

# PPE Technical specifications, standards and norms



## UNICEF Industry Consultation on Personal Protective Equipment needs in Ebola response Technical specifications, standards and norms

Nagwa Hasanin, Shauna Mullally, Ludo Scheerlink

# We need to protect against: EVD **Virus**-Infectious **liquid**

**Liquid:** amount, disease progress

5-10 L of fluid lost daily at a critical stage of their illness. consumed 4.5 L of ORS daily

**Liquid-tight**

**Blood (RBCs):**

RBCs 10,000 nm in diameter

**Resist blood penetration**

**Virus:**

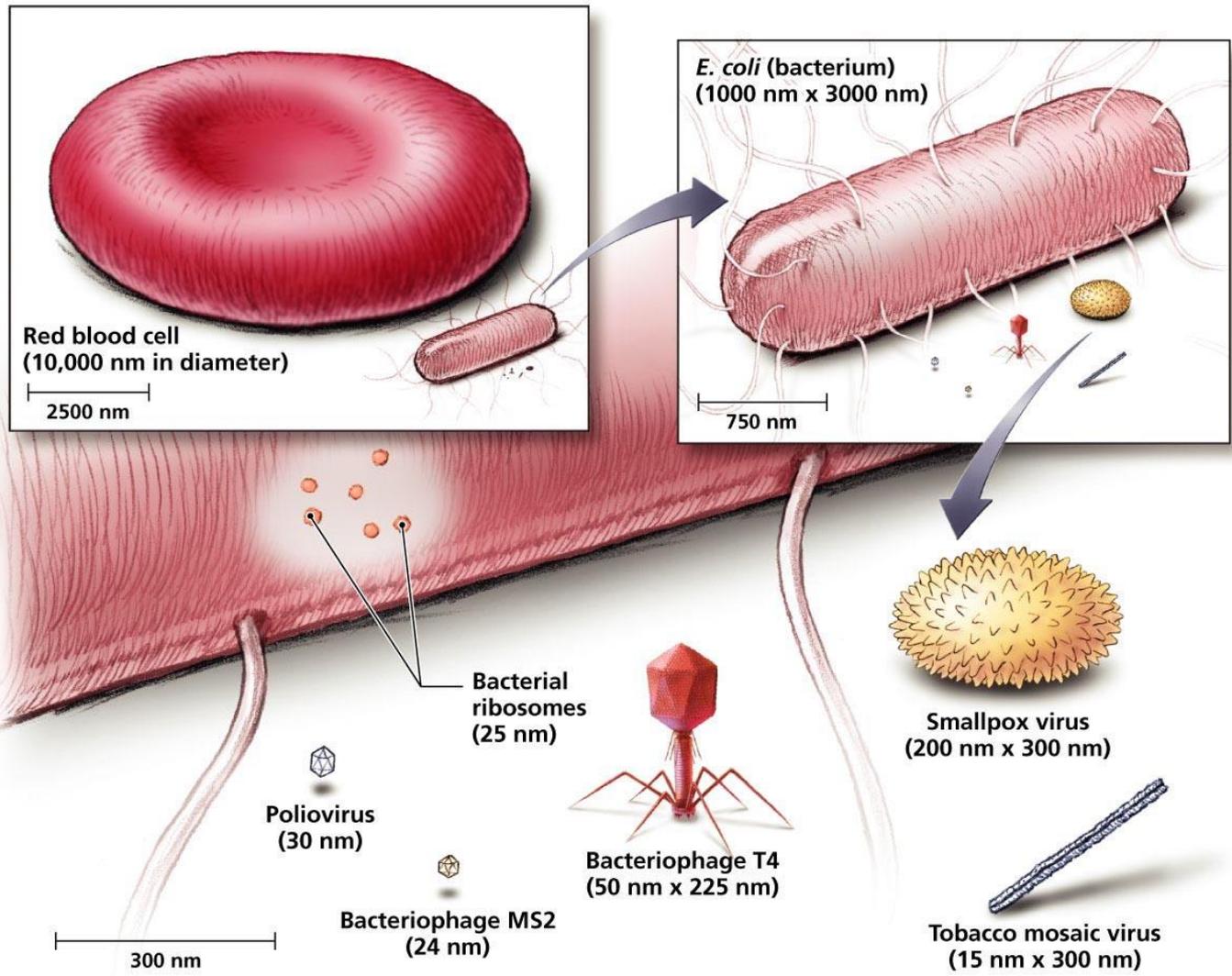
Ebola: diameter approx. 80 nm, length can be quite variable

**Tested against Viral penetration**

other bloodborne virus HIV: 80 nm in diameter



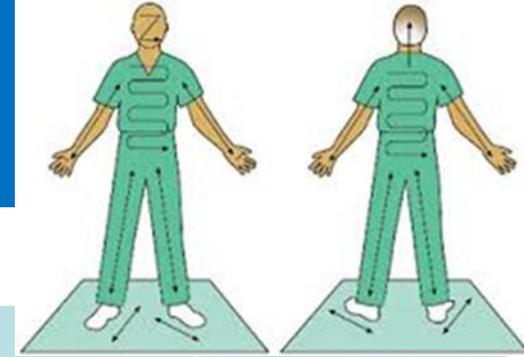
# Biohazard elements



- ØX174 25 -27 nm
- HBV 42 -47 nm
- Adenovirus 70-90nm
- HIV 80 to 110 nm
- Filoviruses 80 nm

Copyright © 2006 Pearson Education, Inc., publishing as Benjamin Cummings.

# PPE products covered



Target protection area	PPE component for ETU	PPE component for CCC	Technical Lead
<b>Body</b>			
Full Body	Coverall/ Hood/ Apron		Nagwa
Partial Body		Gown / Hood /Apron	Shauna
<b>Mucosae</b>			
Eyes	Goggles/ Face shield	Goggles/ Face shield	Ludo
Nose	Respirator / mask	Respirator / mask	Ludo
Mouth			
<b>Proximities</b>			
Hands	Gloves	Gloves	Ludo
Feets	Boots	Boots	Ludo

# Full Body protection: Coveralls (1)

## **Context of use**

- Used for Isolation high risk areas within ETU/ Holding Center

## **Short specifications**

- Disposable, single-use liquid-penetration resistant, biohazard-protective coverall with hood, for use in EVD patient-isolation units suitable for stringent infection prevention and control practices and tested against viral penetration. Protective seams providing barrier equal to fabric

## **Standards**

- CE 89/686/EEC, Category III: Chemical protective coverall, Type 3B / Type 4B comply with EN14605:2005 +A1:2009 (or equivalent) marketing approval certificate
- compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

# Full Body protection: Coveralls (2)

## Context of use

- Used for Isolation high risk areas within ETU/ Holding Center

## Short specifications

- Coverall: Disposable, single-use, liquid-penetration resistant, biohazard protective coverall, co-packed with an apron/gown for use in EVD patient-isolation units suitable for infection prevention and control practices.

- Apron: Gown designed with sleeves, for front protection with complete closure from the back and wrap around-waist ties. Elasticated cuffs. Shin length and below-Knee height.

Both Coverall and Apron are made of fabric that is infective agent tested against viral penetration at minimum 1.75kPa

## Standards

- CE 89/686/EEC, Category III Type 6B comply EN 13034:2005 + A1:2009 (or equivalent)/ / 6PB comply with either EN 13034:2005 + A1:2009 or EN14605:2005 +A1:2009 (or equivalent) marketing approval certificate

- Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

# Full Body protection:

## **Specific issues:**

Limited global capacity for immediate supply

limited supplier base

Relatively Long lead-time (in terms of emergency response)

# Partial Body protection: Hood

## **Context of use**

- Used for Isolation high risk areas within ETU/ Holding Center / CCC

## **Short specifications**

- Disposable, single-use, liquid-penetration resistant, biohazard-protective Hood with or without surgical mask Type IIR, for use in EVD patient-isolation units suitable for infection prevention and control practices and tested against microbial penetration. Cape hood covering full neck and parts of shoulders

## **Standards**

- CE 89/686/EEC marketing approval certificate
- Mask: conform to EN 14683:2005 for type IIR mask (or equivalent standard)
- Compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard) (Preferred)

# Partial Body protection: Protective Gown/Apron

## **Context of use**

- Used for Isolation high risk areas within ETU/ Holding Center / CCC

## **Short specifications**

- Disposable, single-use, liquid-penetration resistant, biohazard-partial-body protective gown /apron with sleeves for use in EVD patient-isolation units and CCC suitable for infection prevention and control practices and tested against viral penetration.

## **Standards**

- CE 89/686/EEC, Category III Type 3PB or 4PB or 6PB comply with EN14605 :2005+A1:2009 or EN 13034:2005 + A1:2009 (or equivalent) marketing approval certificate
- Comply with EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

# Partial body protection: Surgical gowns (1)

## AAMI Level 4, fully reinforced

### Context of use

- Higher risk areas such as CCCs, clinical care – wet areas

### Short specifications

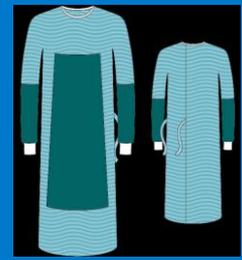
- Surgical gown with long sleeves and a waist tie that binds at side or back
- Non-woven material (SMS, SMMS, etc.), reinforced material throughout gown that passes ASTM F1671
- size approx. 150 cm (W) x 130 cm (L)
- Single use, disposable

### Standards

- Meets requirements for ANSI/AAMI PB70 (US) classification Level 4
  - Only AAMI Level 4 gowns pass test for resistance to penetration by a blood-borne viral pathogen (ASTM F1671)
- May also have CE 93/42: EN 13795 (EU)
- Or equivalent

# Partial body protection: Surgical gowns (2)

## Standard/high performance EN 13795



### Context of use

- Lower risk areas such as CCCs, clinical care - dry area, other lower risk areas in HC facilities

### Short specifications

- Surgical gown with long sleeves and a waist tie that binds at side or back
- Non-woven material (SMS, SMMS, etc.), reinforced in critical areas if HP gown
- size approx. 150 cm (W) x 130 cm (L)
- Single use, disposable

### Standards

- CE 93/42: EN 13795 standard performance (SP) or high performance (HP)
- Or equivalent

# Partial body protection: Surgical gowns

**Specific issues: PPE for Ebola is not the intended use of the product**

## **Supply challenges**

- Limited global capacity for immediate supply
- Relatively long lead-time for quantities requested

**Tests and standards not equivalent across stringent national regulatory authorities**

- EN 13795 (EU) does not include test for resistance to penetration by a blood-borne viral pathogen
- Only AAMI Level 4 gowns pass test for resistance to penetration by a blood-borne viral pathogen (ASTM F1671) in the gown's critical zones

## **Product limitations**

- Definition of 'critical area' not as relevant, not adequate for high-risk
- Sleeves require taping
- Sterility – not necessary

# Partial body protection: Aprons (disposable)



## Context

- ETUs and CCCs over full or partial body protection

## Short specifications

- Single use, sleeveless apron with adjustable back- and neck-band
- Seamless, liquid proof and stain resistant
- Material: durable environmentally friendly plastic, polyethylene (PE)
- Size, approx.: 85 x 130 cm (w x l)
- Thickness: approx. 50  $\mu$

## Standards

- None yet identified

## Specific issues

- Size and thickness
- Sourcing

# Partial body protection: Aprons (reusable)



## Context

- Heavy duty (cleaning activities)

## Short specifications

- Reusable sleeveless protective apron with adjustable back- and neck-band
- Seamless liquid proof and stain resistant
- Material: durable environmentally friendly plastic
- Size, approx.: 120 x 145 cm (w x l)
- Thickness, approx.: 300  $\mu$

## Standards

- None yet identified

## Specific issues

- Size, sourcing

# Thank you



**UNICEF Industry Consultation on  
Personal Protective Equipment needs in Ebola response  
Technical specifications, standards and norms**