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Deployment of ventilators to developing countries: A critical review in light of the Covid-19 crisis

A report for the national Covid-19 scientific taskforce and the executive board of ETH Zurich

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Content

Executive Summary

Deployment of ventilators to developing countries: A critical review in light of the Covid-19 crisis

As part of ETH Zurich's pursuit to contribute to resolving the global corona crisis, we evaluate in this report whether it is reasonable to increase ventilation capacities in countries with resource-limited clinical infrastructure and how the pathway for the industrialization of a minimal-function ventilator in Switzerland could look like. The intention of this work is to establish a decision basis for the Executive Board of the ETH Zurich whether a Swiss contribution to ventilator supply in countries with limited clinical infrastructure should be further considered and implemented.

Need
From disease to local treatment

Part I - Discussion of Covid-19 pathology, strategies and required resources for ventilation therapy of Covid-19 patients

- Ongoing scientific debate on the best medical treatment strategy has implications on required respiratory equipment.
- Non-invasive ventilation could provide good medical treatment in settings of resource-limited clinical infrastructure.
- The choice of treatment strategy must be balanced between medical benefits, protection of staff and available resources.

Part II - Discussion of medical infrastructure and demand for respiratory equipment in developing countries

- Great disparities in medical infrastructure within and between developing countries, meaning that ventilators cannot be used everywhere.
- Providing resources for ventilation to developing countries must be compatible with the available clinical infrastructure.
- Assessing the need for ventilators accurately requires cooperation with governments and humanitarian organizations.

Product & Deployment
From product development to industrialization

Part III - Evaluation of implementation concepts and maturity of ongoing device developments

- Most of the many ventilator development projects are far off from providing a clinically applicable device.
- The Mechanical Ventilator Milano is close to FDA approval and mass production. It can provide invasive ventilation in good clinical infrastructure.
- A Swiss ventilator system is a viable solution for non-invasive ventilation, but months from finalization and production.

Part IV - Analysis of required steps and time frame to deployment of a Swiss ventilator system

- In the corona emergency situation, a drastic reduction of bureaucratic waiting times for regulatory approval is possible.
- The estimated time for completion of product development and regulatory approval is four months.
- The estimated cost of manufacturing is in the range of 2000 - 5000 CHF.

Options to action

1. Ensuring the availability of oxygen should be the major focus in providing treatment to Covid-19 patients in low-resource settings as most patients can benefit from oxygen administration alone and it is essential infrastructure for mechanical ventilation treatment.
2. If a country with an appropriate infrastructure and personnel for invasive ventilation formulates the demand for invasive ventilators, the large scale procurement of *Mechanical Ventilator Milano* systems could be considered and available for deployment in June 2020.
3. If non-invasive ventilation can be part of medical therapy for Covid-19 patients as an alternative to invasive ventilation, more patients could be treated in low-resource settings. Clinical investigations to address this ongoing medical debate should therefore be conducted or at least closely monitored. A tailored swiss made ventilator system could be a viable solution but would require about four months to finalize and start production.

Introduction

The novel coronavirus disease (Covid-19) has presently developed into a worldwide pandemic causing thousands of deaths each week. As a result of infection, a severe bilateral pneumonia can develop, requiring ventilation support as part of life-sustaining intensive care. The reports of overloaded intensive care units from highly infected regions, such as Northern Italy or New York, have triggered worldwide efforts to increase the production of respiratory equipment. These efforts comprise of student teams developing DIY ventilators for decentralised manufacturing as well as automotive companies that produce ventilators through state-funded programs.

While the situation is slowly improving around the world, many low-income countries are still at the beginning of the pandemic. Such countries are most vulnerable against the spread of the virus and lack the clinical infrastructure to handle a higher number of severe Covid-19 cases. Uncontrolled proliferation of the virus in these countries could be detrimental and additionally might in the future cause newly re-imported outbreaks in parts of the world already affected. Humanitarian organisations are currently focusing on empowering people in those countries to protect themselves and reduce transmission.

As part of ETH Zurich's pursuit to aid in resolving this global crisis, we evaluate in this report whether it makes sense to increase ventilation capacities in countries with resource-limited clinical infrastructure and what the pathway for the industrialisation of low-cost ventilators in Switzerland would require. This work intends to serve as a resource for the Executive Board of the ETH Zurich to ascertain whether a Swiss contribution to ventilator supply should be further considered and implemented. An overview of our essential statements is provided in the executive summary on the first page.

This document was compiled based on the results of an investigation over four weeks. It is based on numerous interviews with experts from various fields of medicine, development aid - both from Switzerland as well as from developing countries -, regulatory affairs and medical product development as well as literature research. This manuscript is therefore primarily intended as a collection and comparison of expert opinions. As the knowledge about the disease, its treatment options, and the necessary infrastructure is growing at a rapid pace, this report is at best a collection of current expert opinions, which may be updated soon.

The report is structured into two tracks. The first track deals with the ventilator demand. It challenges our initial assumption that non-invasive ventilation (NIV) can meet a great need in developing countries to treat critical Covid-19 patients in the absence of an intensive care unit (ICU). We discuss the medical use case of ventilation treatment and its infrastructural requirements. Furthermore, we discuss the local healthcare situation and demand for ventilators in individual representative developing countries. The second track deals with the ventilator supply. It challenges our initial assumption that simple systems can be used to meet medical needs and that certification and scaling in Switzerland can be carried out quickly enough to match the demand in time. We provide a comprehensive technical analysis of low-cost ventilator initiatives and a professional estimate of the remaining effort to deployment.

Part I: Covid-19 treatment and required resources

Introduction

The Covid-19 virus appeared late in 2019 in China and first spread mainly in the developed world to South Korea and Japan and Europe and the US. The Covid-19 disease is still not fully understood: while many patients experience only mild symptoms, few infected patients develop severe symptoms, and some require critical care. Consensus on the most effective treatment options is still emerging, and the subject of ongoing scientific discourse. Even though medical treatment guidelines have been developed in the most sophisticated medical infrastructure, the mortality rate among critical patients is found to be still high[1][2][3][4][5].

Currently, the treatment of critical Covid-19 patients is mainly provided by intensive care physicians. Accordingly, the clinical management is based on established procedures and available infrastructure in intensive care medicine and often includes invasive ventilation (IV).

Due to the high mortality rates, several pulmonary experts call to rethink treatment strategies and to use non-invasive forms of ventilation therapy (NIV) instead. This ongoing discussion about the medical benefit and applicability of NIV for Covid-19 patients is highly relevant to the considerations of this report, as treatment with NIV requires less medical infrastructure than treatment with IV and thus would allow treatment in more resource-limited settings.

The objective of this chapter is to summarize the current understanding of Covid-19, present the currently prevalent treatment strategy and compare it from a medical and infrastructural perspective with the non-invasive ventilation treatment proposed by pulmonologists.

Methods

The overview of the currently predominant intensive care treatment is based on interviews with intensive care physicians currently treating Covid-19 patients at the University Hospital Zürich (amongst others Dr. Björn Alex). The argumentation for non-invasive treatment is based on interviews with two distinguished physicians in the field of pneumology (Prof. Dr. Lutz Freitag, Prof. Dr. Dieter Köhler), as well as guidelines from the Association of Pneumological Clinics and the German Society for Pneumology and Respiratory Medicine. In addition, a literature review of current mortality rates in relation to treatment methods was conducted. We want to point out that this document was not written by medical experts and is at best a reflection of the current opinions of medical experts.

1 "Clinical Course and Outcomes of 344 Intensive Care Patients ...." 24 Mar. 2020, https://www.atsjournals.org/doi/abs/10.1164/rccm.202003-0736LE. Accessed 30 Apr. 2020.
2 "Report on 2249 patients critically ill with COVID-19 - ICNARC ...." 4 Apr. 2020, https://www.icnarc.org/About/Latest-News/2020/04/04/Report-On-2249-Patients-Critically-Ill-With-Covid-19. Accessed 30 Apr. 2020.
3 "Covid-19 in Critically Ill Patients in the Seattle Region — Case ...." 30 Mar. 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2004500. Accessed 30 Apr. 2020.
4 "Presenting Characteristics, Comorbidities, and Outcomes ...." 22 Apr. 2020, https://jamanetwork.com/journals/jama/fullarticle/2765184. Accessed 30 Apr. 2020.
5 "Clinical course and risk factors for mortality of adult inpatients ...." 3 Apr. 2020, https://www.sciencedirect.com/science/article/pii/S0140673620305663. Accessed 30 Apr. 2020.

Course of disease and medical care needed

The majority of Covid-19 cases show only mild symptoms and require no or only outpatient treatment. The percentage of cases that require medical care in a hospital ("severe cases") is estimated to be between 15 and 20%[6], but is highly dependent on the number of tests conducted and on the patient age group. For most of these hospitalized patients, a simple administration of oxygen, e.g. through a nasal cannula, is sufficient as treatment. About a quarter of these hospitalized patients are dependent on treatment with ventilators during their illness. If the ventilation therapy fails, the final resort is extracorporeal oxygenation of the blood with devices for Extracorporeal Membrane Oxygenation (ECMO).

Pathology of cases where medical care is needed

At present, it is believed that in severe cases of Covid-19, viral pneumonia occurs as a result of infection with the coronavirus. Understanding the pathology of such corona virus induced pneumonia is still evolving rapidly. Shortly before the completion of this report, a study was published suggesting that Covid-19 is not a viral pneumonia, but a vascular disease affecting various organ systems, especially the lungs[7].

Initially, the observed low saturation of oxygen in the blood (hypoxaemia) in Covid-19 patients was believed to be caused by a typical acute respiratory distress syndrome (ARDS) with decreased diffusion through alveolar membranes and increased lung stiffness, causing laboured breathing and fatigue.
However, recent studies indicate that Covid-19 hypoxemia is instead caused by an accumulation of fluid in the alveoli in parts of the lung and a resulting pulmonary shunt (lung is being perfused, but gas exchange does not take place). In contrast to ARDS, a good portion of the lung remains compliant and allows for normal diffusion. Cases have been observed, where severe hypoxemia did not appear to cause a deficiency of oxygen in tissue (hypoxia) and a sufficient gas exchange could take place to avoid an accumulation of CO2 in blood (hypercapnia). These patients are referred to as "happy hypoxids", as they do not feel suffocated despite low blood oxygen saturation.

Treatment strategies

We will now compare the current consensus on the clinical management strategy of Covid-19 patients (referred to as "intensive care strategy (ICS)") with the alternative approach recently proposed by individual pulmonologists as a reaction to the high mortality of ventilated patients in many parts of the world (referred to as "pneumological strategy (PS)"). Both strategies include both NIV and IV, but in the PS, usually, IV is avoided as long as possible, while in the ICS IV is used much earlier. The underlying rationales are explained in detail in the appendix - in summary: the ICS focuses on the treatment of hypoxaemia, while the PS focuses on the prevention of hypoxia and tolerates hypoxaemia as far as possible. Currently, the clinical outcomes are hard to compare as little clinical data is available for the alternative PS treatment on Covid-19 patients.

The ICS is mainly guided by raising blood oxygen saturation in blood to normal levels (fighting hypoxaemia). If the saturation is lower than 90%, the patients are treated with increasing levels of oxygen flow on the general ward. Non-response to oxygen supplementation in terms of improvement of blood oxygen saturation and a decrease of heart rate and breathing frequency is considered an

6 "Health Systems Respond to COVID-19 - WHO/Europe - World ...." 6 Apr. 2020, http://www.euro.who.int/__data/assets/pdf_file/0006/437469/TG2-CreatingSurgeAcuteICUcapacity-eng.pdf. Accessed 30 Apr. 2020.

7 "Endothelial cell infection and endotheliitis in COVID-19" 20 Apr. 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30937-5/fulltext

indication for IV. For treatment with IV, the patient must be put into an artificial coma, which necessitates further vital support measures. During IV, ventilation pressures and oxygen concentration are carefully increased until the desired saturation is achieved. An exemplary intensive care treatment protocol, which was developed during an interview with Dr. Björn Alex, is shown in the appendix.

The pneumologists main criticism of this strategy is that fighting hypoxaemia is unnecessary as long as there is sufficient supply of oxygen to the organism (no hypoxia). They argue that high pressure and high oxygen treatment during IV could lead to or at least accelerate the development of ARDS. IV-related intubation and sedation are also viewed critically, as it entails its own risks and additional disadvantages for treatment. Their reasoning is further elaborated on in the appendix (statement from Prof. Dr. Lutz Freitag).

The PS is arguing that treatment decisions should be based on the degree of hypoxia. For this purpose, an assessment of the oxygen delivery to the tissue (oxygen delivery DO2 = total amount of oxygen per volume of aterial blood CaO2 * cardiac output CO * constant) rather than the saturation of oxygen in the blood (SaO2) is preferred. Patients are also first treated with simple oxygen administration. Non-responders are additionally treated with continuous positive airway pressure (CPAP) to reduce the pulmonary shunt by forcing liquid out of the alveoli. Patients fatigued from breathing on CPAP treatment are put on NIV treatment. Strong sedation of the patient is not necessary if the NIV devices allow for spontaneous breathing, and only limited pressures are used to avoid ventilation of the stomach. Indication for IV is seen if pre-existing conditions such as heart insufficiency or scoliosis require to unload the breathing apparatus more strongly than possible with NIV. The interviewed experts argue that 80-90% of the patients now treated with IV could be helped with NIV alone.

The main criticism against NIV is the concern of potentially higher risk of aerosol infection of the medical staff caused by leakage from masks. For that reason, current guidelines published by the World Health Organisation (WHO), Jama, BMJ and others advise against NIV[8][9][10]. An additional criticism is that badly or too tightly fitting masks can cause skin damage in the mouth and nose area.

Required infrastructure

The capacity of medical facilities is typically divided[11] into the level general ward and three levels of intensive care units depending on the available personnel and equipment (details in appendix). The level of medical facility required to provide the above treatments is listed in the following table. In simple terms, an ICU with at least level 2 is required to perform IV as life support of the patient has to be ensured, while an ICU with level 1 is sufficient for NIV. In general, the intervention complexity decreases from IV to NIV to CPAP, so that with IV devices NIV and CPAP treatment is also possible. Likewise, CPAP treatment is possible with NIV devices.

8 "History and exam - BMJ Best Practice." https://bestpractice.bmj.com/topics/en-gb/3000168/history-exam. Accessed 30 Apr. 2020.
9 "Management of Critically Ill Adults With COVID-19 - JAMA ...." 26 Mar. 2020, https://jamanetwork.com/journals/jama/fullarticle/2763879. Accessed 30 Apr. 2020.1&isAllowed=y. Accessed 30 Apr. 2020.
10 "2019-nCoV - World Health Organization." 28 Jan. 2020, https://apps.who.int/iris/bitstream/handle/10665/330893/WHO-nCoV-Clinical-2020.3-eng.pdf?sequence=
11 "What is an intensive care unit? A report of the task force of the ...." 25 Jul. 2016, https://www.ncbi.nlm.nih.gov/pubmed/27612678. Accessed 30 Apr. 2020

Table 1: Respiratory treatments and their required infrastructure and equipment as well as use in different treatment strategies

	Oxygen therapy	**CPAP therapy**	**NIV therapy**	**IV therapy**	**ECMO therapy**
Required infrastructure	General ward	ICU Level 1	ICU Level 1	ICU Level 2/3	ICU Level 3
Required equipment	Oxygen supply and mask	CPAP-capable device & mask	NIV-capable device & mask	IV-capable device & tubus	ECMO device
Use in intensive care strategy	Initial therapy,if sufficient to normalize SpO2	Rarely used	Rarely used, avoided due to staff infection risk	If oxygen therapy fails	Last resort
Use in pneumological strategy	Initial therapy, if sufficient to normalize CaO2	If oxygen therapy fails	If CPAP therapy fails	Avoided, due to sedation & potential lung damage	Last resort

Part II: Situation and Demand

Introduction

The Covid-19 has overwhelmed even well-equipped health care systems in developed countries and regions, such as Northern Italy. In some countries the overload was prevented by measures of lockdowns and governmental incentives aimed at the economy, population and healthcare systems. Developing countries with constrained resources may not be able to copy these strategies. They face different challenges in coping with the impact of covid-19 with regard to economic support[12] of the population and availability of resources for medical treatment. As explained in the previous chapter, the treatment of Covid-19 in its more severe stages is very resource intensive and requires adequate infrastructure, well-trained healthcare staff and specialized medical equipment. This chapter aims to briefly review the current pandemic situation in developing countries as well as locally available medical resources and infrastructure in order to subsequently derive and discuss the demand for additional ventilators.

Methods

Developing countries are grouped by the World Bank according to the gross national income per capita into low income, lower middle income and upper middle income countries[13]. Due to the limited time frame of our investigation, we have decided to illustrate the problems induced by Covid-19 using one representative country per category as a case study: low income countries (Tanzania), lower middle-income countries (Ghana) and upper-middle income countries (Ecuador). To attain a holistic picture several interviews with different humanitarian organisations, such as the Covid-19 Task force of Doctors Without Borders, the Swiss Tropical and Public Health Institute (STPH), national branches of Red Cross and local doctors were conducted. In addition, the analysis is based on academic research articles, articles from news outlets, published recommendations of humanitarian organisations and databases of institutions like the WHO.

Current Covid-19 situation and medical infrastructure in three developing countries

In the following an overview of three developing countries (low-income, lower-middle income, upper-middle income) is given in the face of the Covid-19 crisis, describing the current situation, access to medical care and the existing medical infrastructure.

Tanzania (Low-income)

On 16th March 2020, the Tanzanian Minister of Health reported the first case of Covid-19 in Tanzania (Population: 57.3 million). As first measures, the government decided to close all schools and

12 African Arguments: “Africa’s corona response rests on two things: markets and money transfers”, 30.04.2020, https://africanarguments.org/2020/04/02/africa-coronavirus-response-rests-on-two-things-markets-money-transfers/

13 The world bank: “Country Classification”, 25.04.2020, https://datahelpdesk.worldbank.org/knowledgebase/topics/19280-country-classification

universities and quarantine every citizen or foreigner entering the country for 14 days[14]. As of April 29, there are 300 confirmed infections[15] and 10 deaths.

The health services in Tanzania are organized in a pyramidal structure with primary care facilities at the base, followed by mid-level district hospitals, and referral hospitals (which include regional and national hospitals) at the top. If primary care facilities lack the necessary equipment to treat a patient, he will be referred to a hospital of higher rank. Country-wide two thirds of these district hospitals have access to bottled oxygen and the required infrastructure for NIV. Further insights were gained in an interview with a doctor who is working in one of such referral hospitals, the St. Francis hospital in Ifakara, which is responsible for about 800'000 people living in an area approximately as large as Switzerland[16]. It currently has one non-invasive ventilator and oxygen in a bottle which lasts six hours before it must be refilled in the capital. In the district hospitals and primary health care centers less infrastructure has to be expected. Furthermore, for a population of 57.3 million only 38 ICU beds are available in the country[17]. It is not clear to what level of ICU these beds correspond to.

The high risk-group including people over 65 years of age constitute 2.95% of the population[18]. The leading causes of death are Neonatal disorder, Lower respiratory infect, HIV/AIDS, Ischemic heart disease and Tuberculosis[19].

Ghana (Lower-middle income)

Ghana (population 29.7 million) reported the two first cases of Covid-19 on March 12th, 2020. In the West and Central Africa region, Ghana is the third country with cumulative cases of Covid-19. As of April 29, 1550 infections and 11 deaths were confirmed[20].
The healthcare services are organized in a pyramid structure with primary health centers at the base, 155 district (first-level), nine regional (referral), and four tertiary hospitals at the top. 40% of primary health centers are reported to have access to oxygen bottles[21]. First-level hospitals are generally staffed with oxygen supply and may have non-invasive ventilators[22]. Tertiary hospitals are equipped with oxygen supply and at least level 2 ICUs. The Komfo Anokye Teaching Hospital, second largest hospital in Ghana and responsible for the Northern district, has eight Level 2 ICU beds which are each equipped with a mechanical ventilator and allow the provision of IV. In an interview with the head of emergency it became clear that more trained staff is necessary to extend the capacities relying on a mobile ICU. This would nevertheless also require additional medical equipment in the form of monitors, suction machines, SpO2 monitors, mobile X-rays, oxygen tanks/enrichment etc. In face of the Covid-19 crisis the Minister of Information of Ghana reported the nation-wide availability of 200 ICU beds for severe Covid-19 patients[23] and 200 ventilators[24] (not mentioned the type) for a population of 29.7 million.

14 U.S. Embassy in Tanzania: "COVID-19 Information", 29.04.2020, https://tz.usembassy.gov/covid-19-information/

15 World Health Organization: "Coronavirus disease 2019 (COVID-19) Situation Report – 98", 29.04.2020, https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200427-sitrep-98-covid-19.pdf?sfvrsn=90323472_4

16 St. Francis Referral Hospital - Ifakara, 30.04.2020, https://ifakara.org/en/st-francis-hospital/hospital.php?catid=55

17 Sawe HR, Mfinanga JA, Lidenge SJ, Mpondo BCT, Msangi S, Lugazia E, et al. Disease patterns and clinical outcomes of patients admitted in intensive care units of tertiary referral hospitals of Tanzania. BMC international health and human rights.

18 United Nations Statistics Division: "Demographic Yearbooks", 29.04.2020, https://unstats.un.org/unsd/demographic-social/products/dyb/index.cshtml

19 Institute for Health Metrics and Evaluation: Ecuador, 29.04.2020, http://www.healthdata.org/ecuador/

20 World Health Organization: "Coronavirus disease 2019 (COVID-19) Situation Report – 98", 29.04.2020, https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200427-sitrep-98-covid-19.pdf?sfvrsn=90323472_4

21 Saleh K, 2013. The Health Sector in Ghana: A Comprehensive Assessment. Washington, DC: World bank. doi: 10.1596/978-0-8213-9599-8

22 Stewart BT, Gyedu A, et al. Exploring the Relationship Between Surgical Capacity and Output in Ghana: Current Capacity Assessments May Not Tell the Whole Story. 2018

23 MyNewsGH: "200 ICU beds ready to contain critical COVID 19 cases – Oppong Nkrumah", 29.04.2020, https://www.mynewsgh.com/200-icu-beds-ready-to-contain-critical-covid-19-cases-oppong-nkrumah/

24 The New York Times: "10 African Countries Have No Ventilators. That's Only Part of the Problem.", 29.04.2020, https://www.nytimes.com/2020/04/18/world/africa/africa-coronavirus-ventilators.html

People over 65 years of age constitute 5.1% of the population. The leading causes of death are Neonatal disorder, Malaria, HIV/Aids and Low respiratory infect[25].

Ecuador (Upper-middle-income)

The first case was confirmed on February 29th, 2020. On March 11th the government declared the National Health Emergency and established a curfew from 9pm to 5am. At this moment, Ecuador (population: 16.6 million) is one of the countries in Latin America most affected by Covid-19. As of april 29 22,179 infections and 576 deaths are confirmed.
The health system is divided by a public and a private network. Sanitary conditions in the country are acceptable in large cities but very poor in rural areas. However, during this period, the health system does not have enough testing kits and lacks capacity to provide care to Covid-19 patients. There is a drastic lack of oxygen tanks, resulting in a black market for with inflated prices up to five times the normal. People usually must spend hours in waiting lines to fill their oxygen tanks. Furthermore, several complaints were issued, due to the poor management of dead bodies, especially in the city of Guayaquil. The Red Cross Ecuador that is involved in the planning of the crisis response shared their data including the demand for additional ventilators: Ventilators are currently distributed over 178 hospitals: 1220 are operational, 309 are in maintenance and 1073 additional ventilators are required.
People over 65 years of age constitute 6.66% of the population[26]. The leading causes of death are Ischemic heart disease, Chronic kidney disease, Stroke, Lower respiratory infection[27].

Discussion

The available medical infrastructure varies starkly between countries and considerably within a resource-constrained country, which differentiates the priority for medical equipment such as ventilators. While a high-income country like Switzerland has around 250 ventilators per million inhabitants, this number amounts to only 75 in an upper-middle income country like Ecuador (75 per million) and only to 0.7 ventilators per million inhabitants in a low income country like Tanzania (1 bed per million). In high income countries, access to the highest medical infrastructure is available to the entire population, if the outbreak is managed to not exceed certain boundaries of the healthcare system. In low-income countries, clinics in metropolitan areas are able to provide critical care in the form of invasive ventilation to a fraction of society, and in more rural settings, such infrastructure may not be present at all.

In environments with poor clinical infrastructure, ensuring the availability of supplemental oxygen should be a primary focus in the medical management of severe Covid-19[28]. Oxygen therapy is the first treatment given to all patients that require hospitalization (20% of infected patients). Only a quarter of these hospitalized patients require critical care[29]. Oxygen treatment requires the least amount of infrastructure and training of medical personnel and is a prerequisite of all other forms of NIV or IV. Furthermore, the availability of oxygen supply in more rural areas, allows for the treatment of patients in primary health care centers, which would then only require more severe cases to be referred to more centralised facilities with more resources for ventilation. The focus on oxygen therapy is the strategy

25 Institute for Health Metrics and Evaluation: Ghana, 29.04.2020, http://www.healthdata.org/ghana/

26 United Nations Statistics Division: “Demographic Yearbooks”, 29.04.2020, https://unstats.un.org/unsd/demographic-social/products/dyb/index.cshtml

27 Institute for Health Metrics and Evaluation: Ecuador, 29.04.2020, http://www.healthdata.org/ecuador/

28 Dondorp A, Hayat M, Aryal D, Beane A and Schultz M. Respiratory Support in Novel Coronavirus Disease (COVID-19) Patients, with a Focus on Resource-Limited Settings. The American Journal of Tropical Medicine and Hygiene. 2020.

29 WHO numbers

adopted by the Covid-19 task force of Doctors Without Borders which was confirmed both in publication[30] as well as in a phone call.

In settings with a functioning supply of oxygen and stable electricity, the deployment of NIV can be considered. However, it is important to also consider the need for skilled nursing staff with appropriate Personal Protective Equipment for infection prevention, biomedicals for equipment maintenance and availability of single use components and consumables. The standard of care required is similar to ICU Level 1 (as discussed in Part 1). The supply of additional monitoring equipment needs to be ensured before deployment or low cost alternatives should be made available.

Only in hospitals where a functioning intensive care unit is available but some beds are not equipped with invasive ventilators would the purchase of additional ventilators be advisable. IV requires infrastructure of ICU Level 2. This infrastructure takes time to build and requires the presence of trained intensive care doctors and specialized nurses. The treatment of Covid-19 patients that are intubated was found to require almost a 1:1 ratio of patients to nurses in Switzerland[31]. Under such circumstances, additional ventilators allow to increase the number of Covid-19 patients that can be treated.

An exact forecast for the demand of ventilators is difficult and will require the timely and specific input of government or humanitarian organisations. Epidemiologically, it is difficult to predict the number of patients requiring IV in part also due to differences in demography. The age group of 65 years and higher, which constitutes 18% of the population of Switzerland, has a higher mortality rate, but constitutes only 3-7% in the developing countries discussed. Time is also a difficult factor to take into account but the spread of a first and possibly second wave are difficult to predict. Therefore information from representatives of the local health ministries or humanitarian organisations that are coordinated on a national level are required, taking into account the infrastructural situation and capacity of healthcare staff.

Given the high rates of mortality of individuals due to respiratory illnesses in lower income and lower-middle income countries, the deployment of respiratory therapy in the form of oxygen concentrators and ventilators could also provide a sustainable contribution to these regions far beyond the Covid-19 crisis.

Summary

The available medical infrastructure varies not only between countries, but also considerably within a resource-constrained country depending on proximity to metropolitan areas or health care centers, which influences the priorities for medical equipment such as ventilators. In environments with poor clinical infrastructure, ensuring the availability of supplemental oxygen appears to be a primary focus in the management of severe Covid-19.In settings with a functioning supply of oxygen and stable electricity infrastructure, the deployment of NIV can be considered. Only in hospitals with a functioning intensive care unit, but more beds than invasive ventilators, would the purchase of additional ventilators be advisable. An exact forecast for the demand of ventilators is difficult and will require specific input of government or humanitarian organisations. The deployment of medical equipment for respiratory therapy could also provide a sustainable contribution to the medical infrastructure of some developing countries far beyond the Covid-19 crisis.

30 Analysis of Doctors Without Borders: “The Oxygen Divide”, 29.04.2020, http://msf-analysis.org/the-oxygen-divide/
31 Interview Dr. Björn Alex

Part III: Implementation concepts and device development

Introduction

We started investigating the development of ventilators together with the pulmonologist Prof. Dr. Lutz Freitag from the Hirslanden Hospital Group in Luzern, former head of the Interdisciplinary Lung Center of the University Hospital Zurich. He developed a promising concept for a minimal ventilator, and we assigned a company to develop a proof-of-concept prototype based on his idea and his consulting. This study additionally had the goal of gaining insight into the product development process of ventilators and understanding the corresponding hurdles and levers better. In parallel, we analysed the full range of already ongoing ventilator projects to find potential partners whose device developments are already on a mature level. Depending on the state of their project, such partners could benefit from our support through regulatory, manufacturing and testing expertise. Initially, we had focused only on NIV devices, following the recommendation of Prof. Freitag for a realistic treatment strategy in developing countries.

In this chapter, we first elaborate on the underlying assumptions for this investigation, describe our approach for the evaluation of existing projects, then present and summarise the status of the four shortlisted systems and finally discuss their suitability in the context of this project. The reader should bear in mind that the described development status of the devices may have changed at the time of consideration.

Assumptions of this investigation

The following four assumptions are considered to be true for the analysis conducted in this chapter

1. Well-known respirator manufacturers produce sophisticated devices with a wide range of functionality. They, on their own, cannot drastically multiply their production output by the required factor of 5-10, as suggested by The World Economic Forum[32].
2. Ventilation devices that are specifically targeting the ventilation treatment of Covid-19 patients, without considering other functionalities typically included in ventilation devices for intensive care units, are sufficient for use during the Covid-19 pandemic.
3. The non-invasive treatment of Covid-19 patients is a viable option, as long as it remains unclear whether NIV (with masks) or IV (with intubation) is the preferred treatment strategy. All non-invasive ventilators can be operated as first CPAP devices.
4. The requirements published by the UK Medicines and Healthcare Products Regulatory Authority (MHRA) for clinically acceptable ventilators for use in the Covid-19 pandemic are currently the best available guidance for developing new devices for the current crisis.

Based on these assumptions, we focus on low-complexity and rapidly manufacturable NIV systems. The functional scope for the evaluation is defined by the requirements listed by the MHRA. Additionally systems designed for non-invasive treatments are considered.

32 World Economics Forum: “A better answer to the ventilator shortage as the pandemic rages on”, 03.04.2020, https://www.weforum.org/agenda/2020/04/covid-19-ventilator-shortage-manufacturing-solution/

Methods for evaluation

Ongoing ventilator projects considered for evaluation

The systems discussed in this evaluation have been collected from diverse sources:

- Database of open-source ventilator projects[33]: Investigating the systems that are rated among the best 15 during a time period of two weeks
- Promising industry projects found by web search
- Top 10 systems from the give-a-breath challenge of the Fraunhofer Institute[34]
- Systems are known to us through our network

Systems that use a volume displacement approach (most often achieved by compressing a manual resuscitator bag used in out-of-hospital settings) have been excluded from the evaluation, as they do not provide the optimal pressure profile for treating Covid-19 patients, often comprise sensible mechanics and impose a risk due to fatigue of the repeatedly squeezed bag.

Evaluation criteria

The systems considered for evaluation have been analysed regarding the technical feasibility of contained functions, the maturity of the product development and fulfilment of the MHRA requirements. The main functional requirements from the MHRA requirements can be summed up as follows:

1. Pressure controlled (instead of volume-controlled)
2. Adjustable pressure waveform (breathing frequency, inspiratory/expiratory ratio, level of pressure plateau, positive end-expiratory pressure PEEP)
3. Oxygen concentration adjustable and measurable
4. Triggering for synchronisation with patient's own respiratory efforts
5. Tidal volume monitored
6. Backup battery power for at least 20 min of operation

Analysis of the four shortlisted systems

Four systems have been shortlisted, and their analysis is described in the following subchapter. Three of these systems are ongoing development projects chosen based on the criteria as mentioned earlier, and one system is the device development following the concept of Prof. Lutz Freitag.

The four shortlisted systems can be divided into two functional categories that require, despite the need for an electric power supply, different levels of clinical infrastructure to be deployed.

1. **Pressure-source-dependent** ventilators mainly consist of an electronically actuated valve circuit that regulates the pressure to achieve the desired pressure waveform. These systems are relying on the supply of oxygen and medical air at high pressures, usually delivered from the wall socket of hospitals with a certain level of infrastructure.
2. **Blower-based ventilator** concepts include a rotating impeller to generate pressure, driven by an electric motor. In comparison, these systems do not require high-pressure medical air but

33 Robert L. Read, Keeshan Patel, Juan E. Villacres Perez and Avinash Baskaran: “Analysis of Open Source COVID-19 Pandemic Ventilator Projects”, last viewed 25.04.2020, https://docs.google.com/spreadsheets/u/1/d/e/2PACX-1vTYAfldxoliO46VAWH1NlhrwFBn9mguqS2bh1spnLEu4AVVN1cj1vaEm6vOp5Z6UnaAbUwd8dslCXdM/pubhtml

34 Fraunhofer Institute, Munich Re: “Give a Breath Challenge”, last viewed 28.04.2020, https://give-a-breath-challenge.innosabi.com

only an oxygen supply which does not necessarily need to be under high pressure so that oxygen concentrators can be used as well.

First, the two pressure-source-dependent systems will be described (CoroVent, MVM), followed by the two blower-based systems (Covidair, Freitag Blower). The respective teams behind each of the systems have been contacted. Open questions, as well as status updates, were discussed with them. Due to time constraints, only the systems located in Switzerland (Covidair, Freitag Blower) were investigated more closely by visiting the production site and testing the devices on the artificial lung test bench[35] at ETH under the direction of Dr. Marianne Schmid Daners from the Product Development Group Zurich at ETH Zurich.

The following summaries only provide an overview, further information on the four systems, including pneumatic schematics, can be found in the supplementary material.

CoroVent (Prague Technical University)

Figure 1: CoroVent Ventilator System. Further details and pneumatic schematics in the supplementary material.

Core technology

The CoroVent system regulates the supply of gas with standard 2-way valves which are rapidly alternating between the open and close position (similar to pulse width modulation for electrical signals). Mixing of air and oxygen is done within the system, and sensors for pressure and flow measurement are included.

Open requirements

The system does not yet support patient-triggered respiration, does not measure oxygen concentration and only has a volume-regulated, pressure-controlled ventilation mode.

Maturity of device development

The CoroVent device was developed in collaboration with industry and the Czech government based on a proposal of a research group experienced in ventilator design. Integration of patient-triggered respiration is planned for the next version of the device. They do not plan to go through the usual certification process. Still, they expect to get a temporary certification by the Czech Republic to use their design in hospitals during the Covid-19 crises.

Production forecast

The production has already started and is expected to ramp up to several hundred units per day. The sales price is estimated to be around 9'000 EUR.

35 The test bench is a modified and upgraded version of a commercially available artificial lung named TestChest (https://www.organis-gmbh.ch/solutions/testchest/) that allows reproducible and standardized testing.

Mechanical Ventilator Milano

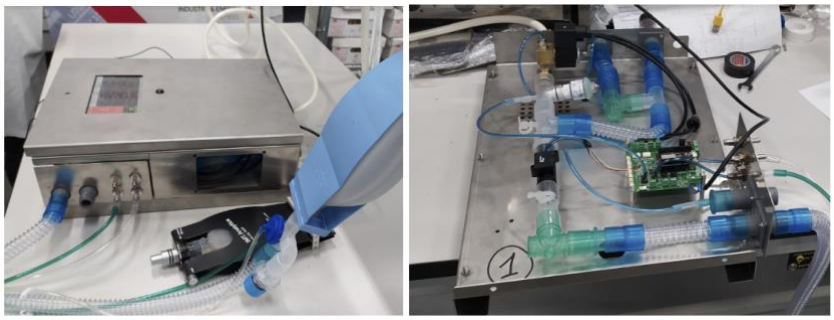


Figure 2: Mechanical Ventilator Milano. Further details and pneumatic schematics in the supplementary material.

Core technology

The Mechanical Ventilator Milano (MVM) regulates the supplied gas pressure within its valve circuit of electrically driven proportional valves based on the signals of sensors for pressure, flow and oxygen. It requires an additional external gas blender despite the supply of high-pressure medical air and oxygen.

Open requirements

The oxygen concentration can be adjusted, but this is done externally with the gas blender.

Maturity of device development

A team of more than 250 engineers, physicists and doctors mainly from Italy and the US developed this comparably mature system based on an old ventilator design from the 1960s. In collaboration with industrial partners, product development was finalised at an astonishing pace.

Production forecast

Legal manufacturers are defined, and they plan to ramp up the production to 300-400 units per day by the end of May 2020. Prof. Cristiano Galbiati (founder and spokesperson of MVM) estimates a sales price of roughly 4'000 EUR.

CovidAir (BCD Microtechnique)

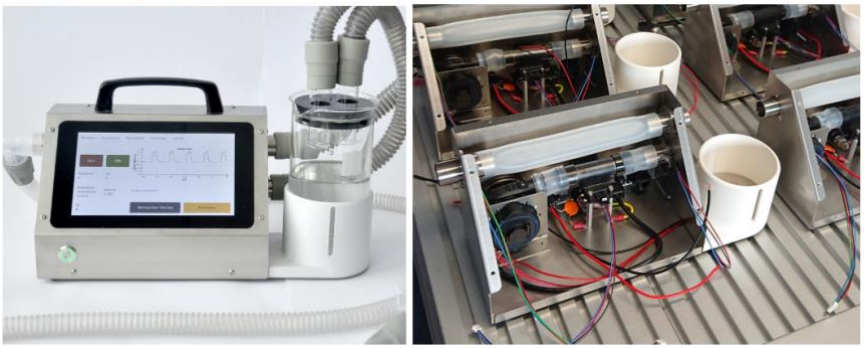


Figure 3: CovidAir Ventilator System. Further details and pneumatic schematics in the supplementary material.

Core technology

The Covidair system generates the desired pressure levels by adjusting the speed of a centrifugal fan commonly used in medical appliances. A pressure and a flow sensor provide the required

measurements for control. In the current setup, the oxygen injection at the inlet of the turbine leads to oxygen leakage.

Open requirements

No mechanism is yet included to mix air and oxygen accordingly, which therefore must be supplied externally. No battery for emergency power supply included.

Maturity of device development

The company BCD Microtechnique (Préverenges, Switzerland) with eight employees has built this system in nine weeks. The user interface, housing and printed circuit board implementation show a mature system. It is estimated that missing features (e.g. an emergency battery) do not require a complete redesign of the system but can be added with comparably low effort. Testing on the artificial lung test bench at ETH was successful for an assorted number of test cases from the MHRA guideline. A technical documentation of the CovidAir system conforming to the standards needed for medical certification is not available.

Production forecast

Currently, 80 units have been produced. The CEO of BCD Microtechnique, Cedric Pahud, estimates a sales price of 5'000 CHF for a lot size of 200 units.

Freitag Blower (Girtec, Prof. Lutz Freitag)

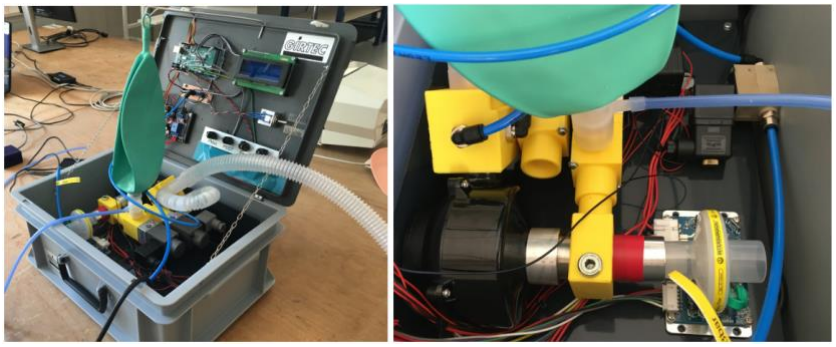


Figure 4: Freitag Blower Ventilator System. Further details and pneumatic schematics in in the supplementary material.

Core technology

This system regulates the speed of a medical-grade CPAP turbine to achieve the desired pressure levels. The two-way valves are used to control the oxygen inflow and to switch between the inspiration and expiration branch. Oxygen can be injected at high or low pressure, therefore also allowing for the use of oxygen concentrators as an oxygen source. This device is designed to save oxygen through efficient feeding.

Open requirements

The oxygen concentration is not measured directly but indicated via a rough visual indication through the inflation of the balloon. The synchronisation to the patient's inspiration and the tidal volume measurement are both dependent on a flow sensor which has not yet been implemented. A battery is not included.

Maturity of device development

Based on the concept of Prof. Dr. Lutz Freitag and developed by the company Girtec, the current state is on a proof-of-concept level. The software implementation does not contain alarms or safety functions, some components are in the early prototyping stage (e.g. Arduino board, Solenoid valve) and no

technical documentation or tests concerning certification efforts has been done yet. Testing on the artificial lunge test bench at ETH was partly successful for an assorted number of test cases from the MHRA guideline.

Production forecast

The CEO of Girtec, Christoph Girsberger, estimates readiness for pilot production in 6 weeks but without any consideration of technical documentation which is a prerequisite for the usage in any country and is likely to prolong development substantially. The sales price was estimated at roughly 2500 CHF.

Summary

Several systems have been shortlisted, ranging from promising systems at a proof-of-concept level to mature product developments that are ready for mass production.

Among these, the MVM system is surprisingly already at a stage where the approval of the Food and Drug Administration (FDA) is granted (as of 01.05.2020) and production capacity is currently being ramped up. According to the manufacturer, 1000 units could be delivered within six weeks. This system is the only device in the presented shortlist that allows IV. Operation requires a clinical infrastructure with high-pressure medical air and oxygen.

If such infrastructure is not available and therapy with NIV is medically adequate, the Covidair device enhanced with concepts and components of the Freitag Blower (e.g. concepts for efficient oxygen injection, switched double-tube exhalation and valve block design) could be a viable solution. However, the delivery of such a device would require several months to finalise product development, technical documentation and preparation for mass production. The effort and extent for this finalisation are further investigated in the following Chapter 4.

Part IV: Finalisation product development & industrialisation

Introduction

Medical devices are developed in a regulated environment to ensure that the benefits of the products placed on the market outweigh the risks to patients. Even in emergencies like the current crisis, no exceptions are made. Such a risk-focused approach requires a company that wants to place a medical device on the market to bring its product to the necessary level of maturity and to provide the respective documentation. This chapter examines the steps required to certify and introduce the CovidAir system to the market and provides an effort estimate for the finalisation of product development. The projected manufacturing costs are estimated for a production of 1000 units.

Methods

The estimation of the finalisation effort was carried out in cooperation with the engineering service provider Zühlke Engineer AG. They specialise in the development and industrialisation of medical devices. The evaluation of the effort required to finalise CovidAir product development was made in the context of the regulated industry and taking into account the current status of CovidAir product development and necessary additions from the complementing Freitag Blower system (e.g the manufactured oxygen valve). The pathway to regulatory approval was proposed taking into account the current extraordinary situation and the provisions of the national authorities to grant a derogation for the placing on the market of ventilators. The estimated manufacturing cost of the device is based on an assumed production volume of 1000 units. The Zühlke network was used to search for potential manufacturing partners and companies that could assume full liability as legal manufacturers. The system that is built on CoividAir system is presented in Part III. The maturity and risk assessment of Zühlke of the prototype design is found in the in the supplementary material.

Regulatory approval

Urgency on ventilator systems requires shortened pathways for product approval to be used in Covid-19 concerned healthcare environments. Several guidance documents support such reduced ventilator delivery and adoption within the EU, without CE marking and limited for the pandemic duration. Swissmedic (the Swiss regulatory agency for medical device approval) supports this by taking over product approvals beside notified bodies. Export to other markets shall be organised using export certificates.

MHRA (UK authority) introduced guidance specifically for development and approval. This guidance was vital for our analysis of the given prototypes of interest. Documentation and performance of prototypes are assessed against those requirements. Latest advice by the Medical Device Coordination Group (EU) was just published. This is the most relevant one for all Europe, now. The detailed provisions are found in the in the supplementary material.

Chances & opportunities:

- Involvement of experienced medical manufacturers of ventilation systems including their given clinical database

Risks:

- Lengthy clarification with competent authorities with regards to (legal) manufacturing partners

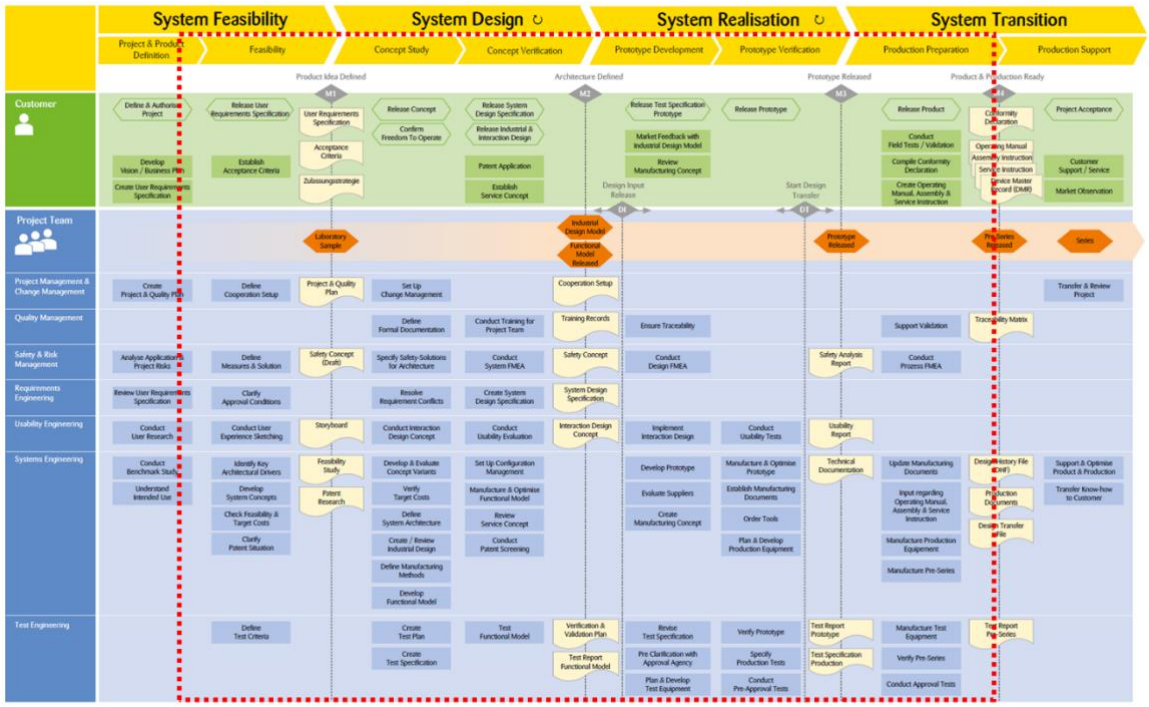
Industrialisation and Manufacturing

Assumptions

- A solution could be built and supplemented on the current design state. There is not a complete redesign necessary.
- Regulatory topics from the early design phase need to be complemented to meet state-of-the-art safety- and technical- requirements.
- Planning is optimised for the short lead time before reducing the cost of goods sold (COGS).
- Production quantity is 1’000 systems per year.
- Proven processes, methods and tools from Zuehlke are applied.
- There are no significant loops planned.
- Clinical evaluation is based on existing data. There are no clinical trials needed.

Estimation and planning

The estimation and planning of the remaining development effort are based on an established Zühlke development scheme for medical devices. This development scheme is shown in the following diagram and is simply intended to illustrate to the reader the multitude of steps required in medical device development, which is considerate for the estimation. The evaluation of the remaining development time is based on individual time estimates for all process steps shown, which were made based on experience from previous projects that had a similar focus and scope.



Project goal: Ready for mass production and placing on the market
There are two scenarios planned as forecast:

Scenario A
(Based on typically expected lead times)
This scenario is typical to be expected

- Lead time: 5 months
- Effort:
  - Expected; 670 personal days
  - Best case 550 personal days
- Expenses: 250k CHF for RA consultants, prototype samples, production- and test equipment, testing laboratories and approval agencies.

Scenario B
(Based on shorter lead times by increased team size)

- Lead time: 4 months
- Effort:
  - Expected; 800 personal days
  - Best case 650 personal days
- Expenses: 250k CHF for RA consultants, prototype samples, production- and test equipment, testing laboratories and approval agencies.

Risks:

- There is a major redesign needed, and development could not continue on the current design.
- There is a major iteration needed due to failed verification.
- There is not enough clinical data available in clinical evaluation.

Manufacturer

All considered ventilator prototypes are just intermediate maturity levels. Beside regulatory conform development issues, there manufacturing topics to be discussed like manufacturing capabilities according to medical device standards or product liability of a legal manufacturer.

Ongoing analysis and interviews with Swiss manufacturers show clear interests to take over such responsibilities. In case there will be sponsors available for this Swiss ventilator initiative those discussions shall proceed with high priority as many open topics still need to be discussed, agreed and finally signed by contract – which will take some time. Those interest statements are just a first indication to understand if partners would be available at all.

Given the new MDCG guidance on regulatory requirements for ventilators and related accessories, there are dedicated constraints identified along with the selection of manufacturers and legal manufacturers. This is strongly linked to an available time frame to bring a new low-cost ventilator system on the market right in time.

Thus, priority must be given to aligning the strategy involving Swissmedic as a competent authority to place ventilators on the market with the selection of interested Swiss manufacturers.

Chances & opportunities:

- Involvement of experienced medical manufacturers and even experts on ventilators will help to get a shorter timeline and managing obvious project risks early
- Reuse of critical system modules by existing ventilator manufacturers

Risks:

- Business case not clear enough for decision process (like clear orders not available, short duration of business as it is limited to Covid-19 period, unclear who is
- The complexity of worldwide delivery might be too critical for partners (like logistics organisation, service, troubleshooting & languages)

Supply chain

Bill of Materials (BOM)

- Some relevant entries are missing in BOM. This has an impact on real COGS (cost of goods sold).
    - Assembling
    - Production testing, quality check
    - Packaging and documentation
- Some components are probably in conflict with requirements like robustness, reliability, biocompatibility, EMC and others. In focus are here turbine, flow sensors, controller, display and others. A substitution of components, which could be necessary as mitigation, could have an impact on lead time and COGS.

Component Supplier

- Majority of components are sourced from a local wholesaler (e.g. Digikey, Distrelec, Farnell) which are known to be expensive. On more substantial quantities, a cost optimisation by direct sourcing could often be made.
- Multiple components are regular “industrial grade”. It could be appropriate to have “medical grade” materials and components in the breathing pathway and for safety-critical components like controller or display. This would typically increase COGS.

COGS

Based on experience and current data and issues, it is expected to have COGS of the final product in the range of 2’000-5’000 CHF.

Risks:

- Critical components in existing design need to be substituted.
- Time-consuming verification required to show compliance with the current design.

Summary

The regulatory pathway, the efforts for finalisation of product development and the manufacturing costs were estimated, and the risks and opportunities assessed. An implementation plan building onto the existing NIV prototype of the CovidAir system, which considers regulatory approval and finalisation of product development estimates the time for completion to four-month.

The costs of manufacturing are expected to be in the range of 2’000-5’000 CHF.

Conclusion

Summary

We reviewed the medical need and treatment for hospitalised Covid-19 patients and found an ongoing scientific debate on the most appropriate medical treatment strategy including either IV (with intubation) or NIV (with face masks) ventilatory support. With each passing day that Covid-19 patients are treated, the medical and scientific community learns more about optimal treatment options. This also results in changing medical opinion, and NIV may become a viable treatment option, as suggested by leading pulmonology experts. From the perspective of deploying ventilators to developing countries, NIV would be preferable because it requires less infrastructure and less specialised medical staff, as no sedation of the patient would be required. However, the appropriate treatment strategy must also be supported by local specialists and must take into account the best treatment for patients, the proper protection of medical staff and the available infrastructural resources.

We reviewed the situation and demand for ventilators in developing countries at three different income levels. We found that the available medical infrastructure varies starkly depending on the country and considerably within a resource-constrained country depending on proximity to metropolitan areas or healthcare centres. Any strategy of deploying ventilators must take into account the available infrastructure and resources of healthcare staff. Given the difficulty of making predictions in this evolving crisis the need for ventilators should be assessed in response to formulated requests from other governments. Besides, the deployment of medical equipment for respiratory therapy could also serve as a sustainable contribution to the medical infrastructure of some developing countries after the Covid-19 crisis.

The reviewed 50 potential ventilation systems that are outside the currently commercially available systems and identified the most promising solution for IV and NIV. The invasive ventilator system, which has been developed in Italy and the US, is already at a stage where FDA approval is granted and production capacity is currently being ramped up. Operation requires a clinical infrastructure with high-pressure medical air and oxygen. The system for NIV is developed in Switzerland and can also be operated without a supply of high-pressure medical air. As this system is at a less mature stage, it would take additional effort to finalise the product development, technical documentation and preparation for mass production.

We further investigated the effort and extent for the finalisation of product development of this NIV system under the consideration of the regulatory pathway, and the estimated manufacturing costs. An estimation of the expenses of manufacturing is expected to be in the range of 2-5k CHF. An implementation plan was derived.

Recommendation

1. In environments with poor clinical infrastructure, ensuring the availability of supplemental oxygen should be a major focus in the treatment of hospitalised Covid-19 patients. This has the most significant impact, requires only the installation of oxygen supply systems and relatively little training for healthcare staff and is also a prerequisite for all other forms of mechanical ventilation therapy. This should be further investigated.

2. If a country has a formulated demand for invasive ventilators and possesses the required infrastructure and specialised healthcare personnel, the ordering and deployment of MVM systems in large numbers is a viable option that should be available by June 2020.

3. The ongoing medical debate regarding the treatment options should be monitored or even a clinical investigation could be conducted. Once more data on non-invasive ventilation is available, and a demand for these devices is established, the procurement and deployment of non-invasive ventilators has a big potential as its reach exceeds that of invasive ventilation. This report outlines an implementation plan to develop affordable non-invasive ventilators made in Switzerland within four months.

Annex

Information about the authors

Prof. Dr. Mirko Meboldt is the chair of the Product Development Group Zurich at ETH Zurich. His main research focuses on the development of new products in the field of mechanical engineering industries, biomedical applications and associated technologies. Before he was responsible for global technology and product development processes.

Kai v. Petersdorff-Campen is research assistant and PhD candidate at the Product Development Group Zurich, ETH Zürich, under the supervision of Mirko Meboldt. He has experience in medical technology through his research on mechanical circulatory support devices and degradable alloys for bone tissue replacement. He co-founded the startup Rowcus, that is developing a mobile radar-based collisions avoidance system for water sports.

Dr. Stefan Boës is working at the Student Project House of ETH Zurich, where he is responsible for mentoring and coaching of the project teams. In his PhD in the field of biomedical engineering he investigated the development and testing of implantable heart assist devices. Previously, he co-founded the Memox Innovation AG and served as president of a business consultancy run by students.

Dr. Martin Batliner finished his PhD under the supervision of Mirko Meboldt in the field of medical device development. Prior to that he had worked in the semiconductor industry for Sensirion. In his PhD he collaborated in a three year project with the medtech startup Onefusion. After his doctorate he joined Onefusion as Head of R&D.

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