ENGINEERS RESPOND TO COVID-19: CASE STUDIES FROM AROUND THE GLOBE

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E4C Fellows:
Nishant Agarwal, India
Marie Floryan, Canada
Jang Hyeon Lyu, South Korea
Helen Lindsay, USA
Carolina Rojas, Panama

Project Advisors:
Caroline Soyars, E4C Steering Committee Member & Univ. of Michigan
Robert Hauck, ASME EGD Committee
Eddine Sarroukh, Philips Foundation & UNDP
Christine Reilley, ASME

E4C Editorial team:
Grace Burleson, Research Manager
Mariela Machado, Program Manager

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Executive Summary

In 2020 the engineering community responded to the urgent need for medical equipment to combat the novel coronavirus (COVID-19) pandemic. Demand for personal protective equipment (PPE) skyrocketed as healthcare providers rushed to the front lines and governments began mandating the use of face coverings in public spaces. Furthermore, ventilators, essential medical devices for treating patients with severe COVID-19 symptoms, were in shortage around the world. Symptom tracking and contact tracing technologies were developed to prevent the spread of the virus. This report highlights just a few of the global engineering community's collective efforts to combat the pandemic and improve safety and well-being of healthcare workers and the public.

The interviews and desk research provides insights on the importance of collaboration with organizations or companies where factors like accelerated government support, revamped funding mechanisms, training, and dedicated task force helped in delivering the solutions. While there have been hundreds of projects, initiatives, and dedicated teams working towards technological solutions to combat the pandemic, this report highlights just a few in Canada, Colombia, Ghana, India, Lebanon, the Netherlands, Panama, South Korea, and the USA.

In Canada, The Canadian Shield partnered with several companies to produce face shields for hospitals through the support of the federal and provincial governments in Canada. Over 300 design iterations were made to meet the end user needs and to adapt to mass production needs.

In Colombia, InnspiraMED was established with the support of hundreds of volunteers from academia, business, and the public sector to meet the demands due to the spread of the virus. Since March 2020, InnspiraMED has executed a variety of initiatives including mass testing for early detection of COVID-19, developed data collection tools to service public health, and designed open-source ventilators and respirators.

In Ghana, a robust engineering workforce mobilized to respond to technology shortages, such as PPE, testing equipment, and ventilators. Partnerships between the Ghana Society of Biomedical Engineers, makerspaces, and universities assembled teams to design and manufacture necessary technologies, such as 3D printed face shields. Through government support, and resources from the Ghanaian garment industry, roughly 15 million face masks have been manufactured and distributed to healthcare facilities and schools.

In India, contact tracing app Aarogya Setu was developed to track the spread of COVID-19. However, the technology has received criticism from experts regarding its security and potential benefits. The government of India did initiate a number of programs to raise awareness about the app and once made it compulsory for the officials to have the app installed but later reinstated the order. The app reached the masses but the measure on the effectiveness is still a point of discussion. Furthermore, in India, a robotics company, Nocca Robotics, has pivoted their business to develop ventilator designs. As of July 2020, the company has a facility with the capacity to manufacture 40 ventilators per day, and has ventilators distributed to eight hospitals in India.

In Lebanon, hundreds of volunteers joined the newly-established Lebanon Response Teams, with the mission to support the needs of the national healthcare system. During the height of the pandemic, the team manufactured and donated 2500 face shields to the government and hospitals, distributed intubation boxes to 24 hospitals, and donated thermometers to a few organizations.

In the Netherlands, Project Inspiration reverse-engineered a ventilator design from the 1960's at Delft University of Technology. The goal of the project was to design and implement ventilators in Low- and Middle-Income Countries through partnerships with health ministries, healthcare workers, and manufacturing and distribution entities. Project Inspiration's ventilator design has been used in collaboration with Respira Guatemala to manufacture and distribute technology in Guatemala.

In Panama, a team of students and faculty at the Technological University of Panama worked together to design a high flow humidifier. Initiated by the Ministry of Health in Panama, the design team has developed a design that costs only 210 USD and can be manufactured in Panama.

In South Korea, more than 120 companies, universities, and government bodies participated in a contact tracing program to cater to the challenging task of acquiring and processing user data. The funding support from the ministry of land, infrastructure, and transport and the Korean CDC helped to build the contact tracing platforms. The development of smart city databases to monitor traffic, environment, housing, and facilities across cities in Korea made it possible for companies like N2M and Dtonic to develop contact tracing datahub.

In the USA, General Electric and Ford Motor Company partnered to produce and distribute more than 50,000 ventilators in 5 months of time. Engineers with expertise in automotive assembly lines designed and implemented a safe and efficient ventilator assembly program. Engineers with medical device experience rapidly completed over 200 design changes from an original ventilator design with goals to achieve rapid manufacturing, device usability in wide-ranging environments, and quick troubleshooting on the assembly line.

Table of Contents

Canada: PPE by the Canadian Shield 4

Colombia: Ventilators by InnspiraMED 5

Ghana: PPE by the Ghana Society of Biomedical Engineers, Impact Hub Accra, Kumasi Hive, and Ghana Tech Lab 8

India: Contact Tracing by Aarogya Setu 11

India: Ventilator Design by Nocca Robotics 12

Lebanon: PPE by Lebanon Response Teams 13

Netherlands: Ventilators by Project Inspiration 14

Panama: Humidifiers at the Technological University of Panama 18

South Korea: Contact Tracing and Smart City Project 21

USA: Ventilators by General Electric and Ford Motor Company 22

Canada: PPE by the Canadian Shield

Written by Marie Floryan

Prior to the onset of the pandemic, Canada was largely reliant on imports to meet their PPE demand, which left many healthcare establishments worried they may not be able to supply front-line workers with essential protection. Many groups and companies became involved in Canada's fight against the COVID-19 pandemic and by mid June 2020, Canada became almost self-sufficient in PPE production.

Inksmith, an education technology company, shifted early on from their regular business practice towards COVID-19 specific production, launching The Canadian Shield project[1]. The project began when a Physician in the Waterloo region told the team about the high demand for PPE, especially for face shields. The team started working on PPE production in mid-March when they were producing around 300 face shields per day. Between March and August, the team grew from 5 to 317 paid employees, the manufacturing space grew from 4,000 to 15,000 sq. ft., and the daily face shield production grew to 2,000,000 face shields per day.

The normal regulatory approval processes in Canada have been drastically accelerated due to the pandemic. The Canadian Shield received a medical device manufacturing license in 3 days. All PPE produced by The Canadian Shield meets Canadian regulations, as well as regulations from some other countries around the world[2].

Early on, the Canadian Shield team worked with local hospitals and health care facilities to distribute their PPE. Once the project gained visibility, they signed contracts with provincial governments[3]. The team also began to consider distributing PPE to other essential workers, such as restaurants and grocery stores[4]. The team noted that having certified products helped them create an online presence and distribute outside of the medical industry.

The Canadian Shield team went through over 300 design iterations since the beginning of the project. The design changes were largely influenced by: the manufacturing equipment the team had access to, material availability, and rapid production goals. One face shield design iteration used button hole elastics, but due to a shortage of these elastics the team had to change their design. One major recommended design practice is to have the end user in mind at all stages of the design and manufacturing process. In the case of the face shields, the team focused on designing for easy assembly and comfort for the end user. The team attributed part of their success to early critical partnerships including school boards, Challenger Motor Freight, and other community organizations.

Because of how quickly this project began, the team was on the cutting edge of pandemic workplace safety. The human resources director at The Canadian Shield shared their team's workplace practices with the Ontario Ministry of Labour so that all companies could adopt safe workplace practices.

The team has contracts with several provincial governments around Canada and the Canadian federal government. Their PPE distribution consists of both sales and donations. They donated over 750,000 face shields to education institutions, enough face shields for every teacher in Canada. Additionally, every week a

[1] The Canadian Shield © www.canadianshieldppe.ca
[2] Interview with Denisa Dica and Andrew Brumwell, The Canadian Shield, September 2020
[3] Government of Canada, Interim order respecting the importation and sale of medical devices for use in relation to COVID-19, September 2020
[4] Government of Canada, Authorized medical devices for uses related to COVID-19: List of authorized medical devices other than testing devices, September 2020

different organization is chosen for donations. The team plans to continue manufacturing PPE in Canada to increase domestic manufacturing.

Colombia: Ventilators by InnspiraMED

Written by Carolina Rojas

While initiatives from different cities worldwide have collectively sought to address either the shortage of oxygen therapy equipment, PPE or the development of tracking applications in response to the complex public health challenge caused by COVID-19; in the city of Medellín in Colombia, Corporación Ruta N and the Mayor's Office of Medellín started the 'Innova por la Vida' initiative that sought to generate quick solutions to contribute comprehensively to the prevention, care and control of the virus. Recruiting hundreds of volunteers from academia, business and the public sector, this initiative has worked on the following initiatives since March 2020[5]:

- Mass testing for early detection of COVID-19
- Apps, platforms and data tools at the service of public health
- Open-source ventilators and respirators
- Strengthening hospital capacities with provision and protection elements for health personnel and patients

One of the flagship projects of Innova por la Vida has been the InnspiraMED project, which has sought the local development of low-cost mechanical ventilators through the collective action of approximately 50 institutions that represent a University-Company-State effort. This project has been articulated by Ruta N and the IDB Lab, initially it had the financial support of the Postobón company, and the HACEB and Auteco Mobility companies have led the production of the ventilators. Three research and development teams led the development of ventilator designs: the Universidad de Antioquia team, the Industrias Médicas Sampedro team and the Universidad EIA team. In a matter of just three months, the teams managed to complete all the prototyping and design phases, and as of late 2020, were in clinical trials.

Colombia has regulatory entities that have been key to the evaluation of the ventilator designs since its inception, the Colombian Institute of Technical Standards and Certification (ICONTEC) and the National Institute for the Surveillance of Medicines and Food (Invima). ICONTEC for its part acts as the National Standardization Organization of Colombia, represents international organizations such as ISO and IEC, and is responsible for reproducing international technical standards to develop Colombian Technical Standards (NTC) to promote standardization, certification, metrology. and quality management in Colombia[6]. In response to COVID-19, ICONTEC made available to the general public free access to its NTC standards, ISO and IEC standards related to COVID-19 through the e-collection platform[7]. For projects such as InnspiraMED, ICONTEC has been the national reference point on the norms and standards to be met for the design, manufacture and proper operation of mechanical ventilators. Meanwhile, Invima acts as the National Regulatory Agency in charge of ensuring that the health standards associated with the consumption and use of food, drugs, medical devices and other products subject to health surveillance are applied. Invima has accompanied more than 20 mechanical ventilator projects developed by different entities in Colombia regarding the validation process of the proper and safe operation of the devices.

The prototypes of the three projects were then evaluated from the design and validation stages to confirm their compliance with the operating standards of the devices. For this, operating parameters such as lung pressure

[5] Innova por la Vida
[6] ICONTEC, Quiénes somos, Accessed: 10/29/2020
[7] ICONTEC, Nuestro propósito es dejar una huella de confianza en cada una de nuestras acciones, Accessed: 10/29/2020

control, tidal volume, ventilation modes or safety alarms were evaluated, and a safety study with animals was carried out. The ventilators were evaluated on two occasions in terms of their electromagnetic performance in the bioengineering laboratories of the Universidad Pontificia Bolivariana and in the anechoic chamber of the Universidad de los Andes[8]. The projects had to pass these tests and verifications for the Invima to pass a phase of clinical trials with humans, which was approved in mid-July after four months of rigorous evaluations of the operation of the devices. Currently the three devices are in the first phase of clinical tests where prolonged operation must be demonstrated in 5 patients of each of the ventilators.

The first phase of clinical trials established by Invima indicates that ventilators must be connected to human patients and working properly for more than 24 hours without presenting adverse events. In addition, the 15 patients who voluntarily agree to be part of the study must be patients who require the assistance of oxygen therapy through mechanical ventilation but who are not infected with COVID-19. Currently, the tests of this first phase are being carried out at three institutions in Medellín, the Hospital San Vicente Fundación, the Clínica Las Américas and the Clínica Universitaria Bolivariana[9]. If these tests are approved, the ventilators will be able to advance to the last phase of clinical testing, Phase II, where the clinical trial is carried out in a cohort much larger than 50 people and the period of trial of ventilator operation is extended, the performance of these should be evaluated weekly.

Although the ventilators are still under evaluation by Invima, approximately 300 ventilators have been manufactured so far[10] and can be used to care for critical patients with respiratory complications caused by COVID-19 under the exceptional use modality allowed under the guidelines of the External Circular 031 of 2020 by the Ministry of Health of Colombia[11]. By early October, more than 150 ventilators had been delivered to hospitals in Medellín and other parts of the country such as Bogotá, Cartagena and Montería[12]. The goal is that these ventilators can serve as backup for the Intensive Care Units in case of outbreaks and can be used as an emergency.

The InnspiraMED initiative has not only led the ventilator design and manufacturing project but has also made an effort to train medical personnel in the use of them and has supported the development of support and protection tools for personnel through manufacturing. of laryngoscopes. More than 350 health professionals have been trained in the handling of InnspiraMED mechanical ventilators. They were also trained in the correct use of PPE, technical skills for advanced airway management in patients with respiratory distress caused by covid-19, and problem solving and decision-making in patient management.

Furthermore, InnspiraMED supported the Simdesign alliance, formed by the Pablo Tobón Uribe Hospital and the EAFIT and CES universities, in its objective of developing video laryngoscopes. These biomedical devices are recognized as essential to carry out procedures with COVID-19 infected patients and the protection of medical personnel, since they are used to safely intubate patients to supply oxygen and reduce the risk of exposure of personnel to aerosols generated by the patient during the procedure. With the financial support of Postobón and the support of the Dynacad and Leonisa companies, 650 video laryngoscopes were manufactured and many of these have already been distributed in medical institutions. It should be noted that the Simdesign alliance began in 2014 the effort to locally design and manufacture these devices at an affordable price; InnspiraMED provided support to accelerate the process and respond to the crisis caused by COVID-19.

[8] EIA, Avanza Innspiramed en fase 1 de ensayos clínicos, August 2020
[9] Invima, La Sala Especializada aprueba el inicio del desarrollo de la fase I para ensayo en humanos del proyecto de ventiladores mecánicos 'InnspiraMED', July 2020
[10] Telemedellín, Ventiladores de InnspiraMed siguen en pruebas: Daniel Quintero, September 2020
[11] Postobón, InnspiraMED avanza en fase 1 de ensayos clínicos y distribución de equipos en el país, August 2020
[12] Telemedellín, 158 ventiladores de InnspiraMED han sido repartidos en el país, October 2020

Although InnspiraMED has come a long way thanks to the collective effort, there is still a long way to go for the ventilator project. One of the biggest challenges the team faces is financial support to reach the goal of manufacturing 900 ventilators. Unfortunately after an institutional crisis that Ruta N was going through, the resignation of 8 of its 10 members of the board of directors and the delays in the authorizations of Invima, the first financier of the project, Postobón, decided to suspend its support for the project. Although the Postobón company has committed to completing the first phase of the clinical trials, InnspiraMED will have to receive external support to be able to start and complete the second phase, and also cover the manufacturing costs of the remaining ventilators[13,14].

Whatever the future of InnspiraMED, this initiative has definitely been an example for the country and the region. Recalling where they were in the beginning to where they have come so far in Colombia, the president of the Colombian Association of Biomedical Engineering (ACIB) Diego Tejada, who has also supported the InnspiraMED initiative, tells how the efforts to respond to the COVID-19 crisis from engineering. Initially, groups of engineers came together through WhatsApp groups to figure out what answers they could give. In this way, initially, biomedical engineers began providing support to put old oxygen therapy equipment into operation in cities such as Medellín, Bogotá and Cali. As a result of some of these efforts, the motivation to design and manufacture these biomedical devices locally grew. Engineer Tejada emphasizes that all these efforts have been able to demonstrate the human capital of biomedical engineers in the country. And it is a reason for admiration that projects such as InnspiraMED, where they are being required to comply with a large number of international standards, have shown that it is possible to develop medical technology of such a high medical level.

The efforts demonstrated by projects such as InnspiraMED have also positively contributed to the cultural and collective perception of locally-produced technology. In Colombia, before COVID-19, the biomedical industry consisted mainly of companies or initiatives focused on the manufacture of prostheses and orthoses, beds, devices based on plastic injection such as cannulas and catheters. On behalf of the chamber of medical devices of the National Association of Entrepreneurs of Colombia (ANDI) they mentioned that more than 90% of medical technology was imported. However, on this occasion, high quality devices and medical requirements are being manufactured. Furthermore, the industries developed so far had not been developed in collaboration with academia. This is the first time that a company-academy-state effort has been evidenced[15].

[13] Postobón, InnspiraMED avanza en fase 1 de ensayos clínicos y distribución de equipos en el país, August 2020
[14] Ruta N, 150 médicos se entrenaron en el uso de respiradores #INNSPIRAMED, June 2020
[15] Interview with Juan Sebastián Osorio, 2020

Ghana: PPE by the Ghana Society of Biomedical Engineers, Impact Hub Accra, Kumasi Hive, and Ghana Tech Lab

Written by Marie Floryan & Caroline Soyars

In Ghana, a robust engineering workforce mobilized to respond to technology shortages that were amplified during the pandemic, resulting in an acceleration of the country's capacity to develop and produce medical devices. The first biomedical engineering program in Ghana began in 2004, and since then multiple biomedical engineering degree programs and professional societies have been established. As a result, the number of biomedical engineers has increased across the country. Despite the presence of biomedical engineering expertise, there are few job opportunities in medical device development and production in Ghana because the majority of medical products are imported. During the pandemic, border closures, medical supply chain disruptions, and increased global demand made it difficult for the government to import sufficient supply of medical equipment. This need prompted several groups across the country to assemble teams of biomedical engineers and makers to produce COVID-19 relief products. Highlighted in this case study are two collaborative initiatives related to the design of personal protective equipment (PPE) and other medical supplies since the onset of the pandemic: 1) Ghana Society of Biomedical Engineers (GSBE) in partnership with Impact Hub Accra and 2) Makers Assemble organized by Kumasi Hive and Ghana Tech Lab.

When the first COVID-19 cases in Ghana were confirmed in mid-March, Dr. Elsie Effah Kaufmann, GSBE president and Senior Lecturer and founding Head of the Department of Biomedical Engineering at the University of Ghana in Accra, was contacted by the Ghana Health Service and the Ghana Institution of Engineering about whether GSBE could produce face masks and other PPE to help fight the pandemic. In response to these inquiries, Dr. Effah Kaufmann assembled a team of approximately 30 volunteers. Team members included GSBE members which were predominantly clinical engineers, current and previous biomedical engineering students, and other members of Dr. Effah Kaufmann's network, including a World Bank employee, the head of biomedical engineering for the Ministry of Health, and the executive director of the Ghana Institution of Engineering.[16] Meanwhile in Kumasi, Kumasi Hive's board members decided they wanted to start internal projects to help slow the spread of the COVID-19.[17]

GSBE and Kumasi Hive formed teams to develop technologies that spanned clinical and community based applications. GSBE initiated six projects: face shield, N95 respirator, ventilator, testing booth, goggles, and aprons. Kumasi Hive pursued 4 projects: face shield, ventilator, hand washing machine, and N95 respirator projects.

Among the COVID-19 technology projects pursued by GSBE and Kumasi Hive, the face shield projects advanced the fastest because materials were readily available and team members were highly engaged. As of August 2020, the other technology projects were still in prototyping stages. These technologies have taken longer to develop due to a lack of dedicated 3D printers for prototyping activities, reliance on imported electronic components, and more extensive regulatory requirements.

GSBE received Ghana FDA approval for their 3D printed face shield design on May 6, 2020. Kumasi Hive's face shield design is also approved by the Ghana FDA. Both groups received Ghana FDA clearance under an emergency use authorization. Products approved under this expedited emergency process are permitted to be distributed to health facilities as donations. If the teams decided that they wanted to commercialize their face shields in the future, they would need to go back to the FDA to go through the traditional process which would

[16] Interview with Dr. Elsie Effah Kaufmann, Ghana Society of Biomedical Engineers, August 2020
[17] Interview with Isaac Nyankum, Kumasi Hive, August 2020

involve providing more testing results, paying a registration fee, and having representatives from the FDA visit the manufacturing facility to ensure quality standards.

The Clinical Engineering Department of the Ghana Health Service (GHS), which operates under the Ministry of Health, handles PPE distribution to health facilities. Donated pieces of PPE, such as the face shields produced by GSBE and Kumasi Hive, are delivered to GHS who then allocates them to public hospitals around the country based on projected need. Each hospital also has their own internal process for receiving and allocating PPE donations.

Both groups have relied on tapping into their personal networks to raise funds for prototyping, regulatory approval, and fabrication. In May, GSBE secured a donation from the First National Bank Ghana. Through the First National Bank's Accelerated Support for Pandemic Intervention and Relief Effort (ASPIRE) program, they donated funds to GSBE to produce 500 face shields[18]. Makers Assemble was similarly funded through private sector connections. George Kwadwo Appiah, the CEO and co-founder of Kumasi Hive, secured funding for Makers Assemble from GIZ, a German company that has previously partnered with the Hive. Although the government helped these initiatives gain momentum by calling for in-country PPE production during the early stages of the pandemic, limited funding has been available from government sources to support these types of maker initiatives and projects during the pandemic.

Currently, face shield production is centered around optimizing usage of in-house 3D printers and partnering with other Ghanaian makers to increase capacity. GSBE has been using an Anycubic I3 Mega 3D printer for in-house fabrication of face shields. If face shields are being 3D printed continuously, the team is able to produce approximately 8 units per day. In order to increase face shield production, GSBE approached Impact Hub Accra, an organization that provides basic infrastructure and capacity building to Ghanaian innovators and entrepreneurs. GSBE and Impact Hub Accra established a partnership that consisted of Impact Hub 3D printing face shield components which were then delivered to GSBE for assembly. This project, in combination with providing manufacturing support for individual entrepreneurs, was the first time Impact Hub was in production mode for weeks at a time; Previous operations were limited to small-scale prototyping projects.[19] This dual approach resulted in the production of over 250 face shields within a month-long period. The team is still working on reaching its 500 unit goal as of August 13, 2020. GSBE has constantly been receiving requests and orders for face shields since the onset of the pandemic, but at this time they are unable to fulfill these requests.

Similarly, the Kumasi Hive's internal production capacity is limited. In order to increase production, Kumasi Hive launched a capacity building project called Makers Assemble in partnership with the Ghana Tech Lab in Accra. The purpose of Makers Assemble is to bring together the skills and resources of designers and makers from around the country to scale up production of face shields and other COVID-19 technology projects once regulatory approvals are obtained. Makers Assemble volunteers began production on August 24, 2020.

Scaling up manufacturing of face shields has been challenging due to material availability constraints and limited financial incentive for Ghana-based plastic manufacturers to convert their production lines. Early on in the pandemic, Impact Hub formed a loose alliance with other Ghana makerspaces in hopes of working together on a larger scale initiative. However, the slowing of imports from China constrained the amount of filament and other raw materials available, thus limiting the capacity for makerspaces to execute large scale production. Meanwhile, GSBE approached Ghana-based companies to explore mass manufacturing opportunities. Through contacts at the Ghana Institution for Engineering and the Association for Ghana Industries, Dr. Effah Kaufmann reached out to several plastic manufacturers that produce consumer products. These factories were reluctant to convert

[18] Business24, First National Bank Ghana supports Biomedical Engineers, Ghana Armed Forces, June 2020
[19] Interview with Kelechi, Impact Hub Accra, August 2020

their manufacturing lines for face shield production because they were not sure if they would recoup initial costs and ultimately turn a profit.

Government support and financial incentive are critical steps for motivating the private sector to manufacture critical supplies during a time of crisis. In Ghana, the government has encouraged the garment industry to produce fabric-based PPEs such as face masks, gowns, scrubs, and head covers.[20,14] This government-led initiative has resulted in the local production of 15 million face masks for front-line workers and schools, thousands of jobs, and an estimated GH$300 million annual contribution to the national economy[15,16]. Future considerations should include replicating this model within other industries to expand and strengthen Ghana's medical device production capacity.

Increased communication between members of the Ghanaian maker community has accelerated COVID-19 technology development and production. Although there were many makers across Ghana, many of them were siloed and lacked access to collaborative spaces. The greater exposure of makers to one another has led to meaningful collaborations which will likely extend beyond the pandemic.

The energetic response of Ghanaian innovators has shown key stakeholders that local production of medical devices is not only possible but impactful. Prior to the pandemic, there was limited interest in pursuing local production of medical devices aside from engineering educators and young biomedical engineers and makers. Healthcare workers, who have traditionally been content with using imported devices, are shifting their mindset as they see and use Ghana made PPEs in hospitals. Academic institutions are also committing more resources to innovation work. For example, the University of Ghana recently approved the establishment of an on-campus makerspace and GSBE plans to partner with them to increase their production capacity and get more students involved.

Thought leaders are optimistic that the medical device ecosystem in Ghana is shifting away from relying on imported medical devices and towards domestic innovation and production. This trend would lead to a steady demand for domestically manufactured medical devices, thereby creating more opportunities for biomedical engineers and makers to start their own companies or work in medical device development roles. Furthermore, support structures and resources for innovative entrepreneurial initiatives may expand at a faster rate because Ghana was forced to look inwards to tackle the COVID-19 crisis.

[20] ABC News Ghana, Ghana begins local production of PPEs, April 2020
[14] Ministry of Trade and Industry, Local Production of PPEs Commences in Ghana, April 2020
[15] GhanaWeb, Coronavirus: Garment industry produces 15 million face masks, PPE's – Akufo-Addo, August 2020
[16] Ghana Talks Business, GH¢300m expected from local face mask production, July 2020

India: Contact Tracing by Aarogya Setu

Written by Nishant Agarwal

Aarogya Setu (translation: The bridge for liberation from disease) is an Indian open-source COVID-19 contact tracing, syndromic mapping, and self-assessment digital service developed by the National Informatics Centre under the Ministry of Electronics and Information Technology (MeitY)[21]. In May 2020, the app was at first mandated for every employee of the government and private organizations, however later the order was retracted on May 17th by the Ministry of Home Affairs, which stated that Aarogya Setu to be "installed by all employees having compatible phones" on the "best effort basis"[22]. The app was rated the highest by the news based on the number of users but no official data is available[23]. Arogya Setu *Mitr* is an additional feature later introduced in the app, the feature allows free tele-consultation on COVID-19. The app provides users the information about their locality, the risk of them being infected, and national and local COVID-19 updates[24]. Interactive Voice Response System (IVRS) has also been launched for feature phones and landlines.

The app requires constant access to the user's phone's Bluetooth and location to keep track. An alert is sent if the user is within 6 feet with a person who has tested positive for COVID-19 based on the database of known cases of infection which is again updated through the app by the user. Keeping into account the language diversity in the region, the app has been made available in 12 languages. However, individuals with hearing and visibility impairment have accessibility concerns with the app. Interacting with a number of users who have the app installed on their phones revealed that they never use the app and mostly keep it in case they are asked to show it while entering public places[25]. Although a study suggests that most people are optimistic towards having a contact tracing app in India[26], all 5 people interviewed as a part of this case study claimed they never switched on the bluetooth to save their phone's battery.

There have been concerns with the technology, including false positives, the potential lack of effectiveness if the takeup of the app is limited to only a small fraction of the population, and, most notably, data security. A non-government organization, Internet freedom foundation (IFF), has been actively questioning the transparency and data security of the app[27]. *Arvi*, a health tech start-up has launched a thermal kiosk that integrates data with Aarogya Setu app through QR code that gives data integration and nullifies the need of deployment of security guards at entrance of offices, railway station and airport for thermal scanning. There is also a feature in the app that allows employers to see the employee's Arogya Setu status and user name to determine work strategy, however this has received criticism. The code for the app has been uploaded on Github and is now open source.

Health advocatory organizations, such as All India People Science Network (AIPSN), have publicly condemned the involvement of third parties in the app development and implementation, such as research institutes and private consultation firms. The AIPSN report states that the app follows an opaque algorithm to declare a person false positive or false negative leading to "social, personal and public health" disturbances[28]. The government of India continues to attempt to address the concerns expressed by advocatory organizations and the public.

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[21] Live Mint, Govt launches 'Aarogya Setu', a coronavirus tracker app: All you need to know, 2020
[22] The Wire, New Guidelines See Home Ministry Ease Up on Compulsory Use of Aarogya Setu in Offices, 2020
[23] The Free Press Journal, Go Aarogya Setu Go: Modi govt's app pushes aside Pokémon GO to become fastest growing mobile app with 50 million users, 2020
[24] The Economic Times, Aarogya Setu Mitr brings a doctor at your fingertips, 2020
[25] Interview with anonymous users having Arogya Setu app, August 2020
[26] Kodali, P. B., Hense, S., Kopparty, S., Kalapala, G. R., & Haloi, B. (2020). How Indians responded to the Arogya Setu app?. Indian Journal of Public Health, 64(6), 228.
[27] The Times of India, NGOs write to Centre on Aarogya Setu's privacy issues, 2020
[28] News Click, Tech, Health Activists Want Law to Protect Leakage, Use of Aarogya Setu Data, 2020

India: Ventilator Design by Nocca Robotics

Written by Nishant Agarwal

Nocca Robotics was originally established from Indian Institutes of Technology (IIT) Kanpur, with a dedication to manufacturing autonomous and modular solar panel cleaning robots. During the start of the 2020 COVID-19 pandemic, the company pivoted towards fabricating low-cost and high-quality ICU ventilators with High Flow Nasal Cannula (HFNC) mode[29]. Nikhil Kurele, the founder and CEO of the company, started with his team in March 2020 when the COVID-19 pandemic broke out. The idea of developing an Indian-made ventilator sprouted when a professor from IIT-Kanpur published a call for technology companies to focus on developing healthcare solutions to deal with the effects of the pandemic.

Due to their experience and expertise in produce design and development, the Nocca Robotics team was able to develop the Nocca V310 ventilator[30]. Kurele described that the design and fabrication were not the difficult step in the process, considering their extensive design experience, rather, ensuring the patient's safety while following the standards took most of the team's time. Adding to that, IIT-Kanpur and the investors from Indian Angel Network (IAN) initiated a task force with experienced professional and medical experts to support the product development.

The first iteration, Noccarc V110, was based on the UK and Canada's emergency ventilator standards. Later on, V310 included additional features such as Bilevel Positive Airway Pressure (BiPAP) and Continuous Positive Airway Pressure (CPAP) modes, Pressure Regulated Volume Control (PRVC) mode with volume and pressure control. The earlier version had manual FiO2 (fraction of inspired oxygen), but now it is equipped with automatic FiO2 mode. The company acquired the International Electrotechnical Commission (IEC) certification through HLL Lifecare to start the distribution of the ventilators[31].

Kurele mentioned that he and the co-founder, Harshit Rathore were always fascinated by robotics when they started with Nocca in 2017[32]. Based out of Pune, Maharashtra, the company's manufacturing facility had the capacity to produce more than forty ventilators by July 2020, with ventilators already installed in eight hospitals. Nocca Robotics partnered with the government through Bharat Dynamics Limited (BDL) at the Ministry of Defence, to ease the manufacturing and aid in delivering to the government hospital[33]. The components used to make the V310 are tested and clinically validated following a seven stage process to give an estimated life cycle of more than five years. As the next step, Kurele aims to fulfill the orders in hand from more than five hospitals and expand over the next few months to meet the demand from multiple cities.

[29] The Economic Times, How strong mentorship upended the low-cost ventilator project of IIT Kanpur-backed Nocca Robotics, 2020
[30] Nocca Robotics, V310 © www.noccarc.com
[31] Financial Express, Breathing new life into healthcare: How a company producing solar panels started manufacturing ventilators, 2020
[32] Interview with Nikhil Kurele, Nocca Robotics, August 2020
[33] Hindustan Times, Covid-19: IIT Kanpur, BDL ink pact to make affordable ventilators, 2020

Lebanon: PPE by Lebanon Response Teams

Written by Helen Lindsay

When the first case of COVID-19 was detected in Lebanon, in February 2020, doctors were concerned that they may see a shortage of medical equipment, particularly ventilators. To prevent this ventilator shortage, healthcare professionals began working with Lebanese engineers to design ventilators that could be made with locally available equipment and components. This was the beginning of the Lebanon Response Teams[34], a group of over 300 engineers, healthcare workers, and researchers with a desire to solve problems to support the healthcare system through the COVID-19 pandemic[35].

As the pandemic evolved, the team recognized that there was a need in Lebanese hospitals for PPE, including masks and face shields, and the design and manufacture of non-contact thermometers and intubation boxes. Following international standards for face shields set out by the Medicine and Health Product Regulation Agency the team designed and prototyped a face shield. Hariri University Hospital tested these prototypes and provided feedback to the engineers for a final design.

One of the biggest challenges for the face shield team was related to funding since Lebanon was facing an economic crisis. The main sources of funding for all projects were from the contributions from the team, the MIT community, and other benefactors. From a medical perspective, the main challenge was the critical nature of developing devices to be used on patients. Usually, the development process for medical devices is lengthy, however, in this case, design to manufacture needed to be completed in about three months due to the urgent need.

Having a response team set up has been a help for the country as it faced a second crisis, the Beirut Port explosion. Hussein El Hajj Hassan, one of the founding members, says that in these types of crisis situations, it is helpful to have a team with identified skills to respond. Since the Lebanon Response Teams were already established, there was open source information to help in the response to the explosion.

During the height of the COVID-19 pandemic, the team manufactured and donated 2500 face shields to the government and hospitals, distributed intubation boxes to 24 hospitals, and donated thermometers to a few organizations. The team also manufactured multiple batches of masks. With additional donations, the team will continue manufacturing protection equipment to give to healthcare workers. This will be very important as the country is still recovering from the explosion and the world faces new outbreaks of coronavirus and additional strains.

[34] Lebanon Response Teams Wiki Page

[35] Frakes, Nicholas, Lebanese volunteers launch heroic effort to help health workers battle coronavirus, The New Arab, March 2020

Netherlands: Ventilators by Project Inspiration

Written by Carolina Rojas

As COVID-19 cases increased and pressure on the supply chain from the high demand for ventilators became evident, Delft University of Technology (TU Delft), a university in the Netherlands, created the Air for All initiative[36]. This 3-project initiative, OperationAIR, BTB-Breath, and Project Inspiration, has focused on designing ventilators to meet the demand in the Netherlands and internationally. OperationAIR and BTB-Breath focused their efforts on the context of Dutch hospitals, designing an emergency ventilator and a ventilator composed of standard parts, respectively. The third project, Project Inspiration, aimed to design an emergency ventilator to be manufactured by Low- and Middle-Income Countries (LMICs)and in low-resource environments.

Project Inspiration, led by Dr. Gerwin Smit, was inspired by the East-Radcliffe ventilator, which was widely used in the 1960's by European hospitals. This ventilator design was based on readily available parts such as the Sturmey-Archer bicycle gear hub and a pressure cooker, used to control ventilator speed and provide humidified air. Dr. Smit imagined a design such as the East-Radcliffe, which required a minimum of electronic components, could be appropriate for low-and-middle-income countries, where these components are not readily available and, given the supply chain strains, would be difficult to obtain. The only available East-Radcliffe ventilator was located at a nearby museum, which decided to make an exception and lend the ventilator to Dr. Smit for the project[37].

With the East-Radcliffe ventilator in their hands, the Project Inspiration team, composed mainly of mechanical engineers, started to reverse-engineer the design. In just about a month, the team was able to replicate the device and start adapting the design to meet modern needs. The bike gear hub was replaced by a motor with variable speed, and an electronic monitoring system had to be integrated. The East-Radcliffe implemented mechanical dials and mechanical volumeters, but these were no longer widely available in the market. Although the design aim was initially to develop a device that didn't rely on electronic components, the team realized that changes in the initial design were required to comply with regulations and use components available in the market. Additionally, the design team was following the UK's MHRA Rapidly Manufactured Ventilator System guidelines, which include a monitoring system as a specification requirement. At first, the Project Inspiration team was small with only 3 to 10 volunteers but eventually amassed up to 40 volunteers, from professors, students, technical staff, and clinicians. Eventually, the design team was composed of three main working groups focused on mechanical design, electronics and software, and device housing.

In an interview with Dr. Gerwin Smit, he mentioned that Project Inspiration's primary objective was to develop a design that could be replicated with basic tooling machines at local workshops in low-resource settings. He had previously visited metal workshops in low-resource settings and had an idea of what could be achieved with conventional machines such as manual milling and drilling machines. Thus, the design team developed components that could be manufactured by these machines, which they were able to achieve for all but one of the final design components. To generate pressure and volume flow to the patient's lung, the design used an arm with an adjustable number and location of weights on it to drive a bellow. The bellow was the most challenging aspect of the design to manufacture, and ultimately the team had to request support from the Dutch company ARA to develop a custom-made part. The company has committed to manufacturing these bellows for the ventilators, and Project Inspiration chose to supply this particular component to collaborating countries. Another component that was more difficult to manufacture was the housing, which they chose to be

[36] TU Delft, Scientists design ventilator made of standard parts, 2020
[37] NOS, Beademingsapparaat uit jaren 60 blijkt nuttig in corona crisis, 2020

manufactured with laser cutters. Although these machines are also available in low-and-middle-income countries, in case there is no access to this equipment, the parts can be manufactured with hand tools.

This project focused on providing a solution for LMICs, not only by developing a context-appropriate device, but also by facilitating the implementation of local production and use. The team has contacted embassies within specified LMICs to begin the implementation process. So far they have been able to get in contact with stakeholders within Peru, Colombia, Mexico, and Panama in Latin America, Nepal in Asia, Ukraine in Europe and several African countries.

The following steps describe the process a country would go through if they want to collaborate with the Project Inspiration team and replicate the ventilator design locally:

1. A consortium needs to be formed, involving a representative from the government, a production partner and representatives from a prominent local hospital.

2. Local doctors need to identify if Project's Inspiration design was suitable for their context and their necessities.

3. The production partner needs to check if the design can be replicated locally. They need to check the bill of materials and identify which components could be acquired locally or needed to be imported.

4. Once the design is approved by local doctors and the production partner has identified it can be replicated locally, Project Inspiration's team works with the production partner to manufacture a prototype to show the basic principle of the device or ship a prototype that they have developed in TU Delft to the target country.

5. Once the production partner has completely familiarized with the design and manufactures a prototype, they can start replicating the design locally. In the case of parts such as the bellow or other electronic components that are hard to acquire locally, the Project Inspiration's team coordinates to ship them to the target country.

Engaging with a supportive and reliable team of local stakeholders is key for implementation success. For example, without a contact in the government specifically of health authorities it would be difficult for the project to continue because ventilators are regulated devices. Government contacts can also be critical in the process of importing parts that can't be acquired locally and granting permits to work in establishments that are not considered essential such as the workshops. Another example is the need to integrate the expertise of a local doctor, someone that can speak of the needs of patients in the country is needed to assess the functionality of the proposed ventilator design within local hospital systems and equipment. Dr. Smit described that for some intended contexts it turned out to not be possible to carry out the project because they were missing one of these partnerships.

Developing a project such as Project Inspiration during a global crisis presented both opportunities and challenges alike. For one, the most challenging aspect of this project has been the distance from the design team to the product's intended context of use, in terms of not only geographical distance but also communication and cultural differences. Furthermore, due to the nature of the project and lockdown, the beginning, the project attracted a lot of volunteers. However, the lockdown in the Netherlands was lifted up quickly and many of the volunteers started to go back to work and could not continue contributing to the project. Maintaining volunteer motivation was also a challenge that the team faced, and, although the crisis allowed remote work, developing a hardware solution remotely made it difficult to keep track of what everyone is doing.

Lockdown also affected a smooth collaboration with interested countries. Partners working in countries that were in total lockdown were unable to work in the workshops. Within Nepal, a landlocked country, the partner was unable to continue collaborating with Project Inspiration because no planes were going to the country and they could not arrange the shipment of components. In other cases even if they were able to ship components, they sometimes were stuck in customs for a long time. Many, if not all, of the interested countries faced the challenge of acquiring electronic components locally because of limited production of these components domestically. As a consequence, teams from these countries depended on the support of the Project Inspiration team to acquire electronic components.

Dr. Smit reflected on the challenges engineers face with such projects, claiming, "I think that the trap for engineers is to think that all problems are technical and we try to come up with a technical solution… I think the problem is that there are many conditions around these devices that are not technical, usually related to policy. As engineers perhaps we should be more involved in changing policies."

By the fourth quarter of 2020, with the assistance of Project Inspiration, two ventilators had been built in Guatemala and are currently undergoing testing, and one ventilator prototype has been shipped to Mexico. Additionally, Project Inspiration is receiving assistance from the Dutch company ARA to build 10 ventilators. These ventilators are subsidized by the Dutch government and will be made available for various countries so that they can evaluate if they can and want to build them locally.

One of Project Inspiration's most successful collaborations as of yet has been in Guatemala. However, this joint collaboration was achieved differently from the others. A TU Delft Mechanical Engineering Master's student from Guatemala, Diego Quan, had already started an initiative in his country named Respira Guatemala and reached out directly to Dr. Gerwin to collaborate with Project Inspiration to bring this solution to his home country. Diego was able to replicate Project Inspiration's idea quickly and effectively in Guatemala because he had a local startup called Quantum Energy and Engineering with his partner Oscar Flores, focused on providing concrete solutions to the needs of people living in poverty. As the pandemic spread and the severity of the shortages of ventilators was announced by their government, they decided to focus all their efforts on the COVID-19 emergency response. On April 4th, the presidential spokesman of Guatemala claimed that the country only had 56 ventilators for a population of 17 million[38].

The Respira Guatemala team first sought out relevant stakeholders from the local health system and manufacturing sector. In about two to three weeks Respira Guatemala, with assistance from a local trusted workshop owner, was able to replicate the first prototype based on the ventilator sent from Project Inspiration. This prototype worked as expected but a few metal components were not compliant with health standards and needed to be anodized. By September a stress test that lasted over three weeks had been completed without errors and the Respira Guatemala team was completing logistics, permissions and legal paperwork to implement the ventilators with the previously agreed hospital, the Roosevelt Hospital in Guatemala City.

Almost all structural components of the ventilator are manufactured by around 20 people in Talleres Hernández and some aluminum parts are anonidize by another company that is supporting this initiative. Members of the team assure that the technical plans provided by Project Inspiration are understandable and easy to follow, plus they have support from the Project Inspiration team along the way. One of the main challenges the team from Respira Guatemala faced in regards to manufacturing was the lack of availability of electronic components in Guatemala. To account for this shortage, they created a working group focused only on electronics. Project Inspiration also supports the local team by sending them special electronic boards and sensors that are very

[38]Quan, D.A., Asturias, K., & Perez, A. (2020). Respira-Guatemala: Una llamada urgente a la acción coordinada para combatir el COVID-19

sensitive. They also received assistance from the Dutch consulate by connecting them with a logistics company that is helping then import special components. Additionally, Respira Guatemala has received assistance from a local company that stepped up and provided an assembly line through which they disassemble the ventilator and decontaminate it.

As an alternative, in regards to validation of the device, Respira Guatemala is relying on the director of the Roosevelt Hospital which is committed to receive the functioning prototypes when they are ready and evaluate them with experts in pulmonology and anesthesiology through internal protocols the hospital has in place. Although members of Respira Guatemala don't know the details of how the device will be evaluated, they are at least certain that the design underwent rigorous testing in the Netherlands and achieved the expected performance even while working two months straight. While there are no standard protocols in Guatemala to design or manufacture ventilators, the Respira Guatemala team has adhered to international standards, and to their benefit, Project Inspiration's ventilator is based and approved by European standards.

Even though Respira Guatemala had its challenges as any project at the beginning and at times they were unsure of what it was required to achieve the goal, Diego, one of the leads of the project mentions that: "they have always had that enthusiasm to challenge themselves and work on them, and in this occasion they said to themselves let's start to see what we need to do and how we can help our country".

Panama: Humidifiers at the Technological University of Panama

Written by Carolina Rojas

Like many countries in the Latin American region, Panama at the beginning of the pandemic recognized that there was a shortage of oxygen therapy devices to care for COVID-19 patients. With the scarcity of these devices in the international market and their high cost, the Panamanian authorities resorted to the possibility of manufacturing them locally. To achieve this, authorities of the Ministry of Health requested support from the rector of the Technological University of Panama (UTP) and the director of the UTP Fab Lab, who worked together with a group of students and volunteers to fulfill the task. The Ministry of Health in Panama wanted to have these devices as soon as possible and at the lowest possible cost in order to have an inventory of sufficient capacity to supply the demand of local hospitals. When the authorities approached the UTP, they had a specific type of high flow humidifiers that they wanted to replicate, the Airvo 2. The Ministry then proceeded to deliver to the Fab Lab UTP one of its Airvo 2 humidifiers that it was no longer in operation, with the idea of replicating this design.

Unlike what was being seen internationally in terms of efforts to develop low-cost ventilators, the Ministry of Health of Panama initially had the goal of manufacturing 100 high flow humidifiers. These medical devices are used to treat patients with respiratory failure, helping them to avert the need for therapies that require intubation. High flow humidifiers achieve this by supplying oxygen usually in conjunction with compressed air and humidification at higher rates than traditional oxygen therapy that only uses an oxygen source like a tank and a nasal cannula. Although this type of oxygen therapy can be carried out without humidification, when oxygen is delivered at high rates through cannulas it dries out the airways. Consequently, humidification is usually complementary to oxygen therapy to reduce damage or trauma to the airways.

The Fab Lab quickly organized a team made up of volunteer students from the Fab Lab, university graduates and professors to work on the design of a high flow humidifier. The main team of the project almost from its inception has been composed of 8 students and graduates of the Faculties of Electrical Engineering and Mechanical Engineering and professors of the Faculty of Mechanical Engineering. All the people who have been actively contributing to the design of the device have done so as volunteers by donating their time and skills. Even the professors and researchers of the UTP involved have not received any pay or bonus for this work. Additionally, as the project started back in March the country was entering a total lockdown due to the spread of the virus. The laboratory director had to request special permits so that a small number of people could work in the laboratory. And some volunteers initially contributed remotely to tasks that enabled this type of work.

To develop a first prototype, the Fab Lab UTP team carried out a reverse engineering process. The Airvo 2 model was used as a basis for the identification of sensors and actuators and in order to meet the conditions of developing a design in the shortest possible time, the design team proceeded to make use of rapid prototyping techniques. Initially, the design team used techniques such as 3D printing, laser cutting, and manufacturing of single-sided, medium-density printed circuit boards. 3D printing was primarily used while the team was iterating and testing specific components.

In the course of just one month, the Fab Lab UTP team managed to develop an initial prototype that integrated all the subsystems that make up a humidifier: mixing, flow generation, steam generation, temperature control and humidity, and that of the user interface. Given the potential state of emergency, this first prototype fulfilled only the basic functions. Unfortunately, one month after starting the project, there was still no guaranteed financing from the Ministry to manufacture the 100 units and thus far all the development was carried out based on donations and individual investment of the equipment and the laboratory. During the course of the summer

months, the design teams continued to improve the product and months later, in August, funding was made available from the Ministry.

The final prototype included changes in the mixing subsystem. This system is mainly composed of a mixing chamber that uses a Venturi tube through which the oxygen flow is passed in order to generate the suction effect of the ambient air. The air and O2 mixture then passes through a filter, before being blown by a fan into a container with steam. Furthermore, the configuration of the camera was changed to be more compact, allowing for higher flows. Other subsystems that were changed, but to a lesser extent, were the steam generation and control subsystems. In the humidifier, steam generation is achieved with a controlled heating system that uses an electrical resistance, a thermistor for measurement and a relay controlled by the main controller. Because a low-cost device was being designed with parts that were available locally, the humidifier heating system was designed using the heating system of a coffee maker. Thanks to the support and donation of a local pharmacy chain, Farmacias Arrocha, the laboratory received 100 coffee machines. Components from the machines have been used in both prototypes, they were reused in order to heat a water reservoir and generate steam.

Furthermore, a vital aspect of the steam generation system is temperature control, since the flow that reaches the patient must not reach high temperatures. For this, the design team developed the control system and manufactured it with the equipment available in the laboratory electronic cards that integrate a controller that allows the control of the temperature and other subsystems of the humidifier. Although the team managed to manufacture functional electronic boards, the manufacturing method available in the laboratory was sufficient to support the design team in rapid prototyping, but the final products were not very robust. Once a functional design was obtained, these cards were commissioned in China. The main benefit of the latter is that they are more easily welded in about half an hour, while this process took up to three hours with the originals. The cards received from China were iterated a second time and the lab is waiting to receive the latest version.

Importantly, the laboratory team turned from the beginning to international references on the standards and requirements of a humidifier for the design of the device. Some of the standards that were considered for the design were: ISO8185: 2007, ISO11195: 2018, ISO5356-1: 2015, and AAMI HE48: 1993 standard.

To date, the prototypes have been reviewed by qualified personnel from the Ministry of Health on two occasions and the necessary changes have been made to the design. Flow, humidity and temperature control tests have been carried out in an experimental and simulated manner. The Fab Lab UTP team is awaiting instructions from the authorities on the process of evaluating the device for approval of its use in a hospital setting.

At the end of 2020, the estimated cost of a single humidifier was approximately 210 USD. These costs only add up to the elements of the final product and do not consider the losses of materials and components due to design iterations and manufacturing failures. In addition, this price does not account for the shipping costs of the different components or incorporates the cost of the additional laboratory equipment that had to be purchased in order to develop welding and printing workstations in the laboratory.

When asked about the challenges he faced during the development of this project, Dr. Rodríguez mentions several factors that proved to be challenging for this project:

- No one in the main team was a biomedical engineer, there was a lot of uncertainty at the beginning and additional efforts were made to integrate specialists in the field to advise the project.
- Because the Ministry of Health wanted the devices as soon as possible, the design team had to rush the process and each working group had to work in parallel with other groups. Dr. Rodriguez comments that: “We made a quick estimation to be able to reach the step of the crisis and then we lost time trying to

adapt to what we had done. We lost time in subsequent stages, if we had done the modeling and selection of materials and components more calmly, we would have saved time in the end. However, everything was done with the intention of obtaining something that would be functional in a short period of time."

- Funding was a critical challenge, the first few weeks the professors and students pitched it to cover expenses, and funds from the lab were used. As the time went by the expenses were mounting and although the project received money from independent donors such as companies from the private sector and businessmen, it was not enough and the lab could not cover everything.

- Reliability of the final prototype of the humidifier ended up being a challenge. All of the members of the team were used to working with prototypes but not with products that would actually be in the market or that needed to achieve high grades of reliability.

- Communication with government stakeholders was not always active and sometimes took extended periods of time. Additional guidance in terms of necessary certifications and steps towards government approval is also needed.

Although the project has had many hurdles, Dr. Rodríguez is hopeful for what can come next. He mentioned that it was proved that "It is possible to quickly develop a functional product that can be replicated locally, making use of modern mechatronic modeling techniques, additive manufacturing and simulation techniques of the computational fluid dynamics of the mixing system." He also comments that there were no negative results from this project, that "the results from this experience gave them a greater capacity for learning how to organize ourselves or organize the processes internally. At the Fab Lab we didn't have a hierarchy or a way to organize staff. We've always had small jobs and on this occasion I had someone working on the electronics supervising two other people, and I had Farid supervising the manufacturing part supervising other people." Additionally, as a result of this project, the Fab Lab UTP is aspiring to be able to become a production center or have part of the Fab Lab available for production, to support small and medium entrepreneurs by manufacturing their products on a small scale.

South Korea: Contact Tracing and Smart City Project

Written by Jang Hyeon Lyu

Contract tracing is used to understand the spread of a virus through identification and monitoring of people who have been exposed to the disease. It can be used to prevent transmission of a virus. Since the start of COVID-19, solutions for contact tracing have been increasing around the globe.

Contact tracing is largely divided into 4 stages: (1) investigation, (2) exposure risk assessment, (3) contact classification, and (4) contact management[39]. During the investigation stage, individual information, such as recent locations and travels over a specific period of time, is collected via interviews. Additional information, such as cellular GPS data and credit card transactions can increase the reliability of the investigation phase. When a case of COVID-19 is confirmed, stage 2 aims to identify individuals who may have been exposed, based on their previous whereabouts[40]. Then, the individual is asked to quarantine in their home and monitor their symptoms.

Contact tracing in Korea was carried out with components of a smart city[41]. A smart city uses a database to monitor traffic traffic, environment, housing, and facilities across cities. Using the smart city data bank and extra data (CCTV footage, credit card transaction data, travel information, and location data) combined with artificial intelligence, it can take only 10 minutes to collect individual data during the investigation stage. The smart city was first designed by the South Korean Ministry of land, infrastructure and transport and more than 120 companies have been involved, including the N2M Company. A representative from N2M described that the basic objective of a smart city is to build open data hubs that can collect and analyze large amounts of data from cities. Based on this platform, N2M built the epidemiological investigation support systems, which emphasized both the need for rapid development and the importance of security of personal information[42].

Kakao, a web service giant in South Korea, joined a state campaign to adopt a QR code electronic registration system to trace visitors to entertainment facilities to prevent COVID-19 outbreaks with unknown sources[43]. Visitors would use their smartphones to register at these locations via posted QR codes. After its development, the Korean government has issued policies requiring high-risk facilities, such as dance clubs and karaoke bars, to use the QR coded electronic visitor registration system. The system was also recommended for restaurants, bars and other vulnerable facilities[44].

Due to the country's experience with MERS in 2015, the general public in South Korea supports and democratically the "Infectious Disease Prevention and Management Act" with built-in privacy protections[45]. The law allows use of personal information in response to a crisis by investigators and contact tracing companies. The locations can only be tracked for a certain period, have to be anonymized, and only certain people can request and use the information. When the pandemic is over, data will be deleted immediately. In general, privacy and security are critical in the design of automated contact tracing programs during pandemics. Importantly, since people's perceptions of the use of personal information differ from country to country, a contact tracing system must be designed according to the cultural and social context in the intended region or country[46].

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[39] Korea CDC, Epidemiological Investigation, 2020
[40] Park, O., Park, Y. J., Park, S. Y., Kim, Y. M., Kim, J., Lee, J., ... & Ko, D. (2020). Contact transmission of Covid-19 in South Korea: Novel investigation techniques for tracing contacts. *Osong Public Health and Research Perspectives*, (1).
[41] Indica, How Korea Does Contact Tracing, 2020
[42] Interview with a representative from the N2M company, September 2020
[43] Yunhap News, Tech firms support virus fight with mobile QR-code apps, 2020
[44] Aju daily, Kakao participates in government's QR code electric registration to trace dance club visitors, 2020
[45] KLRI, INFECTIOUS DISEASE CONTROL AND PREVENTION ACT, 2020
[46] Interview with anonymous expert in the smart city business, September 2020

USA: Ventilators by General Electric and Ford Motor Company

Written by Marie Floryan & Grace Burleson

On March 30, 2020, it was announced that Ford Motor Company and General Electric (GE) Healthcare were partnering to produce and distribute 50,000 ventilators within the next 100 days.[47] The partnership was motivated by the rise of COVID-19 cases in the U.S. coupled with an international shortage of ventilators as manufacturers around the globe were struggling to speed up production to meet the rising demands. According to The New York Times, at the time of the GE and Ford partnership, roughly half of the intensive care ventilators in use in the U.S. were manufactured and imported by foriegn companies, which were in high demand by many other nations, including Italy, Iran, and China; for example. Within the U.S., there were fewer than a dozen U.S.-based ventilator manufacturers, many with a smaller-scaled production, unable to ramp-up to meet the urgent demands. As an example, Allied Healthcare Products, a small ventilator manufacturer, stated it would require at least 8 months to sharply ramp up production.[48]

The decision for Ford and GE Healthcare to partner and produce ventilators was sparked by the U.S. government's call urging large manufacturing companies to assist in the production and distribution of essential supplies and equipment to respond to the pandemic.[49] Aided by the Defence Production Act, the partnership was formed among Ford and GE Healthcare executives, who appointed leads within their respective companies to shift their time and focus to the ventilator project. Although the two groups had never worked together prior to March 2020, the partnership successfully produced ventilators at a rapid rate due to the complimenting expertise: GE engineers provided medical device design and regulation expertise while Ford engineers provided essential assembly line expertise and facility access.

To save time and resources, GE engineers licensed a ventilator design from Airon Corporation, a Florida-based producer of pneumatic technologies for emergency medicine.[50] The specific design, the pNeuton® Model A-E Ventilator,[51] is a purely mechanical design that operates pneumatically, requiring fewer components than electrical-powered ventilators. This simpler ventilator design enabled engineers at GE and Ford to quickly adapt features to optimize for manufacturability. Since Airon Corporation was previously producing 1-2 ventilators per week, it was essential that design changes were made to reduce production time and achieve high-volume, high-speed production. These design changes were completed at an ultra-accelerated speed with support from the FDA's Emergency Use Authorization.[52] For medical devices, standard duration of design iterations can normally take up to a year for authorization and compliance. Overall, to reach their high-capacity production goals, which peaked at over 7,000 produced in a week, the team carried out over 210 design changes to the original Airon design within their limited timeframe.[53]

To execute their rapid manufacturing plan, experienced industrial engineers from Ford Motor Company converted a portion of their Rawsonville Road plant in Ypsilanti, Michigan. In addition to subassembly stations, the final assembly line comprised of 44 workstations, each operated by a single worker, with 88 sub-assembly workstations. To comply with COVID-19 safety protocols, all stations were designed so that workers were at least 6 ft apart and separated by clear plexiglass. These stations used refurbished desks from a nearby office

[47] Ford Motor Company, Ford to Produce 50,000 Ventilators in Michigan in Next 100 Days; Partnering with GE Healthcare Will Help Coronavirus Patients, March 2020
[48] The New York Times, There Aren't Enough Ventilators to Cope With the Coronavirus, March 2020
[49] Interview with Robert Wade (Ford Motor Company) and Tom Christman (General Electric Healthcare)
[50] Airon Corporation
[51] GE Healthcare, pNeuton Model A-E Ventilator Specifications, 2020
[52] U.S. FDA, Emergency Use Authorization
[53] Interview with Robert Wade (Ford Motor Company) and Tom Christman (General Electric Healthcare)

building and included mounted electronic tablets with assembly instructions for operators at that particular station. Small windows were cut in the plexiglass walls so that operators could slide finished components to the next station. At the initial stages of the project, operators consisted of paid volunteers from an international labor union: the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW). Production began on April 20th on the assembly floor, and at the peak of production, the plant was operating twenty-four seven, consisting of three shifts of assembly teams. This effort created over 1000 new jobs.

After completing delivery of over 50,000 units, the Ford Motor Company ceased production of ventilators in late August.[54] This partnership succeeded due to complimentary expertise between industries: with Ford contributing the manufacturing and supply chain expertise and G.E contributing the medical device design and regulation expertise. The government played a key role in initiating the partnership by calling for manufacturing support from large companies and purchasing the ventilators. Their rapid response to the technology demand is also attributed to their access and adaptability of manufacturing facilities, refurbishing of space and equipment, and workforce development.

[54] Bloomberg News, Ford Ends Ventilator Production After Making 50,000, Aug 2020

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