

Women in technology management and clinical engineering: the case of pulmonary ventilators at Covid-19

Mulheres na gestão de tecnologias e engenharia clínica: o caso dos ventiladores pulmonares na Covid-19

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ABSTRACT The imminent risk of shortage of pulmonary ventilators in health services has resulted in several work fronts to maintain and make available the largest possible number of equipment available for the treatment of patients. The worsening of the health crisis has collapsed health services with an isochronic search for beds. Amid the collapse, a new variant of the Sars-CoV-2 strain was detected and the first case of reinfection was confirmed. Among the critical points was the chaotic oxygen scarcity and bed occupancy rates above 90%. We intend to report the participation of the authors in the initiatives to face the pandemic; highlight the participation of women in activities that are crucial to respond, in a timely manner, to the demands arising from health emergencies. Through a research method with a descriptive and exploratory approach, we sought to verify the profile of women working in the management of technologies in facing the pandemic. The recent survey by the Brazilian Association of Clinical Engineering stands out, which found that only 19% of the respondent associates were women. Thus, disseminating and giving broad knowledge of women's actions in this area can collaborate in achieving gender equality and empower all women and girls.

KEYWORDS Device approval. Access to essential medicines and health technologies. Pandemics. Health management.

RESUMO O risco iminente de desabastecimento de ventiladores pulmonares nos serviços de saúde acarretou diversas frentes de trabalho para disponibilizar o maior número possível desses equipamentos para o tratamento dos pacientes acometidos. O agravamento da crise sanitária colapsou serviços de saúde com busca isocrônica por leitos. Em meio ao colapso, foi detectada nova variante da linhagem Sars-CoV-2 e confirmado o primeiro caso de reinfeção. Entre os pontos críticos, foi destaque a escassez caótica de oxigênio e taxas de ocupação de leitos acima de 90%. Pretende-se relatar a participação das autoras nas iniciativas para o enfrentamento da pandemia de relevância internacional. Destacar a participação de mulheres em atividades que são cruciais para responder, em tempo oportuno, às demandas oriundas de emergências sanitárias. Por meio de método de pesquisa de abordagem descritiva e exploratória, buscou-se verificar o perfil das mulheres atuantes na gestão de tecnologias no enfrentamento da pandemia. Destaca-se a pesquisa recente da Associação Brasileira de Engenharia Clínica que verificou que apenas 19% dos associados respondentes eram mulheres, enquanto 81% eram do sexo masculino. Assim, divulgar e dar amplo conhecimento das ações de mulheres nessa área pode colaborar para o alcance da igualdade de gênero e empoderar todas as mulheres e meninas.

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PALAVRAS-CHAVE Aprovação de equipamentos. Acesso a medicamentos essenciais e tecnologias em saúde. Pandemias. Gestão em saúde.



Introduction

The health crisis imposed by the Covid-19 pandemic has required Herculean efforts from health systems. In this effort, the offer and availability of pulmonary ventilators, crucial medical care equipment for the care of severe cases of the disease, was highlighted in the discussions. The asymmetry between the availability of this equipment in the face of historical world demand has generated disputes between countries, with restrictions and prohibitions on exports, such as Law No. 13,993/2020¹, which prohibited exports of pulmonary ventilators and other essential products to fight the coronavirus epidemic in Brazil.

The pulmonary ventilator is an equipment used to provide pulmonary and artificial ventilation. The objective is to provide complete or partial ventilatory support in patients who are unable to breathe through normal airways.

The imminent risk of shortage of pulmonary ventilators in health services led to several work fronts and task forces to maintain and make available as much of this equipment as possible for the treatment of patients affected by the disease. Efforts were used to scale up domestic production, initiatives to carry out maintenance and recover the greatest possible number of pulmonary ventilators, and initiatives for research projects, development and innovation of new equipment. In view of the technological and operational complexity of these equipments, there was a need to highlight the importance of the role of professionals in healthcare technology management and clinical engineering.

The worsening of the health crisis, in January 2021, collapsed health services with an isochronic search for Intensive Care Units (ICU). Amid the collapse, the Oswaldo Cruz Foundation (Fiocruz) detected a new variant of the Sars-CoV-2 lineage and confirmed the first case of reinfection by the new coronavirus in the state of Amazonas. Among the critical points, the following were highlighted: the

chaotic oxygen shortage and ICU bed occupancy rates above 90%².

The extreme urgency in supplying the health units provoked joint actions between civil society and the government. Among them, the 'SOS AM' stood out, including at the national level. The action provided a quick return to the population (individually, with supply of cylinders and oxygen) and primarily to the health network³. A differential in the project was the agility of the processes and the mobilization of clinical engineering professionals at the beginning. These professionals, including the authors of this study, participated in the entire process, from the acquisition to the installation of medical equipment, especially of pulmonary ventilators, in addition to acting in contingency analysis to supply oxygen, providing technical support in the acquisition and technological management of concentrators and oxygen plants.

The management of health technologies is defined in the National Health Technology Management Policy (PNGTS), published in 2011 by the Ministry of Health⁴, as a set of governing activities related to the processes of assessment, incorporation, dissemination, use management and removal of technologies from the health system. This process must have as references the health needs, the public budget, the responsibilities of the three levels of government and social control, in addition to the principles of equity, universality and integrality, which underlie health care in Brazil.

Clinical engineering, on the other hand, can be defined as the branch of engineering dedicated to assisting and even interfering in the health area, with the aim of achieving well-being, safety, cost reduction and quality in the services available to patients and to the hospital's multidisciplinary team, through the application of managerial and engineering knowledge to healthcare technology. These professionals act throughout the life cycle of health technologies, from Research,

Development and Innovation (RD&I), medical-hospital technology management, health technology assessment, technology incorporation and acquisition, regulatory management and market access.

The role of women in the area of technology management and engineering is growing gradually. With regard to engineering, especially in field performances and senior management positions, it is still correlated with male performances; which makes the approach to the topic of greater relevance to the prominence of women in the field of clinical engineering⁵.

To discuss the topic, a survey was carried out, using an electronic form detailed in the Methods section, to know and understand the participation of women in the areas of science and health, with a focus on clinical engineering. 102 forms were answered, in which after refinement, 88 of these were validated. After further refinement, 81 forms were obtained from women with higher education who were working with the use of health technologies in support of the Covid-19 pandemic. Of these, only 56 took the Specialization Course in Clinical Engineering.

In 2020, the Brazilian Association of Clinical Engineering (ABEclin) carried out a survey with the objective of finding out the salary of its members (all who work with clinical engineering). One of the questions was gender, and only 19% of the members who answered the form were women, while 81% were men, out of a universe of 261 answered forms. This allows us to say that the number of women in clinical engineering, that is, who work with health technologies, is significantly lower than that of males⁶.

In direct action to fight the pandemic, ABEclin, in partnership with the Ministry of Health, the Ministry of Economy and the National Service for Industrial Learning (Senai), carried out a survey of volunteers to work in the task force for the maintenance of pulmonary ventilators^{7,8}, in which, of the total of 118 professional volunteers, only 20% were women.

Here, it is intended to report the authors' participation in the field of management of essential technologies to fight the pandemic of international relevance, resulting from the new human coronavirus. Highlight the participation of women in activities that are crucial to respond, in a timely manner, to demands arising from health emergencies. Register and evidence the performance of women in technological management with a view to reaching, encouraging and recruiting greater participation of women in clinical engineering activities and management of health technologies.

Material and methods

The research method chosen for data collection was descriptive and exploratory to address a specific question through literature searches. In this case, the question to be answered corresponds to Covid-19. The literature search was carried out in the database available on the Ministry of Health website, with data from the Brazilian response to the fight against the new coronavirus, and from the ABEclin website, with the activities in support against Covid-19. The registered actions were verified, in addition to researching five closed questions between April and July 2020 using the descriptors combined by the logical operator 'Covid-19' and 'ventilador pulmonar'. The asterisk symbol was used to include the plural term in the search. The terms were used in the field that includes in the search the works that have the term in the title, abstract or keywords, enabling the location of a greater number of documents. A total of five documents were found. *Table 1* shows the distribution of articles found, and *table 2*, the references of the searches carried out.

The search was limited to scientific articles only, in which a total of 13 documents were obtained. Afterwards, the title, abstract and keywords of all works were read, and five articles were selected, classifying them according to the object of study.

The research can be classified as applied in nature, as it aims to generate knowledge for practical application. As for the approach, the research is both qualitative and quantitative, as it involves a deepening of the understanding of an organization while resorting to mathematical language to describe the causes of a phenomenon. The joint use of qualitative and quantitative research allows to obtain more information than if they were done in an isolated way, corroborating the practical experiences of

the authors in technology management processes. The objective is to provide greater familiarity with the problem in order to make it explicit or to build a hypothesis, and a bibliographic procedure, based on previously published material^{9,10}.

The report (*table 3*) presents the authors' recent experiences in initiatives to fight the Covid-19 pandemic, in the technological management of the pulmonary ventilator, considered essential equipment to fight the pandemic.

Table 1. List of articles used in the study

Title	Reference
Rules for the ban on exports of medical, hospital and hygiene products essential to combating the coronavirus epidemic in Brazil.	Brasil. Law No 13,993, of April 23, 2020 ¹
National Health Technology Management Policy (PNGTS)	Brasil, 2011 ⁴
Mulheres em carreiras de prestígio: conquistas e desafios à feminização. Cader- nos de Pesquisa v. 47 n. 163 p. 10-14 jan./mar. 2017	Lombardi MR, 2017 ⁵
Assessing the impact of coordinated COVID-19 exit strategies across Europe	N. WRuktanonchai et al. ¹¹ .
Deep immune profiling of COVID-19 patients reveals distinct immunotypes with therapeutic implications.	Divij Mathew et al. ¹² .

Source: Self elaborated.

Table 2. Data Surveys

Data Surveys	References
Ministry of Health - Brazil	https://coronavirus.saude.gov.br/resposta-brasileira-a-emergencia
Brazilian Association of Clinical Engi- neering (ABEClin)	http://www.abeclin.org.br/post.php?p=213

Source: Self elaborated.

Table 3. Pandemic Experience Reports

Reports of experiences in the Pandemic with the technical support of clinical engineers	Observations
R1 - Report 1 - The clinical engineering provided technical sup- port for the car assemblers to set up the laboratories to repair the pulmonary ventilators and voluntary technical consultancy for the repairs and repairs processes	Automobile assemblers and the Senai network are doing the work on a voluntary basis
R2 - Report 2 - Participation of clinical engineers (individuals and companies) in the repair of pulmonary ventilators. Recruitment of volunteers with technical knowledge about fans.	ABEClin's digital media (Instagram / Facebook / LinkedIn / WhatsApp and Telegram official group) Ministry of Health - Brazil Ministry of Economy - Brazil

Table 3. (cont.)

Reports of experiences in the Pandemic with the technical support of clinical engineers	Observations
R3 - Report 3 - Participation of Technology Management to map the market and sectoral study of pulmonary ventilators to support actions for productive escalation	Ministry of Health - Brazil Ministry of Economy - Brazil
R4 - Report 4 - Participation of Technology Management in monitoring research, development and innovation projects for new pulmonary ventilators	Ministry of Health - Brazil Ministry of Science, Technology and Innovation - Brazil Ministry of Economy - Brazil Brazilian Agency for Industrial Development - ABDI National Health Surveillance Agency - Anvisa

Source: Self elaborated.

Complementarily, a survey was carried out between July 15, 2020 and August 15, 2020, applied through the Google Forms platform, with the purpose of knowing and understanding the performance of women in the areas of science and health, with a focus on clinical engineering and the role in the Covid-19 pandemic. The form was prepared using the online tool on Google Forms, with semi-open questions. The link was forwarded to professionals in the clinical engineering area and disseminated on ABEClin's digital media (Instagram, Facebook, LinkedIn, WhatsApp and Telegram), clinical engineering groups on Facebook and WhatsApp, at the links https://docs.google.com/forms/d/e/1FAIpQLSdvpD8fy8MZ0jyP0Uc6r0z5CshvdkvDAgt7x9KRRjY-CWVJ03A/viewform?usp=sf_link and <https://forms.gle/CzRVWEe1gtYepcrM8>.

The search was limited to 102 forms. Afterwards, a refinement was carried out in which 88 forms were selected, classifying them according to the object of study. The other forms were excluded from the research as they did not deal with consistent information.

Results and discussion

The related reports refer to activities carried out in the sphere of the federal government,

in health services and in clinical engineering class association.

At the federal level, to subsidize and contribute to the productive scale of the national pulmonary ventilator industry, an initial market study was carried out with the mapping of valid sanitary records of national and international suppliers with technical configurations required for the treatment of Covid-19, containing data of the main bottlenecks in the national production process and the identification of critical components, in addition to information on production capacity. The productive scale required government efforts, business and industrial arrangements, financial arrangements and studies of patent situations. The purpose of the effort is to promote an exponential increase in the monthly production of national industries, with valid sanitary records of pulmonary ventilators, to meet the exponentially growing care demand.

In addition to the initiatives undertaken for the production scale of pulmonary ventilators already established in the national market, the performance in technology management supported government actions to support RD&I projects for new pulmonary ventilators. The importance of this process is highlighted, as the development project requires technical specifications

and specific input data, in addition to risk management with component analysis, taking into account the pulmonary severity of patients undergoing Covid-19 treatment. The projects must obligatorily observe the aspects of sanitary regularity, however, given the complexity of the equipment, other aspects must be analyzed for availability in health services, such as characteristics of technology management throughout the life cycle, such as training, maintenance, technical assistance, spare parts, supply of consumables, decommissioning and disposal. It is noteworthy that the pulmonary ventilator is an operator-dependent technology, whose usability, training and interface characteristics are considered to minimize the learning curve. In order to optimize public resources, the versatility of configurations — so that pulmonary ventilators can be used in health services in other clinical conditions in the post-pandemic period — are observed. Thus, analyzes of the projects were carried out with technological readiness and capable of scaling, with the challenge of transforming the viable and functional prototypes, with the guidance of regulatory aspects, and technical-operational aspects, with the minimum criteria that ensure the quality and safety of pulmonary ventilators.

The performance of technology management also collaborated in the processes for comparative evaluation of the technical specifications of pulmonary ventilators, through technical references such as the document ‘Technica lspecifications for invasiveand non-invasive ventilators for Covid-19 Interim guidance’¹¹⁻¹³, published in April 15, 2020, by the World Health Organization (WHO). The assessment was extended to projects for the development of lung ventilators with technological readiness in order to support early assessments of new technologies, in addition to technically contributing to the analysis of tax measures for tariff changes, restrictions on exports of critical equipment to fight the pandemic.

Another considerable fact was the technical analysis of ventilators developed in partnership between industry and government. The industry sought a cost-benefit ratio for scale production, which demonstrated the notorious differential in the assessment by a specialist in the field of clinical engineering. In this example, the analysis confirmed that the equipment developed would not have a market for consumption in the medium and long term.

Another highlighted participation is in the task force for the maintenance of pulmonary ventilators, which brings together more than 500 trained volunteer engineers and technicians, more than 21 partners, and is distributed throughout the federation ready to provide the necessary support to put the largest number of pulmonary ventilators back into operation. It is estimated that 3,600 pulmonary ventilators that impact on health services are out of operation, with more than 2,000 pieces of equipment recovered through this initiative^{7,8}.

In the action of the task force, ABEClin participated with two relevant front lines: in attracting professional volunteers (individuals and companies) and in providing guidance to the entities responsible for preparing the site for carrying out the maintenance of pulmonary ventilators. Guidance took place throughout the entire process chain, from equipment collection at Health Care Establishments (EAS), receipt of maintenance at the site, cleaning, maintenance, calibration until return. More than 1,500 pulmonary ventilators have already been returned.

The recruitment of volunteers took place entirely online through ABEClin’s digital media (Instagram/Facebook/LinkedIn/Official WhatsApp and Telegram Group). The list of volunteers was sent to the Ministry of Health and the Ministry of Economy for the operationalization of the task force⁸.

Guidance notices for outsourced companies for clinical engineering services and professionals in the management of pulmonary ventilators, the search for an exchange of

international experience with other colleagues in the area and the constant work to combat misinformation were also a highlight.

Among so many exchanges of international experiences, the interview conducted with the Italian Association of Clinical Engineering (Associazione Italiana Ingegneri Clinici – AIIC) in March 2020 stands out. The making of preventive and corrective maintenance of medical equipment, mainly the ones used in ICUs, was one of the main orientations of our Italian colleagues. Another relevant point in the interview was the orientation for Brazilian clinical engineering to take advantage of the opportunity of advance information at a time with scarce data for decision making, which is a differential for the preparation of professionals to face Covid-19.

The emotional state was one of the concerns; partnerships with entities through projects such as active listening collaborated to provide relief to professionals in health services.

In the analysis and treatment of the survey data carried out with the 88 valid forms, it was possible to verify that 81 women had a university degree and were working in the management of health technologies in support of the Covid-19 pandemic. As for academic training, it was observed that 56 responded that they had a Specialization Course in Clinical Engineering, 2 had been trained in high school technical courses, and 5 had not informed. Regarding training time, less than 1 year was 17.11%; between 1 year and 5 of studies, 14.47% was obtained; and over 5 years, 28.95%. In relation to working time up to 1 year, 15.91%; between 1 year and 5 years, 28.41%; and over 5 years, 46.59%. The most significant places of

action were in health services, 56.03%; private companies, 21.28%; public area, 9.22%; and academic area, 5.67%.

Final considerations

The crisis caused by the pandemic of the new human coronavirus sparked discussions for the need for professionals who work in the management of medical and hospital equipment in all spheres of management – and, especially, in health services. These professionals, working in technology management and clinical engineering, are still, overwhelmingly, men. The participation of women in these scenarios is highly relevant, although it is still timid due to the limited space occupied. Disseminate and give ample knowledge to the actions of women in this area, create favorable environments and encourage the spaces of health engineering and management positions to be occupied by women in an equal position contribute to the fulfillment of Goal 5 of the 2030 Agenda for the Sustainable Development: Achieving gender equality and empowering all women and girls.

Collaborators

Toscas F (0000-0002-6447-2045)* contributed to the design and planning; drafting and final version of the manuscript. Holsbach LR (0000-0002-9591-132X)* contributed to the methodology, analysis and interpretation of data and review. Santos APLJ (0000-0003-2598-1549)* contributes to the analysis and interpretation of the data. ■

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