2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

Analysis of the Unsuccessful Efforts to Design & Construct Invasive Mechanical COVID-19 Ventilators in Mexico: Did the Current BME Curricula at Mexican Universities Contribute to the Failure?

Joaquin Azpiroz Leehan, *Senior Member, IEEE;* Emilio Sacristán Rock*, Senior Member, IEEE;*
Fabiola Martínez Licona*;*

***Abstract*— Mexico was caught unprepared to deal with the current COVID-19 pandemic. One of the most egregious failures was the incapability to provide an additional 10,000 ventilators in order to cope with the excess demand. The Mexican government proposed a program for funding the development of these devices and over 100 designs were submitted but were of below standard quality and performance. Only three designs have been approved up to date.**

This work analyzes the failures from the point of view of the incapability to design, develop and test locally made ventilator designs, and asks whether the national university system, after a history of 48 years of producing thousands of Biomedical Engineering students in over 60 institutions has become incapable of delivering a design of a medical device of medium complexity.

I. Introduction

It is evident to say that the current COVID-19 pandemic has upended many assumptions and policies regarding health care. Apart from vaccine development, the two main issues regarding treatment were the accessibility of ventilation and supplementary oxygen support. Many countries have responded by developing and constructing additional ventilators and oxygen delivery systems. In Mexico, the number of ventilators before the pandemic was 5523 for a population of over 126 million inhabitants or one for every 23,000 inhabitants, while the number for Canada was one for every 12,000, which were deemed insufficient or the numbers for the UK and Germany, which were one for every 3000 inhabitants. In view of this it would be necessary to obtain an additional 10,000 ventilators in order to provide adequate care for the population [1].

In view of this, several disorganized actions have been carried out: Panic buying of imported ventilators of dubious quality and excessive pricing, development of ventilators of dubious quality as well, and little support by financial and regulatory agencies. In Mexico, over 100 ventilator designs have been proposed. Many of them are copies or are derived from AMBU-Bag or obsolete designs. They do not usually conform to norms. Other problems have been derived from the actions at regulatory agencies. In short: Not very good designs, lack of support from regulatory agencies and a politicized process that gave priority for testing at several government institutions.

The result of this was that an expedited process for review of the new ventilator designs [2,3] turned out to be much more complicated than the standard review processes under the state regulatory agencies [4]. The results were that by the start of 2021, only three ventilator designs had been approved. One is a limited AMBU bag design, proposed by a government-funded technological institute, one was developed at one of the National Institutes of Health, and the third one was already under construction by a renowned company that was dedicated to ventilator design and maintenance. It is ironic that many of the people in charge at the Mexican Regulatory agencies (COFEPRIS and CENETEC) are graduates of Biomedical Engineering programs, and that in Mexico, there are over 60 Universities that offer the BME program.

In view of this institutional failures, we decided to reevaluate the programs and their approaches of all the institutions offering Biomedical Engineering degrees in Mexico. Our aims were to determine if there were any relevant changes over the years, since we evaluated 50 BME programs in Mexico in 2014 and 90 programs in Latin America in 2016. Here we present our findings, which we compare to a recent paper by Linsenmeier & Saterback [5], which was published last June, and which is a review of 50 years of BME education in the US. It is important to note that BME undergraduate programs are almost as old in Mexico, having started in 1973.

II. Methods for Curricular Analysis

Currently there are over 60 undergraduate BME programs in Mexico, although several are very similar, as they belong to different university systems. We selected 25 representative programs and we analyzed the curricular structure, their aims and characteristics as well as the balance of subjects, electives and focus areas, in a manner similar to Azpiroz [2015 and 2017]. The subjects were grouped by areas: Mathematics, Science, Engineering, Programming, Biomedical Engineering and Social Sciences. The institutions were then classified into technical, professional or research universities and several characteristics were noted. For example, whether a capstone/research project was required, and which were the focus areas. The findings were analyzed in a similar manner as the previously mentioned publications

J. Azpiroz Leehan is with the Centro Nacional de Investigación en Imagenología e Instrumentación Médica at Universidad Autónoma Metropolitana-Iztapalapa, Mexico (e-mail: jazpiroz@ci3m.mx).

E. Sacristán Rock is with the Centro Nacional de Investigación en Imagenología e Instrumentación Médica at Universidad Autónoma Metropolitana-Iztapalapa, Mexico (e-mail: esacristan@ci3m.mx).

F. Martínez Licona is with the Centro Nacional de Investigación en Imagenología e Instrumentación Médica at Universidad Autónoma Metropolitana-Iztapalapa, Mexico (e-mail: fmartinez@ci3m.mx).

978-1-7281-1178-0/21/$31.00 ©2021 IEEE

III. Results

Of the 25 institutions, only the data from 23 were kept, as the descriptions of the curriculum of two were not “classical” descriptions of subjects and thus were difficult to categorize. Mostly they described the competencies, but not the subject areas. Three National Universities, 15 State Universities and 4 Private universities were considered, in addition to three Technological institutes which are state/national institutional hybrids.

Regarding the structure and length of the programs, most were 8 semester programs, although eight were 9 semesters long, one was 12 trimesters and two were four-month long terms. In the end the coursework was very similar except for those with 9 semester programs.

Surprisingly, the distribution of the types of courses did not appreciably change. Figure 1 shows these distributions for 2015 and 2021:

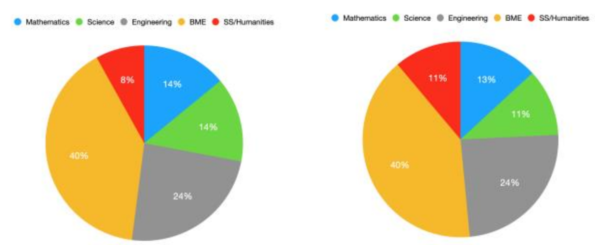

Figure1: Course distributions for Biomedical Engineering programs in Mexico in 2015 (L) and 2021 (R) after many programs were revised.

However, significant changes were detected both in the requirement for capstone projects, which has been reduced, and for the focus areas. Only 24 percent of those programs under study required a bona fide, one-year-long capstone project. Another 36% of the programs require a single capstone “graduation seminar”, while the remaining 40% do not have any capstone project requirements at all. These other institutions require work experience, residencies, final examinations or grade-point-averages for graduation. With regard for the focus areas, it was surprising to observe that 33% of the programs were very strong in their emphasis on clinical engineering and health technology management, another third had an emphasis in instrumentation, while a few had a mixture on focus areas which included physiology, computing and imaging. Rehabilitation engineering and cell & molecular biology were absent from the mix. Two institutions offered a reduced BME core, but with a large cloud of electives (up to 10 BME electives at Metropolitan University, UAM), or three subspecialty areas (Instrumentation, Rehabilitation and Clinical Engineering at UNAM) to choose from. UAM also places much emphasis on choosing the electives to support their one-year-long capstone project.

Most programs were very traditional in the sense that the first two years were dedicated to the teaching of Basic Sciences and Mathematics, followed by many subjects in Electrical Engineering (electrical circuits, analog and digital electronics) and Signals and Systems, and Biomedical Engineering subjects were added as a subspecialty of Electrical Engineering (medical instrumentation and imaging, mostly). Overall, only four of the reviewed programs seemed interesting. Two of them provide design-centered approaches, where different aspects of this are interspersed throughout the four-year program. Two others have a more traditional Electrical Engineering structure at first, but offer a significant number of subjects and projects dedicated to Biomedical Engineering

IV. Discussion

Even though 20 universities added the BME to their curricula, it was surprising to see that there was practically no change in the composition and balance of subjects that were studied, even though some subjects in the Engineering domain moved from classical Electrical Engineering into computing, and CAD, CAM or virtual instrumentation.

Another finding was that most of the institutions that were reviewed were placed within the classifications of Teaching Universities, while only 6.5% could be classified as Research Universities, with an important design core [Krishnan, 2014 and 2015]. Many institutions have shifted away from proposing a model for Technical or technological colleges but are still teaching subjects that are more inclined to support employment in the Clinical Engineering, maintenance and sales sectors. For example, many institutions offer courses on Maintenance of Biomedical Equipment, Health Technology Management, BME in the Public Health Sector instead of Recent Advances in Medical Instrumentation and Design of Biomedical Health Devices. One question regarding the emphasis on technology management is whether this is placing an undue emphasis on regulation to the detriment of bona fide engineering design.

This balance of subjects on offer is very different from what the worldwide BME community is dedicated to. For example, submissions at recent EMBS conferences have been divided into different “Themes”, and the numbers and distribution of these subjects are completely different from what we see as focus areas in BME schools in Mexico:

- Imaging & Image Processing: 23%
- Signal Processing: 16%
- Neural/Rehabilitation Engineering: 14%
- Biomedical Sensors & Wearables: 12%
- Health Bioinformatics: 11%

The rest of the contributions are single-digit percentages. Clinical Engineering, for example makes up only 1% of all submissions at these conferences. In view of this discrepancy among the Mexican and international approaches to the field of Biomedical Engineering, one obvious question is: Are the curricula in the national universities obsolete?

It is important to discuss the BME “core”, since it is here that we find significant differences in approach. There is a long history and influence with Electrical Engineering subjects that were later reevaluated and that started what has been called the blessing and curse of BME: the need to balance depth and breadth of knowledge among different disciplines.

If we analyze the information provided by Linsenmeier & Saterback [2020], it appears that the proposed prerequisites (Math, Physics & Chemistry) are pretty well taken care of by most programs in Mexico. If anything, there is an excess of Math courses that could be revised, as well as some on Organic Chemistry, Vector Calculus, Waves & Optics.

The core subjects are divided into three areas:

- Mechanics, Physiology and Design.
- More Biology, Circuit Analysis, Computing, Statistics, Materials and Instrumentation.
- Signals & Systems and Transport Phenomena

It is here that we also find that there are significant differences. Very few programs place emphasis on mechanics and on Design, which by default places the programs with a significant disadvantage and very near to what could be considered to be a technical, not professional program. At the second level of the core competencies, there is a lot of emphasis placed on the Electrical Engineering legacy courses and this burdens the programs unnecessarily. At the third level, there is practically no study of transport phenomena.

Some changes that we propose within the Mexican programs are to ensure that:

- There is at least one year of courses on Physiology (preferably quantitative physiology) and one or two courses on Cell and/or Molecular Biology
- The following subjects should be included: Bioinformatics, Tissue Engineering, regenerative medicine, Neural Engineering and Nanotechnology
- All programs should include required courses in Capstone Design (preferably a one-year-long sequence).
- Several programs should move in the direction of being design-centered: we believe that all research universities, and many others as well should emphasize subjects dealing with this.

V. Conclusion

Biomedical Engineering Undergraduate education is over 50 years old in the US. It is 48 years old in Mexico, where it was established in 1973. However, the program aims were very different. There are around 120 accredited BME programs in the US, over 60 programs in Mexico and over 100 in Latin America. This is no longer a new discipline.

In the US the aims were to support the Biomedical and Health Device Industry, while in Mexico the aims were to maintain and manage the medical infrastructure that was being installed in government hospitals. These differences in aims still hinder the design & development of health care devices within the country.

One of the main problems that have been unmasked by this crisis in the design and development of devices of medium complexity is that while every BME thinks it can design and build invasive ventilators, this is no chore that can be carried out in a few months. It requires experience, knowledge of design approaches, compliance with regulations, and discipline to go through a review and approval process. Many of these aspects can be addressed in an appropriate curriculum.

We have found out that even validating a ventilator design was difficult, due to the fact that some of the institutions that had a lung simulator, in fact had conflicts of interest because the institutions' Clinical Engineering Departments were in the process of developing and validating their own designs in addition to others. Regulatory agencies (COFEPRIS, CENETEC, which are staffed by Biomedical Engineers that come from the aforementioned Clinical Engineering or Health Technology Management branches or focus areas that are being offered in most Biomedical Engineering curricula nationwide) proposed fast track regulations that turned to be more complicated than the original submission and validation procedures. It appears now that although the personnel were working in good faith, they had never had any experience with procedures such as these, and a design background would have been essential. It is now evident that this is a significant failure of the original vision of the different program creators at a national level.

All of these are suggestions for urgent action in order to move from a framework of managing and maintaining health care technology to the design of medical instrumentation. We have suggested that moving to a curriculum that has a design core would be helpful to strengthen the industry dedicated to the design and development of medical devices in Mexico [9]. These latest failed results only underline the importance of solving this issue. This means not just keeping the status quo locally but developing solutions to important medical problems by designing devices, systems and processes in order to improve human health worldwide.

References

[1] Castañeda-Olivares, F, Lemus Hernández, J.C., Diagnóstico de disponibilidad de respiradores UCI en México. NTHE, Oct. 2020, pp. 58-6804-2018-1114 10321700-203 ISSN 2007-9079

[2] Secretaría de Salud, México CENETEC https://www.gob.mx/cofepris/es/articulos/disposiciones-para-la-adquisicion-y-fabricacion-de-ventiladores-durante-la-emergencia-de-salud-publica-por-coronavirus-2019-covid-19?idiom=es

[3] https://www.gob.mx/cofepris/articulos/informacion-sobre-los-lineamientos-de-ventiladores-actualizacion-9-de-mayo?idiom=es

[4] Secretaría de Salud, México CENETEC, Guía para la Evaluación de Dispositivos Médicos https://www.gob.mx/cms/uploads/attachment/file/397361/ETES_GuiaEvalClinicaDM_17_SPC_13_12_17.pdf

[5] Linsenmeier, R.A., Saterbak, A. Fifty Years of Biomedical Engineering Undergraduate Education. *Ann Biomed Eng.* **48,** 1590–1615 (2020). https://doi.org/10.1007/s10439-020-02494-0

[6] Krishnan, S. Challenges and Models for Baccalaureate BME Program Design, Proc IEEE EMBC 2015.

[7] Krishnan, S. Academic Program Models for Undergraduate Biomedical Engineering Proc IEEE EMBC, pp. 5145-5148, 2014.

[8] Azpiroz-Leehan, J., Sacristán-Rock,E., Urbina-Medal, E.G. and Martínez-Licona, F. (2017) Biomedical Engineering in Latin America: A survey of 90 Undergraduate Programs. IFMBE Proceedings, Vol. 60, Springer. https://doi.org/10.1007/978-981-10-4086-3_27

[9] Azpiroz-Leehan, J., Sacristán-Rock, E., Urbina-Medal, E.G. and Martínez-Licona, F. "Updating the Biomedical Engineering Curriculum in Latin America: Moving from management and maintenance to Design and Development of Medical Devices," *2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC)*, 2020, pp. 6028-6031, doi: 10.1109/EMBC44109.2020.9175362.