WHO rapid advice guideline and technical specifications for Personal Protective Equipment in focus on Ebola outbreak

Medical devices
Essential medicine and health products department
World health organization
**Consultation on WHO rapid advice guideline**

**WHO Guideline Development Group meeting on Personal Protective Equipment in the Context of Filovirus Disease outbreak Response**  
6-7 October, Geneva, Switzerland  
WHO headquarter

**Participants**

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PPE for patient care and non clinical care

- For visitors, health-care workers, cleaners, laboratory staff, anyone providing patient care and/or having contact with contaminated surfaces, blood or body fluids, clinical samples, infectious waste, dead bodies

- **At least:** gloves, gown, rubber boots/closed shoes with overshoes, and mask and eye protection for splashes

- **Impermeable gown or plastic apron** over gown and double gloves for any strenuous activity or tasks with contact with blood and body fluids

- **Respirators** needed only for aerosol-generating procedures

WHO Interim IPC Guidance - 2014 Update
Problems on current PPE use

Incorrect use
- Both goggle and face shield used together
- 5 gloves
- Double masks
- Incorrect doffing (e.g. remove eye protection at first)

A lot of confusions in the field due to too much threatening and less reliable guidelines for PPE in focus on Ebola.

WHO rapid advice guideline for PPE health workers providing clinical care in focus on Ebola

However, almost no scientific evidences!

Please note that we still need to collect more evidences!
What is provided in WHO rapid guideline for PPE

What is a correct use to protect enough against contamination?

- Goggle or a full face shield
- Double gloves is recommended over single gloves
- Should wear body wear with apron

How to wear/remove in the correct way?

- The inner glove should be worn under the cuff of the gown/coverall (and under any thumb/finger loop) whereas the outer glove should be worn over the cuff of the gown/coverall.
- Goggles and face shields should not to be used together.

What is safe and quality products for PPE against Ebola?

- Technical description and images of each product.
- Listed safety and quality standards as much as possible.
Face protection (Goggle and face shield)

Should wear either a face shield or goggles while providing clinical care.

Indirect venting
- Clear plastic
  - Completely covers sides and length of face
- Fog resistant
- Adjustable band
- Scratch resistant
- Good seal
- Clear, polycarbonate or acetate

ANSI/ISEA Z87.1-2010: American National Standard for Occupational and Educational Eye and Face Protection Devices
Face protection
(fluid-resistant medical/surgical mask)

**Should wear a fluid-resistant medical/surgical mask with a structured design that does not collapse on the mouth while caring for patients.**

- Structured design that does not collapse against the mouth

**EN 14683 Type IIR performance, ASTM F2100 level 2 or level 3, or equivalent**

Test methods:
- Fluid resistance at minimum 120 mmHg pressure based on ASTM F1862-07, ISO 22609, or equivalent
- Breathability: MIL–M-36945C, EN 14683 annex C, or equivalent
- Filtration efficiency: ASTM F2101, EN14683 annex B, or equivalent
Face protection
(fluid-resistant respirator, respirator with a full face shield)

Should wear a fluid-resistant particulate respirator while caring for patients during procedures that generate aerosols of body fluids.

- NIOSH N95, EN 149 FFP2, or equivalent
- Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent

Fluid resistance is not required if the particulate respirator is used together with a face shield.

- NIOSH N95, EN149 FFP2, or equivalent
Nitrile gloves are preferred over latex gloves for health workers providing clinical care. **Double gloves are recommended compared to single gloves.**

- **EU standard directive 93/42/EEC Class I, EN 455**: Freedom from hole, physical properties, biological safety, shelf life for medical gloves.
- **EU standard directive 89/686/EEC Category III, EN 374**: Chemical resistance for protective gloves.
- **ANSI/ISEA 105-2011**: American standards for hand protection selection criteria.
- Or equivalent

Nitrile, non-sterile powder-free

Outer gloves preferably reach mid-forearm (e.g. minimum 280mm total length)
Body wear (gown and coverall)

Protective body wear should be either a disposable gown and apron, or a disposable coverall and apron; the gown and the coverall should be made of fabric that is tested for resistance to penetration by blood or body fluids or to blood-borne pathogens.

- Single use
- Avoidance of colours which are culturally unacceptable, e.g. black
- Light colours preferable to better detect possible contamination
- Thumb/finger loops to anchor sleeves in place

Length mid-calf to cover the top of the boots

Different sizes available
### Body wear (gown) standards

#### Fabric of gown

| Option 1: fluid penetration resistant | • EN 13795 high performance,  
|                                      | • or AAMI PB70 level 3  
|                                      | • or equivalent  
| Option 2: blood borne pathogens penetration resistant | • AAMI PB70 level 4  
|                                      | • or equivalent  

Highest performance for gown material found only at critical zones (A and B). Performance of other zones are lower than critical zones.
Body wear (coverall) standards

Test method of a whole suit performance is different from gown.

<table>
<thead>
<tr>
<th>Fabric of coverall</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option 1:</strong> blood and body fluid penetration resistant</td>
<td>meets or exceeds ISO16603 class 3 or above exposure pressure, or equivalent</td>
</tr>
<tr>
<td><strong>Option 2:</strong> blood-borne pathogens penetration resistant</td>
<td>meets or exceeds ISO 16604 class 2 or above exposure pressure, or equivalent</td>
</tr>
</tbody>
</table>

There is no evidence that Ebola virus is able to penetrate through fabric. And no contamination cases caused by WHO PPE.

Note: for each of the two options mentioned above, different products may be available. The coverall material described in option 2 is associated with higher heat stress and less breathability; this reduces continuous wearing time and results in more frequent changes compared to option 1.
Foot wear (rubber boots)

should wear **waterproof boots** *(e.g. rubber/ gum boots)* while caring for patients

Knee-high, in order be higher than the bottom edge of the gown

Different sizes
**Women:**
37(6US), 38(7US), 40(9US)
**Men:**
42(8US), 44(10US)

Optional light colour to better detect possible contamination

Waterproof material *(e.g. rubber)*

Nonslip, have a PVC sole which is completely sealed
Head wear (head cover)

*should wear a head cover that covers the head and neck while providing clinical care* (conditional recommendation, low quality evidence)

- Single use,
- Reaching the upper part of the gown or coverall,
- Adjustable and immovable once adjusted,
- Fabric is preferably fluid resistant

Hood

Surgical head cover

Facial opening constructed without elastic

Head covers is to protect the head and neck skin and hair from virus contamination and the possibility of subsequent unrecognized transmission to the mucosae of the eyes, nose or mouth.
Personal protective equipment in the context of filovirus disease outbreak response rapid advice guideline: summary of the recommendations, WHO, October 2014 (note: related only to clinical care)

Personal protective equipment (PPE) in the context of filovirus disease outbreak response: Technical specifications for PPE equipment to be used by health workers providing clinical care for patients, WHO, October 2014

Field situation: How to conduct safe and dignified burial of a patient who has died from suspected or confirmed Ebola virus disease, WHO, October 2014

Interim Infection Prevention and Control Guidance for Care of Patients with Suspected or Confirmed Filovirus Haemorrhagic Fever in Health-Care Settings, with Focus on Ebola, WHO, August 2014

Clinical management of patients with viral haemorrhagic fever: A pocket guide for the front-line health worker, WHO, March 2014

All technical information on Ebola response is available:

Field situation: How to conduct **safe and dignified burial** of a patient who has died from suspected or confirmed Ebola virus disease, WHO, October 2014

### Step 2: Assemble all necessary equipment

- **Assemble Body Bag to hold the body of the deceased:**
  - Impermeable, vinyl, minimum thickness 400 micron;
  - Should be able to hold 100-125 kilos (200-250 lbs);
  - At least 4 handles included in the body bag to allow safe hand carry
  - Provide full containment of blood borne pathogens

- **Assemble all necessary equipment to prevent infections:**
  - **For hand hygiene:**
    - Alcohol-based handrub solution (recommended) OR
    - Clean running water, soap and towels (recommended) OR
    - Chlorine solution 0.05% (when option above are not available)

- **Personal Protection Equipment (PPE):**
  - One pair of disposable gloves (non-sterile, ambidextrous)
  - One pair of heavy duty gloves
  - Disposable coverall suit (e.g. Tyvek suit) + impermeable plastic apron
    - **Face protection:** Goggles and mask
    - Footwear: rubber boots (recommended) OR if not available shoes with puncture-resistant soles and disposable overshoes

- **For waste management materials:**
  - Disinfectant:
    - One Hand sprayer (0.05% chlorine solution)
    - One Back Sprayer (0.5% chlorine solution)
  - Leak-proof and puncture resistant sharps container
  - Two leak-proof infectious waste bags: one for disposable material (destruction) and one for reusable materials (disinfection)

### Step 6: Placement of the body bag in the coffin where culturally appropriate

1. Transport the body bag to the coffin, which should be placed outside the house, by 2 or 4 persons wearing PPE (depending on the weight of the body and the number of persons in PPE)
2. Place clothes and/or objects of the deceased patient inside the coffin if the family so wishes
3. Allow one of the family members to close the coffin, ensure they are wearing gloves at all times
4. Disinfect the coffin
5. Respect the grieving time requested by the family

- **At the end of this step the coffin is decontaminated and is ready to be transported**
- In case no coffin is available, the body bag should be gently placed on the rear of the pickup vehicle by placing the head towards the front. This should be performed by 2 staff wearing PPE.
Medical devices and biomedical engineers needed in response to the Ebola outbreak

Appropriate health technologies are indispensable to the Ebola response

Due to the urgency of the Ebola outbreak and the WHO’s scale up of international response in west Africa, WHO is providing technical information on appropriate available essential medical devices which are indispensable for treatment centres, community-based units and other preventive activities, in affected and neighbouring countries.

On the 31 October 2014, WHO updated the Rapid Advice Guide Personal Protective Equipment for Ebola response and the technical specifications of the referred equipments, which can be downloaded from

http://www.who.int/medical_devices/meddev_ebola/en/

We also posted the PPE list for CLEANING, WASTE MANAGEMENT, SAFE AND DIGNIFIED BURIALS

<table>
<thead>
<tr>
<th>Item</th>
<th>Generic Item name</th>
<th>Generic Item image</th>
<th>WHO Detailed description</th>
<th>Size</th>
<th>Certification or minimum testing (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goggles</td>
<td><strong>Recommended</strong></td>
<td><img src="image" alt="Goggles" /></td>
<td>Good seal with the edge of the face; adjustable band; easy to adjust fit with all new contours without too much pressure, Endurable and the surrounding area accommodates with prescription glasses; Clear plastic face with fog-resistant resistant; Adjustable head to secure firmly so as not to become loose during clinical activity, indirect ventilation to avoid fogging, May be reusable; provide appropriate arrangements for decontamination and replaceable.</td>
<td>One Size</td>
<td>* US standard FDA, ANSI/ISEA, EN 166/1992; * ANSI/ISEA 207-1-2010, or equivalent</td>
</tr>
<tr>
<td><strong>Respirator mask, high level</strong></td>
<td><strong>Optional</strong></td>
<td><img src="image" alt="Respirator Mask" /></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Face shield (full face)</strong></td>
<td><strong>Optional</strong></td>
<td><img src="image" alt="Face Shield" /></td>
<td>Made of clear plastics and provides good visibility to both the wearer and the</td>
<td></td>
<td></td>
</tr>
</tbody>
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http://www.who.int/medical_devices/meddev_ebola/en/
Apron (disposable, heavy-duty)

Disposable or single use apron,

- Straight apron with bib
- Waterproof material
- 70-90 x 120-150cm (or standard adult size)

Made of polyester with PVC-coated, or other

Minimum basis weight: 250g/m^2

Heavy duty non-woven apron,

- Reusable (provided appropriate arrangements for decontamination are in place)
- Sewn strap for neck and back fastening

Minimum basis weight: 300g/m^2

Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or other

may comply with EN ISO 13688:2013 or equivalent
Rubber gloves

cotton or polyester, rubber coating, waterproof, and acid resistant material

• covering forearm
• minimum cuff length 15cm

EU standard directive 89/686/EEC Category III,
• EN 374 (AS/NZS 2161.10.1.2005) chemical resistance for AKL
• EN 374 (AS/NZS 2161.10.1.2005) for biohazards Level 3 performance
• EN 388 (AS/NZS 2161.10.3.2005) 4101 for abrasion, blade cut, tear and puncture
• EN 420:2004+A1:2009 or equivalent
Our comments and questions

Personal protective equipment (especially, coverall) designed for clinical use in the medical field or infection prevention and control, (not industrial use)?
- Good breathability to reduce frequent cycles of donning and doffing.
- Protection against body splash or fluid, not require high protection against chemicals/ water fluid such as rain coat.
- Less complicated for donning and doffing.

Evidences or clinical researches for appropriate personal protective equipment for clinical use in the medical field or infection prevention and control?
- Gown vs Coverall?
- Fluid resistant surgical mask vs fluid resistant respirator?
- Hood vs head cover?
- Boots vs shoe cover?

Possibility to invent appropriate personal protective equipment for clinical use? e.g. coverall having different fabrics on front and back, or having a venting window on the back?
Thank you very much!

www.who.int/medical_devices/
medicaldevices@who.int
Avoid shaking hands

Personal Protective Equipment (PPE) not required if all below apply:

- Distance >1 meter from interviewee
- Interviewing asymptomatic people
- No contact with potentially contaminated environment

Provide alcohol-based handrub solutions and instructions to perform hand hygiene
IPC Essential Precautions in Healthcare Facilities

- Standard precautions for all patients at all times
- Isolation of suspected and confirmed cases in separated rooms/areas with restricted access
- Exclusively dedicated staff and equipment for isolation rooms/areas
- Hand hygiene with alcohol-based handrub or water and soap
- Use of PPE (see next slide)
- Rigorous environmental cleaning and surfaces/objects decontamination
- Safe injection practices and sharps handling
- Post-exposure evaluation and care following professional accidents

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PPE for patient care and non clinical care

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