

A BREEZE AT ELMO, A BREATH OF LIFE AT COVID-19

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COVID-19 represents the biggest pandemic faced by humanity in the last 100 years. At the time of writing this article there are approximately 5 million deaths from the disease worldwide. In Brazil, at least 608,000 people lost their lives, around 24,500 in the state of Ceará. The first cases were confirmed in Fortaleza in March 2020.

Our capital, an international air hub and with one of the highest demographic densities in the nation, suffered an earlier and more intense impact of the pandemic than other capitals in the Northeast, according to analyzes by the Center for Intelligence of the School of Public Health Paulo Marcelo Martins Rodrigues (ESP). At that time, we were experiencing the threat of imminent catastrophe. There was a lack of ICU beds, mechanical ventilators and the use of non-invasive ventilation (NIV) techniques using masks adapted to the face of patients or high-flow nasal cannulas was not recommended, given the high risk of contamination of health professionals in the frontline.

On April 4, 2020, a meeting called for by the Ceará Foundation for Scientific Development Support, FUNCAP, involved university institutions (University of Fortaleza and Federal University of Ceará), ESP and the Federation of Industries of the State of Ceará and the National Service of Industrial Learning.

On that rainy afternoon, in a remote digital environment, innovative solutions were discussed to mitigate the wave of

serious cases that began to overload the health system. The first idea was to develop a mechanical fan, starting from scratch. I argued strongly against it. As a pulmonologist and intensivist and studying the subject since my medical graduation in 1991, I knew perfectly well that we would not be able to develop a viable equipment for use in a very short period of a few months. I proposed another innovation: a helmet for delivering O₂ with continuous positive airway pressure (CPAP).

I showed an image of an Italian device being used by a patient in Chicago in the US from the work of Dr Patel et al.¹ They demonstrated that the wearing of the helmet, as it is known in English, in patients with Acute Respiratory Distress Syndrome (ARDS), a condition also associated with Covid-19, reduces the need for tracheal intubation in this serious clinical condition. I argued the possible advantages of following the helmet path considering that:

1. we could avoid a good number of intubations and all the consequences of the invasive treatment;
2. The helmet would reduce the risk of contamination for health professionals because it is sealed in the neck, with no or minimal leakage and with a filter in the exhalation;
3. could be used outside the ICU, in wards, requiring only a source of medicinal gases, oxygen and compressed air, reducing

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the need for mechanical ventilators and even ICU beds;

4. It would be more comfortable for the patient, humanizing and increasing the effectiveness of the treatment;

5. being much simpler than a mechanical ventilator it would be feasible to develop it in time to support the healthcare system; and

6. it would be much lower cost and simpler to use by healthcare professionals.

I called it ELMO, the term means helmet for war, and it's still a good-sounding proper name, somehow "humanizing" the device. The name was well accepted at the second meeting of the initial group and a task force was spontaneously formed involving the 5 institutions and professionals from different areas: pulmonologist and intensivist, respiratory physiotherapists, machining and tooling technicians, industrial design and engineers in the clinical areas, civil, mechanical, computing and production.

Once the decision was made, the project was prepared immediately, submitted to the Research Ethics Committee (CEP) of ESP and the innovation chamber of FUNCAP. It was also published for international knowledge at clinicaltrials.gov and later approved by the National Research Ethics Committee (CONEP).

Then, it was designed and converted into prototypes (nine in all) at the Senai Institute of Technology in Electrometalmechanics. The first usability tests were carried out among the researchers and volunteers themselves in a Laboratory dedicated to the project and set up by SENAIS in the Jacarecanga neighborhood.² Only after this phase was started a prospective clinical trial of feasibility that was carried out at Hospital Leonardo da Vinci, hospital exclusively intended for the care of patients with Covid-19.

The study ran from June to October 2020 and the results publicly presented in November. The feasibility of using ELMO in patients with moderate to severe COVID-19 admitted to a ward has been demonstrated. The good physiological response and comfort with the equipment were proven. The success rate was 60%, even a little better than expected³.

In parallel, a patent application was prepared and sent to the National Institute of Industrial Property (INPI), on behalf of the five partner institutions and the authors: Marcelo Alcantara Holanda, Betina Santos Tomaz, David Guabiraba Abitbol de Menezes, Juliana Arcanjo Lino and Gabriela Carvalho Gomes. In October, authorization was obtained from Anvisa by the company ESMALTEC, licensed to manufacture and sell ELMO throughout the country.

Approval came at a decisive moment. The 2nd wave of the Pandemic would start shortly thereafter and reach a peak in late March and April 2021. In an effort unparalleled in history, around 1614 health professionals were trained during this period in the correct handling of the ELMO using a realistic simulation technique by ESP, in the state and in other units of the federation. About 10,000 ELMOS were produced and distributed across the country in these early months of this year.

It is estimated that they have been used in 40,000 patients, and reports of success rates around 60% have been described in public and private hospitals in Ceará. Thousands of patients benefited. Dramatic reports were made on social media and media reports. Social engagement was significant, entities and companies donated a significant number of helmets to the health system.

The initiative gained local and later

national recognition.⁴ This special edition of Cadernos ESP brings 12 articles involving 35 authors with studies and reports of pioneering experiences with the use of ELMO in the treatment of Covid-19. ELMO is a case in point in the field. The state induced innovation with a common purpose of saving lives in a situation of sanitary crisis, the academy and the health school together with the industrial and commercial sectors were called to participate. Social engagement followed. This entire process can help guide the agenda for strengthening innovation in health in Ceará and Brazil.

Transformative innovation takes place through the articulation of the state with industrial and commercial sectors, science and technology institutes (ICTs), academia and society around common purposes of high social relevance. New practices such as teamwork, transparency, knowledge sharing, structures, processes and resources and collaborative networks need to be strengthened.

ESP is now an integral part of that ecosystem. It is part of our missions, and it is our challenge to follow this path together.

Good reading.

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