

Protecting healthcare workers in the COVID-19 pandemic: respirator shortages and health policy responses in South America

A proteção dos profissionais de saúde durante pandemia da COVID-19: falta de respiradores e respostas a partir de políticas de saúde na América do Sul

Protegiendo a los trabajadores sanitarios durante la pandemia de COVID-19: escasez de respiradores y respuestas de políticas de salud en Suramérica

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Background

As a region, Latin America has been disproportionately affected by coronavirus disease 2019 (COVID-19). As of September 2020, seven of the twenty countries with the most COVID-19 deaths were in Latin America, with Brazil having the second-highest number of deaths behind the United States (Johns Hopkins University. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). <https://coronavirus.jhu.edu/map.html>, accessed on 15/Sep/2020). Latin America has been particularly vulnerable to COVID-19 due to income inequality ¹ and underequipped public health systems ^{2,3}.

The COVID-19 pandemic has created major disruptions of the global personal protective equipment (PPE) supply chain, resulting in unprecedented shortages ^{4,5}. Few publications have discussed PPE availability in low- and middle-income countries, particularly in Latin America ³. Although Latin American ministries of health ^{6,7}, medical societies ⁸, and the Pan American Health Organization (PAHO) ^{9,10} have released PPE guidelines, we can still find reports of limited PPE for healthcare workers across the region ^{2,11,12}.

While there have been shortages of all types of PPE, of particular importance are filtering face-piece (FFP) respirators, which filter inhaled air and are used to protect healthcare workers directly caring for COVID-19 patients ⁴. Various FFP respirators exist, such as the N95, KN95, and FFP2 models ¹³. We refer to all as respirators, unless specific make is relevant. This report aims to provide insight into health policy responses to respirator shortages in South America during the COVID-19 pandemic, focusing on quality regulation and extended use, reuse, and decontamination policies in Bolivia, Brazil, Colombia, and Peru (Table 1), which were chosen for inclusion based on existing institutional collaborations.

Respirator availability

Few reports quantify the respirator shortage in Latin America, and most data are from cross-sectional, convenience sample surveys of healthcare workers conducted in the early months of the pandemic. For example, in April 2020 the Inter-American Society of Cardiology surveyed healthcare

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workers from 20 Latin American countries and found only 56% of respondents had access to N95 respirators¹¹. A survey of surgeons in Brazil similarly found that 57% reported N95 respirator availability¹⁴. A national survey from Colombia in April 2020 found nearly 90% of queried healthcare workers did not have respirators available at their institution¹⁵, and another survey from Colombia's Department of Cauca found 15% of healthcare workers reported having to obtain a respirator on their own for use at work in the previous week¹⁶.

While there aren't readily available data quantifying respirator availability in Bolivia or Peru, in our experience there are depleted stocks in both countries. In the rural department of Potosí, Bolivia, for example, only certain hospitals have access to respirators, which are designated for use in specific "COVID-center" areas. Smaller health facilities in Potosí lack access to respirators; should a patient with suspected COVID-19 infection arrive, they are directed to a hospital with a "COVID-center", which may be several hours away. Consequently, many healthcare workers have resorted to purchasing their own respirators.

In response to severe shortages, in March 2020 Brazilian Health Regulatory Agency (Anvisa) advised rationing of respirators and donation of respirator stocks to the public health service¹⁷. By the end of May 2020, the governments of Brazil (Ministério da Saúde. Painel de leitos e insumos. <https://covid-insumos.saude.gov.br/paineis/insumos/painel.php>, accessed on 25/May/2020) and Colombia¹⁸ reported national distribution of large quantities of respirators. PAHO⁹, United Nations Children's Fund¹⁹, and the Colombian Red Cross²⁰ have also been enlisted to provide respirators to regions where shortages have been most severe. However, without data quantifying need, it is difficult to determine the impact of these distributions on shortages. To that end, the U.S. Centers for Disease Control and Prevention (CDC) developed a PPE supply tracker, which includes a burn rate calculator that can be used by individual facilities to determine respirator supply needs (CDC. Personal protective equipment: NIOSH PPE tracker app. <https://www.cdc.gov/niosh/ppe/ppeapp.html>, accessed on 10/Sep/2020).

Quality regulation

Most Latin American countries rely on respirator imports²¹. For example, in Brazil, China remains the primary source of respirators (43.7%) approved by Anvisa, though the percentage manufactured in Brazil (33%) is increasing due to COVID-19-related demand (Anvisa. Banco de dados de produtos para saúde registrados. https://dados.anvisa.gov.br/dados/TA_PRODUTO_SAUDE_SITE.csv, accessed on 12/Jun/2020) Surging demand brings concerns about quality of imported respirators, which must meet specific particle filtration standards⁴. In the United States, imported respirators are tested to identify faulty products²². Of the internationally manufactured N95 respirators tested by the end of May 2020, more than half had a minimum filtration below the required 95%.

Each country has its own regulatory authority tasked with ensuring quality of imported respirators (Table 1)²³. In response to quality concerns identified elsewhere²², Anvisa issued a precautionary ban on certain respirators which did not meet filtration specifications²⁴. All of the banned respirators were manufactured in China, and were allowed to be re-registered as non-FFP masks. In May 2020, the Peruvian General Directorate of Medicines, Supplies and Drugs (DIGEMID) released a list of technical recommendations for imported respirators, including a list of international suppliers to confirm product legitimacy²⁵.

The Colombian National Institute for Food and Drug Surveillance (Invima) eased the approval process for PPE imports²⁶. However, given concerns about respirator quality, easing regulations risks quality issues. The registration data required by Invima for respirator imports include manufacturer, production date, and origin country health authority certification. Invima does not specifically address filtration quality concerns, but does provide a list of approved domestic suppliers²⁶.

The Bolivian State Agency for Medicines and Health Technologies (AGEMED) has not provided clear guidance on respirator standards⁷.

Table 1

Health policy responses pertaining to respirator shortages during the COVID-19 pandemic.

Country	Global rank: COVID-19 deaths *	Regulatory authority ²³	Quality regulation	Extended use/ Reuse	Decontamination	Publication date
Bolivia	22nd	AGEMED	NA	NA	NA	NA
Brazil	2nd	Anvisa	Anvisa addresses imported respirator quality concerns ²⁴	Guidelines from Anvisa ²⁸	Guidelines not specified	May/2020 ^{24,28}
Colombia	11th	Invima	Invima specifies registration requirements for imported respirators ²⁶	Guidelines from medical societies ^{8,29}	Guidelines from medical societies ^{8,29}	Mar/2020 ⁸ ; May/2020 ²⁹ ; Aug/2020 ²⁶
Peru	8th	DIGEMID	DIGEMID addresses imported respirator quality concerns ²⁵	Guidelines from DIGEMID ⁶ and IETSI ³⁰	Guidelines from DIGEMID ⁶ and IETSI ³⁰	Mar/2020 ³⁰ ; May/2020 ^{6,25}

AGEMED: Bolivian State Agency for Medicines and Health Technologies; Anvisa: Brazilian Health Regulatory Agency; DIGEMID: Peruvian General Directorate of Medicines, Supplies and Drugs; IETSI: Peruvian Institute for Health Technology Assessment and Research; Invima: Colombian National Institute for Food and Drug Surveillance; NA: not available.

* Johns Hopkins University. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU) (<https://coronavirus.jhu.edu/map.html>, accessed on 15/Sep/2020).

Extended use, reuse, and decontamination

When respirator shortages cannot be alleviated by increased production or importation, extended use or reuse of respirators may be permitted. The World Health Organization (WHO) states that reprocessing and decontamination of respirators should only be done when facing critical shortages, and only if the functional integrity can be maintained ^{4,10}. The WHO ⁴, PAHO ¹⁰, and N95Decon ¹³, a consortium focused on protocols for N95 respirator decontamination, present several decontamination techniques which do not compromise the filtration capability of respirators, including UV-C irradiation, hydrogen peroxide vapor, and moist heat. While the WHO states respirator decontamination is potentially feasible in low- and middle-income countries ⁴, few low- and middle-income countries have policies in place ²⁷.

In Brazil, respirators may be reused under the following conditions: the respirator must be inspected to ensure functional integrity, and used by the same healthcare worker who is also wearing a face shield ²⁷. However, Anvisa does not specify decontamination techniques for respirators ²⁸ and states that guidelines for decontamination should be determined by the Hospital Infection Control Commission along with individual facilities ²⁸.

The Colombian Infectiology Association (ACIN) ⁸ and Colombian Emergency Medicine Association (ACEM) ²⁹ provided guidance on reuse and decontamination. ACIN recommends the UV-C irradiation, hydrogen peroxide vapor, or microwave techniques for respirator decontamination, or, alternatively, the use of elastomeric respirators or powered air-purifying respirators ⁸. ACEM ²⁹ outlines four decontamination techniques, including UV-C irradiation, hydrogen peroxide vapor, and moist heat, but encourages individual institutions to develop their own protocols. Some hospitals in Colombia have implemented protocols using UV-C irradiation or hydrogen peroxide vapor; however, this is limited to large hospitals in more populated cities.

The Peruvian Institute for Health Technology Assessment and Research (IETSI) published a review in March 2020 on guidelines for extended use and reuse of respirators ³⁰. In response, DIGEMID released its own guidelines ⁶. Extended use is permitted for up to 12 hours, as long as

fit and function is maintained, and respirators may be reused up to five times. DIGEMID also presents various methods for decontamination, but states that healthcare facilities should develop their individual protocols ⁶.

We are not aware of any documents specific to Bolivia which address extended use or reuse of respirators. Certain facilities reportedly have the capabilities to decontaminate with UV radiation or ethylene oxide, which are methods endorsed by the WHO ^{4,13}. However, in hospitals without those capabilities, respirators have been decontaminated by washing with bleach or quaternary ammonium, a process known to compromise respirator filtration.

Conclusions

Our experience suggests respirator shortages remain in Bolivia, Brazil, Colombia, and Peru, but data are limited. In order to quantify the need for respirators in the region, we must obtain more data, and individual facilities should use tools such as the CDC burn rate calculator to guide supply management. As countries work to increase supply in the short term, regulatory agencies must take steps to ensure that imported respirators meet filtration specifications. Likewise, countries should work to increase domestic respirator production in order to minimize the effect of future supply chain disruptions. Reuse and decontamination of respirators should be permitted in the setting of critical shortages, but hospitals must develop protocols to guarantee decontamination methods used do not compromise respirator function. Ultimately, the access to quality respirators is necessary to make sure that healthcare workers caring for COVID-19 patients is safe, and must be a top priority across the region.

Contributors

K. J. Blair was involved with idea generation, project planning, contacting contributing authors, compiling collected data, writing and revising the manuscript, and final approval of the manuscript. S. Martinez-Vernaza and S. M. Gualtero-Trujillo were involved with the collection of data pertaining to Colombia, drafting and editing of the manuscript, and final approval of the manuscript. E. Segura was involved with the collection of data pertaining to Peru, the drafting and editing of the manuscript, and the final approval of the manuscript. J. L. G. Barrientos was involved with the collection of data pertaining to Bolivia, with the drafting and editing of the manuscript, and the final approval of the manuscript. K. Garber and C. Juillard were involved with idea generation and project planning, editing and revising of the manuscript, and final approval of the manuscript. R. Castro was involved with idea generation, project planning, collection of data pertaining to Brazil, drafting and editing of the manuscript, and final approval of the manuscript.

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