Personal Protective Equipment: Regulatory and Supply Challenges during COVID-19 in the Region of the Americas

Alexandre Lemgruber
Medicines and Health Technologies Unit, Department of Health Systems and Services
PAHO/WHO

July 2020
Disclosure

• I declare no conflict of interest.
Objectives

• Present the main challenges related to the regulation of PPE in the context of COVID-19 in the Region of the Americas.

• Present strategies to address the supply challenges related to PPE during COVID-19 in the Americas.
COVID-19 Cases Among HCW by Country (N=97,112)

From June 2 line list (2,073,175 cases)
Letter to the Editor
Reasons for healthcare workers becoming infected with novel coronavirus disease 2019 (COVID-19) in China

Sir,

The outbreak of novel coronavirus disease 2019 (COVID-19) in mainland China has been declared as a public health emergency (PHE) by the World Health Organization (WHO) on January 30, 2020. According to the latest statistics, there are 83,774 confirmed cases and 3010 deaths [1]. During the period of outbreak of COVID-19 or other infectious diseases, implementation of infection prevention and control (IPC) is of great importance in healthcare settings, especially regarding personal protective equipment (PPE), in order to contain the outbreak of COVID-19 in mainland China, the National Health Commission of the People’s Republic of China (NHCCPC) has so far dispatched medical support teams (5,400 medical workers and 1,600 medical supplies) to hospitals and communities with medical treatment in Wuhan and Hubei province [2]. A study by the Health Committee of Guangdong Province released information on the distribution of 2401 healthcare workers in the Guangdong medical support team [3]. Harris (80%) were the predominant healthcare workers in the teams, followed by clinicians (24%), half of clinicians with job titles were deputy chief physicians, and 25% specialized in respiratory and critical medicine [4]. It is worth mentioning that 5.95 (14/239) healthcare workers worked on the front line of severe acute respiratory syndrome in 2003 [5]. Meanwhile, a recent update by the WHO-China Joint Mission on COVID-19, WHO/China report showed that up to February 27, 2020, hospital workers (community hospital acquired not to be defined) had been confirmed infected with COVID-19 with 221, 151 deaths [6]. Nearly 70% of infected healthcare workers were from Hubei province, most cases happened in late January. It is worth mentioning that the proportion of healthcare workers infected by COVID-19 (15.95, 95% CI: 2.5–2.2.5) was significantly lower than SARS (21.1%, 95% CI: 0.2–22.5), [7]. Thus, the director of the National Hospital Infection Management and Quality Control Centre summarized some reasons for such a high number of infected healthcare workers during the beginning of the emergency outbreak [8]. First, inadequate personal protection of healthcare workers at the beginning of the epidemic was a critical issue. In fact, they did not understand the pathogens well and their awareness of personal protection was not strong enough. Therefore, the front-line healthcare workers did not implement the effective personal protection before conducting the treatment. Second, long-time exposure to large numbers of infected patients directly increased the risk of infection for healthcare workers. Also, pressure of treatment, workload, stress and sleep deprivation due to urgent infection for healthcare workers. Third, shortage of personal protection equipment (PPE) was also a serious problem. Frontline emergency responses have been intensified in various parts of the country, which has led to a rapid increase in the demand for PPE. This circumstance increased the risk of infection for healthcare workers due to its lack of sufficient PPE. Fourth, the frontline healthcare workers (except infectious disease physicians) received inadequate training for IPC, leaving them with a lack of knowledge of IPC for respiratory-borne infectious diseases. After initiation of emergency responses, the shortage of PPE and medical supplies has become a critical problem with daily systematic training and practice. Professional supervision and guidance as well as monitoring mechanisms were lacking. This situation further amplified the risk of infection for healthcare workers.

Finally, international communities, especially in other low- and middle-income countries, with potential COVID-19 act breaks, should learn early how to protect their healthcare workers. Furthermore, the COVID-19 confirmed cases have been reported to have surged in South Korea, Japan, Italy, and Iran in the past few days [9]. The increase in awareness of active infection control and prevention measures (IPC) and response would play an important role in lowering the risk of infection for healthcare workers.

Conflict of interest statement None declared.

Funding sources
None.

References

https://www.journalofhospitalinfection.com/action/showPdf?pii=S0195-6701%2820%2930101-8
Regulatory Challenges

• Regulation of Medical Devices in different levels of development in the Region Americas

• Shortages of conventional suppliers of PPE
  ▪ Establishment of minimal requirements for the issuance of EUA
  ▪ Assess the equivalence between standards
  ▪ Validation of certificates

• Establishment of criteria for using regulatory reliance

• Lack of National Laboratories to perform tests in order to confirm the conformity with the performance standards

• Establishment of Regulatory Framework for innovations and local initiatives

• How to make regulatory requirements more flexible without compromising the safety

• Technovigilance even more important with the emergency use authorization

• Increase of substandard and falsified medical products during COVID-19 (COVID-19-related Trafficking of Medical Products as a Threat to Public Health, United Nations Office on Drugs and Crime, 8 July 2020)
Fraudulent and unauthorized N95 respirators may not protect consumers against COVID-19

Starting date: April 14, 2020
Type of communication: Advisory
Subcategory: Medical Device
Source of recall: Health Canada
Issue: Product Safety
Audience: General Public
Identification number: RA-72707

Last updated: 2020-04-14

Summary

- Product: Fraudulent N95 respirators
- Issue: Health Canada is warning Canadians about the risks of using fraudulent and unauthorized N95 respirators, as they may not protect consumers against COVID-19.
- What to do: Check whether your N95 respirator has been certified by the U.S. National Institute for Occupational Safety and Health (NIOSH). If your mask is fraudulent or unauthorized, stop using it as it may not protect you against COVID-19.

What you should do

Media enquiries

Public enquiries

OTTAWA - Health Canada has received reports that fraudulent and uncertified N95 respirators that falsely claim to protect consumers against COVID-19 are being illegally sold to consumers online and in some stores.

In Canada, N95 respirators are regulated by Health Canada as Class I medical devices and are manufactured or imported by companies that hold a Medical Device Establishment Licence. They are also certified by the U.S. National Institute for Occupational Safety and Health (NIOSH).
Mapping of the Regulation of Medical Devices in the Americas Region

- Assessment tool (2017)
  - Sent to the NRA members of the Regional Network of NRA.
  - Feedback received from 21 countries.
Some of the results show the following:

- The legal provisions of 18 countries establish the scope, functions, attributions and responsibilities of the Medical Devices National Regulatory Authority.
- The legal provisions of 12 countries require the National Regulatory Authority to implement a national monitoring system for collecting information about the safety and effectiveness of Medical Devices.
- The National Regulatory Authority of 9 countries have an official laboratory testing for Medical Devices.

➢ There are 3 countries that do not comply with any of the above.
➢ Only 7 NRA comply with all of the above.
Regulation of Medical Devices in the context of COVID-19

- Search for information related to **marketing authorization requirements**; **manufacturing**; **technical specifications**; and **recommendations** for use of:
  - Ventilators;
  - **Personal Protective Equipment (PPE)**
  - 3D printing

- Information from:
  - Members of IMDRF
  - Members of the Regional Working Group on Regulation of Medical Devices
  - Other selected agencies
  - PAHO/WHO
  - Open access standards related to COVID-19

- Document in Spanish and English.
- Updated periodically
Examples of Regulation of PPE in the context of COVID-19 in the Region of the Americas

**ANMAT, Argentina:**
- Simplified mechanism for the expansion and/or initial authorization for the import or manufacture of critical medical products related to the COVID-19 pandemic.
- Emergency mechanism for imported **medical masks and gloves** for 60 days.

**ANVISA, Brazil:**
- Simplified process for marketing authorization of **PPE** and other products; priority given to the requests related to PPE, ventilators and other strategic medical devices for the response to COVID-19; no need for the manufacturer to be previously licensed by Anvisa.

**Health Canada:**
- Interim order respecting the importation and sale of medical devices for use in relation to COVID-19; 3D **printing** and other manufacturing of **personal protective equipment** in response to COVID-19.

**DINAVISA, Paraguay:**
- Resolution DNVS DG N° 013/2020 - Requirements and abbreviated procedures for the authorization of establishments that carry out activities linked to the elaboration, import and commercialization related to disinfectants, alcohol gel, alcoholic solution, **masks and disposable gloves**
Reliance on decisions and regulations of other NRAs

Using decisions of other regulatory authorities to authorize the emergency use of medicines and other health technologies in a pandemic (e.g., COVID-19) (Spanish only) April 27, 2020

- Exceptional circumstances
- Risk assessment
- Emergency use authorizations
- Reference NRAs
- Technical requirements for EUAs for medicines and IVDs
- Decision making
- Postmarketing surveillance
PAHO eligibility criteria for PPE

Quality Management System
The products must be manufactured in compliance with ISO 13485, or an equivalent quality system.
And/or
Certificate of Good Manufacturing Practice (GMP), issued by the National Regulatory Authority of the country of manufacturer.
And/or
MDSAP inspection documentation.

Conformity with regulatory requirements
In the country of origin and at least one of the members of the International Medical Device Regulators Forum (IMDRF):
- Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the United States of America.

Standards
Products must be in alignment with the technical description and with specific standards.
Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages

Audience:
- Regulatory authorities
- Healthcare facility managers
- Decision makers on the use and prioritization of PPE

- June 10th, 2020
- Available in English and Spanish

Challenges in local regulations for reprocessing of respirators

Training of HCW
- Handling of used respirators.
- Proper use of reprocessed respirators

Local validation testing
- Preservation of fit and shape.
- Maximum number of reprocessing cycles.

Protocol of the process
- Human resources, equipment, procurement of consumables, and health worker safety.
- Specific container for reprocessing
- Labeling system
- Predetermined number of reuses
- Procedure for disposal.
Strategies to optimize the availability of respirators

- Minimize respirator need
- Rational and appropriate use of respirators
- Coordinate supply chain management

Optimization of availability of respirators
Regulation of N95 reprocessing in the Region of the Americas

Any N95 reprocessing method that is going to be adopted must be regulated by the competent local regulatory authority.

Regulations:
- USFDA
- Health Canada

Technical notes:
- ANVISA
- Guidelines:
- Ministry of Health of Uruguay

Minimum requirements and essential information:
- Reduce pathogen burden
  - bacterial sporidical testing, viral inactivation testing
- Maintain performance
  - particle filtration efficiency, bacterial filtration and fit testing, maximum suggested reprocessing cycles
- Demonstrate acceptable residual limits
- Provide adequate labelling to users/reprocessors

• List of Priority Medical Devices in the context of COVID-19. 11 May 2020. PAHO/WHO. Available at: https://iris.paho.org/handle/10665.2/52366

• Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages. 6 April 2020. WHO. Available at: https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages

• Using decisions of other regulatory authorities to authorize the emergency use of medicines and other health technologies in a pandemic (eg COVID-19) (Spanish only). 27 April 2020. PAHO/WHO. Available at: https://iris.paho.org/handle/10665.2/52037


Thank you!

Contact: lemgruba@paho.org