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ORIGINAL ARTICLE

Open-source hardware to face COVID-19 pandemic: the need to do more and better

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Abstract

Purpose The usage of open-source hardware (OSH) designs has been put forward as a means to mitigate the shortage of core medical equipment, such as ventilators and of personal protection equipment (PPE) in medical facilities worldwide, resulting from the ever increasing number of individuals affect by COVID-19. This is due to the model allowing for the lowering of costs and widespread distribution of manufacturing. On the other hand, low adherence to its best practices and insufficient development may jeopardize OSH as a viable aid against the pandemic. In this work, we sought to clarify to what extent publicly available designs of ventilator and PPE are developed and abide by OSH standards as measure of the true openness of the solutions.

Methods We searched the Internet and the literature to compile a comprehensive list of ventilators and PPE, while assessing available documentation in order to objectively evaluate key development landmarks (e.g., testing and governmental clearance) and indicators of adherence by OSH standards, as described by the Open Source Hardware Association.

Results Only a few peer-reviewed articles have been found, while a good number of Internet entries of open ventilator and PPE designs were found. Available documentation varied a lot in quantity and quality. Overall, adherence to OSH best practices and level of development were only partially fulfilled.

Conclusions Although this suboptimal performance regarding openness of designs may limit the benefits of the model, data suggests that present open-source efforts are highly beneficial and that they will be able to completely fulfill their mission given more and better OSH is carried out.

Keywords Open source hardware · COVID-19 · Pandemic · Ventilator · Face shield · Mask

Introduction

By the time of the last review of this article, the number of individuals infected with COVID-19, a severe form of acute respiratory syndrome caused by the Sars-CoV-2 member of the coronavirus family of viruses (Gorbalenya et al. 2020), has reached almost one hundred million and casualties have closely approached two million (Dong et al. 2020). In Brazil alone, there are more than eight million cases with over two hundred thousand deaths. Overall, even though with a comparatively low level of lethality, COVID-19 is highly contagious and spreads rapidly (van Doremalen et al. 2020; Liu et al. 2020), at the same time that there are still no efficacious and safe drugs to treat its patients and that mass vaccination is still only in the horizon (Boulware et al. 2020; Guo et al. 2020; Lurie et al. 2020). The exponentially increasing number of afflicted individuals displaying severe symptoms of the disease during the multiple waves of infection represents a considerable challenge for medical services which have been facing an overload of demand for beds, professionals, and equipment (Yang et al. 2020). In fact, concerning shortage of supplies are being felt by hospitals and medical centers worldwide with severe consequences to not only the public health aspect but also regarding the stability of internal affairs and foreign policies as seen

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from international commercial conflicts over provisions of personal protection equipment (PPE) and ventilators (Tong 2020), for example. These justified concerns are the basis for the call for social isolation to "flatten the curve" of hospitalizations of infected individuals, extending the time needed to research treatments and an efficacious and safe vaccine (Dowd et al. 2020).

The SARS-CoV-2 is transmitted, among other means, by contaminated droplets and aerosol particles sprayed by infected individuals during speech, sneezing, and coughing (Leung et al. 2020). The infection causes a variety of symptoms ranging from mild discomfort and anosmia to severe acute respiratory syndrome, in which the patient is frequently unable to breathe without external aid (Huang et al. 2020). In face of this, shortage of medical supplies, particularly PPE, and intensive care core equipment such as ventilators, has been of major concern (Ranney et al. 2020). Shortage of the former can lead to a halt in medical services, even when medical-care personnel is available, given that unprotected professionals may fall victim of the disease (Roberge 2016) or at least refuse to work due to consequently increased unsanitary conditions of the workplace and mental overload (Xing et al. 2020). By its turn and in the same line, shortage of ventilators may render beds and professionals incapable of providing proper treatment to those patients that are seriously affected with respiratory dysfunction.

While the adoption of open science in general—for instance by the lifting of pay-walls of scientific papers related to COVID-19 and fast publication of preprints to accelerate the dissemination of knowledge—is undoubtedly highly beneficial in terms of fostering the response of science to the pandemic in the search for a treatment, a possible work around the issue of PPE and ventilators shortage may be the widespread usage of open-source hardware alternatives (Pearce 2020a; Maia Chagas et al. 2020). According to the definitions by the Open Source Hardware Association (OSHWA), Open Source Hardware (OSH) are tangible technology products, the intellectual property of which (schematics, 3D designs, wiring, software, etc.) is available on the Internet free of any kind of restrictions for others to build, adapt, and use to all objectives intended including commercial usage (www.oshwa.org). OSH products must abide by several directives of best practices which include adequate systematization and organization of information and documents, usage of open development tools and file formats, and adequate licensing. More specifically, OSH best practices include, among others, recommendations that the design must: (1) have a clear description of its finality understandable even by unskilled readers; (2) be available in its full documentation, with its original files in formats that allow distribution and editing, preferentially by free open source software; (3) include any software and firmware necessary for operation; (4) include a detailed bill of materials (BOM); (5) be hosted publicly on the Internet in free-of-charge repositories; (6) have an associated forum for discussions on the design and for the tracking of its versions; (7) contain detailed instructions, with clear photos from different angles, on how to assemble, test, and use the hardware; and (8) to be licensed without restrictions of any kind and for all uses, including commercial. By abiding to these guidelines, the design may be eligible to receive an uniquely identified open-source hardware certification from OSHWA, which is the gold-standard corroboration of the openness of any particular design. Thus, inventors are allowed to include the OSH logo and the unique identifier number on their hardware. It is important to highlight though that such certification is not sufficient to certify that the design complies to technical and legal standards, as issued and verified by governmental agencies such as ANVISA and INMETRO in Brazil, or the FDA in the USA.

The benefits of adopting the OSH model for technological development and innovation, which can be easily extrapolated to a pandemic scenario, have been explored in several books and peer-reviewed publications (Gibb 2014; Pearce 2014; Cota et al. 2020). Very briefly, opening the source of technological products immediately attracts qualified peer review which, by providing informed feedback, voluntarily contributes to their improvement and excellence (Gibb 2014). In parallel, the availability of such open source technology online may considerably reduce the cost to fabricate and distribute it (Pearce 2020c), once third part producers do not have to afford the costs of organized for profit value chains of production, distributions, and sales (Pearce 2016). Finally, easy and free access to the intellectual property underlying technological solutions by third part makers and even by industries enables distribution of fabrication in a dynamical process of meeting production with demand (Pearce 2020b). Thus, the combat against COVID-19 may take advantage of OSH versions of widely needed medical equipment and supplies. On the other hand, OSH is, as it should be, open to disciplined skepticism and informed scrutiny, and it certainly bears its caveats and pitfalls. For instance, at what point an open do-it-yourself solution becomes transferable to the highly demanding medical service? As an example, one can easily find a solution for a face-shield (an item of PPE) built as easily as punching a couple of holes in the corners of a square sheet of acetate to be mounted in a pair of eye-glasses. Nevertheless, is this enough a solution? On the other hand, must PPE and deeply needed equipment, particularly of the OSH kind, go through all the time and resource-consuming process of obtaining medical-grade certification from governmental agencies in this period of medical emergency? In line with this questioning, how to learn the development level of a particular openly published solution, or how to curate the most well-developed ones stored in public repositories (e.g., GitHub, Instructables) with an overwhelming number of entries? To which point the OSH model is related to quality of designs and efficacy of solutions? And finally, especially important when considering OSH, how to evaluate the viability of manufacturing a solution developed by a third part, having only the Internet as a means to share the intellectual property? Or in other terms: how to maximize the efficiency and efficaciousness of the process of online transferring the technology from the inventor to makers? This is crucial to the maker community and industries when deciding on which design should receive their efforts.

In this work, we addressed these questions by reviewing the OSH literature and systematically assessing a sufficiently comprehensive set of PPE and ventilators solutions (many previously listed by other authors in the field and some novel ones we found ourselves) to better understand their development status and also to which extent they abide to best practices of open-source hardware as defined by OSHWA, which is considered a gold-standard for guidelines in the field. It is important to emphasize that these guidelines have been jointly proposed by the community of academics and enthusiasts under the organization of OSHWA, have been under discussion and construction along more than two decades of formal existence of the movement, and have been largely inspired by its successful and much more validated counterpart of open-source software. More specifically we systematized the aspects of (1) availability and quality of information; (2) type of licensing and certification from OSHWA; and (3) development level and legal clearance status. Results are discussed considering the literature of OSH related to the potential excellence of open designs, their economic advantages, and the directives and best practices defined in the field. The experience of our group in the making of OSH items (face shields and ventilators) to aid local medical efforts against COVID-19 and the many problems faced are brought forth to also contribute to such discussion. By doing this, we hope to have contributed with, at least, some rationalization on the usage of OSH solutions in current and future pandemics.

Methods

In order to have a sufficiently comprehensive and updated overview of the state-of-the-art regarding open-source hardware to face COVID-19 pandemic, we divided our efforts in two sequential steps: a thorough review of the literature and the Internet to create a list of solutions and an objective evaluation of entries regarding adherence to OSH best practices and their development status.

Collecting entries of open source hardware

To create a comprehensive list of open-source hardware, we first performed a structured search of related terms in the main publication bases and also on the Internet, considering that many solutions are not yet published. Although with varying syntax across platforms, search terms and their relation (search expression) were always:

(“coronavirus” OR “COVID-19”)

AND

(“open source hardware” OR “OSH” OR “ventilator” OR “respirator” OR “face shield” OR “personal protection equipment” OR “PPE” OR “3D printing”)

We searched the following publication bases: PubMed/Medline, Science Direct, IEEE Xplore, arXiv, medRxiv, bioRxiv, and F1000 Research. To search the Internet, we used Google search engine in advanced mode. This search has been performed initially during the second half of May 2020 and was revised by the end of October 2020. After being curated, the results of the search were then matched against the entries retrieved by both (Pearce 2020a) and (Maia Chagas et al. 2020) to form two expanded sets, one for ventilators and another one for PPE. We purposefully left out other biomedical equipment used in the care of patients with COVID-19, such as intensive care unit machinery, oximeters, finger plethysmographs, electrocardiographs, and others, given that they are of more general usage and that the inclusion of those entries would lengthen this text beyond necessity. Furthermore, a shortage of these equipment is not as concerning as that of PPE and ventilators in the context of the current pandemic.

Evaluation of entries regarding OSH adherence and development status

For each entry in the two sets of open-source hardware, we evaluated key aspects underlying its definition and related best practices. These factors have been more thoroughly described in the foundational work of the area from Gibb (2014) and Pearce (2014) and clearly stated in OSHWA publications and website. We also evaluated the development status of each entry. We thus divided these observations in three axes, the first two related to adherence to OSH best practices and the last one to development level:

I. Availability of online information: project link; downloadable production files; bill of materials (BOM); assembly instructions; testing guidelines; associated discussion forum; operation manuals; and related publication (preprint or peer-reviewed).
II. Licensing and certification: type of license; OSHWA certification.
III. Development status: first functional prototypes; laboratory testing; human testing; and legal medical/government clearance.

For increased objectiveness, the evaluation of these features was carried out by the two first authors of this study independently, and their results were later matched against each other.

Table 1 Assessment of adherence of publicly available ventilator designs to OSH best practices

Project name	Downloadable production files	BOM	Assembly instructions	Testing guidelines	Discussion forum	Operation manual	Scientific publication
Open Ventilator System Initiative	No	No	No	No	No	No	No
Reesistencia	Yes	Yes	Yes	No	Yes	Yes	No
Inspire-OpenLung	Yes	Yes	No	Yes	Yes	No	No
CITI-OpenLung	Yes	Yes	No	No	Yes	No	No
Electrónica Reespirator23-17	Yes	Yes	No	No	Yes	No	No
Open Vent	Yes	No	No	No	Yes	No	No
MUR	Yes	Yes	No	No	Yes	No	No
E-Vent (MIT)	Yes	Yes	No	Yes	Yes	Yes	No
The Pandemic Ventilator	Yes	Yes	Yes	No	Yes	No	No
Pandemic Ventilator 2.0	Yes	No	No	No	Yes	No	No
Proyecto PVPv1.2	Yes	No	No	No	Yes	No	No
Oxygen	Yes	Yes	No	Yes	Yes	No	No
Medtronic Ventilator	Yes	Yes	Yes	Yes	No	Yes	No
Vent4us	No	No	No	No	Yes	No	Yes
Mechanical Ventilator Milano	No	No	No	Yes	No	No	Yes
PAPR	Yes	Yes	Yes	Yes	Yes	Yes	No
Illinois Rapid Vent	Yes	Yes	Yes	Yes	No	Yes	No
Isinnova Easy Covid 19	Yes	Yes	Yes	No	No	Yes	No
VPE-19	Yes	Yes	Yes	No	Yes	No	No
Open Ventilator Spartan	Yes	Yes	Yes	Yes	Yes	Yes	No
e-AR (EAR)	Yes	Yes	Yes	No	Yes	No	No
Respira Works	Yes	Yes	Yes	Yes	Yes	No	No
Open-Source Ventilator Project	Yes	Yes	Yes	Yes	Yes	Yes	No
UCL-Ventura Breathing aid (CPAP)	Yes	Yes	Yes	Yes	No	Yes	No
FLUXTRONIC - Respirador Open Source	Yes	Yes	No	No	Yes	No	No
DQ3D Respiratory Support for CoViD-19	Yes	Yes	No	No	Yes	No	No
Crowdsourced Ventilator-Covid-19	Yes	Yes	No	No	Yes	No	No
The Ventilator Rex (V-Rex)	Yes	Yes	No	No	Yes	No	No
COVID19 Respirador	Yes	Yes	No	No	Yes	No	No
Project Inspiration Emergency Mechanical Ventilator	Yes	Yes	Yes	Yes	Yes	Yes	No
CSSALTlab	Yes	Yes	Yes	Yes	Yes	Yes	No
OP-Vent	Yes	Yes	Yes	Yes	No	No	No

Information on these designs is organized in myriad different ways and has many different levels of elaboration. These factors led to some discrepancies between evaluations (even though small: about 5% of all features of all entries) which were then resolved by a consensus round of evaluation with the participation of the third and senior author of this study.

Results

The search for publications in the repositories returned almost no entries, but the reviews mentioned in the introduction and other few papers (Li et al. 2020; Kroo et al. 2020; Galbiati et al. 2020; Molina et al. 2020). On the other hand, none of the references described as vetted designs by Pearce (2020a) were found in this search. In fact, while reviewing them, it became clear that those studies, although representing valid contributions to the state-of-the-art regarding ventilators for pandemics and low-cost versions, are not directly related to open source designs per se, and their documentation was limited to the peer-review article itself, with virtually no online information. For this reason, these solutions did not make into the present list of ventilators.

The search on the Internet resulted in an unmanageable number of results, probably given the importance of the terms

Table 2 Assessment of publicly available ventilator designs regarding licensing and OSWHA certification status

Project name	License type	OSHWA certification
Open Ventilator System Initiative	CERN-OHL-S V2.0	No
Reesistencia	GNU-GPL 3.0	No
Inspire-OpenLung	CERN-OHL-S V2.0	No
CITI-OpenLung	N/A	No
Electrónica Reespirator23-17	MIT Licence	No
Open Vent	Permissive License	No
MUR	GNU GPL 3.0	No
E-Vent (MIT)	MIT Licence	No
The Pandemic Ventilator	CC BY-NC-SA 3.0	No
Pandemic Ventilator 2.0	N/A	No
Proyecto PVPv1.2	N/A	No
Oxygen	CC BY-SA 3.0	No
Medtronic Ventilator	Permissive License	No
Vent4us	N/A	No
Mechanical Ventilator Milano	CERN-OHL-S V2.0	No
PAPR	MIT Licence	No
Illinois Rapid Vent	Permissive License	No
Isinnova Easy Covid 19	CC BY 4.0	No
VPE-19	N/A	No
Open Ventilator Spartan	GNU-GPL 3.0	No
e-AR (EAR)	CERN-OHL-S V2.0	No
Respira Works	Apache 2.0	No
Open-Source Ventilator Project	CERN-OHL-S V2.0	No
UCL-Ventura Breathing aid (CPAP)	Permissive License	No
FLUXTRONIC - Respirador Open Source	GNU GPL 3.0	No
DQ3D Respiratory Support for CoViD-19	CC BY-NC 4.0	No
Crowdsourced Ventilator-Covid-19	MIT License	No
The Ventilator Rex (V-Rex)	MIT License	No
COVID19 Respirador	CERN-OHL-S V2.0	No
Project Inspiration Emergency Mechanical Ventilator	CC0 1.0	No
CSSALTlab	GNU GPL 3.0	No
OP-Vent	Custom Licence	No

"COVID-19" and "coronavirus" these days, and also because "OSH" is an acronym also for "Occupational Safety and Health", which closely relates to the pandemic. In any case, we were able to notice that many results were related to OSH versions of ventilators and 3D-printable face-shields and masks, but also to a variety of software dedicated to scientific research and medical aid in the context of the pandemic. This led us to tables similar to those previously published (Maia Chagas et al. 2020; Pearce 2020a). On the other hand, some entries for ventilators were excluded from these original lists, once, to the best of our knowledge, they did not represent projects of OSH alternatives, but other forms of contributions to the issue. Some of them were actually projects for the lowering of costs of already available commercial solutions, or initiatives that have compiled many solutions as a starting point for their design, but without a solution of their own, at least by the time of the publication of this work. Furthermore, a few other entries of ventilators found in this search have been added. After the mentioned inclusions and exclusions, a final list for ventilators was compiled in Tables 1, 2, and 3, and for PPE in Tables 4, 5, and 6. The three tables for each type of entry contain, sequentially, the results of our evaluation regarding the aspects I to III described previously: (I) availability of information, (II) licensing and OSWHA certification; and (III) development status and legal clearance.

In the axis of availability of information, most ventilators adhere to essential criteria regarding the readily availability of downloadable production files (90.6%), bill of materials (BOM; 81.3%), and an associated discussion forum (78.1%). On the other hand, less than half of entries have clear

Table 3 Assessment of publicly available ventilator designs regarding development status and governmental clearance

Project name	First functional prototypes	Laboratory testing	Human testing	Legal medical certification
Open Ventilator System Initiative	Yes	Yes	No	No
Reesistencia	Yes	Yes	No	No
Inspire-OpenLung	Yes	Yes	Yes	Yes
CITI-OpenLung	Yes	Yes	No	No
Electrónica Reespirator23-17	No	No	No	No
Open Vent	Yes	No	No	No
MUR	Yes	Yes	No	No
E-Vent (MIT)	Yes	Yes	No	No
The Pandemic Ventilator	Yes	No	No	No
Pandemic Ventilator 2.0	No	No	No	No
Proyecto PVPv1.2	No	No	No	No
Oxygen	Yes	Yes	Yes	Yes
Medtronic Ventilator	Yes	Yes	Yes	Yes
Vent4us	Yes	Yes	No	No
Mechanical Ventilator Milano	Yes	Yes	Yes	Yes
PAPR	Yes	Yes	Yes	No
Illinois Rapid Vent	Yes	Yes	No	No
Isinnova Easy Covid 19	Yes	Yes	Yes	No
VPE-19	No	No	No	No
Open Ventilator Spartan	Yes	Yes	No	No
e-AR (EAR)	No	No	No	No
Respira Works	Yes	Yes	No	No
Open-Source Ventilator Project	Yes	Yes	Yes	No
UCL-Ventura Breathing aid (CPAP)	Yes	Yes	Yes	Yes
FLUXTRONIC - Respirador Open Source	Yes	Yes	No	No
DQ3D Respiratory Support for CoViD-19	Yes	Yes	No	No
Crowdsourced Ventilator-Covid-19	Yes	Yes	No	No
The Ventilator Rex (V-Rex)	Yes	Yes	No	No
COVID19 Respirador	No	No	No	No
Project Inspiration Emergency Mechanical Ventilator	Yes	Yes	No	No
CSSALTlab	Yes	Yes	No	No
OP-Vent	Yes	Yes	No	No

assembly instructions (46.9%), testing guidelines (43.7%), and an operation manual (34.4%). Only a few have a related publication (6.3%). In the second axis of adherence, most entries have some kind of licensing (87.5%), even though they vary a lot among MIT, CERN, GNU, CC, and permissive licenses, with a small prevalence of the first three (Fig. 1a). Regarding development status, although the great majority of solutions have functional prototypes (81.3%), which have been appropriately tested in laboratory to some extent (75%), only a few have been tested in humans (25%) and even a smaller number have been cleared by governmental regulatory agencies (15.6%), even considering emergency-kind conditional authorizations.

The figures on the PPE list are similar. Regarding the availability of information, all entries (100%) of the list have readily identifiable and downloadable production files, bill of materials, assembly instructions, and operation manuals. Most of them (70%) have an associated discussion forum, but less than half (40%) have testing guidelines and only a couple (10%) have been published. Regarding licensing, the majority is licensed (90%) with high prevalence of CC variants (Fig. 1b). On the other hand, and again, not a single one has been certified by OSHWA. Regarding development, all have functional prototypes, but less than half (40%) have been systematically tested in laboratory, only a few have been tested in humans (20%), and none has clearance from governmental agencies.

Documentations were found to be written mostly in English, but also in Spanish and French. They were deposited in different online repositories, including GitHub, GitLab,

Table 4 Assessment of adherence of publicly available PPE designs to OSH best practices

Project name	Downloadable production files	BOM	Assembly instructions	Testing guidelines	Discussion forum	Operation manual	Scientific publication
1 - Surgical-type masks							
COVID-19 MASK v2 3D Printable	Yes	Yes	Yes	No	Yes	Yes	No
Stopgap Surgical Face Mask (SFM)	Yes	Yes	Yes	Yes	Yes	Yes	No
Montana Mask	Yes	Yes	Yes	Yes	Yes	Yes	No
EDAGmask4all	Yes	Yes	Yes	No	No	Yes	No
Maker Masks	Yes	Yes	Yes	No	No	Yes	No
Protection mask covid-19 ffp2	Yes	Yes	Yes	No	Yes	Yes	No
MDA33 Safety mask plan b	Yes	Yes	Yes	No	Yes	Yes	No
VMO mask v2 basic filter	Yes	Yes	Yes	Yes	Yes	Yes	No
Ally Face Mask	Yes	Yes	Yes	No	No	Yes	No
COVR3D customisable masks	Yes	Yes	Yes	No	Yes	Yes	No
2 - N95-type masks							
The Pneumask Project	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Project 1000 x 1000	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nanohack: the open source face mask	Yes	Yes	Yes	Yes	No	Yes	No
The KC Mask: 3D Printed N95 Stopgap Substitute	Yes	Yes	Yes	No	Yes	Yes	No
3 - Face protectors							
Origami Droplet Face-Shield	Yes	Yes	Yes	Yes	Yes	Yes	No
Proto-shield	Yes	Yes	Yes	No	Yes	Yes	No
GliaX face protector	Yes	Yes	Yes	No	Yes	Yes	No
Prusa face protector	Yes	Yes	Yes	Yes	Yes	Yes	No
Georgia Tech face shields	Yes	Yes	Yes	No	No	Yes	No
U. Wisconsin-Madison face shield	Yes	Yes	Yes	No	No	Yes	No

Instructables, and proprietary websites, with a prevalence of the first one.

It is important to state that the set of designs in the lists may not be fully complete and that the real level of adherence of entries in the list to OSH standards and the level of their development may differ to some degree from what has been stated here. The reason for this is because we have compiled the information from what is available from the (very sparse) literature and from the projects' websites. Thus, if online information is not updated with the latest developments, so do not our present results. Moreover, time has passed since the preparation of this text and technologies alongside their documentation may have possibly evolved.

Discussion

Assuming that the present list of OSH solutions for PPE and ventilators is a sufficiently comprehensive one, results clearly show that there is great variance regarding the aspects of adherence to open-source best practices and also of development level, both across technologies and also across specific criteria. For instance, regarding openness, while virtually all entries in both ventilators and PPE lists have readily downloadable production files from their websites, none whatsoever has a certification from OSWHA. Similarly, development level varied a lot: while a few ventilators have been cleared by government agencies, others do not even have presented a functional prototype. There was also variation regarding the repository and language. Finally, variation could be clearly seen in the level of elaboration of documents. For instance, while some assembly instructions consisted of mere exploded views, other projects contained detailed step-by-step explanations including photographs and even videos. In the same vein, some ventilators have been extensively tested and calibrated in very controlled laboratorial conditions, while others have been simply put into motion. If all criteria listed in the tables are considered to have equivalent importance to the aspects of OSH adherence and development status, one can conclude that efforts on these designs are half the way there: mean percentages for Tables 1 plus 2 (adherence to OSH standards), and 3 (development status) are 52.1% and 49.2% for ventilators, respectively; mean percentages for Tables 4 plus 5 and 6 are 67.8% and 40% for PPE, respectively.

Table 5 Assessment of publicly available PPE designs regarding licensing and OSWHA certification status

Project name	License type	OSHWA certification
1 - Surgical-type masks		
COVID-19 MASK v2 3D Printable	CC BY-NC-SA 4.0	No
Stopgap Surgical Face Mask (SFM)	CC-BY 3.0	No
Montana Mask	GNU-GPL 3.0	No
EDAGmask4all	N/A	No
Maker Masks	CC BY 4.0	No
Protection mask covid-19 ffp2	CC BY-NC 3.0	No
MDA33 Safety mask plan b	CC BY-NC-SA 3.0	No
VMO mask v2 basic filter	CC BY-NC-SA 3.0	No
Ally Face Mask	CC BY-SA 4.0	No
COVR3D customisable masks	CC BY-NC-SA 4.0	No
2 - N95-type masks		
The Pneumask Project	CC-BY-NC-SA 4.0	No
Project 1000 x 1000	CC BY-NC-SA 4.0	No
Nanohack: the open source face mask	CC BY-NC 4.0	No
The KC Mask: 3D Printed N95 Stopgap Substitute	CC-BY 2.0	No
3 - Face protectors		
Origami Droplet Face-Shield	CC BY-SA 4.0	No
Proto-shield	CC BY-SA 4.0	No
GliaX face protector	GNU-GPL 3.0	No
Prusa face protector	CC BY-NC 4.0	No
Georgia Tech face shields	N/A	No
U. Wisconsin-Madison face shield	Custom Licence	No

These observations can be paired with the one showing that technologies listed in the tables better abide by criteria representing early steps in making a solution open source (e.g., upload of production files) in contrast to late ones (e.g., OSHWA certification). Under this perspective, it can be found that, while it is considerably easy to find OSH alternatives to PPE and ventilators online, manufacturing and making them properly work may represent a more significant challenge. This line of reasoning can be analogously applied to the results regarding development status, leading to the understanding that functional and open access technology may exist in good numbers, but only a few may be qualified as scientific or medical-grade apparatus. These considerations corroborate those of previous studies. In his review of ventilators for COVID-19, Pearce (2020a) concluded that available systems lacked complete documentation and are still poorly tested and in their early stages of design. Following work from the same author brought forth a complementary conclusion that among the equipment needed to face COVID-19 pandemic, as requested by the Government of India, although most have open-source designs available, only 15% of them fully adhere to the OSH format, which includes usage of open tools and components. This led the author to propose five associated core lines of research for investigation capable of mitigating present and future health crises (Pearce 2020b).

The present depiction of the OSH alternative to fight the COVID-19 scenario may be mistaken as a harsh critic of the model and maybe even a reason for abandoning it. The authors of the present study, in agreement with previously mentioned experts, believe in quite the opposite idea. Even though few designs abide more completely by OSH best practices and, at the same time, are well developed to the point of owning official medical clearance, these exceptions may be of immense value, bearing the potential to turn the table around on the shortage issue. Some good examples of this are the fabrication of the recently made-open Medtronic's ventilator design (https://www.medtronic.com/us-en/e/open-files.html) by a Brazilian medical equipment producer (https://www.saevo.com.br/ventilador-pulmonar-br1/) and the starting of fabrication of the INSPIRE-OpenLung design from the University of São Paulo (USP), authorized by ANVISA. Furthermore, the other less-developed solutions with obscure documentation are possibly on the track to become medical-grade equipment as their authors can better organize and share their intellectual property, given that they receive the appropriate support. In this particular, it is symptomatic that the best performing solutions in our study are those from large and well-established research teams. Finally, some OSH designs, even if developed at a suboptimal level, can more quickly be transferred to the medical service, if

Table 6 Assessment of publicly available PPE designs regarding development status and governmental clearance

Project Name	First functional prototypes	Laboratory testing	Human testing	Legal medical certification
1 - Surgical-type masks				
COVID-19 MASK v2 3D Printable	Yes	No	No	No
Stopgap Surgical Face Mask (SFM)	Yes	Yes	Yes	No
Montana Mask	Yes	Yes	Yes	No
EDAGmask4all	Yes	No	No	No
Maker Masks	Yes	Yes	No	No
Protection mask Covid-19 ffp2	Yes	No	No	No
MDA33 Safety mask plan b	Yes	No	No	No
VMO mask v2 basic filter	Yes	No	No	No
Ally Face Mask	Yes	No	No	No
COVR3D customisable masks	Yes	No	No	No
2 - N95-type masks				
The Pneumask Project	Yes	Yes	Yes	No
Project 1000 x 1000	Yes	Yes	No	No
Nanohack: the open source face mask	Yes	Yes	No	No
The KC Mask: 3D Printed N95 Stopgap Substitute	Yes	No	No	No
3 - Face protectors				
Origami Droplet Face-Shield	Yes	Yes	No	No
Proto-shield	Yes	No	No	No
GliaX face protector	Yes	No	No	No
Prusa face protector	Yes	Yes	Yes	No
Georgia Tech face shields	Yes	No	No	No
U. Wisconsin-Madison face shield	Yes	No	No	No

the application is less demanding in terms of performance and safety, such as the case with some PPE.

In line with previous suggestions, we also understand that the strategy to work around the limitations of the OSH paradigm is to do it more and better. Particularly, while some inventors and ingenious scientists may see the process of obtaining a certification from OSHWA as mere paperwork and/or a vanity corroboration of their research, we take it as an avenue for excellence, which is the fastest track to legal authorization, widespread dissemination, and even to profitable business (Cota et al. 2020; Ferreira 2008; Pearce 2017). By abiding to the OSH best practices, authors maximize integrity, visibility, and high-fidelity reproductions of their solutions. By their turn, these factors attract well-informed feedback that induces improvement, even greater visibility and dissemination, in a closed virtuous circle that culminates in

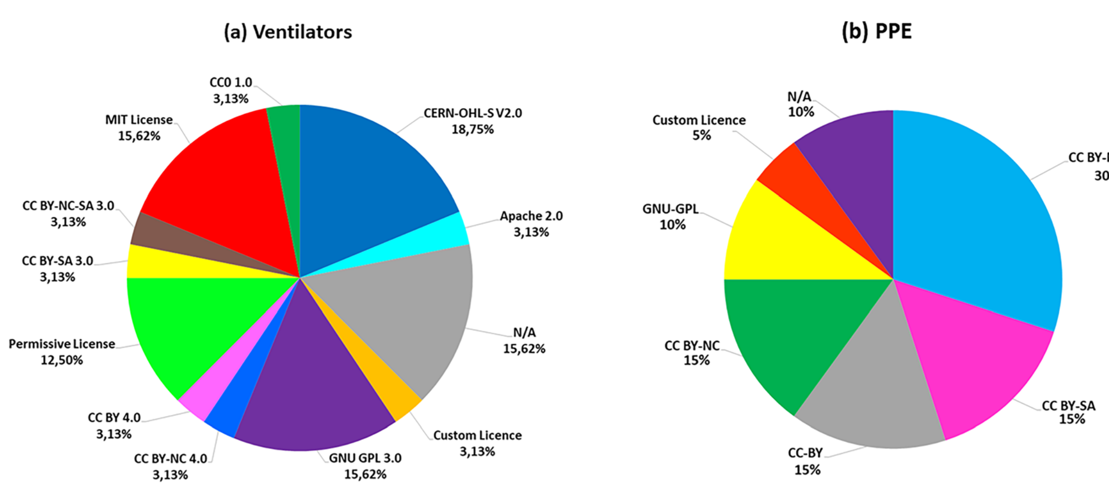

Fig. 1 Distribution of license types used for ventilators (**a**) and PPE (**b**)

(a) (b) (c)

Fig. 2 OSH designs produced by the COVID-19 NÃO São João Del-Rei group of makers: 3D-printed supports for face shields and printer (**a**), complete face shield assembled with acetate foil being worn (**b**), first and only unit of an open-source hardware ventilator manufactured by the group (**c**)—photos: Box Lab Escola Criativa, with permission

excellence (Gibb 2014). Although such seal of adherence to OSH standards is not a warrant of quality and efficacy of any given technology, it is certainly an excellent starting point, once it means handing the intellectual product to widespread scrutiny and review. Additionally, for the interested third part, the certification is an important indicator that his/her efforts to reproduce the hardware have greater potential of success and, thus, it is a major factor to attract audience to contribute to the virtuous circle previously described. Finally, the case for OSWHA certification, in particular, is made here only because it is, to the extent of our knowledge, the only open association that is fully committed to investigate the OSH model and to propose an objective system to evaluate documentation and grant a peer-reviewed validation. Furthermore, it is arguably the most mature technical/scientific association in the world that deals with the topic of OSH. It has been active for almost a decade, it is open to external membership, and it has a rotation of board members and leaders, which are chosen among associates. Additionally, it gathers researchers that are productive in the many unfolding fields of science related to open source hardware.

To further illustrate the importance of fully abiding by the best practices, we proceed to briefly explore a real case of local third part manufacturing of OSH solutions to face the COVID-19 pandemic. Right after the classification of the disease as epidemic by the World Health Organization on January, 30th, a group of scholars, students, makers, and local entrepreneurs from the city of São João Del-Rei, in the country-side of the State of Minas Gerais, Brazil, organized themselves to start production of face shields to be handed as donations to medical services in the region, anticipating the probable shortage of PPE. After deciding for the Prusa face-protector design with small adaptations for improved productivity, a successful crowdsourcing campaign raised funds for the production of three-hundred 3D-printed face shields (Fig. 2a and Fig. 2b) and almost two-thousand acetate foil-only alternatives. As hobbyists and enthusiasts only, the group faced a multitude of difficulties in this initiative, including a steep learning curve of logistics supporting purchase and delivery of consumables, planning of product manufacturing and distribution, "client" management, and other daily challenges of the industry environment. Although the endeavor was quite successful, the group faced major obstacles, jeopardizing a more significant contribution, related mostly to concerns regarding access to information, legal aspects, and design performance. For instance, production of face shields could be considerably larger if commercial usage were granted by the license, once it would not be limited to the amount covered by funds raised. Unfortunately, this is not in the case of the Prusa model, which has a license CC-BY-NC 4.0. In fact, the NC part of the CC license forbids reproduction of licensed material for commercial proposes. For this reason, best practices clearly state that OSH licenses must not do so and a process of certification would certainly have pointed that out. In the same vein, the group seriously considered starting manufacturing OSH versions of ventilators and even assembled a first functional unit (Fig. 2c). However, concerns regarding legal and medical aspects, and also regarding viability of acquiring the needed consumables were major factors for abandoning the idea. Again, better adherence to OSH best practices and certification would be helpful in fostering the initiative.

Conclusion

In this work, by reviewing the literature and the Internet for a list of open-source versions of ventilators and PPE and after objectively assessing their documentation, we were able to observe that publicly available designs only partially abide by the best practices of OSH and are in their early stages of development, on average. Although this is certainly a setback in its proposition as an aid to fight the COVID-19 pandemic, it is our understanding that present contributions are already of great value. Moreover, we firmly believe that more and better OSH practice is what it takes to explore this disruptive model of innovation and technological development to its full potential. Finally, we agree with previous literature that dissemination of the open source philosophy is key to make the community grow by joining people to the ongoing projects. By its turn, this will foster fast and robust development of most needed technological solutions for present and future pandemics.

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Authors' contribution All authors contributed to the study conception and design. Maikon Lorran Santos performed repository and Internet searches, compiled the lists, prepared Tables 1, 2, 3, 4, 5, and 6, and prepared figures. Maikon Lorran Santos and Leonardo Rakauskas Zacharias read online documentation to perform independent evaluation of all criteria listed in Tables 1, 2, 3, 4, 5, and 6. Vinícius Rosa Cota was the supervisor for this study, participated in the consensus round regarding criteria assessment, and wrote the manuscript. All authors read and approved the final manuscript.

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Compliance with ethical standards

The present work has not been submitted for publication, in whole or in part, elsewhere, and all the authors listed have approved the manuscript that is enclosed. We have read and abided by the ethics principles from the Committee on Publication Ethics (COPE) for journal publication.

Conflict of interest The authors declare that they have no conflict of interest.

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