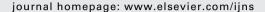
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Contents lists available at ScienceDirect

International Journal of Nursing Studies





Uncertainty, risk analysis and change for Ebola personal protective equipment guidelines



Keywords:
Ebola virus diseases (EVD)
Infection control (IC)
Healthcare workers (HCWs)
Personal protective equipment (PPE)

In early September 2014, we were the first to publicly challenge the guidelines of the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC) and those of many countries which suggested that medical masks be used by health care workers (HCWs) treating Ebola virus disease (EVD) (MacIntyre et al., 2014a). We argued in a previous editorial in the International Journal of Nursing Studies that in situations where there is uncertainty around the transmission mode, a risk analysis framework should be used to select personal protective equipment (PPE) and that the safety of HCWs should be a priority (MacIntyre et al., 2014a). Our editorial attracted considerable attention and comment (Jackson, 2014; MacIntyre et al., 2014b; Martin-Moreno et al., 2014). The CDC has since changed their guidelines, but the WHO has yet to do so (CDC, 2014a). In this paper we discuss the events that influenced the modification of EVD guidelines and factors to be considered in developing frameworks for protection of HCWs.

The current epidemic of Ebola is a global health catastrophe, with the number of cases exceeding 19,000 in December 2014 (WHO, 2014a,b). Official figures are highly likely to be underestimated because many cases are not reaching health-care facilities or being reported. This is an unprecedented epidemic, being the largest in history; the first time Ebola has occurred in more than one country simultaneously; the first time it has affected urban areas and capital cities; and the first time it has been transmitted

outside of Africa (WHO, 2014b). To date around 666 HCWs have been infected and more than half have died (WHO, 2014b). This level of infection requires a more comprehensive analysis of risk-including the health status of health professionals, which may include increased susceptibility of certain individuals. In many countries, particularly in Africa, HCWs may be living with HIV and other health conditions which impair immunity (Connelly et al., 2007; WHO, 2014c).

As long as the Ebola epidemic is uncontrolled in West Africa, there will be an ongoing risk of travel-related cases being imported into other countries (Tatem et al., 2006). One such case has already occurred in the United States (US) and led to the infection of two nurses who were infected despite apparently following guidelines for personal protective equipment. Initially it was suggested that their infections were due to breaches in protocol (Dart, 2014), however, there is no evidence to prove how or why they became infected, and the nurses themselves do not recall any breach (AP, 2014). The cause of their infection may equally have been inadequate protocols for PPE (MacIntyre et al., 2014a,b). In this regard many of these guidelines have failed to consider the voluminous amount of excreta and also the degree of exposure of nurses that care for individuals who are seriously ill (Berry and Davidson, 2006).

Until October 2014, the US Centers for Disease Control (CDC), recommended medical masks for protection of HCWs treating Ebola (MacIntyre et al., 2014a). In addition,

the CDC provided guidelines for the donning and doffing of protective wear for Ebola which appeared to be the same as those for other non-lethal infections (CDC, 2014b). These suggested only a single pair of gloves, and suggested that the second glove be removed by hooking a bare finger under the glove. Given the gloves are likely to be the most contaminated item of PPE, this would pose a high risk of contamination of the bare finger. These guidelines also failed to mention protective head covering, boots or footwear. It appeared that many aspects of HCW protection against Ebola, including the most critical aspects of protection against direct contact were not considered even after several cases of Ebola had been treated in the US. These guidelines also did not consider the complex psychomotor processes of donning and doffing as well as individual health care worker characteristics, including fatigue and potential comorbid conditions (MacIntyre et al., 2014a). Disappointingly there was a climate of naming and shaming of victims, fuelled largely by the popular media and clouding the importance of evidence-based recommendations.

Canadian health authorities responded by recommending more stringent personal protection requirements (Public Health Agency of Canada, 2014). Under increasing scrutiny following the infection of two nurses and with advocacy by nurses, the CDC has changed their guidelines on October 21st to include double gloving, respirators as well as head and foot protection (CDC, 2014a). The donning and doffing poster was also removed after being publicly challenged in the media (Orwellian, 2014), and replaced with a video demonstrating donning and doffing technigues (Medscape, 2014). In contrast, the WHO issued updated guidelines at the end of October 2014 for PPE against filoviruses, which retained the previous recommendation for medical masks for health workers caring for Ebola patients (WHO, 2014d). The October updates contained no substantive changes except for changing double-gloving from an optional consideration to being recommended. The WHO recommends covering the mouth, nose and eyes to protect the mucosal surfaces and to cover hands to prevent infection through contact. Duckbill or cup shaped medical masks are recommended for HCWs so that they do not collapse against the mouth. Practically these types of medical masks are not commonly used in the healthcare setting. A respirator is only recommended by the WHO when conducting an aerosol generating procedure (AGP). No explanation is offered as to why there is a lower level of protection than that suggested in the 1998 version of the WHO guidelines, which recommended respirators for all health workers proving care to Ebola patients (Centers for Disease Control and Prevention and World Health Organization, 1998). Nor is there any explanation for the inconsistency in lower levels of protection recommended for HCWs compared to those for laboratory scientists working with Ebola. The hospital is a far more contaminated and unpredictable environment than the laboratory, making the lower level of protection recommended for HCWs difficult to understand. The WHO has not provided any transparent, evidence-based reasoning or added any references to support their insistence on medical masks for Ebola (WHO, 2014d).

PPE guidelines for infection control have been traditionally driven by the paradigm that infections are transmitted by contact, droplet or airborne routes, and that these are mutually exclusive routes. Central to this view is the belief that only large droplets are found close to the patient, and that smaller aerosolized droplet nuclei travel further from the source. This is based on experiments performed by aerobiologists from the 1940s and 1950s using much less sophisticated measuring tools than those available today (Brosseau and Jones, 2014; Wells et al., 1948, 1946; Wells, 1943), Current evidence is that both small and large droplets may be present close to the patient, that aerosol transmission can occur in close proximity to the source, and that aerosols can be generated even without AGPs (Brosseau and Jones, 2014). In other words, modern methods show that pathogen transmission is far more complex than suggested by these outdated experiments, and that most pathogens can be transmitted by several modes (MacIntyre et al., 2014a). Influenza is a good example, which has traditionally been believed to be primarily droplet spread, yet more recent work demonstrates that it can also be spread by the airborne route (Blachere et al., 2009). It has been argued that it is time to reject the paradigm of droplet versus airborne transmission as artificial, which then removes the major premise upon which PPE guidelines have been made until now (Brosseau and Jones, 2014).

At the same time as recommending medical masks for HCWs, health authorities have conveyed certainty about Ebola transmission (CDC, 2014c,d). The CDC states that Ebola can *only* be transmitted by direct contact with blood and bodily fluids (CDC, 2014c). However, Ebola is poorly studied compared with other infections, being previously limited to small outbreaks since its discovery in 1976 (Pourrut et al., 2005). To put it in perspective, on Pubmed (National Institutes of Health, 2014) there are some 80,000 scientific publications on influenza compared to a mere 2000 or so on Ebola, a large proportion published during the 2014 epidemic (MacIntyre, 2014a). Therefore there is no basis for being certain about Ebola transmission, the understanding of which is central to PPE recommendations and control of the epidemic.

The principal mode of transmission is through direct contact with blood and bodily fluids or contaminated medical instruments (including needlestick injuries), however, several animal studies have shown transmission without direct contact (Dalgard et al., 1992; Jaax et al., 1995; Johnson et al., 1995). The most extensively studied human outbreak was in 1995 in Kikwit in the Democratic Republic of Congo. In this outbreak, there were 55 cases of Ebola where the risk factor for infection was initially unknown. A detailed epidemiologic investigation identified plausible risk factors for most of these, but 5/19 cases who visited an Ebola patient in their home became infected without direct contact (Roels et al., 1999). More questions have been raised from the 2014 Ebola epidemic in the Democratic Republic of Congo, where eight cases are described as having occurred within the incubation period of the index case, but without direct contact with that case (Maganga et al., 2014). To add to this uncertainty, it has been documented that numerous health workers using PPE

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