. Disinfection of PPE, equipment, and surfaces can remove filoviruses if they are contaminated. However, disinfection must not deteriorate the PPE and render it less protective. The World Health Organization (WHO) recommends spraying all PPE used for filoviruses with a 0.5% chlorine solution for disinfection. Disinfection is a necessary component of universal precautions and Infection Prevention and Control: Palich *et. al.* collected swabs from Ebola treatment unit (ETU) surfaces that were in the immediate vicinity of Ebola patients.[31] 32% (n=22) of swabs from high-risk areas tested positive for Ebola RNA, including 16% (n=4) from frontline worker (HCW-F) PPE. None (0/19) of the specimens from low-risk areas tested positive. Swabs were more often RNA-positive when taken from areas near patients with a very high plasma viral load [OR=6.7, 95% CI (1.7-23.4)]. Little is known, however, about adverse events that can occur from disinfection. Mehtar *et. al.* surveyed 500 HCW-F, 550 Ebola virus disease (EVD) survivors (EVDS) and 500 quarantined asymptomatic Ebola contacts (NEVD).[32] Following a single chlorine spraying, Pearson's χ^2 showed there was a significant increase in eye symptoms in all three exposure groups ($p<0.001$). Respiratory symptoms were significant in EVDS and HCW-F groups ($p<0.001$). The EVDS and HCW-F groups reported multiple exposures to chlorine. Following this, respiratory tract symptoms and skin irritation were most significant in both groups (for both, $p<0.001$). For HCW-F with multiple exposures versus a single exposure to

[31] Palich R et al. Ebola virus RNA detection on fomites in close proximity to confirmed Ebola patients; N'Zerekore, Guinea, 2015. *PLoS ONE*. 2015; 12(5): e0177350.
[32] Mehtar S et al. Deliberate exposure of humans to chlorine-the aftermath of Ebola in West Africa. *Antimicrob Resist Infect Control*. 2016; 5(45).

Characteristic 8	Design PPE elements intended for reuse to be resistant to corrosive effects of the disinfectant
	chlorine, unadjusted logistic regression showed a significant increase in the odds of greater chance of infection: Chest conditions: [OR=3.2, 95% CI (2.0-4.9), p<0.001] Deterioration of eyes: [OR=3.3, 95% CI (2.2-5), p<0.001] Skin irritation: [OR=2.4, 95% CI (1.6-3.6), p<0.001]
Applicable standards	International guidelines include recommendations for the concentration, duration, and frequency of spraying with disinfectant. **Liquid and Viral Penetration Testing after X number of disinfection procedures** **ISO 16603:2004** Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood **ISO 16604:2004** Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage **ASTM F1670** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood **ASTM F1671** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System **EN 20811** Determination of Resistance To Water Penetration—Hydrostatic Pressure Test **EN ISO 22610** Test method to determine the resistance to wet bacterial penetration **EN ISO 22612** Test method for resistance to dry microbial penetration **AATCC 42** Water Resistance: Impact Penetration Test **AATCC 127** Water Resistance: Hydrostatic Pressure Test **Durability Testing after X number of disinfection procedures** **ASTM D 5034** Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) **ASTM D5587** Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure **ASTM D5733** Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure **ASTM D1683** Standard Test Method for Failure in Sewn Seams of Woven Fabrics **ISO 13934-1**: Textiles — Tensile properties of fabrics — Part 1:

Characteristic 8	Design PPE elements intended for reuse to be resistant to corrosive effects of the disinfectant
	Determination of maximum force and elongation at maximum force using the strip method **AAMI TIR55**: Human factors engineering for processing medical devices **Glove Testing after X number of disinfection procedures** **ASTM D6319** Specification for nitrile examination gloves for medical applications **ASTM D3578-05**:Specification for rubber examination gloves **ASTM D7160**: Standard Practice for Determination of Expiration Dating for Medical Gloves **ASTM D7161**: Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions **ASTM D412-2013**: Standard test methods for vulcanized rubber and thermoplastic elastomers-tension **ISO 11193-2**: Single-use medical examination gloves - Specification for gloves made from poly (vinyl chloride) **IS0 11193-1**: Single-use medical examination gloves - Specification for gloves made from rubber latex or rubber solution **ISO 10282**: Single use sterile surgical rubber gloves - specification **EN 374**: Gloves Giving Protection from Chemicals and Micro-Organisms **EN 455: EN 455 Part 1**: 2002: Requirements and testing for freedom from holes **EN 455 Part 2: 2011**: Requirements and testing for physical properties **EN 420:2004**: Protective Gloves. General requirements and test methods.

Characteristic 8	Design PPE elements intended for reuse to be resistant to corrosive effects of the disinfectant
Gaps in knowledge	There is limited information on the risks associated with current disinfectants as recommended by WHO. No standard is available for testing the function of reusable materials after disinfection. Manufacturers do not report on the effect of the current disinfectants on their PPE products. There is a need for less toxic but still effective disinfectants. Research should evaluate the optimal concentration of disinfection for PPE and other surfaces. More research is also necessary to understand alternative options for sprays and solutions, as chlorine may not always be readily available in ETUs. There are several available guidelines about disinfection, but there is not one streamlined protocol for HCW-F in ETUs in low-resource and remote areas, such as Sub-Saharan Africa. Lastly, more research is necessary to understand the risks associated with various available disinfectants with different materials including the inclusion engineered virucidal/bacteriocidal effects.

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Table 10. Preferred Product Characteristic: Use materials for PPE elements that do not generate toxicity when disposed in the environment nor generate large volumes of residual waste

Characteristic 9	Use materials for PPE elements that do not generate toxicity when disposed in the environment nor generate large volumes of residual waste
Environment friendly and reduced waste	The goal is to explore the most environmentally friendly material that also adheres to the top priorities for healthcare worker and community environment safety.
Evidence	Current PPE disposal method is by incineration, or by the use of burn pits. No toxicity environmental data exist as to the toxicity or harm of the disposed PPE materials. As part of the full product life cycle, manufacturers should provide waste disposal instructions to support the management of disposal following use of PPE Anecdotal evidence: A massive amount of waste was generated and burned on site often on hospital grounds, generating hours-long plume of smoke on a daily basis. Often, waste was not completely burned and was left intact in the burn pit. In addition, solid waste (PPE) could be found in the landfill within the city limits at any given time during the EVD outbreak, in very close proximity to human settlements.
Applicable standards	**ISO 14001**: Environmental management systems — Requirements with guidance for use
Gaps in knowledge	Research is needed to study the harmful effects to communities and the environment about current PPE waste. some data is needed regarding human safety and exposure with burial or landfill disposal of PPE. The implementation of power generation from waste PPE, in low resource settings should be explored. PPE materials may be disposed in simple or beneficial ways that could, as example, generate energy for local consumption.

368
369 Table 11. Preferred Product Characteristic: Assure packaging and storage conditions keep
370 items intact and protective.
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Characteristic 10	Assure packaging and storage conditions keep items intact and protective
Packaging and storage	Both the inner and the outer packaging should maintain their integrity under high humidity and high ambient temperatures.
Evidence	There is no published data regarding storage integrity of PPE packaging. The potential of stores being *in situ* for periods of 3-5 years (shelf life of PPE) would require external packaging to be of sufficient standard to maintain integrity given the climate conditions, up to $+45^0$ C. described. Anecdotal evidence: The World Health Organization, United Nations agencies, response aid partners and governmental operations in West Africa 2014-16 faced less than ideal storage issues due to lack of quality warehousing and extreme climate conditions. In the scale and breadth of the West Africa Ebola response and the nature of the emergency, re-supplying multi-site operations met with less than optimal storage conditions. PPE containers stored in pallet form collapsed due to ingression of water via humidity, (90%+).
Applicable standards	There is no test method or data available for shelf life or testing of PPE packaging. Some test methods are available (shown below) for medical package testing which may guide manufacturers. After storage in hot and humid conditions, the PPE should maintain its protective and strength characteristics. The following standards may be applicable. **Accelerated Aging Testing** **ASTM F1980** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices **ASTM 573-88** Standard Test Method for Rubber-Deterioration in an Air Oven **Performance Requirements and Classification Standards (for PPE after storage)** **EN 13795** European Standard for Surgical Drapes, Gowns and Clean Air Suits **ANSI/AAMI PB70** Liquid barrier performance and classification of protective apparel and drapes in health care facilities **EN 14126:2003**: Protective clothing. Performance requirements and tests methods for protective clothing against infective agents:

Characteristic 10	Assure packaging and storage conditions keep items intact and protective
	Protective clothing, Re-usable, Infective materials, Biological hazards, Health and welfare facilities, Hospital equipment, Health and safety requirements, Safety measures, Performance, Performance testing **NFPA 1999**: "Standard on protective clothing for emergency medical operations" **Liquid and Viral Penetration Testing (for PPE after storage)** **ISO 16603:2004** Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood **ISO 16604:2004** Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage **ASTM F1670** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood **ASTM F1671** Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System **EN 20811** Determination of Resistance To Water Penetration—Hydrostatic Pressure Test **ISO 22610** Test method to determine the resistance to wet bacterial penetration **ISO 22612** Test method for resistance to dry microbial penetration **AATCC 42** Water Resistance: Impact Penetration Test **AATCC 127** Water Resistance: Hydrostatic Pressure Test **Durability Testing (for PPE after storage)** **ASTM D 5034** Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) **ASTM D5587** Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure **ASTM D5733** Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure **ASTM D1683** Standard Test Method for Failure in Sewn Seams of Woven Fabrics **ISO 13934-1:** Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method **EN 420:2004:** Protective Gloves. General requirements and test methods.

Characteristic 10	Assure packaging and storage conditions keep items intact and protective
	Glove Testing after storage **ASTM D6319** Specification for nitrile examination gloves for medical applications **ASTM D3578-05**:Specification for rubber examination gloves **ASTM D7160**: Standard Practice for Determination of Expiration Dating for Medical Gloves **ASTM D7161**: Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions **ASTM D412-2013**: Standard test methods for vulcanized rubber and thermoplastic elastomers-tension **ISO 11193-2**: Single-use medical examination gloves - Specification for gloves made from poly (vinyl chloride) **IS0 11193-1**: Single-use medical examination gloves - Specification for gloves made from rubber latex or rubber solution **ISO 10282**: Single use sterile surgical rubber gloves - specification **EN 374**: Gloves Giving Protection from Chemicals and Micro-Organisms **EN 455: EN 455 Part 1**: 2002: Requirements and testing for freedom from holes **EN 455 Part 2: 2011**: Requirements and testing for physical properties **EN 420:2004**: Protective Gloves. General requirements and test methods. **Performance Requirements for Medical Packaging** **ISO 11607** Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems **Testing of Packages after storage** **ASTM F88** Standard Test Method for Seal Strength of Flexible Barrier Materials **ASTM F2638** Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier **ASTM F1929** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration Visual Inspection

Characteristic 10	Assure packaging and storage conditions keep items intact and protective
Gaps in knowledge	No known storage or study has been reviewed for this characteristic. Data may exist with manufacturers for which the health and logistics/procurement sectors are not aware of. Research is needed to understand how the storage duration and conditions affect the durability and barrier performance properties of PPE. Natural and accelerated aging test data for PPE as well as packaging is needed from manufacturers. There is limited shelf life data available for PPE from manufacturers. Research on alternative and innovative container and packaging design that does not increase the overall package weigh and offers enhanced rigidity and protection from ingression of humidity could lead to new types of container/storage resilience.

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Annex A Applicable standards and regulations that affect PPE elements

Standards are available to define the performance requirements for clothing or clothing materials used to protect against infectious agents. European and the United States standards differ on clothing recommended to protect healthcare workers against biological hazards from microorganisms. In Europe, the EN 14126 standard typically is used to evaluate and classify coveralls used to protect from infectious agents and EN 13795 is used to evaluate and classify surgical gowns. Unlike surgical or isolation gowns (ANSI/AAMI PB70), there is no widely used classification standard in the United States. Coveralls with materials and seams tested against viral penetration are specified in NFPA 1999–which establishes minimum performance requirements for emergency medical garments, and other PPE for protection from contact with blood and body-fluid-borne pathogens for personnel performing patient care during emergency medical operations. While originally designed for pre-hospital healthcare workers, it could be used for hospital-based healthcare workers as well.

In Europe, EN 14126 defines performance requirements for materials in protective clothing used to protect from infectious agents. Due to the heterogeneity of microorganisms, the EN 14126 standard does not define performance criteria for specific types of microorganisms. The test methods specified in this standard focus on the medium containing the microorganism, such as liquid, aerosol, or solid dust particle. The EN 14126 standard is typically used for coveralls and it specifies ISO 16603 synthetic blood penetration and ISO 16604 viral penetration as test methods used to evaluate the penetration resistance performance of clothing materials to contaminated liquids under hydrostatic pressure. Materials can pass these tests at six different levels, with ISO 16604 Class 6 representing maximum protection and indicating that bacteriophage particles do not pass through the fabric at 20 kPa hydrostatic pressure. In addition to viral penetration, general mechanical performance of the material requires adherence to several ISO standards (abrasion resistance, flex cracking resistance, trapezoidal tear resistance, tensile strength, burst resistance, puncture resistance, surface resistivity, hydrostatic head, water vapor resistance, thermal resistance, resistance to ignition).[33][34]

In Europe, EN 13795 is a recognized standard of quality and conformance to manufacturing, testing and performance specifications for single-use and multiple-use surgical gowns. EN 13795 categorizes products by performance type: high performance versus standard performance gown classes. EN 13795 also describes the standardized and harmonized barrier test methodologies that single-use and multiple-use surgical gowns must undergo including, liquid penetration/water resistance (EN 0811), wet and dry microbial penetration resistance (ISO 22610 and ISO 22612), and other requirements such as microbial and particulate matter cleanliness, linting, bursting strength (dry and wet), and tensile strength (dry and wet).

[33] Verbeek JH et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. *Cochrane Database Syst Rev*. 2016; 4: Art. No: CD011621.

[34] NIOSH. Considerations for selecting protective clothing used in healthcare for protection against microorganisms in blood and body fluids, NIOSH/The National Personal Protective Technology Laboratory Topic Page, July 22, 2015, Available from http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html.

In the United States, ANSI/AAMI PB70 2012 establishes a system of classification for surgical gowns and isolation gowns used in healthcare facilities, based on their liquid barrier performance. Also, ANSI/AAMI PB70 2012 specifies labeling requirements and test methods for determining the compliance of protective clothing labeled with liquid barrier claims or liquid-borne microbial barrier claims. Levels 1 through 4 specify the degree of protection provided by the gowns, with Level 4 being the highest and conferring protection against viruses at a pressure of 13.78 kPa using ASTM F1671 viral penetration resistance test method.

NFPA 1999 is mostly used in the United States and lists performance requirements of garments including coveralls, multi-piece clothing sets, or partial body clothing used by emergency medical personnel and first responders. These requirements include viral penetration resistance, tensile strength, liquid integrity, and seam strength, and other physical hazard resistance properties. NFPA 1999 is primarily intended for emergency medical first responders, but its scope also covers medical first receivers.

Comparison of the commonly used test methods used test methods for determination of barrier effectiveness of protective clothing [1, 2], current regulations and standards available in some of the countries are available in the literature[35].

Standards originating from	Identifier	Used most widely
International standards	ISO	Global, all countries?
U.S.	AAMI and others	Only for US and territories
EU	EN	European Union
UK	BS EN	Only for UK and allied countries
Germany	DIN EN	Germany
Japan		

As seen, there are few standards are available to test, classify or define the performance requirements for some PPE used to protect against infectious agents. However, standards used in different countries vary. Because these test methods and performance requirements cannot be compared directly, it is difficult to assign equivalency between PPE classified according to one standard used in some countries with another standard used in other counties. The lack of globally used harmonized standards that list the minimum performance requirements for health care PPE used against biological agents makes the development of guidelines and comparison of products difficult.

[35] Balci, F. Selcen Kilinc. "Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use." *American journal of infection control* 44.1 2016): 104-111.