Ebola Virus Disease: Personal Protective Equipment, UNICEF Specifications

UNICEF Supply Division

March 2015

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Ebola Virus Disease: Personal Protective Equipment UNICEF Specifications for High-Risk, Low-Resource Settings

The 2014-2015 Ebola Virus Disease (EVD) outbreak has a high infection and case fatality rate (CFR). To date (beginning-March), the outbreak has reached 23,934 cases and 9,792 deaths, with a CFR of 41%.¹ Frontline workers engaged in outbreak response are amongst those exposed to an elevated level of high-risk.² World Health Organization (WHO) reports 839 healthcare workers developed EVD of whom, 491 have died (CFR of 59%).³ In order to break the transmission of EVD between frontline workers and their surrounding working environment, adherence to strict infection prevention and control procedures is mandatory. In addition to the firm application of contact and standard universal precautions, all personal protective equipment (PPE) supplied to those areas must be adequate and effective in protecting frontline workers from infection; provide a maximum safety level against infective agents; and be used in accordance with instructions.

Global response and recommendations as per the "right" PPE standards to be used in the safety management of EVD were not harmonised at the onset of the outbreak. Ideally, the selection of appropriate PPE is based on a hazard risk assessment and the case management activities in frontline areas, including patient care centres and burial sites. Unfortunately, such data is currently not available from countries affected by widespread and intense transmission of EVD. The current situation suggests that in those areas frontline workers are amongst those with exposure to the highest risk hazard of EVD.

In this context, PPE refers to the different extended biological protection barriers used in combination to prevent both percutaneous and mucocutaneous exposure to EVD during the provision of medical and supportive care, when coming in contact with EVD suspected or confirmed individuals. It includes barriers for head, nose, mouth, eyes, hands, and feet, as well as full body protection. All PPE must be fluid-resistant, impermeable and protect against contamination from blood, body fluids or viral contaminated patient-used equipment. In selecting the right PPE specifications for frontline workers, the degree of contact with infectious material, and the potential for infected fluid penetration should be considered

In response to the risks highlighted above, UNICEF has identified, and is currently procuring, PPE supplies according to the technical specifications as listed below. For more detailed information on UNICEF PPE supplies, please refer to Ebola Virus Disease: Personal Protective Equipment and Other Ebola-Related Supplies note.

SELECTION RATIONALE AND SPECIFICATIONS

1 <u>BODY PROTECTION - Coveralls / Protective Apron (Gown) with sleeves in high-risk</u> <u>settings</u>

1.1 Selection rationale

In accordance with the European Directive on PPE <u>CE 89/686/EEC</u>, biological protective coveralls fall under *Category III*: Chemical Protection Coveralls. The selection of coveralls is based on garment fabric, seam treatment and fabric/garment performance testing against specific norms.

¹ World Health Organization, *Ebola Situation Report*, WHO, Geneva, 4th March 2015.

² Frontline workers: Burial teams, healthcare workers, water and sanitation officers, cleaners, amongst many others...

³ WHO, Ebola Situation Report.

Chemical protective coveralls certified to a specific *Type* have different performance classes in terms of protection, durability and comfort. As part of the EVD PPE, the appropriate selected protective coveralls should provide the following:

- High impermeability to liquid: *Type 3* (liquid-tight) and *Type 4* (spray-tight) conforming to <u>EN</u> <u>14605:2005</u> are the appropriate coveralls providing higher protection against liquid penetration. In addition, the coveralls' seams are stitched and taped to provide the same level of liquid impermeability as the fabric.
- Impermeability to blood: Conforming to <u>EN 14126:2003</u>. The fabric used in manufacturing coveralls has to pass <u>ISO 16603:2004</u>: laboratory test methods used to measure penetration resistance by blood and body fluids using synthetic blood. Six performance classes exist of which one is the lowest and six is the highest.
- Fabric material tested against viral penetration: Conforming to <u>EN 14126:2003</u>. The fabric used in manufacturing coveralls has to pass <u>ISO 16604:2004</u>: laboratory test methods used to measure penetration resistance by blood-borne pathogens using bacteriophage Phi-X-174. Six performance classes exists of which one is the lowest and six is the highest.

<u>Table 1 UNICEF Accepted Performance Classes for Infective Agent Testing Standards and Coveralls</u> <u>Class Type</u>

| EN 14126: Performance requirements and test methods for | Coveralls protection Type | |
|--|---------------------------|------------------|
| protective clothing against infective agents | Type 3 Coveralls | Type 4 Coveralls |
| ISO 16603: Screening pressure test: Resistance to penetration by blood and body fluids using synthetic blood. | Class 3 | Class 3 |
| ISO 16604: Resistance penetration by blood-borne pathogens using a bacteriophage Phi-X-174. | Class 2 | Class 2 |

Source: European Committee on Standardization / International Standardization Organization.

There are possible unknown risks that could build up on the coveralls during the provision of medical/cleaning services and activities in patient isolation areas located within EVD centres. EVD is classified as Risk Group 3 as per the European Directive 2000/54/EEC (protection of workers from risk related exposure to biological agents at work). Accordingly, UNICEF has specifically solicited the above ISO standard ISO 16604:2004 as the most critical standard in selecting coveralls to provide protection against viral transmission in the case of EVD. Only coveralls passing this ISO with a minimum performance class 2 are considered suitable for use in high-risk areas.

1.2 UNICEF standard materials and specifications

The list of coveralls below are sourced and supplied through UNICEF and provide products and options which meet the highest standard of protection.

1.2.1 <u>Coveralls: Option 1 - Coveralls</u>

UNICEF Material Numbers, Product Range. Indicative Average Price: Type 3: \$11.37 Type 4: \$5.20

- S6780241 Coveralls, protection, Cat. III, type 3/5, S
- S6780232 Coveralls, protection, Cat. III, type 3/5, M
- S6780236 Coveralls, protection, Cat. III, type 3/5, L
- S6780233 Coveralls, protection, Cat. III, type 3/5, XL

- S6780237 Coveralls, protection, Cat. III, type 3/5, XXL
- S6780243 Coveralls, protection, Cat. III, type 3/5, XXXL
- S6780270 Coveralls, protection, Cat. III, type 4, S
- S6780273 Coveralls, protection, Cat. III, type 4, M
- S6780271 Coveralls, protection, Cat. III, type 4, L
- S6780274 Coveralls, protection, Cat. III, type 4, XL
- S6780272 Coveralls, protection, Cat. III, type 4, XXL
- S6780275 Coveralls, protection, Cat. III, type 4, XXXL

UNICEF Specifications:

Disposable, single use liquid-penetration resistant, biohazard-protective coveralls with hood. For use in EVD patient-isolation units suitable for stringent infection prevention and control practices and tested against viral penetration. Protective seams provide a barrier equal to the fabric. Conforms to <u>CE</u> <u>89/686/EEC</u>, Category III: Chemical protective coveralls, Type 3B / Type 4B and complies with <u>EN</u> <u>14605:2005+A1:2009</u> (or equivalent) marketing approval certificate. Complies with <u>EN 14126:2003</u>, passing infectious agent test according to <u>ISO 16604:2004</u> standard at a minimum exposure to a pressure of 1.75kPa (class 2) or equivalent international standard. Available in various sizes: M, L, XL, XXL and XXXL.

1.2.2 <u>Coveralls: Option 2 - Combined Coveralls + Protective Apron (Gown) + Sleeves</u>

To ensure the highest level of protection for frontline workers, *Type 6B* coveralls are recommended to be worn in combination with a protective apron. The options provided offer the same protection as **Option 1**, but are to ensure alternative sourcing to increase access should supply availability be constrained.

UNICEF Material Numbers, Product Range. Indicative Average Price: Type 6B: \$5.34 Type 6B: \$16.00 co-pack

- S6780314 Coveralls, protection, Cat. III, type 6B, M
- S6780311 Coveralls, protection, Cat. III, type 6B, L
- S6780315 Coveralls, protection, Cat. III, type 6B, XL
- S6780316 Coveralls, protection, Cat. III, type 6B + Apron, disp, co-pack, M
- S6780312 Coveralls, protection, Cat. III, type 6B + Apron, disp, co-pack, L
- S6780313 Coveralls, protection, Cat. III, type 6B + Apron, disp, co-pack, XL

UNICEF Specifications:

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

Apron / gown are designed with sleeves for front protection with complete closure from the back and wrap around-waist ties, with elasticated cuffs, shin length and below-knee height.

Both coveralls and apron are made of fabric that is infective-agent tested against viral penetration at a minimum pressure of 1.75kPa. Conforms to <u>CE 89/686/EEC</u>, Category III, Type 6B, complying with <u>EN 13034:2005+A1:2009</u> (or equivalent) / or $6PB^4$ complying with either <u>EN 13034:2005+A1:2009</u> (or equivalent) marketing approval certificate. Coveralls and sleeved

⁴ **Note:** PB denotes gown partial body protection as arms, feet and back not covered, as opposed the full body protection by the coveralls.

aprons conform to <u>EN 14126:2003</u>, passing infectious agent tests according to <u>ISO 16604:2004</u> standard at a minimum exposure to pressure of 1.75kPa (class 2) or equivalent international standard.

1.2.3 Protective Apron (Gown) + Sleeves

UNICEF Material Numbers, Product Range. Indicative Average Price: \$8.05

- S6780293 Apron, sleeved, Cat. III, type 3, S
- S6780292 Apron, sleeved, Cat. III, type 3, M
- S6780291 Apron, sleeved, Cat. III, type 3, L
- S6780294 Apron, sleeved, Cat. III, type 3, XL
- S6780295 Apron, sleeved, Cat. III, type 3, XXL
- S6780296 Apron, sleeved, Cat. III, type 3, XXXL

UNICEF Specifications:

Disposable, single use, liquid-penetration resistant, biohazard-partial-body protective apron / gown with sleeves for use in EVD patient-isolation units and Community Care Centres (CCC). Suitable for infection prevention and control practices and tested against viral penetration. Conforms to <u>CE</u> <u>89/686/EEC</u>, Category III, Type 3PB, 4PB or 6PB, complying with <u>EN 14605:2005+A1:2009</u> or <u>EN 13034:2005+A1:2009</u> (or equivalent) marketing approval certificate. Conforms to <u>EN 14126:2003</u>, passing infectious agent test conforming to <u>ISO 16604:2004</u> standard at a minimum exposure to a pressure of 1.75kPa (class 2) or equivalent international standard.

2 BODY PROTECTION - Surgical Gown in low-risk settings

For use in lower-risk areas such as CCCs triage, clinical care or other lower-risk areas in HC facilities.

UNICEF Material Numbers, Product Range. Indicative Average Price: \$2.45

• S6780244 Gown, surgical, non-woven, disp

UNICEF Specifications:

Surgical gown with long sleeves and a waist tie that binds at the side or back. Non-woven material, liquid penetration resistant in critical areas (chest and sleeves). Size approximately 150 cm x 130 cm (w x l). Single use, disposable. Conforms to <u>CE 93/42: EN 13795</u> standard performance (SP) or high performance (HP), or equivalent.

3 HAND PROTECTION - Gloves

3.1 Examination Gloves

UNICEF Material Numbers, Product Range. Indicative Average Price: \$5.66 box of 100

- S6780251 Gloves, examination, nitrile, non-sterile, S / BOX-100
- S6780252 Gloves, examination, nitrile, non-sterile, M / BOX-100
- S6780253 Gloves, examination, nitrile, non-sterile, L / BOX-100
- S6780254 Gloves, examination, nitrile, non-sterile, S / BOX-200
- S6780255 Gloves, examination, nitrile, non-sterile, M / BOX-200
- S6780256 Gloves, examination, nitrile, non-sterile, L / BOX-200

UNICEF Specifications:

Disposable, ambidextrous, non-sterile, single-use, nitrile examination gloves with a thickness at fingertips of ≥ 120 um, conforms to <u>CE 89/686/EEC</u>, Category III and <u>EN 374-1/2/3/4:2003</u> (gloves giving protection from chemicals and micro-organisms) and <u>CE 93/42: EN 455-1, 2, 3, 4</u>. Available in various sizes: M, L and XL.

3.2 <u>Surgical gloves</u>

UNICEF Material Numbers, Product Range. Indicative Average Price: \$0.29 pair

- S0327530 Gloves, surgical, powder-free, sterile, single use, pair, size 6.5
- S0327510 Gloves, surgical, powder-free, sterile, single use, pair, size 7
- S0327520 Gloves, surgical, powder-free, sterile, single use, pair, size 7.5
- S0327530 Gloves, surgical, powder-free, sterile, single use, pair, size 8
- S0327540 Gloves, surgical, powder-free, sterile, single use, pair, size 8.5

UNICEF Specifications:

Pair of single use, sterile surgical gloves, anatomically shaped: one right-handed, one left-handed. Material: Natural latex. Powder-free, selected surgical gloves sizes: 6.5, 7, 7.5, 8, 8.5. Total length: approximately 270 mm / Width: approximately 102 ± 5 mm. CE marked and conforms to <u>CE 93/42</u>: <u>EN 455-1, 2, 3, 4</u>.

3.3 Heavy-Duty gloves

UNICEF Material Numbers, Product Range. Indicative Average Price: \$1.60 pair

- S6780263 Gloves, heavy-duty, rubber / nitrile, pair, S
- S6780259 Gloves, heavy-duty, rubber / nitrile, pair, M
- S6780264 Gloves, heavy-duty, rubber / nitrile, pair, L

UNICEF Specifications:

Nitrile: minimum length 32-38 cm. Left/right pair. Knit inner lining to facilitate slide-in and removal. Thickness at fingertips: \geq 380 um. Cleanable with water and disinfectant (resisting both ethanol solutions 70% and chlorine solutions >0.5%). Heavy-duty, conforms to <u>EC 89/686/EEC</u>, Category III: <u>EN 374-2, 3, 4</u>, <u>EN 420</u> and <u>EN 388</u> (High cracking-, puncture- and abrasion resistant, levels: \geq 4-1-0-1) or equivalent standards. Available in sizes: S, M, and L.

4 <u>FOOT PROTECTION - Boots / Boot covers</u>

4.1 **Boots**

UNICEF Material Numbers, Product Range. Indicative Average Price: \$11.33

- S6780257 Boots, rubber / PVC, reusable, pair, size 42
- S6780262 Boots, rubber / PVC, reusable, pair, size 43
- S6780258 Boots, rubber / PVC, reusable, pair, size 44

UNICEF Specifications:

Rubber or PVC, no steel reinforcement, material thickness approximately: 2.0 mm, knitted inner lining, slide-in and removal contour insole, preferable white.

4.2 Boot Covers

UNICEF Material Number, Product Range. Indicative Average Price: \$128.46 box of 50

• S6780269 Boot cover, anti-skid, elasticated / BOX-50

UNICEF Specifications

Disposable knee-length impermeable boot cover made of fabric tested against blood penetration with ties and elastic top and antiskid sole.

5 <u>EYE PROTECTION - Goggles / Face shield</u>

5.1 Goggles

UNICEF Material Number, Product Range. Indicative Average Price: \$4.13

• S6780266 Goggles, protective, indirect side-ventilation

UNICEF specifications

Plastic wrap-around safety goggles with indirect ventilation, preferably on the side with wide viewing angle, translucent frame and broad strap to increase comfort for long time wear. Anti-fog treatment. Conforms to <u>EC 89/686/EEC</u>, Category III: <u>EN 166</u> or equivalent.

5.2 Face shield, reusable and single use

UNICEF Material Number, Product Range. Indicative Average Price: \$20.00

- S6780265 Face shield, fog-resistant, full face-length
- S6780308 Face shield, fog-resistant, full-face, disp

UNICEF Specifications

Screen thickness approximately 1 mm. Full face-length from headband down by approximately 30 cm. Adjustable headband, designed for comfort in tropic climate. Anti-fog treatment / coated. Conforms to <u>EC 89/686/EEC</u> Category III: <u>EN 166</u> or equivalent.

6 NOSE AND MOUTH PROTECTION

6.1 <u>Respirators</u>

UNICEF Material Number, Product Range. Indicative Average Price \$1.53

• S6780268 Mask, high-filtration, FFP2/N-95, no-valve, non-sterile

UNICEF Specifications

Disposable, none-valve respirators. Folded duckbill preferred. Two Elastic loop (back of the head and neck). Malleable nose-bridge. Conforms to <u>EC 89/686/EEC</u>, Category III: <u>EN 149:2001</u> FFP2 particle protection (filters at least 94% of airborne particles and <8% inward leakage, includes aerosols), or equivalent: US Standard Centres for Disease Control (CDC) National Institute for Occupational Safety and Health <u>NIOSH 95</u>, 42 CFR 84 (N-95: none-oil resistant).

6.2 Surgical Mask type IIR

UNICEF Material Number, Product Range. Indicative Average Price: \$0.08

• S6780245 Mask, surgical, type IIR, disp

UNICEF Specifications

With straps (2x2), no elastic ear loops, splash resistance (IIR), identifiable in / outside, with 3 or 4 ply and malleable nose-bridge. Conforms to <u>CE 93/42: EN 14683</u> (or equivalent). Tested against bacterial filtration with an efficiency (BFE) of \geq 98 %, Type II. Breathing Resistance (∂ P), IIR, \leq 49.0 Pa/cm². Splash resistance >120 mmHg.

7 Body Protection - Apron

Plastic apron worn over the coveralls (specified above) or gown as a first soiled layer. It does <u>not</u> protect total body area but adds additional protection. Depending on the procedure, it can repel excess fluid, particularly during activities related to washing, cleaning and handling bodies / cadavers.

7.1 Heavy-Duty Apron

UNICEF Material Number, Product Range. Indicative Average Price: \$1.32

• S0305000 Apron, heavy-duty, rubber / PVC, reusable

UNICEF Specifications

Reusable straight, sleeveless, protective apron with adjustable back- and neck-band. Seamless liquid proof and stain resistant. Both back- and neck-band can be adjusted/fastened allowing for easy donning and doffing. Colour preference white. Material: durable environmentally friendly plastic. Size approximately: 120 cm x 160 cm (w x l). Thickness, approximately: 300 um. Cleanable with water and disinfectant (ethanol 70% and chlorine solution 0.5%).

7.2 Disposable Apron

UNICEF Material Number, Product Range. Indicative Average Price: \$20.27

• S0305020 Apron, protection, plastic, disp / PAC-100

UNICEF 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, approximately: $85 \times 130 \text{ cm} (\text{w} \times 1)$. Thickness: approximately 50μ .

8 Head Protection - Hood with or without integrated mask

UNICEF Material Number, Product Range. Indicative Average Price: \$5.00

- S6780287 Hood, protection, Cat. III
- S6780317 Hood, protection, with mask, integrated, Cat. III

UNICEF 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. Tested against microbial penetration. Cape hood covering full neck and parts of shoulders. Conforms to <u>EC 89/686/EEC</u> marketing approval certificate. Mask: conforms to <u>EN 14683:2005</u> for type IIR mask (or equivalent standard). Complies with the <u>EN 14126:2003</u>, passing infectious agent test according to <u>ISO 16604:2004</u> standard at a minimum exposure to a pressure of 1.75kPa (class 2) or equivalent international standard.

9 <u>CADAVER - Body Bag (Biohazard Containment)</u>

9.1 Body Bag - Adult Size

UNICEF Material Number, Product Range. Indicative Average Price: \$14.18

• S0990002 Body bag, infection control, adult

UNICEF Specifications

Body bag with full-length U- or J-shaped zipper, with double runner. High quality black or white zipper, smooth running with teeth made of nylon. Large plastic or tissue loops, on each of the zip-runners to allow for easy manipulation. Zipper sewed into the body bag fabric with double stitch. Stop for the zipper reinforced into the body bag. Non-porous, body fluid leak-proof bag during handling and transportation of the cadaver. The bag is highly tear-proof and puncture resistant. Seams are entirely heat-sealed, width approximately 10 mm. Material: non-PVC, preferably linear enforced PE, EVA or PEVA (polyethylene vinyl acetate). Does not contain chlorides. The bag disintegrates over a period of 5 to 8 years when buried in soil. Thickness: 300 to 400 um. Colour: white. Carry capacity: 120 kg. Minimum of six padded carry handles integrated into the body bag fabric. Fabric around the handles reinforced with same material as the body bag. Integrated transparent label pouch for placement of identification tag. Size of the pouch is approximately 10 cm x 15 cm (w x l). Single use and disposable. Dimensions, unfolded, approximately: 230 cm x 100 cm (w x l). Dimensions, folded, approximately: 45 x 35 cm (l x w). Shelf life: 6 year.

9.2 Body Bag - Child Size

UNICEF Material Number, Product Range. Indicative Average Price: \$6.55

• S0990003 Body bags, infection control, child

UNICEF Specifications

Body bag with full-length U- or J-shaped zipper, with double runner. High quality black or white zipper, smooth running with teeth made of nylon. Large plastic or tissue loops, on each of the zip-runners to allow for easy manipulation. Zipper sewed into the body bag fabric with double stitch. Stop for the zipper reinforced into the body bag. Non-porous, body fluid leak-proof bag during handling and transportation of the cadaver. The bag is highly tear-proof and puncture resistant. Seams are entirely heat-sealed, width approximately 10 mm. Material: non-PVC, preferably linear enforced PE, EVA or PEVA (polyethylene vinyl acetate). Does not contain chlorides. The bag disintegrates over a period of 5 to 8 years when buried in soil. Thickness: 300 to 400 um. Colour: white. Carry capacity: 50 kg. Minimum of six padded carry handles integrated into the body bag fabric. Fabric around the handles

reinforced with same material as the body bag. Integrated transparent label pouch for placement of identification tag. Size of the pouch is approximately 10 cm x 15 cm (w x l). Single use and disposable. Dimensions, unfolded, approximately: 120 cm x 80 cm (w x l). Dimensions, folded, approximately: 45 x 35 cm (l x w). Shelf life: 6 year.

For further questions or additional information, please contact:

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Other UNICEF information notes are found at <u>http://www.UNICEF.org/supply/index_54214.html</u>.