

Personal protective equipment in the context of filovirus disease outbreak response

October 2014

Introduction

This document provides a summary of recommendations for personal protective equipment (PPE) to be used by health workers providing clinical care for patients with filovirus infection (Ebola and Marburg). The recommendations have been developed in accordance with the WHO Rapid Advice Guideline procedures. The technical specifications accompanying these recommendations are available in Annex 1.

Principles guiding PPE use

Controls

Preventing virus transmission in health-care settings requires the application of procedures and protocols referred to as “controls”. These are, in order of Infection Prevention and Control (IPC) effectiveness: administrative controls, environmental and engineering controls, and personal protective equipment (PPE). Although PPE is the most visible control used to prevent transmission, it must be used in conjunction with administrative and engineering controls (such as facilities for barrier nursing and work organisation, water and sanitation, hand hygiene infrastructure, waste management and ventilation). PPE must be correctly selected and used in a safe manner; this is especially important when putting on and removing PPE, and decontaminating PPE components.

Standard precautions

It is not always possible to identify patients with filovirus infection because early symptoms are non-specific. For this reason, it is important that **health workers use standard precautions consistently when providing care to all patients, regardless of their diagnosis. Their rigorous implementation is crucial for the control of outbreak situations.**

Standard precautions include:

- hand hygiene
- point-of-care risk assessment for appropriate selection and use of PPE to avoid direct contact with patients' body fluids (including blood, stool, amniotic fluid, urine and respiratory secretions), mucous membranes and non-intact skin
- respiratory hygiene (cough etiquette)
- prevention of needle-stick or sharps injuries
- safe waste management
- cleaning, disinfection (and sterilization, where applicable) of patient-care equipment and linen
- cleaning and disinfection of the environment.

For further details on standard precautions and best practices for infection prevention and control of filovirus infection in health care settings, refer to *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* (available at http://www.who.int/csr/resources/publications/ebola/filovirus_infection_control/en/).

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Workforce health and wellbeing

Safeguarding the health and wellbeing of health workers at the work place, including the provision of hand hygiene and appropriate PPE, is a priority for, and the responsibility of policy-makers, employers, managers and the health workers themselves. Making optimum provisions for protecting the health and safety of the work force is considered a basic responsibility of the employer:

- A risk assessment of the work place must be carried out by competent experts appointed by the employer.
- All health workers at risk must be provided with adequate, effective and sustainable control measures which are commensurate to the risk.
- Health workers should be informed of the risks they may face, and the mitigating effects of PPE when used consistently and correctly. Compliance with all control measures is the responsibility of the health worker.
- Policymakers and managers need to consider issues such as climate conditions and cultural norms to ensure uptake of protection measures and maximise compliance.
- The recommended PPE must be available and accessible to health workers.

Implementation

Implementing these recommendations will require training that is suitable for different categories of health workers (including supervisors), and takes into account, where necessary, local customs and cultural acceptability. Adequate resources (human, material and financial) must be made available.

Resource management

Resource management includes stock management, availability of different sizes and shapes of PPE, placement of items for easy access, quality of items purchased and line management for reporting shortages. Written protocols need to be in place for the management of used and potentially contaminated medical devices, including safe discard and decontamination and re-use if recommended by the manufacturer.

Recommendations

Protection of the mucosae of the eyes, nose and mouth

Recommendation 1: All health workers should have the mucous membranes of their eyes, mouth and nose completely covered by PPE while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation. High quality evidence for protecting mucous membranes compared to no protection.

Recommendation 2: All health workers should use either a face shield or goggles while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation. Very low quality evidence for the comparative effectiveness of face shields and goggles for the prevention of filovirus transmission to health workers.

Rationale and remarks

Protection of the mucous membranes of the eyes, nose and mouth is an integral part of standard and contact precautions. Contamination of mucous membranes is probably the most important mode for filovirus transmission. Hence, PPE to protect mucosae is essential. These devices should be taken off as late as possible during the PPE removal process, preferably at the end, to prevent inadvertent exposure of the mucous membranes.

There is currently no scientific evidence comparing the effectiveness of face shields and goggles, worn with an appropriate head cover (see recommendations 11 and 12), for the prevention of filovirus transmission to health workers. Their effectiveness was considered equal and either device could be used as determined by other factors, including the personal preference of the health worker and local availability of good quality items which meet the specifications provided separately. Face shields and goggles, however, should not to be used together.

Considerations include:

- **Fogging:** Fogging affects both face shields and the goggles, although it may affect face shields to a lesser degree. Fogging reduces visibility and may thus compromise both the ability of the health worker to provide patient care and his or her safety. Industrial-type anti-fogging sprays may be useful but their effectiveness can be reduced in hot and humid climates. Goggles with ventilation may help to reduce fogging, but vents should not allow blood and body fluids to contaminate the internal surface or the eye.
- **Visibility:** Face shields allow more of the face to be visible to the patient, facilitating communication and interaction between patient and health workers. Face shields provide a wider range of view for the health worker, which is usually considered safer. Goggles that allow panoramic vision also offer similar advantages.
- **Prescription glasses:** Health workers who wear prescription glasses should be given the choice between goggles and face shields, while ensuring an adequate fit and avoiding fogging.

Recommendation 3: Health workers should wear a fluid-resistant medical/surgical mask with a structured design that does not collapse against the mouth (e.g. duckbill, cup shape) while caring for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation, low quality evidence when comparing medical/surgical mask with particulate respirator for transmission of filovirus infections.

Recommendation 4: Health workers should use a fluid-resistant particulate respirator while caring for patients with filovirus disease during procedures that generate aerosols of body fluids in order to prevent virus exposure.

Strong recommendation, moderate quality evidence when evidence on aerosol-generating procedures for other pathogens is also considered.

Rationale and remarks

The purpose of the medical/surgical mask is to protect the nasal and mouth mucosa from splashes and droplets of infectious material. Since filoviruses are not transmitted through the airborne route in humans, respiratory protection with a particulate respirator is not required.

Structured (e.g. duckbill, cup shape) medical/surgical masks are considered more comfortable than particulate respirators by end users. In hot and humid climates, a structured (e.g. duckbill, cup shape) mask that does not collapse against the mouth when wet through respiration or transpiration is safer than a mask without this design.

A medical/surgical mask should always be worn with appropriate eye protection (either with a face shield or goggles; see recommendations 1 and 2 above). The mask/respirator should be fluid resistant when used with goggles. Fluid resistance is not required if mask/respirator is used together with a face shield. Wearing more than one mask at the same time does not provide additional protection and is not recommended.

Not all N95 particulate respirators are necessarily fluid resistant; only N95 respirators labelled as 'surgical N95 respirator' are tested for fluid resistance.

Gloves

Recommendation 5: All health workers should wear double gloves while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation. Moderate quality evidence for double gloving as compared to single glove use.

Rationale and remarks

Double gloves are recommended compared to single gloves to decrease the potential risk of virus transmission to the health worker due to glove holes and damage to gloves from disinfectants such as chlorine; double gloving may also reduce the risk from needle-stick injuries and contamination of hands when removing PPE. The confidence in effectiveness was assessed as moderate based on accumulated evidence for transmission of other blood-borne pathogens such as HIV and hepatitis viruses.

Although there is some degree of decreased tactile sensation, impaired dexterity, and discomfort related to double gloving, studies demonstrate that in most cases the feeling of impaired tactile sensation is overcome within a few days, even when performing delicate surgery.

Preferably, the outer glove should have a long cuff, reaching well above the wrist, ideally to the mid- forearm. In order to protect the wrist area from contamination, 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.

Use of tape to attach gloves to gowns/coveralls should be avoided, as this may interfere with safe gown/coverall and glove removal because of the need for additional manipulation and the risk of tearing of the gown/coverall, potentially resulting in contamination. There is no evidence that more than two gloves on each hand provide further protection; this has the potential to interfere with dexterity and add complexity to glove removal, and is not considered safe.

Best IPC practice dictates that gloves should be changed between patients. However, feasibility issues (i.e. provision of clean gloves and waste disposal within the patient treatment and isolation area) were of concern. Because of this, the GDG did not reach consensus on the recommendation for changing gloves between patients inside the clinical area. Nine members were in favour of changing gloves between patients, two were against, and two members abstained.

The following 2- step procedure could help facilitate changing gloves safely while providing clinical care for patients with filovirus disease: 1) disinfect the outer gloves before removing them safely and 2) keep the inner gloves on and disinfect them before putting on a fresh outer pair. Alcohol-based hand rubs are preferred when disinfecting hands and gloved hands. If a glove becomes compromised, it should be changed using the procedure described above.

Sterile gloves are not required except when performing a sterile procedure as per standard IPC recommendations. Adaptations of the gloving procedures described above may be required for specific surgical and obstetric procedures.

Recommendation 6: Nitrile gloves are preferred over latex gloves for health workers providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation. Moderate quality evidence on effectiveness and safety of nitrile gloves over other alternatives.

Rationale and remarks

Nitrile gloves are recommended because they resist chemicals, including certain disinfectants such as chlorine, and nitrile is more environmentally friendly than latex. There is a high rate of allergies to latex and contact allergic dermatitis among health workers. However, if nitrile gloves are not available, latex gloves can be used. Non-powdered gloves are preferred to powdered gloves.

Gown/coverall

Recommendation 7: Health workers should wear protective body wear in addition to regular on-duty clothing, (e.g. surgical scrubs), while caring for patients with filovirus disease in order to prevent virus exposure

Strong recommendation, high quality evidence for using protective body wear as against using no protection, based on accumulated evidence from other infections with similar modes of transmission.

Recommendation 8: Compared with other forms of protective body wear, the choice of PPE for covering clothing 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.

Conditional recommendation, very low quality evidence comparing effectiveness of gowns and coveralls

Recommendation 9: The choice of apron should be, in order of preference:

- **Disposable, waterproof apron**
- **If disposable aprons are not available, heavy duty, reusable waterproof aprons can be used if appropriate cleaning and disinfection between patients is performed.**

Strong recommendation, very low quality evidence comparing effectiveness of disposable and reusable apron

Rationale and remarks

Protective body wear is recommended as part of contact precautions based on evidence and is applicable in filovirus disease as well. Coveralls and gowns are equally acceptable as there is a lack of comparative evidence to show whether one is more effective than the other in reducing transmission to health workers. Gowns are considerably easier to put on and, in particular, to take off, making them a safer alternative when removing PPE. They are generally more familiar to health workers and hence more likely to be used and removed correctly. These factors also facilitate training in their correct use. Heat stress is significantly less for gowns and they are more likely to be available in areas commonly affected by filovirus disease. An additional consideration is that, in some cultures, gowns may be more acceptable than coveralls when used by women.

Protective body wear that is fluid resistant is recommended to mitigate against the possibility that infected body fluids could penetrate and contaminate the underlying clothes or skin with possible subsequent unrecognized transmission via the hands to the mucous membranes of the eyes, nose or mouth.

An apron should be worn over the gown or coveralls; it is easier to remove a soiled apron compared to gowns and coveralls. An apron is generally worn for the entire time the health worker is in the treatment area. If the apron is visibly soiled, a disposable apron should be removed and changed. Feasibility issues, such as availability of new aprons and waste disposal within isolation areas, must be addressed. Health workers wearing a reusable apron should leave the ward to clean, disinfect and remove the apron.

Footwear

Recommendation 10: All health workers should wear waterproof boots (e.g. rubber/ gum boots) while caring for patients with filovirus disease in order to prevent virus exposure.

Strong recommendation. Very low quality evidence comparing boots with other types of foot wear.

Rationale and remarks

Waterproof boots are preferred over closed shoes because they are easier to clean and disinfect and because they provide optimal protection when floors are wet. In addition, rubber boots can protect from sharps injuries. If boots are not available, health workers must wear closed shoes (slip-ons without shoelaces and fully covering the dorsum of the foot and ankles). Shoe covers, nonslip and preferably impermeable, should ideally be used over closed shoes to facilitate decontamination. Boots do not need to be removed on leaving the PPE removal area provided they have been cleaned and disinfected; the same pair of boots can be worn until the end of that day's work or shift.

Head cover

Recommendation 11: All health workers should wear a head cover that covers the head and neck while providing clinical care for patients with filovirus disease in order to prevent virus exposure.

Conditional recommendation. Low quality evidence for effectiveness of head cover in preventing transmission

Recommendation 12: The head cover is suggested to be separate from the gown or coverall, so that these may be removed separately.

Conditional recommendation. Low quality evidence comparing different types of head covers.

Rationale and remarks

The purpose of 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. Hair and hair extensions need to fit inside the head cover.

Recommendation 11 is conditional since there is no evidence to support use of a head cover over a hood (covering the shoulders) or hair cap for preventing transmission of infection. The need for covering all skin surfaces including the back of the neck was discussed in detail during the GDG meeting. There was no consensus among the GDG: nine experts were of the opinion that all skin surfaces should be covered, three disagreed and one was absent during voting.

Recommendation 12 is conditional since there was no comparative evidence of effectiveness in preventing transmission between a separate head cover and a head cover that is integrated in the coverall. When a separate head cover is not available, a coverall with hood can be worn provided that the hood is put on after eye, nose and mouth protection so that mucosal protection is maintained after taking off the hooded coverall.

Annex 1: PPE technical specifications

Item	Technical specifications
Goggles Recommendation 2	<ul style="list-style-type: none"> ● Good seal with the skin of the face ● Flexible frame to easily fit all face contours without too much pressure ● Covers the eyes and the surrounding areas and accommodates for prescription glasses ● Fog and scratch resistant ● Adjustable band to secure firmly so as not to become loose during clinical activity ● Indirect venting to reduce fogging ● May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable ● Quality compliant with the below standards, or equivalent: <ul style="list-style-type: none"> - EU standard directive 86/686/EEC, EN 166/2002 - ANSI/ISEA Z87.1-2010
Face shield Recommendation 2	<ul style="list-style-type: none"> ● Made of clear plastic and provides good visibility to both the wearer and the patient ● Adjustable band to attach firmly around the head and fit snugly against the forehead ● Fog resistant (preferable) ● Completely covers the sides and length of the face ● May be re-usable (made of material which can be cleaned and disinfected) or disposable ● Quality compliant with the below standards, or equivalent: <ul style="list-style-type: none"> - EU standard directive 86/686/EEC, EN 166/2002 - ANSI/ISEA Z87.1-2010
Fluid-resistant medical/surgical mask Recommendation 3	<ul style="list-style-type: none"> ● High fluid resistance ● Good breathability ● Internal and external faces should be clearly identified ● Structured design that does not collapse against the mouth (e.g. duckbill, cup shape) ● Quality compliant with the below standards, or equivalent: <ul style="list-style-type: none"> - EN 14683 Type IIR performance - ASTM F2100 level 2 or level 3 or equivalent
Particulate respirator Recommendation 4	<ul style="list-style-type: none"> ● Shape that will not collapse easily ● High filtration efficiency ● Good breathability ● Quality compliant with standards for surgical N95 respirator: <ul style="list-style-type: none"> - NIOSH N95, EN 149 FFP2, or equivalent ● Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent ● Quality compliant with standards for particulate respirator worn with full-face shield: Only to be used together with a face shield <ul style="list-style-type: none"> - NIOSH N95, EN149 FFP2, or equivalent

Item	Technical specifications
Gloves Recommendations 5 & 6	<ul style="list-style-type: none"> ● Nitrile ● Non-sterile ● Powder free ● Outer gloves preferably reach mid-forearm (minimum 280mm total length) ● Different sizes ● Quality compliant with the below standards, or equivalent: <ul style="list-style-type: none"> - EU standard directive 93/42/EEC Class I, EN 455 - EU standard directive 89/686/EEC Category III, EN 374 - ANSI/ISEA 105-2011 - ASTM D6319-10
Disposable gown Recommendation 8	<ul style="list-style-type: none"> ● Single use ● Length, mid-calf to cover the top of the boots ● Avoid culturally unacceptable colours e.g. black ● Light colours are preferable to better detect possible contamination ● Thumb/finger loops to anchor sleeves in place ● Quality compliant with either of two standards, depending on resistance of materials: <ul style="list-style-type: none"> - Option 1 (tested for resistance to fluid penetration): EN 13795 high performance level, or AAMI level 3 performance, or equivalent <li style="text-align: center;">OR - Option 2 (tested for resistance to blood-borne pathogen penetration): AAMI PB70 level 4 performance, or equivalent
Disposable coverall Recommendation 8	<ul style="list-style-type: none"> ● Single use ● Avoid culturally unacceptable colours e.g. black ● Light colours are preferable to better detect possible contamination ● Thumb/finger loops to anchor sleeves in place ● Quality compliant with either of two standards, depending on resistance of materials: <ul style="list-style-type: none"> - Option 1 (tested for resistance to blood and body fluid penetration): Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent <li style="text-align: center;">OR - Option 2 (tested for resistance to blood-borne pathogen penetration): meets or exceeds ISO 16604 class 2 exposure pressure, or equivalent <p>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.</p>
Waterproof apron Recommendation 9	<ul style="list-style-type: none"> ● Disposable or single use ● Made of polyester with PVC-coated, or other waterproof material ● Straight apron with bib ● Minimum basis weight: 250g/m² ● Covering size: approximately 70-90cm width x 120-150cm height, or standard adult size ● Either <ul style="list-style-type: none"> - Option 1: Adjustable neck strap with back fastening at the waist - Option 2: Neck strap allowing for tear-off with back fastening at the waist

Item	Technical specifications
Heavy duty apron Recommendation 9	<ul style="list-style-type: none"> ● Heavy duty non-woven apron ● Straight apron with bib ● Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or other fluid resistant material (e.g. rubber, PVC) ● Water proof, sewn strap for neck and back fastening ● Minimum basis weight: 300g/m² ● Covering size: approximately 70-90cm width x 120cm-150cm height ● Reusable (provided appropriate arrangements for decontamination are in place)
Waterproof boots Recommendation 10	<ul style="list-style-type: none"> ● Nonslip, have a PVC sole which is completely sealed ● Knee-high, in order be higher than the bottom edge of the gown ● Optional light colour to better detect possible contamination ● A variety of sizes to improve comfort and avoid trauma to the feet
Hood or headcover Recommendation 11	<ul style="list-style-type: none"> ● Single use ● Preferably fluid resistant ● Adjustable and immovable once adjusted ● Facial opening constructed without elastic, reaching the upper part of the gown or overall
Surgical scrubs: trousers and top	<p>Surgical scrubs are for use as regular on-duty wear and are not considered PPE. Details are provided for ease of procuring these items. Scrubs are preferable to street clothes while the health worker is on-duty.</p> <ul style="list-style-type: none"> ● Tightly woven ● Minimum linting ● Non-sterile, reusable or single use ● Top/tunic: short sleeves ● Trousers: drawstring waist enclosure ● Different sizes

Annex 2: Background to the development of this guideline

Development of these recommendations included: development of a scoping document for approval by the WHO Guideline Review Committee; development of key questions; a systematic review of the literature; a literature review and an online survey on the values and preferences of expatriate health workers; an evidence-to-recommendations exercise using the GRADE framework; and an expert consultation.

The research question for the systematic review was: What are the benefits and harms of double gloves, full face protection, head cover, impermeable coveralls, particulate respirators, and rubber boots as PPE when compared with alternative less robust PPE for health workers caring for patients with filovirus disease? The systematic review yielded no comparative evidence for the different types of PPE.

An in-depth literature review on the values and preferences of health workers regarding PPE, but not specifically focusing on filovirus disease, was carried out. An online survey was also conducted among expatriate health workers with experience caring for patients with Ebola virus disease to obtain information on their values and preferences regarding PPE. The responses to the survey included aspects such as comfort, ease of use, and sense of protection (safety).

A thorough mandatory training on the use of PPE followed by mentoring for all users before engaging in any clinical care is considered fundamental for preventing filovirus disease among health workers. In addition, based on experience in the field, the ready availability of PPE items, along with their familiarity and acceptability were considered important when selecting PPE. The use of disposable, rather than reusable, items was generally preferred.

Annex 3: Methods used for the development of this guideline

A Guideline Development Group (GDG) meeting was convened on 6 and 7 October 2014. The Group was comprised of 13 experts who were invited based on their knowledge, experience and technical expertise. According to WHO requirements for guideline development, members participated as independent experts and did not represent any agency, institute or country. All GDG members completed WHO Declaration of Interest forms, which were reviewed by the Steering Group prior to the meeting. None of the GDG members declared any conflict of interests relating to the matter under discussion.

The biology of the virus and its modes of transmission were considered in the development of the recommendations. There was sufficient information available to make strong recommendations on the use of PPE and its specifications as barriers to transmission. Patients with filovirus infection usually have profuse vomiting and diarrhoea. The GDG noted that the virus load is highest in blood, although bleeding is seen in only a minority of patients. Other body fluids such as vomit, faeces, sweat, saliva, urine, amniotic fluid and semen, may also contain virus (on occasion, high levels of virus can be found) and be involved in transmission. The main route for acquisition of filovirus infection is through contact of infected blood or other body fluids with the mucous membranes of the mouth, nose and eyes. Transmission can occur through direct contact with these body fluids, or through contact with fomites (i.e. touching inanimate objects), such as the floor, utensils and bed linens that have recently been contaminated with infected body fluids. Transmission through intact skin has not been documented, but infection can be transmitted through non-intact skin and through penetrating injuries of the skin, such as needle-stick injuries.

Based on this information, the experts agreed that it was most important to have PPE which protects the mucosae – mouth, nose and eyes – from contaminated droplets and fluids. Hands are known to transmit pathogens to other parts of the body or face and to other individuals. Therefore, hand hygiene and gloves are essential, both to protect the health worker and to prevent transmission to others. Face cover, protective foot wear, gowns or coveralls, and head cover were also considered essential to prevent transmission to health workers.

A fundamental principle guiding the selection of different types of PPE was the effort to strike a balance between the best possible protection against filovirus infection while allowing health workers to provide the best possible care to patients with maximum ease, dexterity, comfort and minimal heat-associated stress. Heat-associated stress while wearing impermeable PPE is of particular concern as it can place health workers at increased risk of accidental exposure to filovirus.