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Letters to the Editor

Counterfeit filtering facepiece respirators are posing an additional risk to health care workers during COVID-19 pandemic



To the Editor:

Occupational safety measures, such as the use of appropriate personal protective equipment (PPE), are of great importance during an epidemic or pandemic. These situations are usually characterized by a shortage of PPE supplies, especially in nonproducer countries. This was also the case of the current coronavirus diseases 2019 (COVID-19) pandemic.¹

From the beginning of the COVID-19 pandemic, a huge number of health care workers have been infected and died.² The spread of the virus and the lack of appropriate knowledge about the transmission routes lead a sense of insecurity in the general population, causing panic buying (and shortage) of filtering facepiece respirators (FFR).

FFR are disposable protective devices, supposed to protect from the inhalation of droplets and droplet nuclei (eg, FFP2, FFP3, N95, KN95).³ Their filtration properties and fit characteristics are attested according to national regulations. An appropriate certification and a correct label usually attest the adherence to these regulations proving safety for the wearer. Even if slightly variable, national regulations usually provide for similar standard test conditions, and FFR from different countries can be referred as “equivalent.”³

During the current COVID-19 pandemic, some institutions had to rely on private donations for PPE provision. Besides, many health care workers have decided to get their PPE on their own, from unofficial retailers or using e-commerce. In this context, it may be difficult

to perform quality control checks, with the risk for health care of receiving and using low-quality products or frauds in clinics.

The phenomenon of counterfeiting or altering FFR is not new, and it has already been reported during 2009 flu epidemic. The US Occupational Safety and Health Administration had already issued warnings about the importance to check for the presence of markings witnessing the certification by National Institute for Occupational Safety and Health (NIOSH). Counterfeit FFR are defined as “products that are falsely marketed and sold as being NIOSH-certified and may not be capable of providing appropriate respiratory protection to workers, and altered FFR as ‘non-approved modifications to a NIOSH-certified respirator’.”⁴

Beside the lack of availability, the cheapness of counterfeit FFR is another common reason for their easy spread in the market. The presence of an industrial lockdown, imposing a stop to non-necessary productions, can also lead factories to perform a rapid reconversion toward the production of FFR, thus contributing to the attractiveness of counterfeiting. Moreover, FFR can be altered just to enhance their appearance. This is the case of the so-called “fashion respirators,” including original respirators with additional logos, decorations or materials glued or stapled. All these cases represent risks for workers’ safety.

Several cases of counterfeiting have already been reported.⁵ The Center for Disease Control and Prevention (CDC) has listed out some suspect characteristics of counterfeit respirators. Table 1 summarizes the main suspect characteristics of counterfeit compared to appropriate FFR.⁵ Among the suspect features, there are ear loops designs, the absence of markings or references to national regulation or approval number on the FFR or the presence of flawed ones, the presence of decorative add-ons, a declared approval for children or multiple packaging.

The CDC has provided additional tips for the users to detect unreliable sellers, for example, when unlimited stocks are declared or if websites contain bad grammar and other errors.⁶ The European Commission offers an alert system for dangerous products, including FFR, to receive reports from the authorities of the member states about suspected products found on the market. Through the EU

Table 1
A comparison between legitimate and potentially counterfeit FFR

	Legitimate	Potentially counterfeit
Design	Headbands	Ear loops
Markings	Approval number Brand name or registered trademark Filter class and filtering efficiency level	No approval number No name or altered name Filter class and filtering efficiency level can be both present or absent or spelled incorrectly
External appearance	Clear referring to national regulation No decorations	No markings or flawed reference Decorative materials or add-ons
Declared approval	For adults only	For adults or children
Seller	Authorized, consistent prices and items over time, email address connected to the website as primary contact,	Previously trading different items (ie, trendy items), price fluctuations, hidden contacts or free email as primary contact, blank pages, broken links or errors in the website.

FFR, filtering facepiece respirators.

commission portal, users can search for alerted products, seeing pictures, characteristics and if measures were ordered by public authorities. It is also provided a list of contacts to make a report to national authorities.⁷

To date, the risk of infection associated with the use of counterfeit FFR has not been estimated since no specific data are available. However, it is reasonable to believe that counterfeit FFR pose an additional risk of contagion to health care workers due the potentially lower protecting capacity. An analysis conducted by the US National Personal Protective Technology Laboratory demonstrated that the filtering capacity of not NIOSH-approved FFR can vary considerably, from 24.1% to equal to the standard (minimum level >95% for N95 type).⁸

Health care workers should alert local competent authorities when in doubt about the appropriateness of FFR in use. Should health care workers' safety rely on the individual ability to detect counterfeit FFR before using? Are institutions making all the possible efforts to avoid making these products available to health care workers?

Countermeasures are urgently needed at both government and institutional levels. Informative campaigns to increase awareness, formal training on how to recognize counterfeit FFR and rigid quality standard check before the distribution to health care setting can help limiting the risk associated with this phenomenon.

The table briefly provides the characteristics of legitimate FFR in comparison with potentially counterfeit ones that can be used as warnings signs for the user. Information were retrieved from CDC.^{5,6}

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It's not the heat, it's the humidity: Effectiveness of a rice cooker-steamer for decontamination of cloth and surgical face masks and N95 respirators



To the Editor

In the setting of the coronavirus disease 2019 pandemic, health-care facilities have been forced to adopt strategies to extend or reuse personal protective equipment (PPE) such as N95 filtering facepiece respirators and surgical face masks.¹ Cloth face masks worn in public settings where social distancing cannot be maintained are also typically reused multiple times between laundering. A variety of strategies for decontamination of PPE are under investigation, including use of ultraviolet light and hydrogen peroxide vapor.² However, sending used respirators to a central processing facility for hydrogen peroxide vapor treatment is likely to be labor-intensive and costly and ultraviolet light is suboptimal for decontamination of soft surfaces.³ There is an urgent need for simple and widely available methods to decontaminate PPE, including cloth masks.

One potential method to decontaminate face masks and respirators is moist or dry heat.³ Previous reports suggest that moist heat at 65°C for 20 minutes is effective against viruses such as influenza.^{3,4} In Taiwan, 1 common practice used for decontamination of cloth face masks is using a short cycle of treatment in a rice cooker or other kitchen steamer. This method has the advantage of being widely available and easy to use, particularly for cloth face masks. Therefore, we evaluated the efficacy of steam treatment applied via a rice cooker-steamer vs similar levels of dry heat for decontamination of cloth and surgical face masks and N95 respirators.

We studied surgical face masks (Precept; Arden, NC), 3M 1860 N95 respirators (3M; Saint Paul, MN), and cotton and quilting fabric cloth face masks being distributed to visitors and personnel not involved in direct patient care at a Cleveland area hospital. The test organisms included a clinical isolate of methicillin-resistant *Staphylococcus aureus* and the nonenveloped, single-stranded RNA virus bacteriophage MS2 which was prepared as previously described.³ The test protocol has been reported previously.³ In brief, 10- μ L aliquots containing 10⁶ colony-forming units or plaque-forming units of the test organisms suspended in 8% simulated mucus were inoculated onto 1-cm² areas on both the outer or inner surfaces of the respirators or face masks.³ The inoculated masks or respirators were subjected to a cycle of treatment in a steamer (Aroma; San Diego, CA) lasting approximately 13-15 minutes, including 8-10 minutes of heating and 5 minutes of steam. For comparison, inoculated masks or respirators were subjected to dry heat at 100°C for 15 minutes in an oven (Thermo Fisher Scientific; Waltham, MA). After treatment, the