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# Counterfeit Filtering Facepiece Respirators are posing an additional Risk to Healthcare Workers during COVID-19 Pandemic

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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 non-producer 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 healthcare 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 (e.g. 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 healthcare 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 healthcare 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 U.S. Occupational Safety and Health Administration (OSHA) 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 towards 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 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 healthcare workers due the potentially lower protecting capacity. An analysis conducted by the U.S. National Personal Protective Technology Laboratory (NPPTL) 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]

Healthcare workers should alert local competent authorities when in doubt about the appropriateness of FFR in use. Should healthcare 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 healthcare 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 healthcare setting can help limiting the risk associated with this phenomenon.

**Table 1. A comparison between legitimate and potentially counterfeit FFR**

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

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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