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Safe and effective re-use policy for high-efficiency filtering facepiece respirators (FFRS): Experience of one hospital during the Covid-19 pandemic in 2020

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ABSTRACT

The high transmissibility rate of the Severe Acute Respiratory Syndrome Coronavirus 2 facilitated an exponential growth in the number of infections, posing a tremendous threat to healthcare systems across the world. The use of Non-oil 95% efficiency (N95) respirators demonstrated to reduce the risk of virus transmission. The escalated demand in N95 respirators during 2020 generated a massive shortage worldwide which resulted in serious implications, one being an increase in healthcare providers' costs. In response, various optimization strategies were implemented. This study aimed to assess the implementation of a safe and effective re-use policy for high-efficiency filtering facepiece respirators (FFRs) in a high-complexity university hospital in 2020. Associated costs were estimated through a descriptive accounting analysis of resources saved. Acceptability, appropriateness, and feasibility rates were 80.5%, 78.8%, and 83.6%, respectively. With an implementation cost of approximately 10,000 USD, there was a 56.1% reduction in FFRs consumption, compared with a non-policy scenario, with savings exceeding 500,000 USD in 2020. In a pandemic scenario where it is vital to spare resources, a FFRs rational use policy demonstrated to be a highly cost-efficient alternative in order to save resources without increasing contagion risk among healthcare workers.

Introduction

The 2019 coronavirus disease (COVID-19), caused by Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), was declared a pandemic in early 2020. By October 31, 2022, more than 6.5 million people had died of the disease worldwide [1]. The high transmissibility of this pathogen enabled exponential growth in the number of infections, posing a tremendous threat for health systems in the world [2–5].

Non-oil 95% efficiency (N95) respirators, also known as high-efficiency filtering facepiece respirators (FFRs), were approved by U.S. National Institute for Occupational Safety and Health, and widely used since the beginning of the pandemic as part of the personal and protective equipment (PPE) against SARS-CoV-2 [6]. The use of FFRs demonstrated to reduce the risk of virus transmission, especially in aerosol-generating procedures [7]. However, the escalated demand in FFRs during 2020 generated a massive shortage worldwide which resulted in serious implications [8,9].

In Italy, an insufficient quantity of PPE was the unfortunate cause of contagion and deaths of thousands of healthcare workers. In less than three months, after the first case was confirmed, more than 8% of healthcare personnel were infected with SARS-CoV-2 [10]. In low and middle-income countries, the situation was especially dire. For instance, by December 31, 2020, approximately 16.7% of health workers in Colombia had been infected [11].

The escalated demand for PPE likewise markedly increased healthcare providers' costs. In the United Kingdom, billions of PPE units were purchased with increases in value per unit of up to 1277%, elevating costs by 10,000 million sterling pounds compared to prices in 2019 [12]. In the United States, there was also an increase in such costs of up to 2000% [13]. This market competition left small health facilities and middle and low-income countries' health centers with the low ability to acquire PPE, as they were forced to buy fewer units at very high prices [14].

In response, various PPE optimization strategies were implemented. For FFRs, strategies included extended use, reuse by rotation, and reuse after disinfection [15–19]. The former strategy was based on the concept that extended use conferred greater protection compared to not using a respirator due to a residual filtration effect. The second approach con-

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Table 1
Chronology of indications for the use of FFR.

Date	Indication for FFR	Use and replacement
April 6, 2020	Healthcare workers in respiratory areas	One for each confirmed COVID-19 patient
	Surgical personnel in symptomatic or suspected COVID-19 patient case	One per procedure
	In AGP *	One per procedure
	Some health professionals †	One every 15 days
July 28, 2020	People who during their workday do not manage to maintain a physical distance of more than two meters	Two, used every other day and replaced every 15 days
	All health workers and staff during the care of any patient	Two, used every other day and replaced every 15 days
	All administrative staff with public contact	Two, used every other day and replaced every 15 days
	Staff in respiratory areas and emergency room	One for each shift
August 28, 2020	Indication for disinfection with UV chamber No change in indication	No changes in use or replacement

* AGP: aerosol generating procedures.

† Anesthesiologists, dentists, otorhinolaryngologists, pulmonologists, speech therapists, pulmonary rehabilitation staff, ophthalmologists, head and neck surgeons, endoscopy personnel, respiratory therapists with manipulation of the airway of patients must wear an FFR and obtain a replacement every 15 days.

sidered the virus's capacity of vanishing from surfaces over time, and the latter was based on the ability of physical and chemical methods to destroy the virus [16]. Ethylene oxide, heat at different temperatures and humidity, vaporized hydrogen peroxide, and ultraviolet germicidal irradiation (UVGI), all have proven to eliminate SARS-CoV-2 [17–19]. UVGI has the advantage of effectively eradicating various pathogens [20–25] without compromising the fit, appearance, odor, nor filtration capacity of these respirators after more than three disinfection cycles [18,26].

This study highlights the importance of deploying PPE rational use strategies in a hospital-setting, in order to avoid resource shortages, and reduce overall costs while protecting healthcare workers at risk of contagion in the midst of a pandemic without vaccines for protection. The aim of this study was to assess the implementation of a safe and effective re-use policy for high-efficiency FFRs, and estimate potential savings in a high-complexity university hospital such as Fundación Valle del Lili (Cali, Colombia), during the COVID-19 pandemic in 2020.

Methodology

Fundación Valle del Lili is divided into one main hospital and four outpatient centers within the city. It comprises of 625 hospital beds, 114 intensive care unit beds, 695 physicians, and more than 5300 employees with potential exposure to SARS-CoV-2.

An implementation strategy consisting of four phases was developed within the framework of effective replicable FFRs re-use and disinfection programs. These phases were included in order to achieve the successful adoption, implementation, and sustainability of an institutional respirator reuse policy. In addition, an accounting analysis of cost savings was performed.

Evaluation phase

This phase consisted of the evaluation of conditions before policy implementation, including the identification of PPE demand in healthcare workers exposed to COVID-19, and the supply barriers encountered during the pandemic.

Pre-implementation phase

An interdisciplinary group was established to evaluate scientific evidence regarding the rational use of the PPE policy, which comprised guidelines on the use of FFRs according to the degree of SARS-CoV-2 exposure, and their re-use through decontamination using UVGI. FFR-use indications were defined by the institution's Infections Committee (See Table 1).

A strict follow-up on the number of FFRs used monthly at the institution was carried out.

The average cost of each respirator varied greatly during 2020 due to market conditions and the negotiation capacity of each buyer. However, assuming an average price of 2.40 USD, a conservative calculation of savings was performed.

When the PPE policy protocol was implemented at the beginning of the COVID-19 pandemic, access to FFRs and regular replacements was strictly limited to healthcare workers at higher risk of exposure, while those at lower risk of exposure continued to use conventional surgical facemasks. Conversely, due to FFR scarcity generated by the increasing worldwide demand, respirator replacement time for low risk personnel was considerably longer than for workers at higher risk (Table 1). However, with the rapid spread of infection, FFR access was extended to any health professional in close contact with patients, as they were all considered at risk of infection.

The need to establish a FFR reuse policy to ensure the safety of all personnel was evident. Thus, the design, piloting, and implementation of a proper disinfection system for FFR was carried out. Here four methods were evaluated: autoclave (heat and humidity system), vaporized hydrogen peroxide, steam using microwaves and UVGI.

After the first disinfection trial, the use of autoclave, vaporized hydrogen peroxide, and steam using microwaves, were excluded from the study due to inefficiency and high costs. When evaluating autoclave disinfection, although up to 100 respirators could be decontaminated at a time, it was proved to be time-consuming and expensive as well. Each cycle using an autoclave had a duration of about 120 min and direct costs of approximately 100 USD. Indirect costs of possibly greater value due to the need of staff to operate the disinfection equipment were likewise included.

Disinfection with vaporized hydrogen peroxide was also assessed, resulting in even higher costs than disinfection with autoclaves (217 USD per disinfection cycle of 10 respirators). Lastly, steam using microwaves damaged 40% of the respirator after a first disinfection cycle, with detachment and total burn of the nasal metal piece.

UVGI was the only method included in the study after the pre-implementation phase. UVGI uses disinfection chambers equipped with UVC light-emitting bulbs at 1.3 J/cm2, potency described effective in eliminating SARS-CoV-2 [27]. In this scenario UVGI showed 1) preservation characteristics: unaltered shape and filtration capacity after multiple cycles; 2) cost-efficiency by disinfecting up to 8 respirators in 3 min, no need for additional personnel to operate the machine and low maintenance costs (approximately 10 USD per month); 3) practicality while being used; and 4) safety, since the UV light automatically turns off when the hatch is opened.

Implementation phase

With these findings, a progressive plan for the installation of disinfection UVGI chambers was executed, beginning in specific areas to meet the site and personnel needs. A respirator disinfection protocol was developed and widely diffused in the institution through virtual platforms and flyers placed above the disinfection chambers. Moreover, during the first weeks of the protocol implementation, training was provided between staff shift changes in order to guarantee proper use of the UVGI chamber.

In a period of 16 weeks, from July 22 to November 10, 2020, 19 UVGI disinfection chambers were installed, 12 in the main hospital, and the remaining 7 distributed among the outpatient centers.

To evaluate the results of the implemented disinfection policy, three metrics were defined: difference in consumption of FFR units, total expenditure, and user satisfaction. The first two metrics evaluated financial impact; a before and after policy implementation analysis was performed.

An average of 18 FFR units per person per month was estimated in the scenario without the policy implementation. This was determined considering 216 working hours per month divided by 12-hour shifts, and a workload of 18 shifts of 12 h each per month.

Risk classification of health workers was based on the Ministry of Labor's framework of the General System of Occupational Risks, which divided exposed workers to SARS-CoV-2 accordingly into three groups: direct, intermediate, and indirect [28].

Healthcare workers in direct contact with suspected or confirmed SARS-CoV-2 cases were classified as workers at direct risk of exposure. Personnel who may have had contact or exposure to a person suspected or confirmed with SARS-CoV-2 were considered workers at intermediate risk of exposure. Workers with incidental exposure to suspected SARS-CoV-2 cases, given that exposure to the biological risk factor was unrelated to their functions, were classified as workers with indirect risk of exposure. For analytical purposes, mandatory FFR use was determined for personnel with direct and intermediate risk of exposure.

Maintenance phase

The FFR reuse policy was advertised through continuous awareness campaigns in order to promote the correct use of disinfection chambers to all the hospital's healthcare and administrative personnel.

Policy implementation success was measured through surveys that evaluated the acceptability of the disinfection process including: acceptability of intervention measure, perception of the appropriateness of the intervention, and feasibility of the disinfection method chosen. Each survey had four statements that were validated and translated into Spanish [29]. For analytical purposes, responses were divided into three groups: completely agree/agree, neither agree nor disagree, and completely disagree/disagree.

The condition of each FFR after disinfection was measured using an inspection survey sent to all personnel through institutional e-mail (electronic forms were provided on the Microsoft Forms platform). The survey aimed to evaluate the respirator's physical damage, general appearance, seals, odor, and nasal clip condition post-disinfection.

Results

Table 2 shows the number of people at risk of contagion in the institution according to the degree of exposure. On average, a total of 948 people had direct exposure, 2417 intermediate, and 1503 indirect, in any given month. The increase in direct and intermediate risk of exposure personnel stood out, with a positive month-on-month variation in all months except for September. It is important to note that the increase in exposed personnel in the months of October and November coincide with the opening of a new hospital site with more than 800 employees.

Fig. 1 shows the expected FFR consumption and the observed consumption. In 2020, the expected and observed total number of FFRs used by direct and intermediate risk workers was 377,266 versus 165,685, respectively. Total expected FFR supply costs for direct and intermediate risk workers were 905,438 USD vs 397,644 USD for observed respirators used.

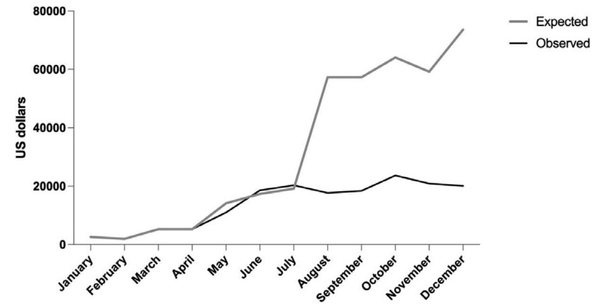

Fig. 1. Expected vs observed FFR consumption in 2020.
Average FFR units used per month per person after the rational use policy implementation was 3.9. The cost of building the disinfection chambers was 540.60 USD per chamber, for a total of 10,271 USD. Estimated costs of space, use, and energy consumption were 13.50 USD per month per chamber. In the first month of operation, the total installation cost was 203 USD.

Implementation indicators results

A total of 224 responses were obtained for the policy implementation effectiveness surveys, accounting for approximately 5.5% of direct and intermediate risk workers. Percentage of personnel that "Completely agreed" and "Agreed", on acceptability, intervention appropriateness and feasibility of intervention measures were 80.5%, 78.8%, and 83.6%, respectively (see Table 3).

The inspection survey included a total of 351 respondents, of which 88% considered the use of disinfection chambers to be straightforward. A total of 50.8% did not report any wear after using the system. Of the total, 76.4% reported the respirator in optimal conditions after UVGI disinfection, 91.7% experienced normal sealing, and 85.2% reported a normal nasal clip. However, 79% of users reported odor, of which 24.2% described it as intense and 24.5% as moderate. Thirty-five percent of users reported the presence of fibers in the respirator. In the observations section of the survey, some workers stated problems such as intolerable odor and local itching or rhinorrhea caused by contact with loose fibers produced by continuous respirator re-use (see Table 4).

Discussion

This study assessed the implementation, results, and monetary savings of a strategy to rationalize the use of FFR, in a high-complexity institution during the COVID-19 Pandemic before vaccines were available. The policy was based on two pillars: a rigorous assessment of workers using FFRs, and the implementation of a disinfection system with low costs and high acceptance. The decision to use UVGI over other methods was based on the results of the pre-implementation phase. UGVI showed to be practical and efficient, conserving both the respirator's physical characteristics and functionality after multiple cycles, while maintaining low operating costs. These findings are consistent with the literature [17–26].

Overall, UVGI was highly accepted as a disinfection method and considered to be an appropriate and feasible intervention among users. However, downsides included the perception of bad odor and the presence of fibers after multiple disinfection cycles and the reuse of the FFR. Still, we considered it unlikely that adherence to its use was significantly affected by these factors due to the good acceptance and credibility of this disinfection method by personnel.

The evaluation of the respirator rational use policy implementation resulted from a time series difference between expected and ob-

Table 2
Total personnel exposed to SARS-CoV-2 according to the risk of exposure.

risk of exposure	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Indirect	1802	1439	1434	1456	1456	1710	1347	1379
Direct	786	963	1065	1172	1172	868	747	811
Intermediate	1857	2164	2073	2011	2011	2693	3248	3280
Total	**4445**	**4566**	**4572**	**4639**	**4639**	**5271**	**5342**	**5470**
Direct + intermediate	2643	3127	3138	3183	3183	3561	3995	4091
Variation%		18.3%	0.4%	1.4%	0.0%	11.9%	12.2%	2.4%

Table 3
Survey results evaluating the policy implementation success (N = 224).

	Completely agree/Agree	Neither agree nor disagree	Completely Disagree/ disagree
Acceptance measure (AIM)			
The disinfection process of FFR meets my approval	79.0%	9.4%	11.6%
The FFR disinfection process is appealing to me	81.7%	8.0%	10.3%
I like the disinfection process	74.1%	12.9%	12.9%
I welcome the process of disinfection of FFR by UV light	86.2%	6.7%	7.1%
TOTAL	80.2%	9.3%	10.5%
Intervention appropriateness measure (IAM survey)			
The disinfection of FFR by UV light seems fitting	79.9%	12.5%	7.6%
This disinfection process seems suitable	79.5%	10.3%	10.3%
This disinfection process seems applicable	80.8%	9.4%	9.8%
This disinfection process seems like a good match	75.4%	14.3%	10.3%
TOTAL	78.9%	11.6%	9.5%
Feasibility of intervention measure (FIM survey)			
The disinfection of FFR by UV light seems implementable	78.6%	14.3%	7.1%
Instructions about the disinfection of FFR by UV light seem possible	84.8%	9.8%	5.4%
The disinfection of FFR by UV light seems doable	89.3%	8.5%	2.2%
The disinfection of FFR by UV light seems easy to use	81.7%	10.3%	7.6%
TOTAL	83.6%	10.7%	5.6%

AIM: Acceptability of Intervention Measure.
IAM: Intervention Appropriateness Measure.
FIM: Feasibility of Intervention Measure.

Table 4
General inspection survey results (N = 351).

RESPIRATOR'S CHARACTERISTICS	SCORE	% of responses
Disinfection process	5 (Very easy)	68.9
	4 (Easy)	19.1
	3 (neutral)	6.8
	2 (Difficult)	3.1
	1 (Very difficult)	1.7
General condition	Optimal	76.4
	Deformed	13.7
	They do not fit	6.6
	Detached	3.4
Sealed	Normal	91.7
	Does not seal	8.3
Nasal clip	Normal	85.2
	Worn out	11.4
	Detached	3.4
Odor (bad)	Mild	30.2
	Moderate	24.5
	Intense	24.2
	None	21.1
Wear	With fibers	35.0
	Rough	7.7
	Burned	4.8
	Deformed	1.7
	None	50.8

served FFR consumption. With an implementation cost of approximately 10,000 USD, a total of 211,581 respirator units were saved, reducing potential FFR consumption in 56.1%, and generating savings of more than 500,000 USD per year for a hospital of approximately 4000 employees at risk.

The literature review conducted by Rowan and Laffey [30] described the reuse and decontamination of PPE in different health centers due to the scarcity of this equipment. To our knowledge, however, our study is the first to assess the cost savings associated with an optimization and disinfection strategy for PPE.

Although the measurement of the effect of the policy on the COVID-19 infection rate in users was outside the scope of the study, the prevalence of SARS-CoV-2 infection in the institution in 2020 was 8.1% among physicians, 8.3% in other health professionals, and 15.1% in administrative personnel. No published data for other hospitals in the country were found for comparison. The closest possible comparison is with the inhabitants of the same city. The preliminary results of a national study of the seroprevalence of COVID-19 show that by November 2020, the prevalence of infection in Cali was 30% [31].

In the context of an emerging pandemic with an unknown virus and no specific treatments nor vaccines available, the adequate use of PPE (including FFR) was key to tackling COVID-19, especially as it lowered transmission coming from hospital personnel.

Limitations to the present study included the lack of data on virus eradication from FFR. Additionally, selection bias might have occurred with survey respondents since they were voluntary and completed online.

Conclusion

The policy developed and implemented by this hospital was deemed to be a success. It showed the importance of implementing programs that work hand by hand with health workers, taking into account not only their needs but opinions in order to effectively address public health matters. This strategy demonstrated to be easily implemented, appropriate, and feasible. Respirator's reuse resulted in important cost-savings, without sacrificing FFR's filtration properties. Respirator scarcity was properly tackled, allowing hospital operations to continue while allocating economic resources to other needs, all in the midst of the pandemic.

Therefore, in a pandemic scenario where it is key to spare resources in scarcity and financial crisis, policies on the rational use of PPE are promising in assuring protection to hospital personnel, and in turn providing adequate health care services while saving resources.

Declaration of Competing Interest

None declared.

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Ethical approval

Not required.

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