Lessons Learnt from Rapid Development of CPAP Ventilator Vent-I During Covid-19 Pandemic in Indonesia

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Hightlights:

- This paper describes the process of a rapid development of the CPAP ventilator "Vent-I" during the COVID-19 pandemic using appropriate technology and locally available components.
- It was found that noble values and spirit are very important success factors, i.e. *gotong royong*, social entrepreneurship, pioneering and volunteerism
- Public trust is a very valuable social capital during the development and crowdfunding.
- Collaboration between academic institutions, industry and the relevant authority from the very beginning will speed up the development and certification process.

Abstract. Here, lessons learnt during the development of CPAP ventilator "Vent-I", aimed to help COVID-19 patients with breathing difficulties, are presented. Within only weeks, Vent-I was developed, complying with functionality, safety and reliability requirements and passing the clinical trial. It was then distributed to hospitals all over Indonesia. Two billion rupiahs were raised through crowdfunding within one week. When the project was officially closed, more than one thousand Vent-I devices had been distributed and more than twelve and half billion rupiahs had been raised. Currently, commercialization and mass production of the device have been started. From this project several lessons can be learnt. First and foremost, the spirit of *gotong royong*, sincere collaboration within the community to help each other – is still firmly rooted within the people and the society. Noble values, i.e. sincerity,

Received …, Revised…, Accepted for publication ...

DOI: 10.5614/j.eng.technol.sci.2020.52.5.x

sensitivity and concern about the needs of the community, willingness to serve voluntarily, and public trust, made the team dare to try and face failure. The spirit of social entrepreneurship, willingness to listen to the user, and collaboration with the relevant authority can accelerate development process. The availability of knowledge and skills that constitute an innovation ecosystem in Bandung, supported by business, social institutions and government, was also a key success factor.

Keywords: *CPAP ventilator; COVID-19; noble values; regulatory sandbox; Vent-I.*

1 Introduction

On the 2nd of March, 2020, the first positive COVID-19 patients in Jakarta, Indonesia was announced by the government [1,2]. Two weeks later schools and universities in Jakarta [3] and Bandung [4] were closed down, including Institut Teknologi Bandung. Teachers, lecturers and students were requested to conduct all teaching and learning activities from home [5]. Soon afterwards, large scale social restrictions were implemented [6].

At the time, it was observed that the COVID-19 virus caused breathing difficulties in patients and hence there was suddenly a shortage of medical ventilators available in hospitals [7,8]. Many countries tried to procure these ventilators, but they were not available in the market. On 23rd of March, 2020, having deep concern about the shortage of this medical equipment, Ms. Jam'ah Halid requested Dr. Syarief Hidayat to make an emergency ventilator to ease the shortage. The request was accepted and within a week, a multidisciplinary team was formed. The team consisted of lecturers and students from Institut Teknologi Bandung, who immediately started to develop the ventilator, medical doctors from the Faculty of Medicine, University of Padjadjaran, who gave insight to the developers about the function and specifications needed to fight the pandemic, supported by a crowdfunding campaigner from Rumah Amal Salman. It was then decided that the name of the ventilator would be 'Vent-I' (*Ventilator Indonesia*).

It turned out that the project made history in terms of the extremely rapid development and deployment of medical devices during a pandemic crisis in Indonesia. Hence, it is important that the process, the spirit and the lessons learnt from this project can be shared with a wider audience. In this paper, the rapid development process of Vent-I and the lessons learnt from this project are presented.

2 Development of Vent-I

At the beginning of the project, there was information about several open source ventilator designs, such as a ventilator based on an ambu bag plus several 3D printed components, and ventilator sharing [9-13]. At the very beginning, the team decided that the Vent-I should become available in large quantities in a very short time and that the functionality and specifications should be based on what was requested by the doctors. Hence, the selection of the appropriate technology, the mechanism, the mechanical and electrical components, the sensors, and the production process was conducted carefully to ensure that this aim could be achieved. In this situation, it was very difficult to obtain critical components, especially medical related. Hence, the technical team had to find some available alternatives for the parts and components, or a workshop that could manufacture the parts and components. Therefore, one of the important design criteria was that, as much as possible, the components should be available locally or able to be manufactured by local vendors and assembled quickly without special training.

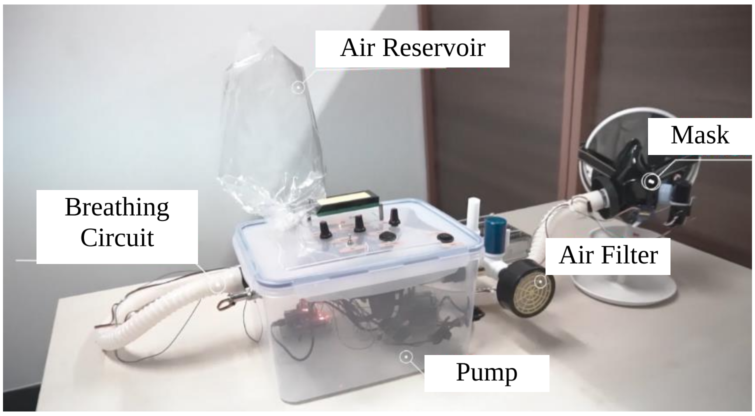

Figure 1 The first prototype of the Vent-I made of non-medical components available in the market.

The first prototype of Vent-I, shown in Figure 1, was demonstrated to the doctors on the 30th of March, 2020. It had three main functions: continuous positive airway pressure (CPAP) [14], continuous pressure control (CPC), and synchronized pressure control (SPC). The doctors then suggested that the team should focus on the CPAP function only, which is for patients at an intermediate stage – still conscious but starting to have breathing difficulties. This was because more patients were admitted to the hospital at this stage than in a more critical stage. If patients can be treated at this stage, they can be prevented from entering ICU. The other consideration was that a CPAP ventilator can be operated by general practitioners and nurses at a standard ward, since the number of doctors specializing in anesthesiology and intensive care is very limited [15,16].

It was then decided that the main blower of Vent-I was going to be the continuous centrifugal type with a BLDC motor and equipped with an H13 HEPA filter, with CPAP/PEEP pressure 5-15 cmH_2O, medical oxygen input pressure 2-4 bar, oxygen content FiO_2 52-55%, mixed air flow rate 30-35 lpm, mixed air temperature 34-37 °C, and humidity 100%. The PEEP mechanism was developed using hydrostatic water mixed with disinfectant.

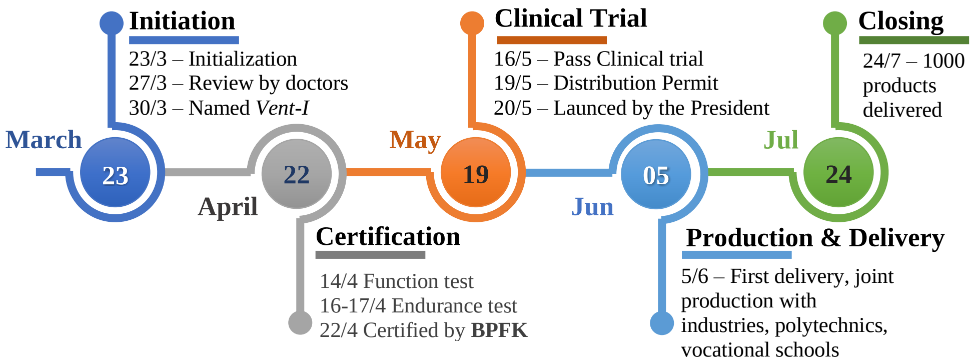

Figure 2 Time line of the project.

As shown in Figure 2, within days, coordination meetings with several ministries were held and in the first week of April, a team from *Balai Pengamanan Fasilitas Kesehatan* (BPFK – Health Facilities Security Center) Jakarta, Ministry of Health visited the team and provided technical assistance to ensure the conformity of the Vent-I specifications to the regulations so that it could be certified.

On the 14th of April, 2020 the certification process of Vent-I CPAP started at BPFK Jakarta. The Vent-I was tested for functionality, electrical safety, emergency features and endurance. On the 22nd of April, 2020 Vent-I had passed all of the tests [17]. A clinical trial was then started for ethical clearance, followed by a series of tests on COVID-19 patients at hospitals. By the 16th of May, 2020 the clinical trial had been passed and a distribution permit was obtained. Figure 3 shows the different types of Vent-I that were developed, produced and distributed. Finally, as shown in Figure 4, at the celebration of National Awakening Day, 20th of May, 2020, the Vent-I was officially launched by the President of Indonesia, Mr. Joko Widodo [18].

Figure 3 Several types of Vent-I developed and delivered.

Figure 4 President Joko Widodo officialy launched Vent-I.

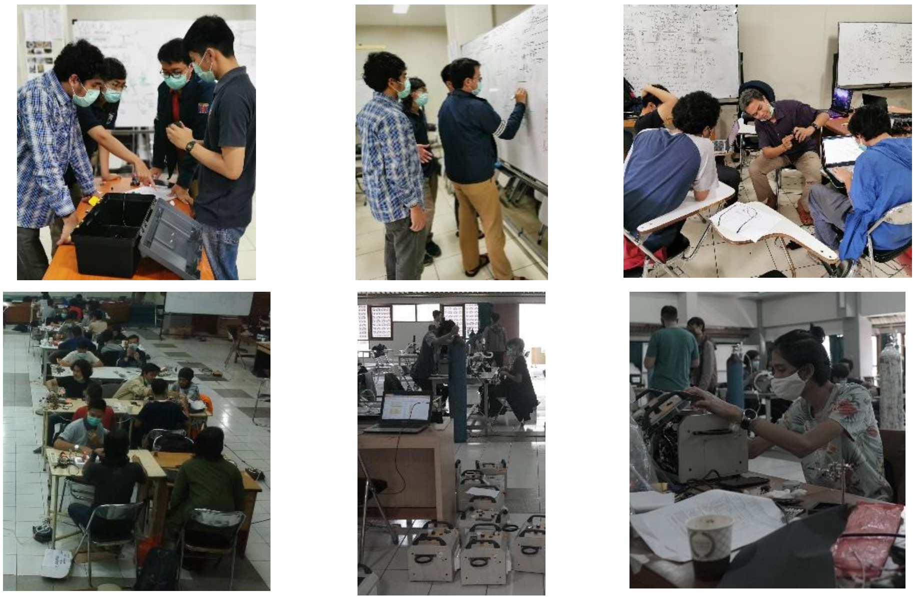

Figure 5 Classroom and mosque function hall converted to factory.

Parallel to that, the preparation for production had started. Several classrooms were converted to workshops and the main function room of the university mosque held an assembly line, as depicted in Figure 5. Several vocational higher institutions and high schools were eagerly involved in the project, led by someone from the industry. Many details were taken care of, from the casing design, noise reduction, development of production procedures, finding vendors and suppliers that were still operating, and many others. Some critical components, such as the blower impeller and the pressure sensor, were designed and manufactured locally. Finally, on the 5th of June, 2020, the first Vent-I was delivered to a hospital. When the project officially closed by 24th of July, 2020 about 1000 Vent-I devices had been delivered to hospitals all over Indonesia [19]. Figure 6 shows the distribution of the Vent-I to hospitals in Indonesia.

From the moment the crowdfunding started in early April, the response from the public had been extraordinary, far beyond the initial expectations. Within days, about two billion rupiahs were raised and when the project closed, about twelve and half billion rupiahs had been raised from about 2000 donations, both private and institutions/corporations.

It turns out that the pandemic provided an excellent opportunity to rapidly develop, certify and distribute a medical device, which might have taken years in a normal situation. Although Vent-I was developed using appropriate technology available locally during the pandemic situation, several creative ideas emerged, and eight patent requests from this project have been submitted.

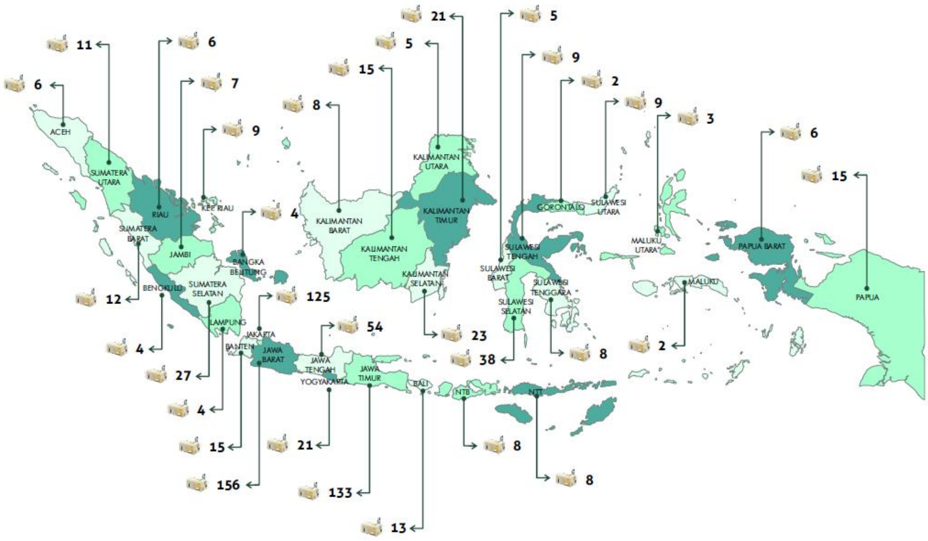

Figure 6 Distribution of Vent-I when it reached 784 deliveries.

3 Lessons Learnt from the Project

3.1 Noble Values and Spirit

It was later realized that the prime mover of the team, so it could be formed and function immediately, were sincerity and noble values, as mentioned by Dipojono, Chairman of the Academic Senate of ITB during the centennial commemoration of technical higher education institution in Indonesia [20]. The traditional Indonesian spirit of *gotong royong*, a sincere collaboration within the community to help each other, is still very firmly rooted in the people and society.

3.1.1 Social-entrepreneurial Spirit

The spirit of being sensitive and concerned about the situation of the people, the willingness to try to solve problems, the capability to see the issue as a great opportunity, and the courage to face failure moved this project forward at the start. When most people stayed at home to avoid crowds, the team dared to do the opposite: go out, meet, think, and work tirelessly to face the challenge.

3.1.2 Pioneering and Volunteerism

During the formation of the team, it was not easy to invite lecturers and students to join, since the situation at the beginning of the pandemic was still very uncertain. However, a handful of them were really looking for an opportunity and a way to contribute. Some lecturers and students came forward enthusiastically and joined the team immediately from the beginning. Also from the beginning it was declared that this project was purely social and all individuals would contribute voluntarily.

It was found later, especially for the students, that although they spent a lot of time and effort voluntarily they gained much more in developing their character, skills and knowledge. The students learned how to work collaboratively, in a multidiscipline environment, under a lot of constraints, time limitations and pressure due to high expectations from the public. The students experienced one full cycle of product development, not only related to the technical aspect of the product but also related to the supply chain of parts and components, regulations, the certification process, production, crowdfunding, distribution and public accountability. The students learned how to design an experiment and build a prototype. They learned how to present their ideas, take initiative, propose different solutions. They also faced failures and had to deal with unexpected results. This has been a once-in-a-life-time experience for those who dared to face the challenge, which will influence their future greatly. Figure 7 shows several of the students involved in the project, during the closing of the project.

Figure 7 Student volunteers with the Vent-I series

3.1.3 Public Trust as Valuable Social Capital

During the crowdfunding campaign, it was learned that trust was one of the main contributing factors to the success of the campaign. The combination of Rumah Amal Salman, a registered charity run by the university mosque foundation, which coordinated the campaign, fully supported by SESAMA - an ITB alumni movement for technology development and concern for community, and two well-known universities in Bandung: Institut Teknologi Bandung and Universitas Padjadjaran, , as the developers of Vent-I, gave the team the trust of the public. The public was immediately willing to donate, even before the product was ready and working as expected. Public trust is very valuable social capital, which made the team dare to face potential failure [21].

3.2 The Importance of Being Self-sufficient

As also mentioned by Dipojono in his speech [20], this pandemic raised awareness that the country should hold the key and strategic technology and production capability. It is very important for a country to have human resources and institutions that acquire and maintain specific skills and knowledge. In an emergency situation like this pandemic, these skills and knowledge can be collectively implemented to provide an immediate solution. In this project, several universities, polytechnics, and vocational high schools, together with local industries collaborated, where each institution contributed their skills and expertise to the project.

This innovation ecosystem, comprising academics supported by practitioners (medical doctors and industry professionals) with specific knowledge and skill available in Bandung, was shown to be one of the key success factors of the project. In addition, support from the government in Jakarta, which is three hours away, as well as from the community and businesses, was also very important. This kind of innovation ecosystem should be maintained and duplicated in other areas. When mobility and logistics were disturbed by the pandemic, being in the same area was a great advantage.

3.3 Collaboration from the Start

3.3.1 Listening to the user

Understanding what is really needed is very important and it can be obtained by listening to the user and to experts. The involvement of medical doctors in this project was essential, since they provided significant information and contributions to the project. Empathize, the first step of design thinking is one of the key success factors in product development and was well implemented in this project. The design process, from the specification to the embodiment of the

Vent-I, was conducted jointly by engineers, product designers and doctors. Figure 8 shows the discussion between engineers and doctors during the development of Vent-I. All aspects were looked at, from technical aspects, availability of components, safety features, ergonomics, comfort of the patient, user-friendliness of the control panel as well as some clinical aspects (sterilization of the product, humidity and temperature of the pressurized air, oxygen content, etc.). All were conducted rapidly, within several days.

Figure 8 Discussion between designers, engineers and doctors in informal meetings in the early days of the development.

3.3.2 Regulatory sandbox in a process of innovation

At their first visit, the authority still treated the Vent-I as a full-feature ventilator that should be certified according to the standards for full-feature ventilators, while actually it was not one. Through several discussions between the engineers, doctors and the authority, a common understanding and an agreement were reached. It was found that through intensive communication and trust between institutions, not only the product was being developed but also the standard, the requirements and acceptance criteria were developed in order to get a safe, functional and reliable product. This also shows that collaboration between institutions is a must. The Vent-I development process can be seen as a case study on how a regulatory sandbox, as described by Brodjonegoro [22], was directly implemented in a process of innovation.

4 Concluding Remarks

It can be seen through this project that the traditional Indonesian spirit of *gotong royong*, sincere collaboration within the community to help each other, is still very firmly rooted in the Indonesan people and society. Noble values and spirit were shown by the trust given to the project, as reflected by the sum of the fund that was immediately donated, even before the prototype was ready and working as expected. The same spirit was also shown by the lecturers, students, doctors and professionals who volunteered, spent their time and contributed their expertise to the project. This is an excellent social capital which should be always be maintained.

It can also be seen that the social-entrepreneurial spirit, that sees the problems and challenges as a great opportunity, made this work possible under high constraints and pressure. Understanding what is really needed by listening to the user and to experts was also a key success factor in this project. Intensive communication, collaboration, and trust between academics/engineers, government/authority, doctors, industries have overcome many hurdles in this project. Not only that, this project has also built self-confidence of the team, as well as opened up many new networks and future opportunities.

Acknowledgements

It would have been impossible to deliver more than one thousand Vent-I devices without all the support and donations received. The Vent-I team would like to acknowledge and extend their gratitude and appreciation to these individuals, institutions and corporations who have supported this project in many ways and many forms, especially to: Institut Teknologi Bandung; Universitas Padjadjaran; YPM Salman ITB; Ministry of Health, Ministry of Research and Technology, Ministry of State Enterprises, Ministry of Defense, Ministry of Education and Culture – Republic of Indonesia, National Disaster Management Authority, COVID-19 Response Acceleration Task Force, Health Facility Security Center – Jakarta, West Java Provincial Government, 3rd Military Regional Command/Siliwangi, West Java Regional Police, Bandung City Government, ITB Alumni Association, Yayasan Solidarity Forever, Syamsi Dhuha Foundation, SESAMA – Pengembangan Teknologi dan Kepedulian, PT Mobar Sarana Energi, PT Pura Barutama, Politeknik Manufaktur Bandung, Politeknik Negeri Bandung, Universitas Pendidikan Indonesia, Politeknik Negeri Batam, Institut Teknologi Nasional, Universitas Nurtanio, Universitas Komputer Indonesia, Universitas Diponegoro, Politeknik TEDC Bandung, PT Dirgantara Indonesia, PT Bukaka Teknik Utama, PUDAK Scientific, Eastern Pro Engineering, Elcoprs, RS Hasan Sadikin, RS Santo Borromeus, RS Advent Bandung, RS Paru Dr. H. A. Rotinsulu Bandung, Melinda Hospital, Dinas Pendidikan Provinsi Jawa Barat, SMKN 1 Cimahi, SMKN 4 Bandung, SMKN 6 Bandung, SMKN 8 Bandung and all volunteers who made a significant contribution to this project.

The Vent-I team would also like to express their appreciation to all individuals, communities, and institutions who have donated to this project, especially to: Bank Indonesia, BUMA Peduli, Kliring Penjaminan Efek Indonesia, Indonesia

Stock Exchange, Indonesia Central Securities Depository, Triputra Grup, Indonesia Power, PT Herba Penawar Alwahida Indonesia, Telkom Indonesia, Yayasan Hasanah Titik, Terminal Peti Kemas Surabaya, Komatsu Indonesia, Majelis Telkomsel Taqwa, Pertamina Hulu Energi, PT Trans Pacific Petrochemical Indonesia, Enerren Technologies, BNI Syariah, BCA, Dompet Dhuafa, Badan Pengelola Keuangan Haji, DT Peduli, Mastel, PGS ITB & Rekan, Alumni Mesin 85 ITB, Alumni ITB PLN, Alumni ITB 79, Yayasan Indonesia Bright, Alumni Bimbel Karisma, Alumni IKMP Bandung, Mabrur 77, ICTA USA, Alumni Elektro 87 ITB, Piobio Indonesia, IA SMAN 3 Bandung, MT Madinah, MT Makarresh, IA ITB ANTAM, Alumni Mesin 84 ITB, Group Lasykar Sepuh Jakarta, IA Tambang 2009 ITB, UMI Wellington, Alumni GRIPS Tokyo, MT Al Islah, Pensiunan Dosen Tambang 1957, Pengurus YKPI & PPYKPI, Alumni SMAN Tegal 1976, IA ITB Yogyakarta, PPI Shizuoka – Jepang, IC Magnet School, POMG TK-SD Mutiara Bunda Bandung, Macrology Indonesia, Alumni Haji Salman 2017, Jamaah Masjid IKEA Alam Sutera, Komunitas Motor Benelli Indonesia, Road Pirates MC Indonesia, DPW AGBSI, Alumni SMAN Garut 1971, DPW KLHK, Serabut Kelapa and 1983 other individual donors.

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