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

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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,

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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 techniques (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

in the current epidemic have contracted Ebola despite no direct contact (Cohen, 2014). The likelihood of respiratory transmission being a secondary mode of transmission is further supported by the finding of high levels of Ebola virus in the lung (Martines et al., 2015). Yet the sum of this evidence has repeatedly been ignored or its relevance minimized in the current PPE controversy.

A common public health message in developed countries is that Ebola is "hard to catch". More likely given current experience is that it is more effectively *treated* and treated earlier in developed countries, rather than harder to catch. The apparent contradiction inherent in this oft-chanted mantra is obvious when we consider that:

1. The epidemic in West Africa was amplifying exponentially until October 2014.
2. Health workers using full PPE (including in the US and Spain) have become infected.
3. The reproductive number of Ebola in this outbreak is consistently estimated to be around 2 (Althaus, 2014; Fisman et al., 2014; Meltzer et al., 2014; Nishiura and Chowell, 2014), which is the same as pandemic influenza. In some outbreaks, such as in the DRC (Maganga et al., 2014) and Nigeria (Fasina et al., 2014), the R0 from the index case has been between 12 and 21, which is higher than most known infectious diseases. In comparison, MERS Coronavirus, has a much lower R0, estimated to be around 1 or less (MacIntyre, 2014b).
4. Ebola results in an enormously high viral load in the blood and body fluids, the likes of which are not seen with other viruses (Martines et al., 2015; Wong et al., 2014).

We have argued for use of the precautionary principle for Ebola given the uncertainties around transmission, the high viral load, the high case fatality rate, and the absence of proven treatments or vaccines (MacIntyre et al., 2014a). There is also the potential that the rigor of wearing N95 masks may prevent work-arounds and emphasize the importance of protective principles.

It is also important to ask why so many health workers using PPE and with no history of direct contact, and others with only minimal contact have become infected (Cohen, 2014; MacIntyre, 2014c). Whilst authorities have blamed breaches in infection control protocols, there are at least three explanations as to why health workers who followed PPE guidelines may have become infected (MacIntyre, 2014c). It may well be true that there could have been lapses in infection control or that mistakes with donning and doffing could have been made. However, it may equally be true that the PPE guidelines were likely not sufficient for protecting health workers from secondary modes of transmission such as aerosols. A third explanation is that health workers may have been infected somewhere other than while providing clinical care to Ebola patients, which is possible in the West African setting, a scenario supported by Dr Kent Brantley who believes this to be the case, as he used strict PPE in the Ebola ward (Cohen, 2014). Several health professionals from Sierra Leone, including the leading viral hemorrhagic fever expert Dr Sheik Hummar Khan and the head nurse of the Lassa fever Ward, Mbalu Fonnie, used full PPE and still succumbed to Ebola (Vogel, 2014). It is speculated that others among their colleagues became infected in the community and not at work, but there is no proof as to where they acquired the infection (Vogel, 2014).

A reasoned approach to understanding health worker infections with Ebola must consider all possible explanations. In the US and Spain, the third explanation of infection outside the clinical care setting is unlikely, which means lapses in protocol and faulty guidelines must both be considered. In Spain, the infected nurse was blamed for her infection (Fischer et al., 2014), reportedly contaminating her face with a glove as she doffed. Yet recall bias is likely in this situation, where an infected nurse, if asked a leading question, is likely to remember perceived risks differently to a nurse who is not ill. Whilst lapses in protocol are possible, particularly when staff are exhausted, inadequate guidelines and recommendations must also be considered, as they were in the US following the infection of two nurses. The second US nurse to become infected was surprisingly considered a "low risk" contact because she had nursed an Ebola patient using recommended PPE, and was therefore allowed to catch a flight whilst incubating (and possibly in the early stages of) the infection (Davidson, 2014). Why was a nurse who treated the patient considered a low risk contact?

Ebola is clearly a serious occupational health and safety risk for health workers, many of whom have become infected despite using PPE. For example, in the Kikwit outbreak, attending a funeral increased the risk of infection by three times, whereas being a HCW increased it by 9 times (Roels et al., 1999). At the time of our original editorial, no Médecins Sans Frontières (MSF) worker had been infected (MacIntyre et al., 2014a), but in the short space of two months since then, 23 MSF workers have become infected, despite their strict protocols (MSF, 2014). This risk to HCWs must be recognized and reflected in conservative guidelines for protection.

During this epidemic, governments and agencies planning for Ebola have drawn on lessons from pandemic influenza planning. This is helpful in some instances, but dangerous in others—Ebola is unlike influenza in several respects, including the major biological waste management issues and the vastly higher case fatality rate. The case fatality rate of Ebola is 50–90% which is far higher than the 2009 influenza pandemic (0.01%) (WHO, 2009) and even SARS (9.6%) (WHO, 2014e). Even the lower case fatality rate observed in the US is orders of magnitudes higher than the last pandemic of influenza. The consequence of making mistakes with influenza guidelines may be a few weeks off work, but for Ebola, there is a high probability of death, so there is far less margin for error in formulating guidelines for infection control.

In infection control, most guidelines which heath workers are asked to follow, such as guidelines for vaccination, inserting intravenous lines or for handwashing, are driven primarily by concerns about patient safety and protecting patients from nosocomial infection. In hospital infection control, patient safety is important

because they are ill and vulnerable, may be immunosuppressed, and a healthcare associated infection may adversely impact on overall morbidity and mortality.

The discipline of infection control has developed from a patient safety perspective primarily (Brosseau, 2014), which may explain the sometimes casual approach to HCW protection witnessed during this Ebola epidemic. With Ebola, HCWs too are vulnerable, and are at high occupational risk for infection. The primary purpose of guidelines for Ebola PPE should be the protection, occupational health and safety of the HCW as well as preventing transmission of infections. Given the desperate global shortage of HCWs, particularly in West Africa (Chen et al., 2004), and the importance of maintaining a health workforce which is confident about their own safety, it is critical that they be afforded the best protection possible when dealing with a formidable disease such as Ebola.

The Ebola epidemic has also cast a spotlight on emerging infectious diseases and has highlighted uncertainty, inconsistency and ambiguity in guidelines during an emerging epidemic (Cowling and Yu, 2014). The epidemic ravaging Africa has cast a spotlight on the need to deal with uncertainty and in the case of equipoise, one should move forward with a judicious and measured approach to managing risk. Understanding knowledge, attitudes, beliefs and human behaviors are likely to be as important to the protection of HCWs as is the understanding the biology of the virus. In order to protect the health of the individual, scientists and health care professionals need to be responsive to an evolving understanding of epidemiology and biology and not be hesitant in challenging previous recommendations in light of emerging evidence or field observations.

Conflict of interest

CR MacIntyre has conducted several investigator driven trials of respirators vs face masks, one of which was funded by an Australian Research Council Linkage Grant, where the industry partner was 3M, a manufacturer of PPE. 3M also provided supplies of surgical masks and respirators for the investigator-driven trials in health workers in China. H Seale was also involved in this research as a co-investigator. A Chughtai has had filtration testing of masks for his PhD thesis conducted by 3M Australia.

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