Technological Innovation Of Oxygen Therapy In The National Health System During COVID-19: Experience Report

Inovação Tecnológica da Oxigenoterapia no Sistema Único de Saúde Durante a COVID-19: Relato de Experiência
Innovación Tecnológica de La Oxigenoterapia En El Sistema Nacional de Salud Durante La COVID-19: Informe de Experiencia

RESUMO
A escassez de respiradores hospitalares durante a pandemia de COVID-19 comprometeu o atendimento de pacientes graves no Sistema Único de Saúde (SUS). Este relato de experiência descreve o desenvolvimento de uma tecnologia inovadora para oxigenoterapia, criada por um grupo interdisciplinar que atua na perspectiva do ensino-em-serviço. Foram produzidos 140 protótipos do "Conector Nasal de Alto Fluxo (CNAF) adaptado" por impressão 3D, com custo unitário de R$510,00. O dispositivo gerou um fluxo de 15 L/min de oxigênio, com possibilidade de ampliação para 30 L/min por um acréscimo de R$100,00. Sistemas comerciais completos de alto fluxo de oxigênio podem atingir R$25.000,00. A solução desenvolvida reduziu significativamente os custos e ampliou o acesso à oxigenoterapia no SUS, demonstrando o potencial da inovação tecnológica para otimizar recursos e melhorar a assistência em saúde.
PALAVRAS-CHAVE: Respiração Artificial; Tecnologia biomédica; Práticas Interdisciplinares; Acesso à saúde; Custos hospitalares.

ABSTRACT
The shortage of hospital ventilators during the COVID-19 pandemic has compromised the care of critically ill patients in the Brazilian Unified Health System (SUS). This experience report describes the development of an innovative technology for oxygen therapy, created by an interdisciplinary group that works from the perspective of in-service teaching. 140 prototypes of the "adapted High Flow Nasal Connector (CNAF)" were produced by 3D printing, with a unit cost of R$510.00. The device generated a flow of 15 L/min of oxygen, with the possibility of expanding to 30 L/min for an additional R$100.00. Complete commercial high-flow oxygen systems can cost up to R$25,000.00. The developed solution significantly reduced costs and expanded access to oxygen therapy in the SUS, demonstrating the potential of technological innovation to optimize resources and improve health care.
KEYWORDS: Artificial Respiration; Biomedical technology; Interdisciplinary practices; Access to health; Hospital costs.

RESUMEN
La escasez de respiradores hospitalarios durante la pandemia de COVID-19 comprometió la atención a pacientes críticos en el Sistema Único de Salud (SUS). Este informe de experiencia describe el desarrollo de una tecnología innovadora para la oxigenoterapia, creada por un grupo interdisciplinario que trabaja desde la perspectiva de la docencia en servicio. Se produjeron 140 prototipos del "Conector Nasal de Alto Flujo adaptado (CNAF)" mediante impresión 3D, con un costo unitario de R$ 510,00. El dispositivo genera un flujo de 15 L/min de oxígeno, con posibilidad de ampliar a 30 L/min por R$ 100,00 adicionales. Los sistemas completos de oxígeno comercial de alto flujo pueden costar hasta R$ 25.000,00. La solución desarrollada redujo significativamente costos y amplió el acceso a la oxigenoterapia en el SUS, demostrando el potencial de la innovación tecnológica para optimizar recursos y mejorar la atención de salud.
PALABRAS CLAVE: Respiración Artificial; Tecnología biomédica; Prácticas interdisciplinarias; Acceso a la salud; Costos hospitalarios.

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INTRODUCTION

In Brazil, the rapid increase in COVID-19 cases and the growing demand for hospitalizations for respiratory support have tested the resilience of the Unified Health System (SUS), revealing a deficit in the supply of medical and hospital equipment and supplies, such as artificial respirators, oxygen and medicines. This situation revealed weaknesses that compromised the SUS's ability to absorb the impact of the crisis and adapt to it, especially in relation to the acquisition and production of these materials, contributing to the exhaustion of the system. [1]

As a consequence, there was a lack of oxygen and mechanical ventilators in Intensive Care Units (ICUs), which resulted in an alarming increase in mortality due to respiratory failure. [2] Given the shortage of equipment and rising costs, the need to implement adaptive strategies to ensure adequate care for patients became evident. It was in this context that healthcare professionals on the front lines of the pandemic sought innovative strategies to address this problem that required a rapid response. Thus, an initiative was created by a university hospital to create a device that was capable of increasing oxygen supply: the "adapted HFNC". This feat sought to mitigate damage in an atypical scenario and contribute to the resilience of an overburdened healthcare system.

Oxygen (O_2) supplementation is an intervention widely used in the management of acute hypoxemia and can be performed through nasal devices. Low-Flow Nasal Catheters are open systems in which air leaks from the oxygen source, providing 4 to 6 liters of O_2 per minute, corresponding to an inspired oxygen fraction (FiO_2) of 37 to 45%. These are safe devices whose most frequent complication is drying of the nasal mucosa, which in some cases can lead to local bleeding. Therefore, it is an option indicated for mild hypoxemia without prolonged use. [3]

High Flow Nasal Catheters are systems capable of delivering an FiO_2 of up to 100% of moistened and heated air with a flow of up to 60 liters per minute [4], making it an interesting option for the treatment of severe acute ventilatory dysfunction. [5] Among its benefits are shorter mechanical ventilation time, reduced mortality, reduced risk of ICU admission and lower reintubation rate in acute respiratory failure. [6,7,8]

Although Brazil has significant purchasing power and has universities and companies with scientific potential, it

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still has a strong technological dependence on equipment from abroad. The country does not have its own production of various medical materials and the headquarters of multinational corporations are located abroad, as is the industrial production of their products. [9] Thus, in calamitous situations, there is a shortage of resources and difficulties in importing and emergency purchasing, as the countries that host large industries also need these technologies. Added to this is the fact that during the COVID-19 pandemic, the flow of goods was reduced due to the closure of activities at ports and airports. [1]

Therefore, it is imperative that research institutions direct their efforts towards the field of technology and innovation, in order to restructure themselves and develop new approaches in times of crisis. Otherwise, the SUS will be vulnerable to the dynamics of international companies. Health services, especially those linked to universities and research centers, cannot remain oblivious to the challenge of innovation, given the current global scenario marked by armed conflicts and a sudden increase in extreme weather events [10]. In this sense, this report aims to describe the experience of developing an innovative technology used in the oxygen therapy of patients with COVID-19 that was developed by an interdisciplinary team based on in-service teaching activities. This technology demonstrated cost-effectiveness and contributed to strengthening the healthcare network.

METHOD

This is an experience report and therefore has a retrospective nature, with a descriptive and exploratory documentary focus. The narrative covers the period from January to December 2021 and was based on the following documents: "development project"; "invention declaration - protocol No. API 0219"; "standard operating procedure" and "work instruction" of the adapted HFNC. All these documents were prepared by professors and professionals linked to Hospital São Lucas (HSL), Escola Politécnica and Parque Científico e Tecnológico (TecnoPUC) of the Pontifical Catholic University of Rio Grande do Sul (PUCRS). Additionally, information was consulted on websites of medical and hospital equipment companies, the National Health Surveillance Agency, the Ministry of Health and the World Health Organization.

Regarding the description of the scenarios in which the adapted HFNC was developed, HSL is a philanthropic university hospital, considered a hub for both health care and teaching and research, with participation in studies of national and international relevance, such as the tests of the Coronavac® vaccine and the first vaccine against dengue fever that will be distributed by the SUS by 2025. 11 TecnoPUC is home to around 178 organizations, including the Polytechnic School and the FabLab laboratory of the Center for Support to Scientific and Technological Development (IDEIA/TecnoPUC). This infrastructure allows for the articulation of numerous companies and startups, connecting experts from Brazil to provide services and technical support, and promoting the development of technological innovations.[12]

RESULTS

This report will not focus on clinical results, but will emphasize the intellectual and material aspects that were fundamental to the development of an innovative technology. However, to illustrate the practical application, it is relevant to mention that the adapted HFNC was used in approximately 235 patients over 18 years of age admitted to the HSL ICU, all with acute respiratory distress syndrome related to COVID-19. Subsequently, the device was used in other patients in seven philanthropic hospitals, most of them located in Rio Grande do Sul. The study that allowed the use of the adapted HFNC in humans was approved by the Research Ethics Committee (CEP) of PUCRS, under Protocol No. 4,592,176.

Focusing on the narrative about the development of the adapted HFNC, in 2021, during the pandemic, there was a commercial high-flow O_2 system, recognized for its excellent clinical performance, which was only available in private hospitals, since it is a technology not incorporated into the SUS. Given this access barrier and the growing need to offer greater oxygen flows to COVID-19 patients in the ICU, it was proposed to make adjustments to the commercial model, with the aim of making it accessible on a large scale for patients hospitalized in the SUS.

At this point, the fundamental role of in-service teaching is highlighted as an integral part of the results, since the initiative was conceived by a professor, preceptor and head of service, who was intrinsically committed to providing hospital care to patients and training health professionals. Therefore, it is clear that the search for a financially sustainable and clinically effective alternative was the result of his involvement in teaching and doing.

Next, to make the development of the prototype viable, partnerships, means and resources were sought within the university ecosystem. This stage was facilitated by the collaboration between health care and clinical research carried out at the hospital, together with the development of technologies at the Polytechnic School/TecnoPUC. Several professionals were involved in creating the prototype, including engineers, doctors, physiotherapists, nurses, nursing technicians and legal support staff.

Thanks to interdisciplinary efforts, the adapted HFNC was developed as

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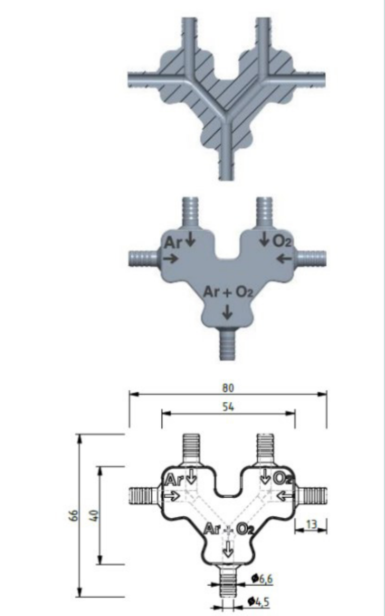
a 3D printed part in the FabLab laboratory of IDEIA/Tecnopuc. The material used was Polyethylene Terephthalate Glycol (PETG), a white thermoplastic polymer that stands out for its flexibility, durability and toughness. PETG is a recyclable material, produced by adding CHDM (1,4 cyclohexanedimethanol) to PET (Polyethyl Terephthalate). Due to its resistance, this plastic is widely used in prosthetic projects, for example. [13]

The HFNC, produced from PETG, is smaller than the palm of an adult hand and weighs approximately 20 grams. The time required to print each part is 1 hour and 50 minutes, using the Ender 3® 3D printer (Shenzhen, China), which operates with the fused deposition modeling (FDM) process. During printing, a PETG thread is deposited by a heated extruder, where the plastic becomes malleable enough to be applied precisely by the print head, layer by layer, in the printing area, resulting in the final 3D part. The extrusion temperature of the material, which corresponds to the temperature of the 3D printer nozzle where the filament is heated and melted, is 235 °C.

The adapted HFNC works as an O_2 and compressed air mixer in High Flow Systems. Its configuration and measurements are shown in Figure 1. It has two inlets, one for air and the other for O_2, coupled to two flowmeters with a capacity of[15] L/minute that lead to a single outlet, where the Air + O_2 are mixed.

Figure 1: Internal and external view of the device and measurements in millimeters (mm).



During the pandemic, 120 prototypes of the adapted HFNC were produced. To formulate the cost estimate calculation, aspects related to the development of the project (R$447.66) and the resources required for manufacturing (R$62.33 per part) were considered, totaling R$509.99 per unit. Detailed information on this is presented in Table 1 and cost projections for scale production are shown in Table 2.

Table 1: Production cost per piece in reais

	Technician hours	Technical cost	Machine hours	Machine cost	Material grams	Material cost	TOTAL
Project cost	3	R$ 149,22					R$ 447,66
Cost per piece	0,33	R$ 149,22	1,83	R$ 1,89	12,67	R$ 0,76	R$ 62,33

Note: The design cost is unique and is added only once to the production calculations. The latter, in turn, is multiplied by the number of parts.

Table 2: Cost projection in reais for large-scale production of the adapted HFNC.

Units	Cost (R$)
1	509,99
10	1.070,97
100	6.680,71
1.000	62.778,16
10.000	623.752,66

Considering its composition (PETG) and purpose (Air + O_2 mixer), the adapted HFNC is considered a waste that does not present a biological, chemical or radiological risk to health or the environment. In other words, it can be sent for reuse, recovery, recycling, composting, reverse logistics or energy recovery, as long as it is described in the waste management plan. [14]

To assemble and use the adapted HFNC in the ICU, the interdisciplinary team developed a Standard Operating Procedure and a Work Instruction that provide detailed guidance on the process of operating this technology. In addition, a Platform was created to help doctors and physiotherapists adjust the flowmeter according to the specific needs of each patient. It allows determining the desired total flow and FiO_2, providing the values

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that should be adjusted in the compressed air and O_2 flowmeters, thus ensuring precise and personalized care.

DISCUSSION

The concept of innovation refers to the introduction of goods or services that are new or that present significant improvements in relation to existing ones. [15] The adapted HFNC, as its name suggests, is a modification of an existing piece of equipment that was previously inaccessible to SUS hospitals, especially during the COVID-19 pandemic, when the demand for this type of device increased considerably. Therefore, it is essential that accessibility to technological devices be considered a central aspect of the innovation process in SUS, in order to expand the system's capacity to offer effective responses in emergency situations.

IN-SERVICE TEACHING AND INTERDISCIPLINARITY.

In this report, the need to make technology accessible is deeply linked to in-service teaching and interdisciplinarity. The latter is considered a fundamental characteristic of the health innovation system. The development of new technologies requires the collaboration of several professionals, including physicists, electronic engineers, materials specialists, designers, among others, and therefore requires a robust structure, with a high degree of interaction and interdisciplinarity. [16,17] In this context, university ecosystems (undergraduate and postgraduate courses and teaching hospitals) play a crucial role in the design, development, implementation, sharing and evaluation of technological innovations.

In addition, in-service teaching, as a training process that is integrated into the daily routine of services, promotes learning based on collaboration, articulation and integration between educational and health institutions. [18] This provides a fertile scenario for technological innovation aimed at the needs of the SUS. As a result, it is observed that the quality of health care is directly related to professional training that provides effective technologies to serve the population. Thus, in order to generate knowledge and promote scientific and technological advances that impact the provision of health services, it is essential to train new professional profiles shaped by the perspective of in-service teaching. [19]

PROTOTYPE AND COST-UTILITY.

Commercial high-flow systems are relatively simple and consist of three main components: flow generator, humidifier, and nasal cannula. The O_2 flow generator can be classified as a mixer, turbine, or venturi. This component accounts for the largest share of the total cost of the system. The oxygen humidifier used is the same as that found in other clinical ventilation devices. And the nasal cannula consists of two high-flow tubes, known as prongs, that connect at both ends. It is a low-cost component, intended for single use and is generally non-reusable. [9,20,21,22] In Brazil, the prices of the main complete systems that offer a flow of 60 L/minute of oxygen range from R$14,000 to R$25,000.

The part printed in the IDEIA/Tecnopuc FabLab (adapted HFNC) can be integrated into the oxygen supplementation structure already in place in hospitals, eliminating the need for a flow generator. The prototype developed at PUCRS cost R$509.99 and was able to generate a flow of 15 L/minute, which is already considered a high flow of O2. However, it is possible to increase this capacity by attaching a 30 L/minute flowmeter, which would result in an increase of approximately R$100.00 per manufactured unit. Therefore, the cost of the adapted HFNC with a flow of 30 L/minute would be approximately R$610.00.

The humidifier used in the adapted HFNC can come from several clinical ventilation devices. Therefore, the only component that needs to be purchased is the high-flow nasal cannula. Currently, there is a national option that is autoclavable (can be reused up to 30 times) that costs R$345.00. Considering this possibility, the total price of the complete system using the adapted HFNC would be R$955.00 for the hospital. This would generate savings of between R$13,000 and R$24,000 compared to the complete systems available on the Brazilian market.

In terms of operation, the high-flow oxygen system provides positive expiratory pressure, which helps prevent air recirculation and reduce dead anatomical space. By offering high levels of oxygen and greater comfort compared to other ventilation devices, it becomes an excellent option for the treatment of severe acute ventilatory dysfunction. [5] A retrospective study conducted in the United Kingdom, published in 2022, analyzed patients hospitalized with COVID-19 in the public health system and revealed that the high-flow oxygen system was able to provide a 53% survival rate in situations with limited organ support. In addition, this system was used as a safe tool to provide respiratory support to patients in outpatient units, helping to alleviate the burden on ICUs. [23]

LIMITATIONS

The main limitations of using the adapted HFNC are related to the availability of oxygen in healthcare institutions. The device can operate with flows of up to 30 L/min, corresponding to half the capacity of commercial systems. Therefore, in places with difficulties in the supply of O_2, its implementation may face operational restrictions, although on a smaller scale than conventional devices. In addition, the use of the adapted HFNC requires the presence of trained physiotherapists for its indication, installation, monitoring and adequate management. As support material, the Standard Operating Procedures, Work Instructions and the Platform were prepared to meet the technical needs. Finally, tests have not yet been carried out to determine the durability of the piece in clinical practice, and the therapeutic results of the device are being evaluated in ongoing studies, which already indicate promising prospects.

CONCLUSION

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The shortage of oxygen therapy equipment during the COVID-19 pandemic highlighted the need for innovative and affordable solutions to strengthen the SUS. This report demonstrated that 3D printing can enable the development of low-cost devices, allowing for increased access to oxygen therapy in a crisis scenario. The interdisciplinary initiative focused on in-service teaching proved effective in creating a viable and economically sustainable alternative.

In addition to cost reduction, the experience highlights the potential of universities and research centers in generating technologies aimed at public health. Collaboration between academia and health services can accelerate the incorporation of innovations, making the SUS more resilient to health emergencies. Expanding this model can contribute to the development of affordable solutions, directly benefiting the population.

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