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Special Session Title:

 $\operatorname{COVID-19}$ in Latin America, efforts, success, and lessons to learn - Part 2

Special Session Organizer Name & Affiliation:

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Special Session Speaker Name & Affiliation 1:

Jesús Manuel Dorador González , ENES-Juriquilla-UNAM, México

Special Session Speaker Name & Affiliation 2:

Biomedical Systems Department, Engineering Faculty, UNAM, México

Special Session Speaker Name & Affiliation 3:

Alexander Somarribas, ACOBEM, Costa Rica.

Special Session Speaker Name & Affiliation 4:

Joaquin Azpiroz Leehan, Cl3M-Universidad Autónoma Metropolitana, Mexico

S Special Session Speaker Name & Affiliation 5:

Special Session Speaker Name & Affiliation 6:

Theme:

- 🔘 01. Biomedical Signal Processing
- 🔘 02. Biomedical Imaging and Image Processing
- O3. Micro/Nano-bioengineering; Cellular/Tissue Engineering &
- O 04. Computational Systems & Synthetic Biology; Multiscale modeling
- 🔘 05. Cardiovascular and Respiratory Systems Engineering
- O 06. Neural and Rehabilitation Engineering
- O 07. Biomedical Sensors and Wearable Systems
- 08. Biorobotics and Biomechanics
- O9. Therapeutic & Diagnostic Systems and Technologies
- 10. Biomedical & Health Informatics
- 11. Biomedical Engineering Education and Society
- O 12. Translational Engineering for Healthcare Innovation and Commercialization

Special Session Synopsis— Max 2000 Characters

During the global health emergency caused by the SARS-COV 2 virus, also known as COVID-19, several working groups globally made joint proposals to solve urgent problems considered priority to be attended. There were some success cases, in which ideas, designs and technological developments had a direct impact on improving patient care and protection for healthcare professionals. In the last year there have been efforts all around the world in the development of medical technology, generation of reconversion protocols for hospitals and public areas, research to have a better understanding, diagnosis and monitoring of patients with COVID-19, the creation of a vaccine, among others; where health care professionals (clinicians, researchers from different areas, biomedical engineers, among others) have been working at an incredible pace to contain the pandemic as much as possible. However, COVID-19 has highlighted the deficiencies or weak points in health systems around the world, but also it highlighted the relevant role of science and technology in the development of solutions to face COVID-19. Some opportunity areas related to the process of generation and validation of medical devices were also evident, as well as different reasons that did not allow for expeditious collaborations between scientists, industry and regulatory agencies. In addition, in many Latin American countries, the lack of resources and infrastructure deficiencies leave health care specialists in unfavorable situations facing COVID-19, forcing them to adapt according to their own particular situation in order to face the pandemic.

This special session aims to provide a place where different healthcare specialists in Latin America may present their reality facing COVID-19, and share their experiences, efforts and lessons learned during the course of the COVID-19 pandemic.

Speaker 1 – Academic Initiatives to Attend the Health Emergency in México.

Jesús Manuel Dorador González, ENES-Juriquilla-UNAM, México

Abstract— In the initial stage of the pandemic caused by SARS-Cov-2, Mexico's lack of technological sovereignty with respect to the requirements of supplies and equipment for the health sector, as well as the worldwide insufficiency of these, became evident. To face this problem, academics from different faculties and institutes of the National Autonomous University of Mexico joined forces to solve pressing problems during the health contingency. This talk will explain the process that led to the formation of multidisciplinary teams for the development of equipment and prototypes under the premise that they could be manufactured in Mexico through a university network of scientific and technological collaboration, sharing ideas and available infrastructure.

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Speaker 2 – Design and Evaluation of an Invasive Mechanical Ventilator.

Serafín Castañeda Cedeño, Biomedical Systems Department, Engineering Faculty, UNAM, México

Abstract— As respiratory diseases due to the COVID-19 pandemic spread around the world, there was a severe shortage of mechanical ventilators, suppliers and manpower to operate these specialized medical devices. Inevitably Mexican healthcare systems began to face the tough challenges of acquiring mechanical ventilators to support patients in intensive care units. One of the initiatives driven by Universidad Nacional Autónoma de México was to bring together engineers, physicians, companies and students for the development of a mechanical ventilator designed for rapid mass production in response to severe pandemic effects. This conference describes the design and evaluation of an invasive piston-based mechanical ventilator for the COVID-19 emergency.

^{*}Research supported by DGAPA- PAPIIT IV100320 "Desarrollo de Insumos e Instrumentación en atención a la emergencia sanitaria por el COVID19".

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Speaker 3 – Strategies and Results by the Costa Rican Health System.

Alexander Somarribas, ACOBEM, Costa Rica.

Abstract— The objective of this conference is to provide an overview of the strategies and actions that have been carried out by the Costa Rican health system: the results of hospital reconversions, initiatives for the development of pharmacological compounds to reduce the rate of hospitalizations and deaths, efforts of technological development initiatives as well as the acquisition of medical devices and strategies for vaccine administration.

I. INTRODUCTION

Costa Rica, as in other countries around the world, acted as a mirror to jointly try to solve initially the care of critical patients in the health emergency caused by SARS-COV 2.

State and private universities successfully promoted some ideas, designs and technological developments, basically related to pulmonary ventilation, which at the peak of the pandemic had the greatest impact. We also copied the model of hospital reconversion, tests were carried out with equine serum in patients with Covid-19 whose results promised to be encouraging and satisfactory: no allergies, reduced recovery time, as well as reduced probabilities of severe adverse effects. However, not everything has been positive, since 6 patients died and 16 have not recovered; these results were predicted by the health managers of the study.

On the other hand, the National Rehabilitation Center, now called Centro Especializado de Atención de Pacientes con COVID-19 (CEACO), has also been reconverted and is currently in operation. But the Costa Rican health system, maintaining equanimity and considering that we are not a country where we are strong in the development and manufacture of technology, opted to strengthen the simplest protocols within the reach of the population, such as maintaining distance, use of masks, hand washing, and the use of alcohol gel. This has ultimately been reflected in the reduction of COVID-19 cases as well as in the reduction of diarrhea and respiratory infections.

It is worth mentioning that large investments have been made in the purchase of medical equipment, but the best results have been achieved with smaller investments such as EDUS (Expediente Digital Único en Salud), which has been used and added an Integrated Vaccine System (SIVA) dedicated only for the follow-up of vaccinated persons. With the COVID-19 vaccination plan it is possible to have traceability throughout the execution process, with this information systems are available to track the COVID-19 vaccines and to relate in each vaccinated person the laboratory manufacturer of the medicine used, the corresponding lot number and the expiration date, in accordance with the integration of the available information systems. Traceability is the follow-up of a product through all the internal processes of the organization from the time it enters until it reaches the end user, which implies that each vaccine is monitored from the time it is received until it is delivered to the health services. When the vaccine enters the institution, Sistema de Gestión de Suministro (SIGES) records the variables corresponding to presentation, lot number and expiration date. The follow-up continues in the local drug warehouses of the Pharmacy Service of each health center through the Sistema Integrado de Farmacia (SIFA). Finally, when the vaccine arrives at the vaccinatories, the Sistema Integrado de Vacunas (SIVA) which is part of the EDUS, indicates the vaccine dose to be received, the manufacturing laboratory, lot number and corresponding expiration date for each person. The Caja Costarricense de Seguro Social is the executing agency responsible for the reception, storage, conservation, distribution and application of the vaccines according to the order established for the five risk groups. The institution maintains the supervision and controls in the application process of the vaccine against COVID-19 in accordance with the guidelines of the Ministry of Health. Likewise, it continues and has strengthened the Costa Rican vaccination scheme, which we hope will serve as an example for other countries.

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Speaker 4 – Lessons from the Failed Covid-19 Ventilator Initiatives

Joaquin Azpiroz Leehan, CI3M-Universidad Autónoma Metropolitana, Mexico

Abstract— Mexico's response to the deficit of mechanical ventilators in light of this new pandemic has been very unsatisfactory. This work analyzes some of the issues that were found and proposes that we learn from previous mistakes in order to strengthen our community in R&D for medical devices.

II. INTRODUCTION

Every time you put a system under stress, you reveal its weaknesses.

It is obvious That the SARS-Cov2 pandemic caught everyone unprepared. This disease attacks many organs and systems, but perhaps the respiratory system is the one that is placed under the heaviest attack. It is common to find patients who require supplemental oxygenation and mechanical ventilation.

In Mexico, the installed base of ventilators was 5000, when the estimated need before the pandemic was 20,000. The disease drastically worsened this deficit. This same problem appeared in many other countries. Mexico has hundreds of engineering schools, over 60 BME programs and a moderately strong manufacturing industry, so it was not surprising to find many of these institutions proposing emergency ventilator designs. Many, but not all were based on a proposal by MIT for AMBU bag mechanization.

Medical device manufacturers and the automotive industry (Ford, VW) joined these efforts, so when the CONACYT (National Council for Science and Technology) published a funding program to build between 500-2000 ventilators, over 70 submissions were sent.

III. METHODS

Work evaluating several ventilator designs was carried out at the National Center for Research in Medical Imaging and Instrumentation, CI3M. It is a National Laboratory at Universidad Autónoma Metropolitana. Several technologies and designs were evaluated both with a test lung (Michigan Instruments, Model 1600) and with porcine models. Although we tested a small proportion of all of the proposals, we were asked to do a final evaluation of designs that were finally approved for use, and after being in contact with the community of developers and regulatory instances as well, we can summarize our unofficial findings as follows.

IV. RESULTS

The results not only from this program, but for all of the country's institutions showed that there is a broken system for aid for the procurement, design and development of medical devices in the country.

1: Procurement has suffered from corruption, price gouging and the establishment of political connections in order to get import permits. Every official in affairs related to the R&D of ventilators wants to be in the limelight, and this has led to "expedited" procedures for emerging designs that took 3x longer times to market than the original procedure.

2: Everyone thinks that the design & construction of a mechanical ventilator is easy, while this is not so, so this led to a very large number of designs that did not meet the stated specifications.

3: Testing and validation was difficult. There were not many facilities for testing and validation of these designs, and some of these had conflicts of interest (had testing facilities but were in the process of designing their own models). Out of the 70 prototypes that were submitted, until recently, only 2 ventilators were approved conditionally by the regulatory agencies.

V. DISCUSSION & CONCLUSION: LESSONS

1: A politicized process is not helpful.

2: Quick and dirty is not good. Prototypes did not conform to specifications. Even input from the automobile industry is not good enough.

3: Good designs are derived from medium to long-term research, as some institutions have shown.

4: We should strengthen our Design & Development core subjects in our BME curriculum.

5: We should streamline our evaluation and validation of prototypes, leaving this authority to one entity instead of three, as it is now current in the new "fast, emergency" process.

We at CI3M hope that this analysis will lead to greater discussion as to how to address and direct more and better funding for Bona Fide efforts to strengthen the capabilities to design & develop medical device technology in our country.

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