



REVIEW

A review of open source ventilators for COVID-19 and future pandemics [version 1; peer review: 1 approved]

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Abstract

Coronavirus Disease 2019 (COVID-19) threatens to overwhelm our medical infrastructure at the regional level causing spikes in mortality rates because of shortages of critical equipment, like ventilators. Fortunately, with the recent development and widespread deployment of small-scale manufacturing technologies like RepRap-class 3-D printers and open source microcontrollers, mass distributed manufacturing of ventilators has the potential to overcome medical supply shortages. In this study, after providing a background on ventilators, the academic literature is reviewed to find the existing and already openly-published, vetted designs for ventilators systems. These articles are analyzed to determine if the designs are open source both in spirit (license) as well as practical details (e.g. possessing accessible design source files, bill of materials, assembly instructions, wiring diagrams, firmware and software as well as operation and calibration instructions). Next, the existing Internet and gray literature are reviewed for open source ventilator projects and designs. The results of this review found that the tested and peer-reviewed systems lacked complete documentation and the open systems that were documented were either at the very early stages of design (sometimes without even a prototype) and were essentially only basically tested (if at all). With the considerably larger motivation of an ongoing pandemic, it is assumed these projects will garner greater attention and resources to make significant progress to reach a functional and easily-replicated system. There is a large amount of future work needed to move open source ventilators up to the level considered scientific-grade equipment, and even further work needed to reach medical-grade hardware. Future work is needed to achieve the potential of this approach by developing policies, updating regulations, and securing funding mechanisms for the development and testing of open source ventilators for both the current COVID19 pandemic as well as for future pandemics and for everyday use in low-resource settings.

Keywords

ventilator, pandemic, ventilation, influenza pandemic, open source, open hardware, COVID-19, medical hardware

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1

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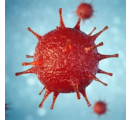
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report

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Any reports and responses or comments on the article can be found at the end of the article.



This article is included in the [Disease Outbreaks gateway](#).

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Introduction

Coronavirus disease 2019 (COVID-19), caused by a novel coronavirus (SARS-CoV-2), is in part so dangerous because it threatens to overwhelm our medical infrastructure at the regional level, causing spikes in mortality rates¹⁻⁴. Within the medical infrastructure, there are critical technologies that are generally available, but simply do not exist in a high enough density to handle the excessive volume of patients associated with pandemics⁵. Thus, people die unnecessarily throughout the world because of a combination of COVID-19 infections and the lack of access to some of these technologies⁶. Ventilators are an example of technologies that are currently in critical short supply^{7,8}. Mechanical ventilators are essential for treating both influenza and COVID-19 patients in severe acute respiratory failure^{9,10}. Past studies have shown that intensive care units (ICUs) will not have sufficient resources to treat all patients requiring ventilator support during a massive pandemic¹¹⁻¹³, and ethically challenging triage^{14,15} would need to be used to decrease mortality over first-come first-served basis for ventilator allocation among patients. Some work has shown promise for using a single ventilator to support multiple patients during a disaster surge¹⁶⁻¹⁸. In addition, it has already been shown that 3-D printed manifolds can assist with rapidly deploying this solution and there are [open source designs](#)¹⁹. This is not necessarily straightforward²⁰. Although some countries, like the United States, have stockpiles of ventilators²¹, there is consensus that there is not enough supply for serious pandemics²²⁻²⁵ and that rationing would be needed²⁶. The current medical system relies exclusively on specialized, proprietary, mass-manufactured ventilators from a small selection of suppliers. This supply model clearly fails when there is a sudden surge in demand for a relatively low-volume specialty product such as ventilators in a pandemic as analyzed here. The vast majority of medical equipment is heavily patented by a few specialty medical firms that sell small volumes because during 'normal' times, a medium-sized hospital only needs a handful. These firms have historically aggressively protected their intellectual monopolies²⁷⁻²⁸ to the detriment of human lives (for a recent example, consider the fact that a manufacturer threatened to sue a maker for 3-D printing life-saving valves in Italy for patent infringement)²⁹. In addition, non-practicing entities continue to attempt to actively prevent medical treatments from being deployed, even during the current COVID-19 pandemic³⁰. Putting aside the absurdity of patenting and then obstructing others from using obvious inventions in normal times³¹⁻³³, in the wake of a pandemic where millions of lives are at stake, it is intuitively obvious that this type of greed is no longer acceptable.

Fortunately, with the recent development and widespread deployment of open source small-scale manufacturing technologies^{34,35}, there is now another way – mass distributed manufacturing³⁶⁻³⁹. In this new model, designs are developed and then shared with open source licenses freely on the Internet so that others can simply download and replicate the design on their own equipment, even at the household scale⁴⁰. There has been tremendous and ongoing success of open source scientific hardware proliferation⁴¹⁻⁴⁶, where lower-cost and superior-functioning custom equipment as compared to proprietary scientific tools⁴⁷⁻⁵⁰. Based on such scientific hardware results, there appears to be a

significant opportunity to apply open source design principles⁵¹ and mass-scale collaborative distributed manufacturing technologies to make medical equipment⁵²⁻⁵⁵. In the current situation, this would at least partially overcome medical supply shortages⁵⁶⁻⁶¹ in general, and specifically for ventilators.

Of these enabling technologies, the most advanced is the fused filament fabrication (FFF)-class of desktop 3-D printers that have spawned from the self-replicating rapid prototyper (RepRap) project⁶²⁻⁶⁴. With the distributed manufacturing model, designs are downloaded even in remote areas and are manufactured on demand as needed⁶⁵ from readily available (and possibly recycled⁶⁶⁻⁷⁸) materials. These 3-D printers are, in general, not particularly fast when making products, but with tens of thousands of 3-D printers already strategically deployed all over the world⁷⁹, they have the capacity to fabricate an incredibly diverse and large range of products (growing exponentially)⁸⁰, which have already been shared with open source design licenses. Here, the potential will be analyzed for hardware that can be as-much-as-possible digitally manufactured using accessible low-cost fabrication tools like RepRap-class 3-D printers and then readily constructed from widely accessible materials and simple tools (e.g. DIY hardware store sourced along with Arduino-class microcontrollers).

In this study, after providing a background on ventilators, the academic literature will be reviewed to find the existing and already openly published vetted designs for ventilator systems. These articles will be analyzed to determine if the designs are open source both in spirit (license)⁸¹ as well as required practical details, which include possessing the design source files (e.g. CAD) as well as production files (e.g. STL), PCB layouts and other electronics design files, bill of materials (BOM), list of tools required, wiring diagrams, firmware and software, as well as instructions for the assembly, calibration and operation. Next, the existing Internet and gray literature will be reviewed for open source ventilator projects and designs. Lastly, as this is a rapidly evolving area, future work will be described to enable wide-spread mass distributed manufacturing of open source ventilators to fight against the current COVID19 pandemic as well as for future pandemics and to provide the devices to low-resource regions of the world that are underserved even in normal times.

Analysis of literature

Oxygen therapy coupled with mechanical ventilation is meant to support patients so that an adequate oxygen saturation (>88%) in arterial blood is maintained⁸². The mechanical respiratory cycle has four parts: 1) inspiration, where the exhalation valve of the ventilator is closed and the ventilator uses pressured air to cause gas to flow into the lungs; 2) cycling, where change-over from inspiration to expiration occurs; 3) expiration, where the main ventilatory flow is interrupted and the exhalation valve opened to allow gas to escape from the lungs, and 4) triggering, where the changeover from expiration to inspiration occurs. According to Andreoli *et al.*⁸², mechanical ventilators are classified on what factor terminates inspiratory flow, as follows: 1) pressure-cycled ventilators terminate flow when preset pressures

are reached in airways; 2) volume-cycled ventilators provide a set volume of gas to the patient over a range of pressures (but a maximum pressure is set to avoid damage to the patient's lungs during delivery of the set tidal volume); 3) time-cycled ventilators set tidal volume by setting the inspiratory time and flow rate; and 4) flow cycled ventilators, where the inspiratory flow is terminated when the inspiratory flow rate drops below a specific level. The most common commercial modes of mechanical ventilation both provide a specified number of breaths per minute (BPM) and are 1) synchronized intermittent mandatory ventilation (SIMV) where patients can take additional breaths over the set rate and 2) assist control (AC) that uses triggering so that if the patient makes an effort to breathe, it helps them, and if not, it maintains the set rate. These modes can be used alone or in concert with 1) continuous positive airway pressure (CPAP), which uses a high-pressure reservoir and constant flow of gas that exceeds the patient's needs; 2) positive end-expiratory pressure (PEEP), which increases the residual reserve capacity and allows for many alveoli and small airways to remain open that would otherwise close off; or 3) pressure support ventilation (PSV), which adjusts the pressure on the fly as the patient breathes to maintain a preset inspiratory pressure. For those designing open source ventilators using any of those modes and methods, there is a good base of established literature to draw upon. The classic background is available in Hess, *et al.*'s 1996. *Essentials of mechanical ventilation*,⁸³ Tobin's 2010 *Principles and practice of mechanical ventilation*⁸⁴, and Owens' 2018. *The Ventilator Book*⁸⁵. In addition, Chapter 4 in the openly accessible book *Equipment in Anaesthesia and Critical Care: A complete guide for the FRCA*, provides a good starting point to help makers understand existing designs and terminology for ventilators⁸⁶. Texts are available for the use of a ventilator for the standard of care of patients with acute respiratory distress syndrome (ARDS)⁸⁷, ventilator management for the NIH⁸⁸, and the practical use of oxygen for patients⁸⁹. A 2017 state-of-the-art review of mechanical ventilation is presented by Pham *et al.*⁹⁰ It provides basic schematic diagrams for all of the main classes of commercialized ventilators and reviews their pros and cons.

Existing peer-reviewed literature

The peer-reviewed literature itself is currently limited, but there has been some research on low-cost ventilation, even if the source is not available. First, a field portable ventilator system for domestic and military emergency medical response has been conceptually designed, but does not include enough information to construct it (e.g. the software was written in assembly language and not shared)⁹¹. This article does contain design considerations that may be useful for open source designers.

A new, compact and low-cost mask respirator concept has been developed and prototyped successfully⁹². The blower unit was able to provide adequate ventilation to the test lungs. In addition, the integrated sensor for airway pressure was able to detect airway occlusion and leakages. It is a relatively low-power device and could be operated wirelessly with batteries. It provides a cross-sectional view of the blower unit and some details, but again, not enough to be considered full open hardware or to be

easily replicated. It should be noted, however, that many of the components are within RepRap-class 3-D printing capabilities.

In addition, research has been undertaken on a pre-stage public access ventilator (PAV)⁹³. The PAV is made up of several low cost technologies including a self-designed turbine and a range of sensors for differential pressure, flow, F_{iO_2} , F_{iCO_2} and three-axis acceleration measurements. The PAV was tested under three conditions to show that it was adequate for an automatic emergency system: 1) pressure-controlled ventilation (PCV), 2) PCV with controlled leakage and 3) PCV with simulated airway occlusion. The PAV was tested for and showed effective ventilation for tidal volume, breathing frequency and inspiratory pressure. Similarly, there has been a proposal to replace artificial manual breathing unit (AMBU) bags with electric blowers to act as emergency ventilators⁹⁴.

In contrast, another approach is to build a low-cost ventilator utilizing an AMBU bag that is not based on constant blower use⁹⁵. The study by Mukaram Shahid showed the AMBU setup was able to perform all the functions of a conventional commercial ventilator for a far lower cost (<\$100US excluding labor). The automated AMBU device was able to adjust the breathing rate and the volume of the air, which is comparable to older ventilators. However, it was also able to regulate the inspiration to expiration ratio and PEEP rate. Shahid's system comes with two modes: 1) mandatory ventilation (as in older models) and 2) assisted ventilation (as with most current systems). Thus, the medical personnel can choose to use either the built-in triggering mechanism (assist boosted mode), which alters the respiration pattern once it detects a change in air pressure, or set a time interval for the respiration pattern. The article contains pictures, an electric schematic, a control loop diagram, and very basic results. Again, this can be used as starting point, but there is not enough shared to replicate in the open hardware fashion.

Next, a low-cost (\$420 prototype) portable mechanical ventilator was designed and prototyped that delivers breaths by compressing a conventional bag-valve mask (BVM) with a pivoting cam-actuated arm pushed by an electric motor⁹⁶. This eliminates the need for a person pushing on the BVM, which is generally viewed as only a short-term solution. This system uses knobs to determine the tidal volume appropriate to the patient (usually 6–8 mL/kg of ideal body weight), adjustable BPM of 5-30, and inhalation to exhalation time ratio options of 1:2, 1:3 and 1:4 and a minimum respiratory rate⁹⁷. This design is run with an open source Arduino micro-controller⁹⁸ and the article provides enough details to be used as a guide for others to build a similar device, but not the full plans, code, etc. needed to qualify as an open source hardware device.

The most relevant design is a pneumatic ventilator specifically designed for pandemics, which has a low oxygen consumption⁹⁹. In this study by Williams *et al.*, they describe and test three simple, pneumatically powered, low oxygen-consumption ventilators. The three designs were tested for different lung compliances (i.e. different ventilator workloads) on the delivered

F_{iO_2} and oxygen consumption. They used a commercial mechanical test lung for these tests (Vent Aid; Michigan Instruments Inc., Grand Rapids, MI, USA). The results of this study support the potential for mass distributed production of a low-cost, gas-powered, volume-controlled ventilator with a low oxygen consumption (anywhere with oxygen at 2–4 bar). The designs could alternatively be operated on hospital compressed air. The single use, self-inflating bellows system prevents cross contamination among patients. In addition, the system possessed one-way and safety overpressure valves, which could be incorporated into other designs. The designs are in part supplied including basic principle schematics, an example BOM, but falls far short of what is expected for a complete open hardware design.

There are also completely different approaches to the design of a ventilator, such as the high-frequency oscillatory ventilator¹⁰⁰, but only basic design schematics and preliminary testing is provided. Thus, within the peer-reviewed literature, most of the quasi-appropriate ventilator devices use a standard ventilation bag that is cyclically compressed by either an electromechanic or pneumatic setup and controlled by a microcontroller. Fortunately, the most complicated part of these designs is the controls, which is made accessible by the maturation of Arduino-based microcontrollers that can actuate and sense over a wide array of accessible and already-developed technologies (e.g. [code libraries](#) are available). It should be noted that most of the low-cost options in the literature used the bag approach, but that modern commercial ventilators are generally not manufactured with bags, bellows or pistons due to performance concerns. These concerns may be overcome by the nature of a pandemic, as well as by replacing low-cost components during failure, but this does indicate failure detection is warranted and certainly preferred in an open source ventilator design.

Open source ventilator designs shared on the web

There are a number of proprietary commercial low-cost products like the [Pumani bubbleCPAP](#) for infants, [D-box](#) or [One Breath Ventilators](#) (not yet for sale), which could be used to relieve some of the demand for conventional ventilators. Rather than attempting to conduct a market review of such devices, however, because presumably hospitals facing a shortage of ventilators would already consider all commercially-available and regulated/approved systems, this section will investigate the growing body of knowledge to help makers develop open source ventilators as well as the preliminary designs. This section was largely supported by information gathering of the rapidly evolving open source Internet communities such as [Project Open Air](#), which is a group of “[Helpful Engineers](#)” on the platform Just One Giant Lab. They have congregated to help in the COVID-19 pandemic by developing open source solutions and of most relevance to this study, on a project specifically on the development of [open source ventilators](#). Their documentation and information is [freely available](#). Although just starting, as of 17 March 2020, they have over 2,500 registered volunteers and over 9,000 on their Slack team. In addition to an offset ventilator, in [their first round of project proposals](#), they have prioritized oxygen concentrators and personal protective equipment (PPE) as their top priority projects. In addition, their future work will focus

on tube connectors and building a database for local manufacturers able to produce hardware with high score in reviews. There are other teams including those organizing around the open source wiki [Appropedia for an open source ventilator](#). Facebook has an [Open Source COVID19 Medical Supplies Group](#). There is a long-going [Pandemic Ventilator Project](#) that hosts their designs on [Instructables](#). The RepRap community is starting on an [open-source oxygen concentrator](#), which can be used alone or in tandem with an open source ventilator. [Hackaday](#) has recently called for a medical hackathon to design and deploy an open source ventilator¹⁰¹. Other communities are crowd-sourcing information about [COVID-19 medical technologies](#) and developing a [Coronavirus Technology Handbook](#). Some resources for makers are appearing as [basic specification](#) provided by Botta. In addition, The Center for Safety, Simulation, and Advanced Learning Technologies (CSSALT) at the University of Florida has started an [open source ventilator project](#) based on hardware store components on the assumptions that the FDA will waive clearance for the bare-bones design if there is a massive shortage. The CSSALT system is one of the most professionally documented, with full files available for each sub-system and published engineering specifications for the ventilator that could be useful even for open hardware designers using completely different approaches. They are maintaining their documentation on [GitHub](#). Many of the sub-modules, however, have not yet been developed, nor have a team working on them. Other projects are also using GitHub, like [Jackson’s Open Respirator project](#), but are at the very beginning stages of development as of this writing. To assist these efforts the UK government has issued [guidelines](#).

One approach favored by both the academic literature as well as the maker community is just to use manual ventilators – BVMs/AMBU bags. There are many commercial suppliers available and there is very preliminary documentation for open source manual ventilation for the developing world^{102,103}. Although, in theory, purely manual ventilation could work to provide ventilation for patients over long periods, there is a real concern of both the availability of the needed man-power, as well as the continued exposure of the laborer. In addition, using a bag-valve mask may increase aerosolization of virus, and in general medical staff are not supposed to bag mask before intubation due to that risk. Many of the open source designs rely on this BVMs/AMBU bags approach where one automates the manual squeezing. It only needs an exhaust system and PEEP valve. Students at Rice University have also created an automated bag-valve mask device that fits around a normal BVM using a dual rack and pinion design with a servo motor that continuously operates (open/close) squeezing the bag a specific amount to supply air. Rice provides a full [non-peer-reviewed report](#), that is considerably richer in details than most of the others. It offers their design strategy, a partial BOM, basic testing, the [source code](#) as well as a summary of the standards and regulations necessary to go to market. Unfortunately, in their preliminary testing, the servo motor failed after only 11 hours of service and Rice is withholding the full CAD designs and results. To overcome the limitations of both the MIT and Rice designs, [a group in Ireland](#) formed and is moving along with full open source documentation of [OpenLung on GitLab](#). They are on their

fifth iteration as of this writing based on the surrounding low-cost BVM/AMBU bag concept discussed above. Another project building off the MIT design is [DIY Ventilators](#). Finally, the open hardware [OxyGEN project](#) is also using automated AMBU approach and although at the preliminary stages their 3-D and MATLAB design files are hosted openly on [GitHub](#).

Makers are also considering other types of non-invasive ventilators (NIV) such as those based CPAP (an alternative to PEEP), which is a form of positive airway pressure ventilator that applies mild air pressure on a continuous basis. A 3-D printed CPAP fan has been designed and tested as a blower and the design files (AutoDesk Fusion 360) and STLs are [freely available](#). Another approach is to turn a commercial CPAP machine into a ventilator currently under development on [GitHub](#) by Lee. Lee built the system around an Arduino nano and has performed very basic tests to it that show that it provides enough pressure for a ventilator used on COVID-19 patients; however, there is not nearly enough information to recommend it for medical use. In addition, there are bi-level positive airway pressure (BiPAP) machines that are commonly used at home to treat sleep apnea and lung diseases as they decrease the effort of breathing by changing the pressure for inhalation and exhalation. Home-use BiPAPs could be used in place of hospital NIVs, but care would need to be taken because poor interfaces could generate viral aerosols¹⁰⁴. Negative pressure ventilation (iron lung) overcomes this problem, helping lung function by pulling from the outside (there has been some development on [Appropedia](#)). It provides a full BOM, but insufficient details for replication or complete open source documentation.

In addition, several makers have developed pandemic ventilators, such as John Strupat, some time ago¹⁰⁵, but unfortunately, in addition to the lack of testing, the source does not appear accessible. Another approach is to use a blower, as in the [Pandemic Pressure Control Ventilator](#) being developed openly on Hackaday.io by Frank. Other open source projects are at their beginnings, like the [TogRespirator](#) project housed on GitHub developed for a Science Hackday Dublin 2020, [DIY and open source respiratory](#) and a project to build an open source ventilator on [GoFundMe](#).

In the review of Internet-reported ventilators, it is somewhat disappointing that many of the most promising designs do not share their source code. In fact, in some cases, little more than a picture or video are available. The newer projects do tend to be following better documentation protocols. Unfortunately, despite the many promising approaches in the maker community, the one problem that the vast majority of the current partial designs have in common is that there is not nearly enough information available about their performance to recommend them for medical use.

Future work needed

It is clear from this review of the peer-reviewed, gray and open web literature on open source ventilators, that there is considerably more work to do. The tested and peer-reviewed systems lacked complete documentation and the open systems that

were documented appropriately were either at the very early stages of design (sometimes without even a prototype) and were essentially only basically tested (and some were not tested at all). With the considerably larger motivation of an ongoing pandemic, it is assumed that these projects will garner more resources and members (as is happening with the Open Air Project) to reach a critical mass to make significant progress to reach a functional and replicable system. Although the motivation of working during a pandemic on a device that may save your life is high, the access to resources, however, is far from optimal. Already, many locations throughout the world are essentially forcing citizens to shelter-in-place, which restricts access to government and university labs, as well as to makerspaces and fab labs. In addition, some areas of the world are suffering from supply disruptions and shipping challenges. This perhaps underscores the importance of developing open source hardware for disasters before the disaster strikes. Future work is needed to develop policies and funding mechanisms for such work as it appears rational to make a small investment in developing and sharing the designs for any critical hardware.

This review article uncovered other limitations to this approach. First, due to 1) potential legal issues challenging an open source ventilator design, and 2) the general lack of useful technical information in patents (the average Instructable generally has more useful information for constructing a device than a patent despite that being a requirement of obtaining a patent), patents were not included in this review. It should be noted, however, that there are currently over 277 inactive patents in addition to those that have expired covering ventilators. Researchers can obtain this list with direct links to these patents using the [Michigan Tech Free Inactive Patent Search](#)¹⁰⁶. There may be useful information contained in those documents that could help open source ventilator designers.

Another challenge with this approach is maintaining a proper level of sterility of devices fabricated using distributed means. Specifically, for the FFF-based 3-D printing parts, it has been reported that the prints are sterile at the time of print¹⁰⁷. If not kept in a sterile environment, however, they could quickly become biologically contaminated. One approach to deal with this is to use washing or a chemical bath. A relatively complete analysis of the chemical compatibility of commercial 3-D printed plastics is available¹⁰⁸. If a specific polymer is needed that cannot be 3-D printed easily, it is possible to make molds in high-temperature plastics, such as polycarbonate, and then use lower temperature plastics to make disposable single use plastic parts¹⁰⁹. Similarly, silicone molds can be made from a 3-D printed reverse mold and used in the same way¹¹⁰.

Even when more mature open source ventilator designs are available and can be safely manufactured by a distributed means, another area of critical future work is validation of these designs. In the medical sciences, open source devices like syringe pumps^{111,112} are already established¹¹³⁻¹¹⁶ and have been developed into sophisticated devices¹¹⁷⁻¹²². However, these devices are used in labs in general and not on people continually. For medical professionals to use an open source ventilator,

they first must be convinced it will do no harm to them (or others) as well as to the patient. As COVID-19 was reported to spread via droplets, contact and natural aerosols from human-to-human, there has been a concern that high-risk aerosol-producing procedures may put medical personnel at high risk of nosocomial infections, which is a concern for some designs reviewed here¹²³. During the airway management, enhanced droplet/airborne PPE is needed and the study by Zuo *et al.* provides a list of other recommendations to overcome this challenge. There have been some developments in 3-D printing some of these PPE^{124,125}. Similarly, for designs that could aerosolize the virus, a negative pressure room would be necessary and future work is needed to design an open source approach to creating such rooms. Likewise, the greatest concern for untested open source ventilator designs is that they harm the lungs of the patients; there is significant literature in this area of ventilator-induced lung injury^{126–133}. There are, however, solutions for preventing this, like controlling the tidal volume^{134,135}. Thus, the designers of open source ventilators must ensure that their designs have safety features to prevent ventilator-induced lung injury, as well as having basic testing of the prototypes to ensure that the designs themselves are thoroughly vetted.

Within the open source scientific equipment community, such procedures are relatively well established and have been working reasonably well through normal peer review of hardware-based articles like those published by *HardwareX*, the *Journal of Open Hardware*, and *PLOS One*. For medical equipment that could be all that stands between life and death, this vetting is even more important and open calls for papers for a [Special Issue on Open-Source COVID19 Medical Hardware](#) are attempting to address this.

However, technical validation may not be enough. Medical hardware used on humans is also more complicated, as any studies involving humans needed to verify its functionality on people, need institutional review board approval and, if in regulated areas like the U.S., such a study would need an Investigational Device Exemption to allow for a non-FDA approved device to be used as part of a study. This is only a temporary approval and the full device would need actual FDA approval for legal deployment unless the laws are changed (or were temporarily suspended during a pandemic). These same regulatory roadblocks are in place in other nations, which has conventional ventilator manufacturers skeptical that even conventional manufacturers of other products (e.g. vacuum cleaner and automobile manufacturers are doing this now in the UK) could switch over to

produce ventilators¹³⁶. Clearly, this process is a problem during a pandemic. Both for the current situation and during potential future situations, there is a need to limit liability on the part of the designers, makers and users of such open source medical hardware¹³⁷. Substantial future work is needed in this area. Interestingly, this gives less-developed countries with a less-formalized regulation and litigation infrastructures a distinct advantage for protecting their citizens during a pandemic by deploying open source ventilators. Although it should be pointed out that personnel and training then become the limitations to deploying mass medical efforts, even if open source ventilators are available. So, future work is needed to create training materials and translate it into the languages spoken throughout the world as well.

Conclusions

There is clear technical potential for alleviating ventilator shortages during this and future pandemics using open source ventilator designs that can be rapidly fabricated using distributed manufacturing. The results of this review, however, found that the tested and peer-reviewed ventilator systems lacked complete documentation and that the current open systems that were documented were either at the very early stages of design or had undergone only early and rudimentary testing. With the considerably larger motivation of an ongoing pandemic, it is assumed these projects will garner greater attention and resources to make significant progress to reach a functional and easily replicated open source ventilator system. There is a large amount of technical future work needed to move open source ventilators up to the level considered adequate for scientific-grade equipment and further work still to reach medical-grade hardware. Future work is needed to achieve the potential of this approach not only on the technical side, but also by developing policies, updating regulations and securing funding mechanisms for the development and testing of open source ventilators for both the current COVID19 pandemic, as well as for future pandemics and for everyday use in low-resource settings.

Data availability

No data are associated with this article.

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This is a really good, thorough review of open source ventilators, including both a good technical background, a review of existing peer reviewed projects, and a summary of current efforts. I would thoroughly recommend it to anyone considering joining or using an open source ventilator project, as it's particularly good at pointing to some relevant literature that describes the requirements and principles of operation. The conclusion of the article is that we're not there yet - most of the published designs are not sufficiently complete to be easily replicated, while most of the current open projects are not rigorously tested.

The review of peer reviewed articles is interesting and does a good job of rating the different solutions in terms of openness; it is disappointing that these articles don't generally give sufficient information to reproduce the ventilator, but also unsurprising. This lends a great deal of weight to the current move towards more openness in science, where protocols, data, and schematics can be shared in data archives along with papers - but of course that's rarely done retrospectively.

The review of "internet and gray literature" seems objective and reasonable to me, and while such a review cannot possibly stay exhaustive given the frequency with which such projects are appearing, it does seem to cover many of the projects I've heard of. More important than an exhaustive list, however, is the discussion of the common issues to most of the DIY projects - the need for careful testing, quality control, and proper authorisation. Most discussions have focused only on technical validation - but as the author rightly points out, this is not the only way medical devices must be assessed. At least as pressing as the technical challenge is the difficulty of getting new suppliers and new devices through a quality assurance process that gives medical professionals the confidence that they can safely use said devices.

Openness is an important, and often surprisingly contentious, issue. Of the projects that are discussed, only relatively few make available complete designs for their solution. This is particularly surprising in the case of some projects from high-profile institutions that have already been widely reported in the media as "open" while not yet having released any designs. The commonly-accepted practice in open software is that complete designs, including source code and documentation, are made available to the public, and that a project is not considered open until this happens. Similar norms are being established for open

hardware projects, supported by organisations such as OSHA and GOSH.

Given the safety-critical nature of a ventilator, it's reasonable to be reluctant to release untested designs out of a desire to be responsible. Given the time-critical situation, sharing documentation and designs may also be considered lower priority than product development. However, the intent to share a design in the future misses the myriad benefits of open hardware - in terms of scrutiny, feedback, and improvements from the community. It also stifles the development of a community around the design, and there are many cases of promised openness never materialising. My own view is that projects ought not to claim openness until their designs are publicly available under an appropriate license, but there are definitely valid ethical and practical concerns here, and I would welcome an open debate on the best way forward.

The one statement in the article that I'm slightly troubled by is the suggestion that developing countries may be at an advantage due to their less robust regulatory systems. Firstly, while it is true that many countries in the Global South do have less formal economies, their regulations are often very tightly aligned with those in richer nations - for example, the Tanzanian medical device regulations closely mirror those used in the EU. If different standards are adhered to, it may be because the regulations are not implemented fully, rather than because the government has intentionally applied lower standards. Also, the better-resourced regulatory bodies in rich nations are more able to accelerate the process of approval if needed; it is not clear to me that a medical device would clear the bureaucratic hurdles and achieve approval any faster in a developing country, indeed the process can be much slower. It is also a very thorny ethical issue to trial medical interventions in the Global South that would not pass ethical scrutiny in richer nations, particularly as the interventions are often being proposed by people from said richer nations. I don't think the author is suggesting this, but I do feel it's a point worth highlighting. While there is often an argument made that low quality medical supplies may be better than nothing, it is also reasonable to expect that developers of technology shouldn't do anything to citizens of Low and Middle-Income Countries (LMICs) that they wouldn't do to patients in their own nation. Indeed, most ethical review panels in the UK apply exactly this criterion.

The challenge of creating a safety-critical medical device that can be produced in a distributed manner is significant, and I think the article reflects this. I could not agree more with the statement that "technical validation may not be enough" and would probably go further, to say that technical validation alone is not sufficient to ensure patient safety. While many open ventilator projects now exist and have gathered impressive numbers of volunteers, there remains a significant global challenge to enable such projects to be regulated appropriately, either in the current crisis or longer-term. The existing system of medical device regulation is slow, expensive, and conservative; while this conservatism has its roots in the entirely reasonable desire to prevent harm to patients, the way the system is implemented makes it extremely difficult to certify a medical device without the resources of a large company. Reform of these regulatory systems could enable a more agile approach to the design and manufacture of safety-critical components, but a satisfactory supply chain will also require significantly more quality management than is present in a typical "maker space" run by volunteers, hobbyists, or even experienced engineers. Questions around training and liability are also of paramount importance; while litigation against volunteers acting in good faith seems unduly harsh, there must be accountability in the supply chain of medical devices. Otherwise, we push responsibility onto the clinical staff using uncertified equipment, which adds a crippling burden to front-line staff who are already working at the limit of their capacity.

Overall, I think it's right to keep an optimistic tone, while acknowledging the obvious difficulties associated with the current challenge. It's likely that, while there are many 3D printers available around the world, formal structures that do not yet exist will be needed to enable them to be fully employed to solve supply

issues in this and future crises. Whether or not it is possible to make use of community designed and built ventilators in the coming months, I look forward to a world where critical supplies can be designed and produced openly for the common good. If we take the opportunity to put LMICs on a more equitable footing with respect to richer nations, the future may be more inclusive, as well as more resilient.

Is the topic of the review discussed comprehensively in the context of the current literature?

Yes

Are all factual statements correct and adequately supported by citations?

Yes

Is the review written in accessible language?

Yes

Are the conclusions drawn appropriate in the context of the current research literature?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Automated microscopy and open source hardware

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Comments on this article

Version 1

Reader Comment 31 Mar 2020

Santhosh Kumar Rajamani, Banas medical college and research institute, India

Even the ventilation protocols used in Ventilators is a proprietary and patented. This leads to confusion and patient injuries notably under ventilation, pneumothorax. Even the ventilation strategy has to be Open sourced. Great idea and best of luck!

Competing Interests: None

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