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REVIEW ARTICLE

Ensuring Worker Safety during an Ebola Virus Disease Outbreak

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ABSTRACT

The West Africa outbreak of Ebola Virus Disease (EVD) 2014-2016 was unprecedented in terms of its impact not only in Guinea, Sierra Leone and Liberia but also internationally. This had major implications for response and support to these three countries in dealing directly with the crisis, as well as emergency preparedness in other countries. Britain's regulator for health and safety at work (Health and Safety Executive; HSE) provided technical advice on the correct personal protective equipment (PPE) and its safe use in support of the emergency response to Sierra Leone. For UK preparedness, HSE provided technical input to update guidance from the Governmental Advisory Committee on Dangerous Pathogens (ACDP) on safe practices for healthcare workers (HCW) caring for suspected EVD patients and safe laboratory procedures for handling samples.

Diagnostic laboratories set up temporarily at Ebola Treatment Centres(ETCs) in Sierra Leone had limited facilities compared to conventional high containment pathogen laboratories, but at safety critical points a combination of safe working practices and engineered protection ensured the safety of laboratory workers.

A network of High Consequence Infectious Disease (HCID) units was established in hospitals across the UK in preparation for a possible influx of suspected EVD patients. These mostly needed to rely on PPE to protect healthcare workers from exposure to potentially infectious body fluids. To evaluate the protective effectiveness of these PPE ensembles and the safe removal of contaminated PPE, a scenario-based exercise was developed based on the use of simulant body fluids tagged with fluorescent markers. Visualisation of cross-contamination provided a powerful training and evaluation tool.

This paper provides an overview of how a combination of these initiatives ensured the safety of laboratory workers in both well-resourced and resource-limited facilities and the safety of healthcare staff in situations where they potentially were exposed to large volumes of infected body fluids.

Introduction

In the EVD outbreak in West Africa in 2013 to 2016 there were in total 28,616 confirmed cases and 11,310 reported deaths, of which 14,122 cases and 3,955 deaths occurred in Sierra Leone (World Health Organization; WHO; data).

In the early stages of the outbreak, many HCW were infected with Ebola Virus (EV) of a high fatality rate peaking at 60-70% [1]. More recently, in the 2018 EVD outbreaks in Democratic Republic of Congo, Situation Reports from WHO (http://www.who.int/ebola/situation-reports/drc-2018/en/) showed that early in the first outbreak (first Situation Report, 11th May 2018) 34 cases and 18 deaths included three HCW (two suspected and one who had probably died of the disease). By early July 2018 (Situation Report 14), with no more cases having been reported for 21 days, there were a total of 53 confirmed and probable cases and 29 deaths. Of these, five HCW were reported as being affected, four of these being confirmed cases and two deaths. This further emphasises the risk that caring for patient's places on HCW and the need for adequate protection. This is relevant not only in countries where an outbreak occurs, but also in other countries that may need to prepare for the possibility of people returning from an outbreak area with suspected infection.

In laboratories handling EVD clinical diagnostic samples or undertaking research with EV, one of the highest hazard pathogens known, there is a need to have in place adequate means of protecting the laboratory workers and support staff.

This review aims to provide an overview of how the safety of HCW can be ensured in situations where they are potentially exposed to large volumes of infected body fluids, and also how laboratory workers were protected from infection in both well-resourced and resource-limited facilities. HSE's role in this is described.

Outbreak Response and PPE Advice

At the start of the EVD outbreak in West Africa, HSE worked with other UK Government departments to develop the UK emergency response, principally to Sierra Leone. Initially, medical aid to Sierra Leone was provided by the UK Army Medical Services who deployed staff supplied with suitable PPE and trained in its safe use. As National Health Service (NHS) medical staff were trained and deployed to continue the medical aid, HSE specialists used their technical expertise in PPE performance to provide advice, ensuring that the correct PPE was sourced for HCW working at treatment centres in Sierra Leone and to develop protocols for safe PPE use. Figure 1 shows the PPE ensembles used in ETCs in Sierra Leone during the EVD outbreak. These ensembles were based on those used by Medecins Sans Frontieres, and included a heavy duty all-in-one suit, hood, apron, wellington boots and multiple layers of gloves.

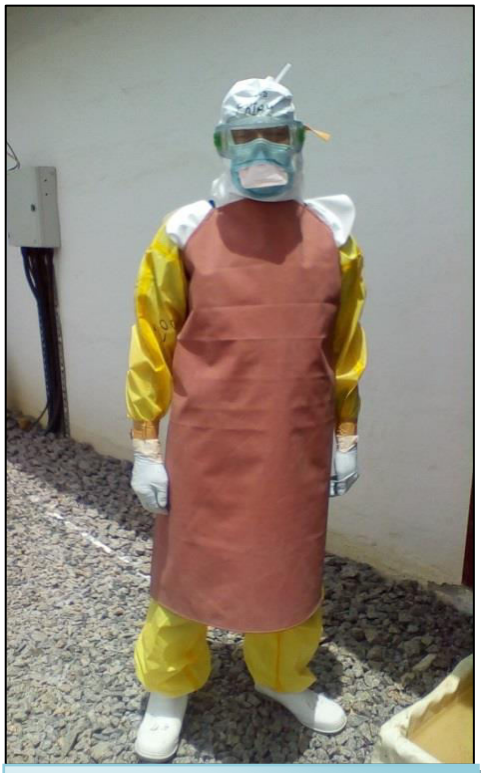

Figure 1: PPE ensemble used by medical staff caring for patients in ETCs in Sierra Leone during the EVD outbreak 2013 – 2016.

Preparedness plans for the UK also included measures to be taken if travelers from EVD-affected countries were to present at hospital with symptoms consistent with EVD. Existing facilities at the Royal Free Hospital (RFH) in London provide 'Trexler'-based care, i.e., a sealed tented system for the patient which is operated under negative pressure and provides a safe barrier for nursing staff [2]. However, this is not always suitable or available for all patients and therefore a PPE-based option was also developed. In case there were more patients than could be accommodated at RFH, a network of 'Surge Centers' was set up in infectious disease units at hospitals in Newcastle, Liverpool and Sheffield, where

PPE would be worn in place of the Trexler system. In addition, all acute care providers were expected to implement appropriate PPE systems for safe assessment of a febrile traveller, i.e., one suspected of having EVD, returning from West Africa. At the time, and in the absence of a clear evidence base, choices were made using guidance from expert bodies such as WHO, Public Health England (PHE) and the US Centers for Disease Control and Prevention (CDC), as well as considering price and availability. These factors, alongside the urgent need to equip the Surge Centres, led to variations in PPE choices around the UK for the assessment of suspected Ebola patients. The paucity of published evidence to support PPE choice was highlighted in a Cochrane review report [3] and a WHO report [4]. They concluded that more rigorous simulation studies should be planned to address this, as well as standardised doffing procedures and training advice.

The UK Army had devised pre-deployment simulation-based training using a fluorescent tracer to assess competency in PPE use for a large number of personnel and provide them with safety reassurance [5]. To aid future preparedness, the NHS in England and PHE launched the HCID programme with a remit to develop a unified, national PPE ensemble and donning/doffing protocol, for use when assessing patients with a possible HCID. The authors of this paper, together with medical staff from Sheffield Teaching Hospitals NHS Trust, used the Army training method as a starting point to develop a novel simulation-based exercise. With this exercise, the safety of the PPE protocols used by Surge Centres was evaluated in a simulation of first assessment of a patient with any possible HCID, including airborne pathogens.

A mannequin was adapted to expose volunteer HCW to synthetic bodily fluids (vomit, sweat, diarrhoea and cough), each of which contained a different coloured fluorescent tracer [6]. During the exercise, they undertook a variety of simulated clinical tasks while at the same time being exposed to the simulated bodily fluids which cross-contaminated their PPE. After exposure, HCW were examined under UV lights to visualise the fluorescent contamination, which was otherwise invisible. Contamination was recorded on a 35-grid body map and photographed, and HCW were screened again after removing PPE to detect any personal contamination. The exercise was videoed, allowing retrospective analysis of contamination events and user errors [7]. Based on the evidence obtained from these exercises, a consensus was agreed with all the Surge Centres on a unified, national PPE ensemble and donning/doffing protocol [8]. Figure 2 shows the unified PPE ensemble for use during first assessment of a patient with any possible HCID.

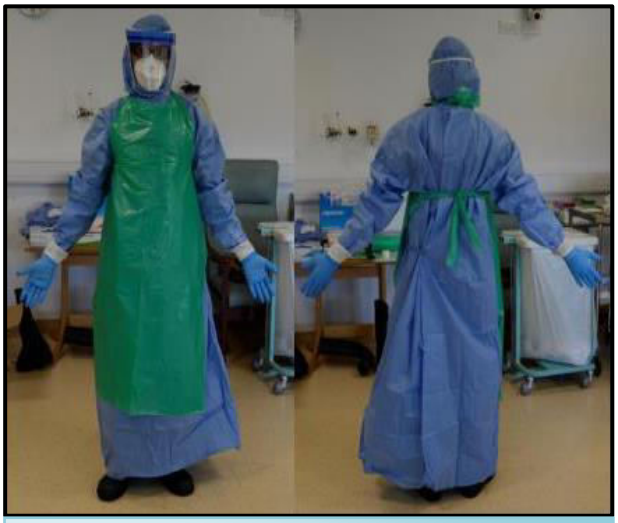

Figure 2: New 'HCID assessment PPE' ensemble, front and back [8].

Guidance on safe working with viral haemorrhagic fevers

In the UK, ACDP had guidance on working safely with haemorrhagic fever viruses. A working group, which included authors of this paper (VP, CMB, BC), updated this guidance with information obtained from the EVD outbreak, as well as precautions to be taken with patients returning to the UK and the handling of patient samples [9].

Safe working in the laboratory with patient samples

Under non-outbreak circumstances and in well-resourced countries, viruses such as EV are handled under conditions of the highest containment at biosafety/containment level 4 (BSL-4/CL4). This usually involves sealed laboratories working under cascades of negative pressure and with samples handled either in 'glove-box' style Class III Biological Safety Cabinets

(BSC) or by staff wearing positive pressure air-fed suits. However, such facilities did not exist in Sierra Leone. Consequently, EV testing laboratories were built co-located with ETCs. PHE were tasked by UK Government to establish diagnostic laboratory capability at ETCs in Kerry town, Port Loko and Makeni. The aim of these laboratories was to assist in rapid diagnosis of samples to screen patients, to support treatment and to confirm disease-free status of patients prior to discharge. PHE provided the laboratory equipment, developed laboratory protocols and trained staff for deployment to operate the laboratories. One of the authors of this paper (BC) was deployed for two five-week periods in 2015 to work at the Makeni ETC laboratory.

Because of constraints on time and resources, it was not feasible to build and run a conventional BSL-4 laboratory; therefore there was a strict reliance on laboratory procedures to ensure the safety of laboratory staff. Samples were received either from the ETC medical staff or from the community delivered via courier. ETC samples were usually VacutainerTM blood tubes, secondary packaged in plastic Falcon tubes then placed in plastic seal-top bags. Community samples of blood tubes or buccal swabs in tubes were usually bagged and then placed in rigid plastic transport containers. On receipt of these, the ETC samples were immersed in 5000ppm sodium hypochlorite solution and the outer containers of community samples were wiped with the same solution, with a contact time of at least 10 minutes for both, this having been validated as effective to kill EV [9]. After this, samples were taken into a Flexible Film Isolator (FFI) for processing. The FFIs were of a bespoke design validated by PHE and comprised an isolator similar to a Class III BSC but made from heavy duty polythene film hung on a rigid metal frame. Access into the isolator for sample handling was via gauntlets, with a rigid plastic pass box available to transfer materials in and out of the isolator. The isolator was maintained at negative pressure while in use by a mains-operated extract fan with a back-up battery in case of mains failure. Inlet air was via a single High Efficiency Particulate Air (HEPA) filter and extract air via a double HEPA filter, with a magnehelic gauge providing visual assurance of the operating conditions. This is described in more detail in [10], and an FFI in use in the Makeni ETC laboratory is shown in Figure 3.

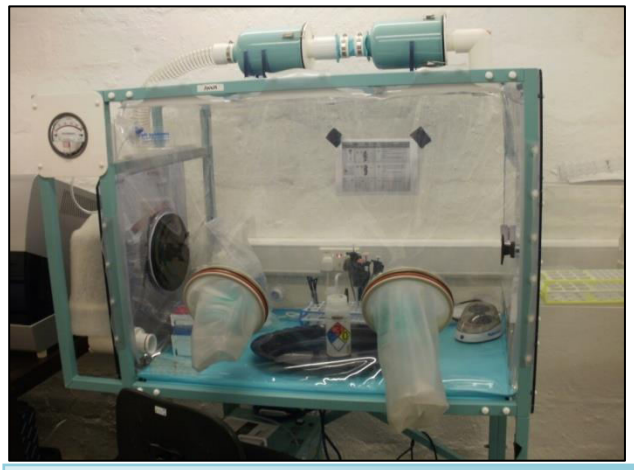

Figure 3: Bespoke design FFI used in ETC laboratories in Sierra Leone to handle blood samples potentially containing EV.

Because of space limitations, to ensure safe working the amount of equipment in the FFIs was kept to the minimum required, i.e., pipettes and tips, tube racks and a micro-centrifuge, spray bottles of sodium hypochlorite solution and wipes. Working with the protection afforded by these FFIs meant that PPE worn by laboratory staff comprised surgical gowns and nitrile gloves, with additional nitrile gloves worn over the gauntlets inside the FFI which could be replaced as required in case of cross-contamination.

Surface-decontaminated samples were transferred into the FFIs and only then were they removed from their outer packaging, with sample tubes then surface decontaminated before opening. Subsamples of blood were removed for malaria testing and then blood was centrifuged to harvest serum. Swab samples were also centrifuged to remove debris. Each subsample of serum/swab was then mixed with Buffer AVL (Qiagen) which contains a chaotropic salt (guanidine isothiocyanate) which inactivates live EV while retaining viral RNA intact for testing [11]. Sample tubes were decontaminated then bagged and these then decontaminated ready for removal from the FFI. The samples went through a further precautionary heat inactivation step before RNA extraction and PCR to

detect and quantify the presence of EV RNA [12]. In summary, the safety-critical steps taken for samples and equipment in the ETC laboratories were as follows:

For samples:

- Hypochlorite-based decontamination of outer packaging of samples on receipt;
- Opening and handling of samples potentially containing live virus only inside FFI;
- Validated chemical inactivation of live virus before secondary containment, hypochlorite decontamination of outer packaging of samples and removal from FFI;
- Additional heat inactivation step before further handling of samples out of FFI for RNA extraction and PCR.

For equipment:

- Safety checks and visual inspection of FFI every morning;
- Segregation of work in FFI and wiping down with hypochlorite;
- Re-usable items such as tube racks were bagged and surface decontaminated with hypochlorite before removal from FFI, and these items were then immersed in hypochlorite before washing and re-using;
- All internal surfaces of FFI were wiped down with hypochlorite, then detergent then water (to neutralise the hypochlorite and prevent damage to the film material) every evening.

Because several laboratory staff was working with samples and equipment each day, all of the above safety critical steps were supported by signed documentation to ensure the steps had been completed. During the EVD outbreak, a total of 376 volunteers staffed the PHE laboratories and across all the laboratories 53,624 samples were tested with 2,470 of these proving positive. The Makeni laboratory tested 25,370 of these with 325 proving positive [13]. No laboratory workers were infected despite the scale of the operation.

Revision of International Laboratory Biosafety Guidance

WHO is currently revising its Laboratory Biosafety Manual (LBM), with one of the authors of this paper (CMB) a member of the editorial team. The purpose of this manual is to encourage countries to implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms. Since the third edition of this manual (published in 2004), technologies have and continue to evolve and with them changes in associated risks. Therefore, the fourth edition of the LBM proposes a shift in focus from a prescriptive guidance document to a risk- and evidence-based approach to biosafety. The forthcoming LBM also aims to have a technology-neutral, cost-effective approach ensuring laboratory facilities, safety equipment and work practices are proportionate and sustainable across the globe [14].

Conclusions

In outbreaks of infectious disease, the risk of cross-infection for HCW caring for patients and laboratory workers handling samples is high. In some situations HCW will have to rely on PPE to prevent cross-infection, but with the correct selection and use of PPE ensembles, including evidence-based testing and training in safe removal of potentially contaminated PPE, it is possible to fully protect the HCW. In the laboratory, even where facilities usually associated with handling high hazard pathogens are not available, putting in place the right training, following good microbiological practices and incorporating practical control measures at safety-critical steps can ensure the safety of laboratory workers and ancillary staff, e.g., those disposing of laboratory waste.

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