PRODUCTION OF SURGICAL MASKS: STRATEGY TO COMBAT COVID-19

PRODUÇÃO DE MÁSCARAS CIRÚRGICAS: ESTRATÉGIA NO COMBATE À COVID-19

PRODUCCIÓN DE MÁSCARAS QUIRÚRGICAS: ESTRATEGIA PARA COMBATIR EL COVID-19

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Objective: to report the experience of production of surgical masks by a committee of technological innovation production. Method: descriptive study of the experience-report type. The production process involved six seamstresses, one cutting the hospital nonwoven fabric, one at the Overlock stitch machine to make the finish of sides and four sewing with the Straight stitch machine. A 60-grammage nonwoven fabric, white thread and a cloaked galvanized wire were used. Result: production reached 1,300 surgical masks per day. The process was managed by two nurses. Conclusion: the strategy reported represented the production of 63,000 units of surgical masks and was an alternative to meet the demand for surgical masks in health services, contributing to improve the safety of health professionals within the scope of COVID-19.

Descriptors: Prevention & Control. COVID-19. Coronavirus Infections. Health Services Management. Personal Protective Equipment.

Objetivo: relatar a experiência de produção de máscaras cirúrgicas por uma comissão de produção de inovação tecnológica. Método: estudo descritivo do tipo relato de experiência. O processo de produção envolveu seis costureiras, uma cortando o tecido-não-tecido bospitalar, uma na máquina Overlock para fazer o acabamento nas laterais e quatro, costurando na máquina Reta. Foi utilizado tecido-não-tecido gramatura de 60, linhas brancas e arame galvanizado encapado. Resultado: a produção chegou a 1.300 máscaras cirúrgicas por dia. Todas passaram pelo teste de qualidade em uma central de distribuição antes de serem encaminhadas aos serviços de saúde. O processo foi gerenciado por duas enfermeiras. Conclusão: a estratégia relatada representou a produção de 63 mil unidades de máscaras cirúrgicas e foi uma maneira alternativa de suprir a demanda de máscaras cirúrgicas nos serviços de saúde, contribuindo para melhorar a segurança dos profissionais de saúde no âmbito da COVID-19.

Descritores: Prevenção & Controle. COVID-19. Infecções por Coronavírus. Gestão de Serviços de Saúde. Equipamento de Proteção Individual.

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Objetivo: informar la experiencia de producción de mascarillas quirúrgicas por una comisión de producción de innovación tecnológica. Método: estudio descriptivo del tipo informe de experiencia. El proceso de producción implicó seis costureras, una cortando la tela no tejida bospitalaria, una en la máquina Sobrebilada para bacer el acabado en los lados y cuatro cosiendo en la máquina Recta. Se utilizó una tela no tejida de 60 gramos, bilos blancos y un alambre galvanizado camuflado. Resultado: la producción alcanzó 1.300 máscaras quirúrgicas por día. El proceso fue gestionado por dos enfermeras. Conclusión: la estrategia reportada representó la producción de 63.000 unidades de mascarillas quirúrgicas y fue una forma alternativa de satisfacer la demanda de mascarillas quirúrgicas en los servicios de salud, contribuyendo a mejorar la seguridad de los profesionales de la salud en el contexto da la COVID-19.

Descriptores: Prevención y Control. COVID-19. Infecciones por Coronavirus. Gestión de Servicios de Salud. Equipo de Protección Personal.

Introduction

The new Coronavirus was identified as the cause of an outbreak of respiratory disease first detected in Wuhan, China, in December 2019. The disease came to be known as COVID-19 and became a global health problem, mainly due to its rapid geographical dissemination⁽¹⁾.

On March 11, 2020, COVID-19 was characterized by the World Health Organization (WHO) as a pandemic. The disease has affected a large number of people, with lost lives and impacts on social, mental and economic life unprecedented in world history. Until June 20, 2020, there were 11,241,655 confirmed cases worldwide. The United States was the country with the highest number of cases (2,839,542), followed by Brazil (1,577,004), Russia (674,515), India (673,165) and Peru (299,080). The incidence of new cases has increased in Brazil, with 64,265 deaths and 7.0% of lethality, affecting mainly the Northeast Region⁽²⁻⁵⁾.

The disease is caused by SARS-CoV-2 and is transmitted by contact, by droplets and aerosols present in speech, cough, sneezing of the infected individual, or during procedures involving the respiratory tract and generating aerosols (nasal or orotracheal intubation and aspiration, cardiopulmonary resuscitation, ventilation with manual resuscitator, noninvasive ventilation, bronchoscopy examination, collection of nasal and ophopharynx tests)⁽⁶⁻¹⁰⁾. Another possible route of transmission is fecal-oral, in view of the identification of the virus in anal swab⁽¹⁰⁾. The dissemination of SARS-CoV among people

usually occurs after close contacts, and health professionals who provide care to these patients are particularly vulnerable⁽³⁾.

The Brazilian Unified Health System (UHS), especially in large centers, is challenged daily by the number of people affected and by the severity of the COVID-19. With the continuous community transmission of individuals, the damage of this disease is expected to continue increasing and, consequently, requiring more organized health services and health professionals actively working on the front line.

Therefore, one of the major challenges of the respiratory pandemic is the effective protection of health professionals. According to WHO recommendations, professionals should use personal protective equipment (PPE) for aerosol generation procedures, N95 respirators (a respirator with filtration capacity and resistance to particulate materials with 94% efficiency for particles smaller than 0.3µm, commonly known as N95), isolation insulation aprons and gloves^(3,6-7).

For the treatment of low-risk patients (without fever or respiratory symptoms, close contact with a COVID-19 patient), the use of a surgical mask is required to protect against droplet transmission⁽¹¹⁾.

Occupational exposure and high transmission among health professionals is a worldwide concern, in view of the commitment of this workforce. Studies have shown thousands of professionals affected by COVID-19 in Italy

and China⁽¹²⁻¹⁴⁾. Data released by the Ministry of Health (MH) in the Influenza Epidemiological Surveillance Information System (SIVEP-Gripe) reported 1,219 cases of deaths from severe respiratory syndrome in health professionals. Of these, 697 (57.1 %) were caused by COVID-19 and 367 (30.1%) are under investigation; highlighting that this is a section of severe cases in these categories, and does not represent the total of those affected by the disease. The most affected professions, among the hospitalized cases of severe respiratory syndrome, were nursing technician/assistant (429), physician (247) and nurse (243). Of the 1,219 reported cases, 176 died, most of them (138) from COVID-19. The professional categories most affected with death were nursing technician/assistant (67), physician (31) and nurse $(21)^{(3)}$.

Also in relation to nursing, until July 10, 2020, the Federal Nursing Council (COFEN) recorded 249 deaths of professionals with confirmed diagnoses, 33 suspected deaths, 214 hospitalizations, 9,515 confirmed professionals, 23,996 reported cases⁽¹⁵⁾. These professionals are in direct, close, repeated and prolonged contact with inpatients. There are still no studies demonstrating the real situation of contamination and number of deaths from coronavirus among medical professionals, physiotherapists and others.

Several factors are related to the contamination of health professionals, including continuous scarcity and inadequate use of PPE. In order to ensure protection for health workers and prevent the transmission of the new coronavirus among these professionals, the availability of PPE in their health units of work is fundamental. Studies indicate that the mask, used properly, properly adapted to the face, is capable of retaining particles and viruses transported through the air, so that they do not reach nearby individuals⁽¹⁶⁾.

Another study identified that the use of the surgical mask or N95 decreased the risk of infection among health professionals who cared for people with COVID-19⁽¹⁷⁾. In a case report, 41 health professionals (85% used surgical masks and 15%, N95) were exposed to aerosol generation procedures (endotracheal intubation,

extubation, noninvasive ventilation and open circuit aerosol exposure) in a patient with severe pneumonia, later confirmed for COVID-19. All professionals tested negative 14 days after the date of exposure. The absence of positivity, hand hygiene and the adoption of other standard procedures is likely to protect professionals from virus contamination⁽¹⁸⁾.

The scarcity of this equipment is a problem that has worried the WHO and the nations affected by the pandemic. The Brazilian Ministry of Health assesses the national risk of scarcity of these PPE as very high⁽³⁾. It is worth noting that the absence of PPE generates anxiety, refusal of care, increased absenteeism, fear of death and contamination of family members, which affects even more health services.

This scenario of lack of PPE has led professionals and researchers to discuss, plan and develop solutions for developing technologies in products, services and processes to combat COVID-19, caused by the new coronavirus.

With the considerations presented, the objective of this manuscript is to report the experience of production of surgical masks by a committee of production and technological innovation.

Method

This is a descriptive study, of the experiencereport type, of the strategies implemented by the Committee of Production and Technological Innovation in the fight against COVID-19. In the descriptive study, the researchers observe, tell and elucidate a purpose, event or phenomenon⁽¹⁹⁾.

The Committee was created by the Medical and Nursing Department (DEM) of the Federal University of Viçosa (UFV), located in the mining forest area, Minas Gerais, Brazil. The committee consisted of two nurses, who coordinated the committee, two engineers and a nursing technician, also relying on support members, namely: a pharmacist, a physician and a biologist. All members were university professionals. The objective of the committee was to discuss, plan and develop solutions for developing technologies in products, services and processes to combat COVID-19, preferably with low-cost technology. The activities were carried out from March to July 2020.

The initiative arose by observing the scarcity of PPE available to health professionals in the COVID-19 scenario in the city and in the region, and because of the idea that new solutions were necessary to meet the new demand. The university initially promoted a campaign to collect N95 masks, surgical masks, gloves, liquid alcohol and 70% alcohol gel to be donated to hospitals and Basic Health Units (BHU). However, this measure was not sufficient to meet the need of health institutions in the city and the region in the long term, because it was an emergency and long-lasting situation, which required an extraordinary stock.

Thus, due to insufficient PPE stock, the committee had the initiative to produce surgical masks. The lack of PPE was highlighted as a global problem due to the increased global demand, driven by a set of factors, such as the number of cases of COVID-19, panic-driven purchase, unawareness and unnecessary storage. All this resulted in the scarcity mainly of surgical masks and respirators, but also in the insufficient supply of hospital clothing, face shields and goggles. In addition, there is a limited capacity for expansion and industrial production of PPE currently⁽²⁰⁾.

Initially, the Committee conducted a research for standards and publications on the production

of masks for use in the health area, resulting in Resolution RDC n. 356 of March 23, 2020, as the main source of information and guidance for the production of surgical masks. It is a temporary standard on the requirements for the manufacture, import and acquisition of medical devices identified as priority, due to the international public health emergency related to SARS-CoV-2⁽²¹⁾.

This resolution highlights that surgical masks should be made of Nonwoven Fabric Material (NWF) for dental-medical-hospital use, have at least one inner layer and one outer layer and, mandatorily, a filtering element⁽²¹⁾. Thus, a partnership was established with a professor from the Department of Domestic Economics at the university, which had a laboratory equipped with cutting table and sewing machinery, for the definition of the mold. Two prototypes were elaborated, a skewed model and a straight one, strictly following the instructions of the National Health Surveillance Agency (ANVISA).

The prototypes (Figures 1 and 2) were tested by four health professionals, and after the tests, the seam of lateral strips was changed from vertical to horizontal position. In view of the cost-benefit, safety and production time, the straight model was chosen, made with fabric strips (Figure 3). The production of the mask model with elastic was not feasible, due to the difficulty of finding this material on the market at the beginning of production and the increase in cost.

Figure 1 - Prototype 1 of the surgical mask

Source: Created by the authors.

Figure 2 – Prototype 2 of the surgical mask



Source: Created by the authors.

Figure 3 - Final model of the surgical mask, with nasal clip



Source: Created by the authors.

According to the definitions of ANVISA, the committee considered that the surgical mask should be made in order to adequately cover the area of the nose and mouth of the user, having a nasal clip consisting of malleable material that would allow the proper adjustment of the contour of the nose and cheeks⁽²¹⁾, thus fulfilling all the requirements of RDC n. 356.

To begin the process of producing surgical masks, a partnership was established with a businesswoman in the city. The process was coordinated by the businesswoman and two nurses, professors at the DEM. Four Straight and one Overlock sewing machines were used; white threads, a cloaked galvanized wire and 3,000 meters of 60-grammage NWF of dental-medical-hospital use were acquired, with a report of bacteriological filtration efficiency provided by the material supplier.

The production process involved six seamstresses, one at the cut (A), one at the Overlock machine (B) and four at the Straight machine. Seamstress A was responsible for the daily cutting of the fabric and separated it into packages of 40 units, which was distributed to four seamstresses who performed the central folds and then sent to seamstress B to perform the side finishes with the overlock. Finally, seamstress B sent the fabric to the other four seamstresses to place the strips, the wire and finish the production. Thus, the standardization of the product was guaranteed throughout the assembly line.

The production process involved six people, and was divided as follows: a seamstress was responsible only for cutting the fabric, which was performed daily, separating lots of 40 units. Each seamstress received a package with 40 units for production, performed the central folds, sent to a second seamstress that was only at the overlock to finish the sides, and returned to the seamstress of origin to put the strips, the wire and finish. The daily working time was eight hours, Monday to Friday. All were hired, four by the university, and the others were employees of the partner businesswoman.

After production, the masks were sent daily to a distribution sector, within the university, and quality tests were performed by a nurse or a nursing technician. The analysis aimed to verify the existence of holes, size adequacy, masks without wires, tie strips and seam errors. In case there were any faults, the mask was returned to the production.

After the quality test, the masks were packed in plastic bags labeled with university identification data, composition, filtration efficiency, quantity and packing date, for later distribution. With this work, 63,000 surgical mask units were made.

Results and Discussion

For the successful experience, there was an arduous search, by the committee, to find the supplier of the material for production. The university paid for the purchase of all the inputs for the production of surgical masks and the workforce, by hiring the seamstresses.

To meet the biosafety issue, the seamstresses complied with the care of the work environment, before and after the activities, the floor was sanitized with sodium hypochlorite solution 0.5%, and all machinery and working instruments, with 70% alcohol. All the people involved in the production process wore masks, caps, aprons and disposable shoes.

The production reached 1,300 units per day. To achieve this production, there was need for the commitment of a coordinator following the process daily, a seamstress assuming the cut, and five more at the machines, with a weekly work load of 40 hours.

All production was daily sent, in containers purchased specifically for this purpose, to a distribution center within the university, coordinated by a professor from the DEM. This center made a detailed survey of the demand for PPE in the city and region, for planning and distribution, according to production capacity and aligned with the needs of a COVID-19 unit of the university (which treats patients with flu syndrome or suspected/confirmed COVID-19), as well as the two local public hospitals, the municipal basic health units and the six laboratories of the university, registered by the Ezequiel Dias Foundation to perform the tests for the detection of SARS-CoV-2.

Regarding the cost-benefit of the manufacturing process compared to the acquisition of disposable masks, it was quite satisfactory, considering the estimated value of 0.32 R\$ (thirty-two cents) for each unit produced, while the current market value is around 2.85 R\$ each unit, in addition to the difficulties of being found and establishing contracts.

A study conducted with data from the Federation showed that a box with 50 units of masks costed in early February 4.50 R\$ and, at the end of March, it costed up to 300.00 R\$⁽²²⁾. In the same way, another study, conducted in June 2020, reported that the price of an N95 mask increased R\$20.00, which was also observed in surgical masks. Furthermore, depending on the brand, location and product, it could cost over 220.00 R\$, an average increase of 258%⁽²³⁾. Despite the increased prices, the demand for masks continued to grow in health services, in the economic sectors and also for domestic use⁽²²⁾.

To maintain production, DEM professors managed the entire process: the acquisition

of inputs, the production and distribution of masks. And to maintain aseptic production, they supervised the work environment and guided professionals on the care of hand hygiene, disinfection and cleaning of the place and equipment for making masks. The main concern of those involved in this experience was the provision of protection for health professionals, because the media, social media and even scientific researches already demonstrated the growing infection among these professionals and its relationship with the lack of PPE. Professionals who did not use PPE or used it inadequately, with high-, medium- or low-risk exposure, became symptomatic and tested positive for SARS-CoV-2. Contamination can occur during a simple physical examination or manipulation of the patient $^{(6)}$.

The university is a space where teaching, extension and research activities assume a great importance in the production of knowledge, technologies and solutions to meet the needs of the scientific community and society, especially in cases of public health calamity such as this. In this sense, the committee was proposed, representing the great potential that the university has to create, develop and produce new ideas, uniting professionals from various areas and with different knowledge. We believe that this scientific convergence, together with the efforts of the community, can help in coping with COVID-19.

The experience described strengthens the diverse possibilities, skills, competencies and performance of nurses in favor of the community, focusing on being an agent of transformation of reality. Nurses should appropriate a vision of innovation, expanding their skills with actions beyond care, which enables the creative practice of differentiated strategies to approach new themes or new challenges, dealing with a disease present in the community. The leadership of nurses in the actions of process coordination, education and guidance of seamstresses increases this idea and stimulates the involvement and commitment of all to combat a disease or a pandemic.

The experience allowed for the production of 63,000 surgical masks to be donated to hospitals and other health services in the city and region.

The limited amount of the masks produced resulted from the scarcity and difficulties to find the necessary inputs, which represented, due to the COVID-19 pandemic, a reality in Brazil and in the world.

Conclusion

The present report contributed to the work of seamstresses in the city and to the supply of PPE in health services, representing an alternative to supply the demand for surgical masks in the care environments and to show the possibility of nurses performing intervention in the working conditions of health professionals and the community. It was possible to assist with the means for prevention, safety and reduction of transmission and infection of the disease among professionals who are on the front line in the fight against COVID-19.

The activities developed promote the importance of the university, the performance of researchers and health professionals for the benefit of society and, also, the importance of multiprofessional and multisectoral bonds.

Collaborations:

1 – conception, design, analysis and interpretation of data: Andréia Guerra Siman and Flávia Batista Barbosa de Sá Diaz;

2 – writing of the article and relevant critical review of the intellectual content: Andréia Guerra Siman, Flávia Batista Barbosa de Sá Diaz, Luciene Muniz Braga, Marisa Dibbern Lopes Correia, Lilian Fernandes Arial Ayres and Simone Graziele Silva Cunha;

3 – final approval of the version to be published: Andréia Guerra Siman, Flávia Batista Barbosa de Sá Diaz, Luciene Muniz Braga, Marisa Dibbern Lopes Correia, Lilian Fernandes Arial Ayres and Simone Graziele Silva Cunha.

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