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OPEN.EFFECT
EFFECTIVENESS OF OPEN-SOURCE HARDWARE IN TIMES OF A PANDEMIC

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IN COOPERATION WITH

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EFFECTIVENESS OF OPEN-SOURCE HARDWARE IN TIMES OF A PANDEMIC

OPEN.Effect

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Contents

1 Introduction and aims

The highly contagious SARS-CoV-2 pandemic spread across multiple countries all around the world. The disease attacks the breathing system, which led to an increased demand for medical grade ventilators. Due to the sudden rise in demand, the supply chain was unable to catch up and lives were in danger. Therefore, individuals, communities, companies and research institutions started to design and develop ventilators, which could be manufactured through local and commonly available resources. This led to a surge in open-source hardware (OSH) projects. However, details about the current status, achievements and challenges of these projects were not clear. This is where the project OPEN.Effect was started to analyze and find out more about the effectiveness of OSH projects.

The main aims of the project were to:

- evaluate the performance and effectiveness of the open source projects developing complex medical ventilators,
- identify the practices that fit the projects and gaps that need solutions when working with open communities and medical equipment and
- derive recommendations for future research and support to the open-source project communities.

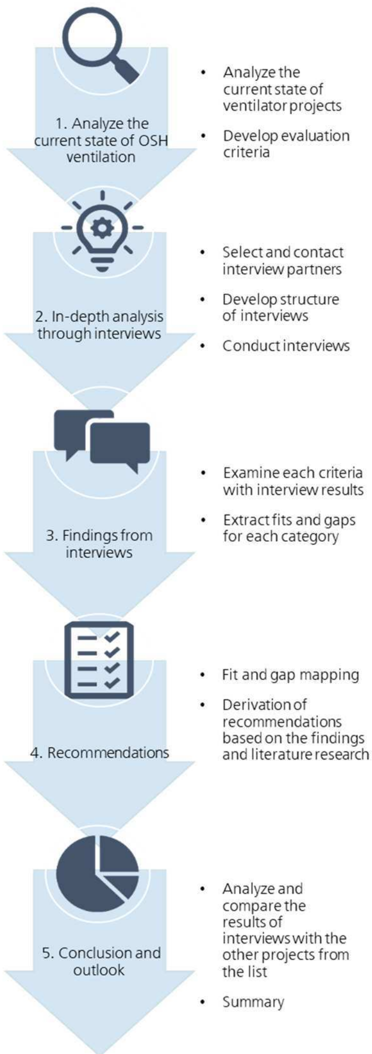
This report summarizes the results of the project. In the following sections, the approach followed in the project is detailed. Each step of the approach is explained and the findings are detailed.

2 Approach

Considering the aims a five-step approach was followed in the project (Figure 1).

1. **Analysis of the current state of OSH ventilation**: This step deals with finding and analyzing open-source ventilator projects and their current state. To analyze the projects, evaluation criteria were developed.
2. **In-depth analysis through interviews**: To analyze the projects further a few projects were requested to participate in interviews. The interviews were structured using the evaluation criteria, in order to find fit-gaps experienced by them.
3. **Findings from interviews**: From the interviews, findings about the best practices and challenges are summarized. The best practices or the fits are the processes/methods/activities which enabled them to obtain desired results. Challenges are the gaps they encountered to achieve the desired results.
4. **Recommendations**: The fits and gaps are mapped with possible recommendations for future projects. The recommendations aim at providing guidelines for future open-source hardware projects to achieve desired state.
5. **Conclusion and outlook:** Based on the analysis of projects conclusions are derived and an outlook into the future is discussed.

Figure 1: Approach



3 Analysis of the current state of OSH ventilation

A quick look into the open source community in times of the current pandemic shows a broad variety of projects that are developing and manufacturing ventilators. For the study, it was important to find them and understand what the current status actually was. During the finding process the evaluation list developed by a non-profit organization called Public Invention (PI) was discovered. The list is called the COVID19-vent-list (CVL) [PUB20a]. It is an extensive list of 137 OSH ventilator projects and they were evaluated across seven categories namely: openness, buildability, community support, functional testing, reliability testing, COVID-19 suitability and clinician friendly. It is an active list; hence the total number of projects may vary with time. In an effort to avoid duplication and enable enhancement of the existing list, a collaboration was initiated. The collaboration with the PI team was aimed at updating the existing project progress across the existing categories, developing new categories to measure effectiveness, and to contact project participants for interviews.

To update the existing projects, the projects were individually analyzed. This was done by going through their websites, repositories and related articles online. The next step was to develop new categories for evaluation. The categories had to enable the identification of:

- state of maturity,
- capability and effectiveness, and
- challenges faced across the lifecycle of the project

Based on research and using the existing categories of CVL, 13 final categories were derived [STE06] [PEN05]. These are shown in Figure 2. Each of these categories was defined with a 5-level scale. Each level was defined and elaborated to form the complete evaluation criteria. Each of these criteria are briefly described in section 5.2 where the interview findings are discussed. The scales vary from 0 to 5 or from 1 to 5.

Figure 2: Interview categories

A rating of one indicates the first level of the respective category. For some criteria however, it was necessary to include a rating of zero as there were projects in a very early phase or relevant information was missing. Hence, they could not be rated on par with the rating of one. A rating of five corresponds to achievement of the highest level of maturity for that criterion. The categories are defined below:

- **Openness** examines the degree to which a project is open source. It also examines the license strategy and level of openness of documentation.
- **Buildability** examines the degree to which recreating of the project is possible through the project documentation. This can be supported through different methods or approaches.
- **Community support** examines the community support received by the project. This can be in terms of contributions, registrations and downloads.
- **Functional testing** is an important step to verify the functionality of the ventilator. Some of the important tests are to test pressure/volume limits and oxygen mixing. In this category, the extent to which the functional tests have been carried out is evaluated.
- **Reliability testing** examines the reliability and durability of the ventilator which should be examined in order to determine the consistency of a test across longer periods of time.
- **COVID-19 suitability** category looks into the degree to which the product is suitable to the requirements of usage for COVID-19 treatment (such as defined by the RMVS – Rapidly Manufactured Ventilator System [MED20]).
- **Clinician friendly** examines the degree to which the ventilator is suitable for use in clinics/ professional areas. In addition, the consideration of a user-friendly design and execution is examined.
- **EMC testing** is a requirement for electronic devices to receive national approvals. This category examines the consideration and progress of Electromagnetic compatibility of the ventilators.
- **National agency/EU approvals** are based on regulations which play a major role in the medical device market. They also vary depending on the country. In this category the approval status of the projects is examined.
- **Usage in field** determines if the devices developed by the projects have been successfully deployed in hospitals, or on patients for use.
- **Financing** for manufacturing is an important category. General financing of the projects themselves are examined. In addition, the business models of the projects are also questioned here.
- **Manufacturability** examines the readiness for manufacturing, by determining the completeness of documentation and ability to mass manufacture.
- **Units produced** questions about the number of manufactured units of end product.

4 In-depth analysis through interviews

As mentioned in the Introduction, for a deeper analysis of the current state of ventilator projects, interviews were chosen as the suitable method. Interview is qualitative research method and occurs with direct communication with an interview partner. This method was chosen because of its effectiveness and suitability to receive the specific answer to the open-ended questions. The interviews took place through web conferences. The interviews were supported with a presentation to show the structure and questions to the participants. In the following sub-sections, the selection of interview participants, the general structure of the interview and the questions are detailed.

4.1 Selection of interview participants

The selection of projects was based on the initial ratings on the CVL. The aim was to investigate a broad mix of projects with high, medium and low rating across the categories. This represented completed projects as well as ongoing projects. A group of 20 projects were finalized and requested for an opportunity to interview them. Fourteen projects responded with interest to participate. First the averages of criteria are compared to get a comprehensive insight about how the taken sample to interview represents the other projects.

At the time the projects were selected, the CVL consisted of 113 projects. A project in this investigation is seen as unresponsive, if the community support criterion value of a project lies under rating of three. That is unresponsive projects, or those without any point of contact are seen as inactive for this research´s purposes. These projects are referred to as "inactive" or "unresponsive" projects, which amount to a number of 53 projects in the CVL.

As already mentioned, criteria scale from one till five while others rate from zero to five. A zero rating means that the criterion does not (yet) apply to the project or there is no corresponding information available in the project's documentation. Hence, a zero rating is removed from the average calculation. This applies to criteria functional testing, reliability testing, COVID-19 suitability, clinician friendly and national approvals. For certain comparison of criteria this has to be kept in mind.

The criteria for all the projects were reviewed and rated before the interviews. All criteria except, manufacturability, units produced and financing are considered for average rating in the CVL. The purpose of the CVL was to share knowledge between teams and to rate and compare designs versus companies which manufacture these. For a more comprehensive comparison of the results from the interviews on the other hand the criteria manufacturability is also considered here for practical reasons. This should be kept in mind, since this criterion looks obscure in comparison to the CVL for obvious reasons.

The diagram (Figure 3) compares the averages of the criteria from the CVL and the interviews at the time the projects were selected. The overall average of all projects (average of all ratings) in the CVL is of value 1.7 (out of 5), while the sample taken to interview has an overall average of 2.53. Excluding unresponsive projects, the overall rating of the CVL rises to 2.03 (Indicated by the growth in category averages in Figure 3 after eliminating unresponsive projects).

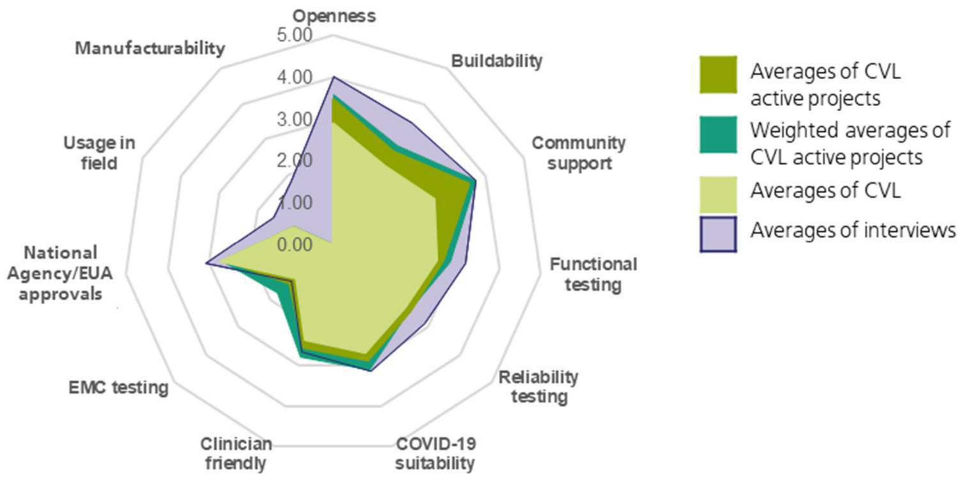


Figure 3: Comparison of overall averages

In addition, the ratio of the averages of the projects are considered and compared. The population and the ratio of rated projects are displayed in the following table (with active and all projects for CVL). If averages of CVL projects are weighted with the same ratio as the sample, criteria averages rise (Figure 3). Similar comparisons at a later point of time during the project can be seen in the annexure (A1). High rating projects have an overall average rating of four and higher. Low rated projects are of overall average below three.

Table 1: Ratio of rated projects

	Interview sample	COVID19-vent list	
		all	active
High rating	0%	0,9%	1,7%
Middle rating	21%	2,6%	5%
Low rating	79%	96,5%	93,3%

Relatively well rated projects were selected for the interview sample, although there is no high rated project in it (This is because at this time there was only one project with high average rating, and were not able to participate in the interview). This selection was made against the background that best practices were expected here in particular and also, to capture the challenges they faced. Also, projects of a certain maturity were selected in order to be able to cover as many criteria as possible, which in turn increases the average compared to projects in earlier stages. This is especially the case for buildability, as this criterion explicitly indicates the maturity of the project (a project that can be rebuilt has undergone iterations and hence of certain maturity). In addition, it was also important to understand if the projects were successful in handling the highly regulated market of medical devices.

4.2 Structure of the interview

The interviews were structured into three mains to cover three parts. The parts are demography, evaluation of project and conclusion (see Figure 4). The demography questions aim at receiving general answers about the interview participant/s and the project. The next part, aimed at going through the evaluation criteria and discussing about the project in parallel. In addition, the best practices and challenges faced for the criteria were also captured. In the last part, the discussion was summarized and future plans were discussed.

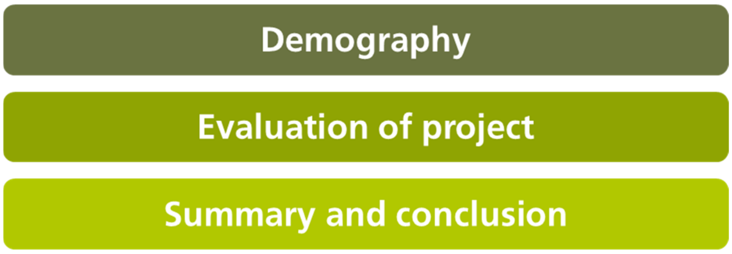


Figure 4: Structure of the interview

5 Findings from interviews

Interviews with 14 selected projects were conducted. Twenty-seven interview participants with diverse fields of expertise took part in the interviews. The duration of an interview was 90 minutes and consisted of 24 questions. In addition, the participants were free to discuss further questions. This section summarizes the results of the interviews for each of the three parts as mentioned in sub-section 4.2.

5.1 Findings from demographic questions

The questions in this section were aimed at understanding:

- the organization or the community the interview participants are working in,
- the interview participants and their role in the project,
- the ventilator in general,
- current phase the project finds itself in,
- the target group of the project and
- how the changing knowledge of the virus impacted the project

Out of these questions, a summary of the statistics is provided in the next few sub-sections.

5.1.1 Expertise of interview participants

The diagram below shows agglomeration of the 27 interview participants depending on their role in the project. The majority of the participants worked in the fields of engineering and project management. In addition, in the interview partners were familiar with hard-/software design and development, systems and requirements engineering which showed a broad demographic diversity of actors in project activities. This gives a comprehensive overview with answers illuminated from many sides. Although specialized in one field, project members also often took interdisciplinary tasks too.

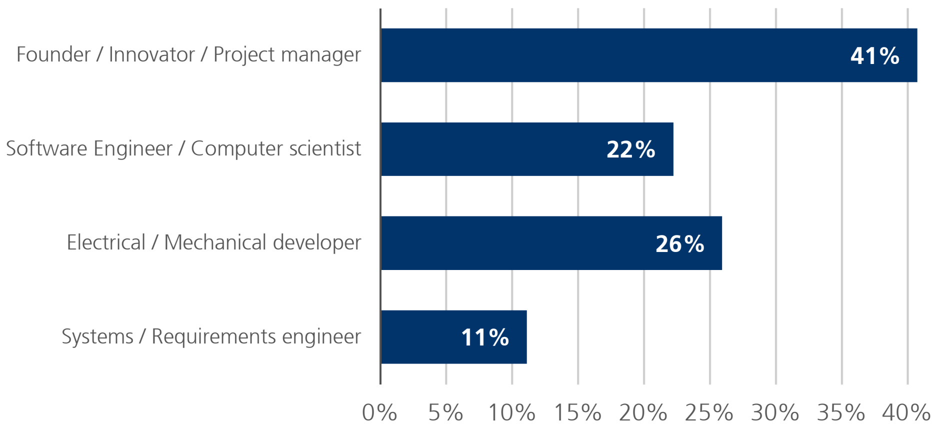
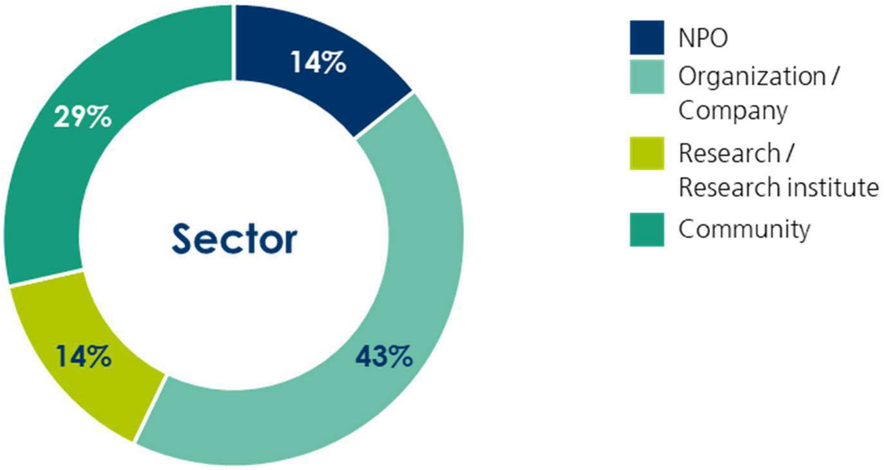


Figure 5: Expertise of interview participants

5.1.2 Sector of organization

The distribution of the interview participants across various sectors is represented in Figure 6. The majority of the projects at 43% belonged to an organization (or company). One of them works in a limited liability company, as it would have taken a long time to establish itself as an NPO and would have delayed the project. Another one, although more likely to take on the characteristics of a community, is owned by company and is therefore counted as such. The second largest sector with 29% was communities in terms of people specialized and interested in the scope of the project, but on private initiative. With 14% percent each was represented by participants who are a part of Non-profit organizations (NPO) or a part of research field, either as research institute or working in the purpose of research.

Figure 6: Sector of projects

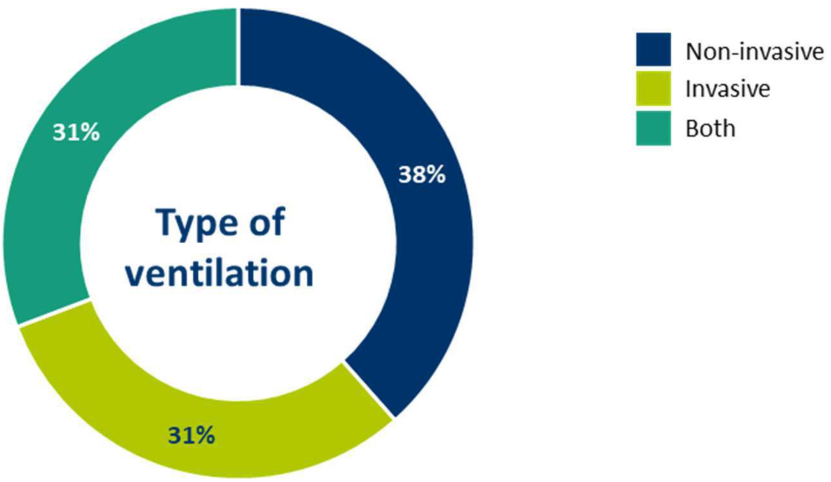


5.1.3 About the projects

This section is dedicated to the general questions about the ventilator project by examining the type of ventilation, the support of spontaneous breathing mode and their target group. Also, the current phase the project find itself in.

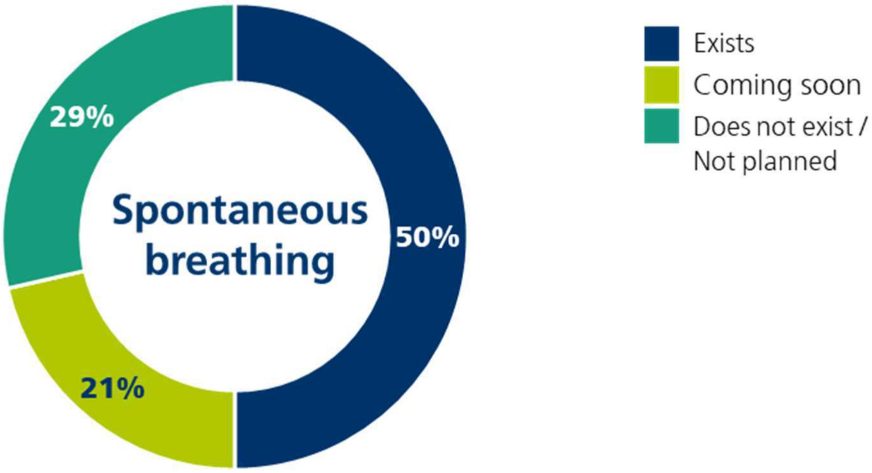
Type of ventilation can be categorized into invasive and non-invasive [BRO03]. Invasive ventilation is when the patient is supported through a tube which is inserted into the airways. Non-invasive ventilation is when the patient is supported through a facial mask without an invasive procedure [HOO20]. Out of the investigated projects, five (38%) solutions support non-invasive ventilation, four (31%) only invasive ventilation and four (31%) support both modes. The distribution of type of ventilator across projects is shown in Figure 7.

Figure 7: Type of ventilation



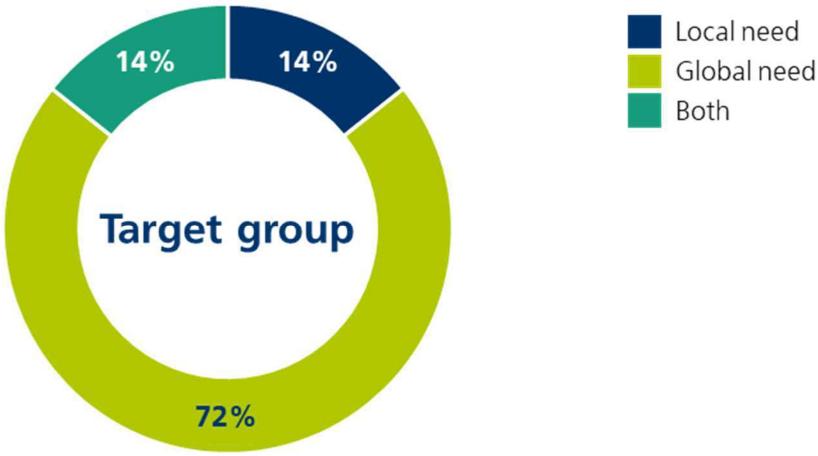
An important feature of medical ventilation devices for COVID-19, articulated in June based on medical learnings was support for spontaneous breathing mode. This mode supports patients who have the ability to breath on their own and the ventilator has to recognize and adjust to the patient's breathing cycles [NIC20]. Seven (50%) of the interviewed projects support this mode while three (21%) of them have plans to integrate the mode and the other four (29%) have no plans to integrate or support spontaneous breathing mode.

Figure 8: Spontaneous breathing



Most of the projects with a total of 72% are targeting at fulfilling global ventilation needs, 14% were more focused on fulfilling local needs. The remaining 14% started with a focus on local needs and expanded their focus towards a global target group.

Figure 9: Target group



The next question was regarding the current phase of the project. This was briefly categorized into design, prototype, test, approval and manufacture phases. These phases are also represented in Figure 10. Although represented linearly the process is highly iterative. From the interviews 7% of the projects are in the design phase, which represents that they are in the initial phases of designing the ventilator. The next phase, prototype represents projects which are developing prototypes based on their designs. 43% of the interviewed projects are in this phase. The iterative arrows between design and prototype represent the iterative nature between the two phases. Testing is the following phase where the prototypes are tested and 28% of the projects have completed this phase, resulting in final prototypes. The next stage for these projects is to apply and receive national approvals. 7% of the interview projects are going through this process. 14% of the projects have received approvals and are in the manufacturing phase to produce multiple ventilators.

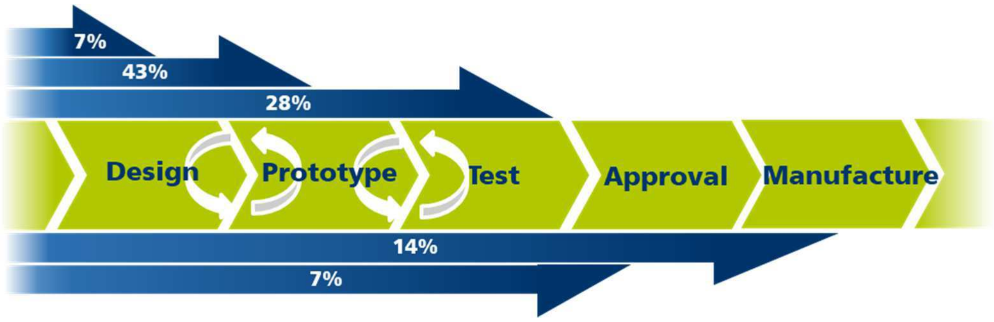


Figure 10: Current state of projects

Impact of evolving knowledge about disease during pandemic time is of special interest because it indicates the need for flexibility due to changing requirements. It was throughout estimated as high except for one. This one project is focusing on developing a buildable basic device in the first place due to scarcity of resources and medical unsophistication in this region. Reasons and examples on how changing knowledge of the disease impacted the development are shown in Figure 11.

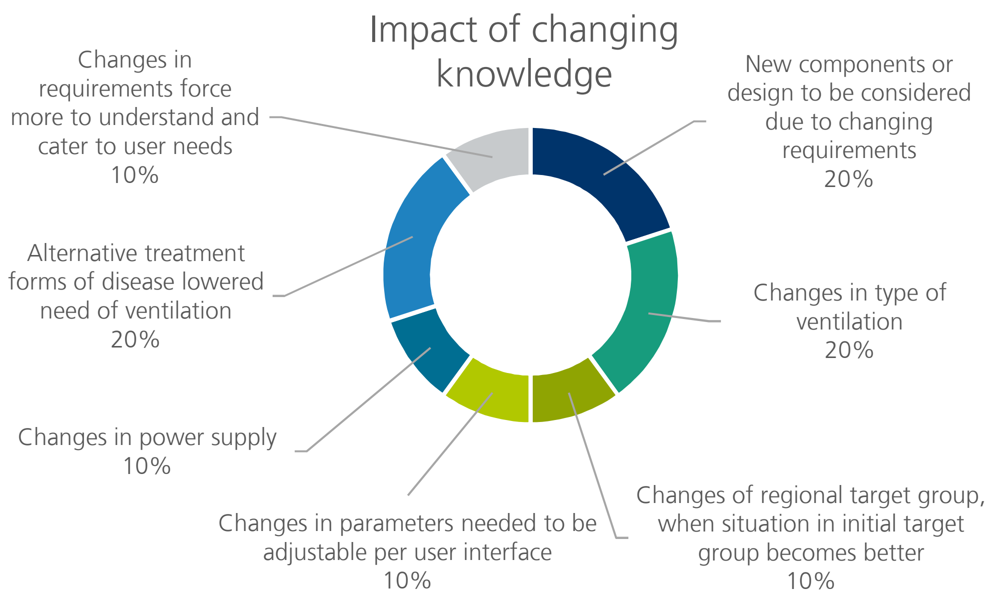


Figure 11: Impact of knowledge

5.2 Findings from evaluation criteria

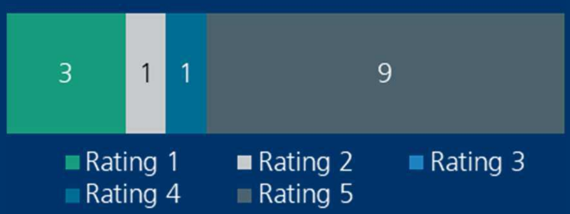
In this sub-section, the findings about the projects for each of the evaluation criteria are summarized. Each category has a dedicated page, on left hand side the evaluation criteria is mentioned with the descriptions for the 5-scale rating. Below the ratings the respective interview statistics are depicted for these scales. On the right side, for each criteria the challenges and the best practices from the interviews are also summarized. Sometimes the interview participants themselves indicated solutions they wished for, which are considered for the final recommendations in section 6.

Openness

Open-source hardware practices

Rating descriptions and interview statistics

1. Not open
2. Declared to be open, but no plan to publish
3. Existing repository with at least initial plans
4. Clear license strategy and regular updates to plans
5. Fully open, everything documented, responsive community and clear license



Challenges

Figure 12: Challenges in openness

In the category openness, the most mentioned challenge was community management, followed by getting accustomed to OSH platforms and liability issues of open-source medical projects.

Best practices

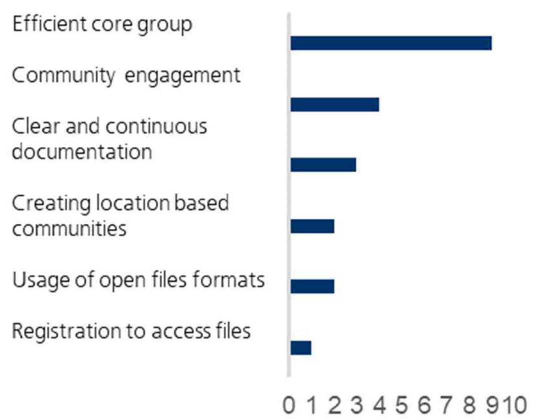


Figure 13: Best practices in openness

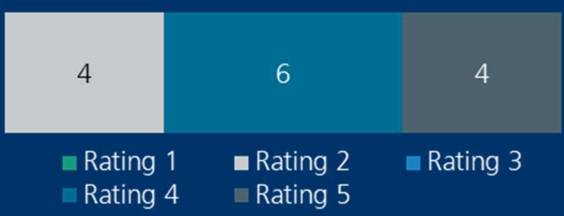
The commonly followed best practice is to establish an efficient core group. This mostly consisted of a diverse team usually located in the same geographical region.

Buildability

Ability to reproduce

Rating descriptions and interview statistics

1. Unbuildable due to lack of open documentation
2. Documents available but they require guesswork
3. All software and hardware transparent and documented. Some manufacturing instructions, such as a build video
4. Complete documentation suggesting reproducibility
5. Has been successfully reproduced by another team purely from documentation



Challenges

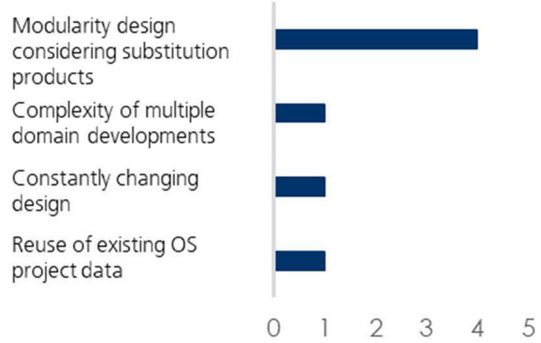


Figure 14: Challenges in buildability

Considering buildability of a project, the main issue is to design for modularity. The parts and resources available can vary depending on geographical locations. Most interview partners also mentioned that they do not share any design until it is complete to prevent unclear information in community and to result a faster process.

Best practices

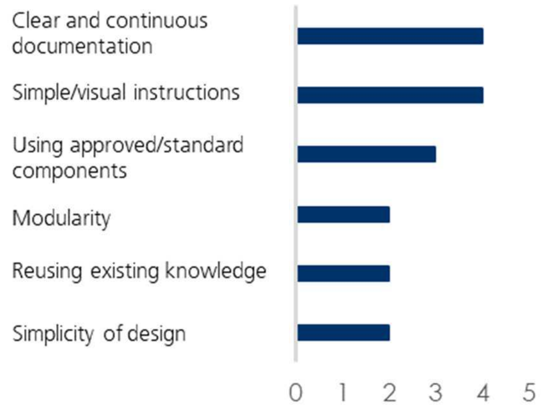


Figure 15: Best practices in buildability

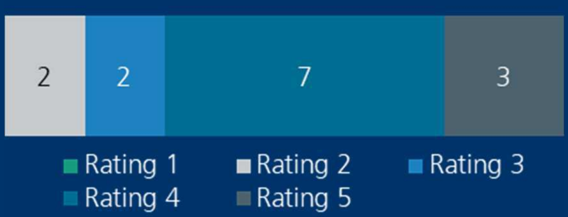
As mentioned in challenges, modularity and using standard components can play a huge role in buildability. Providing simple instructions can enhance the projects buildability regardless of the knowledge of the person who rebuilds it.

Community support

Level of community interactions

Rating descriptions and interview statistics

1. Inactive: no point of contact
2. Point of contact, but unresponsive
3. Responsive leader or manager, more than one volunteer
4. Active community, weekly activity and reports, existing git-repository or other shared documents
5. Large, active and open community



Challenges

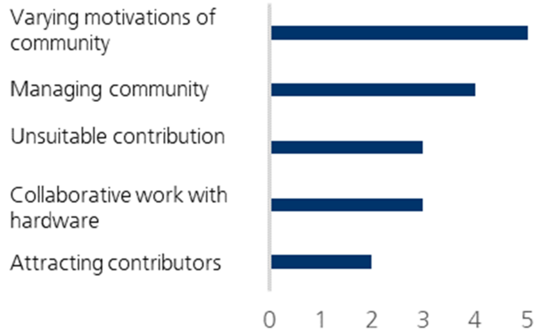


Figure 16: Challenges in community support

In the category community support the main challenge mentioned was varying motivation of community. The interest in the contributing community shifts with time leading to smaller and inactive communities. Hence, managing a community to receive effective support is a challenge.

Best practices

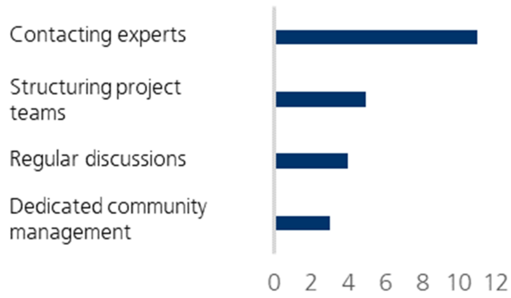


Figure 17: Best practices in community support

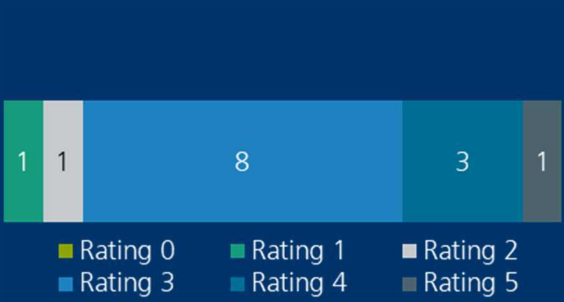
Having a diverse community with relevant subject experts was a major advantage. Also dividing the community into structured teams with defined task led to a better contribution level from community, whereby regular meetings formed a cornerstone for this. Also, a dedicated communications management underlies this aspect.

Functional testing

Testing various functionalities

Rating descriptions and interview statistics

0. In design phase, not listed or tested
1. Tested with a bag
2. Tested with a test lung
3. Tested for pressure and volume limits, with breath rate control
4. Tested for alarms, multiple modes, O_2 mixing
5. All test green (if asserted as a feature)



Challenges

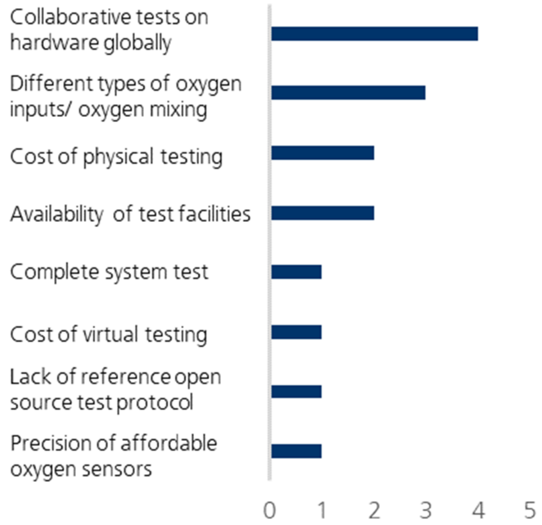


Figure 18: Challenges in functional testing

In functional testing, the aspect of collaboratively testing of hardware projects globally is a major challenge. The cost and availability of testing also play a major role as challenges. There is also a lack of comparable testing protocols for open-source hardware applications. For ventilator projects, technical issues concerning oxygen mixing and handling different types of inputs were highlighted as challenges.
Next to the financial issues, another common challenge while performing tests in general is the risk of private forking. This resulted in private testing practices which were not openly disclosed. Some projects stopped before reaching testing phase because of the reducing need.

Best practices

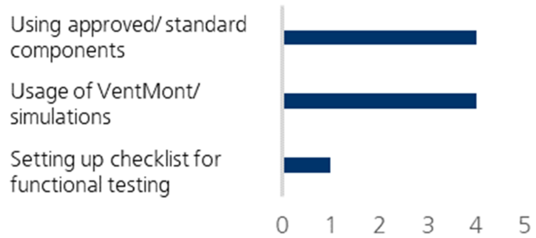


Figure 19: Best practices in functional testing

To enable initial in-house testing, devices such as VentMon [PUB20b] were used. VentMon is a device which helps to test open-source ventilator designs virtually. In addition, use of already established and/or tested standard components has been indicated as a successful practice.

Reliability testing

Testing the reliability and durability

Rating descriptions and interview statistics

0. Not listed
1. Operates for one hour
2. Operates for 12 hours
3. Operates for 12 hours passing all functional test s acceptably (low exception rate)
4. Independent team operates for 48 hours passing all functional tests, data logs reviewed
5. Mean time between data failure starting to become meaningful

Challenges

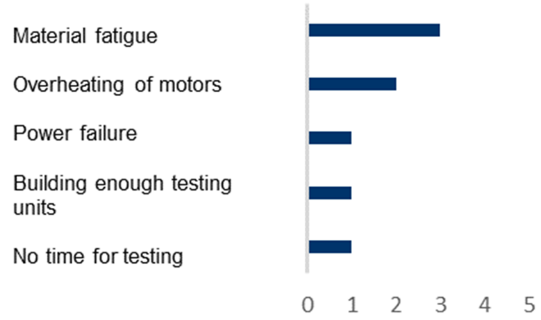


Figure 20: Challenges in reliability testing

During reliability testing just a few problems with respect to material fatigue of the Ambu bag and overheating of motors were reported. Endurance tests, the overheating and performance degradation of the components was noted as a challenge.

Best practices

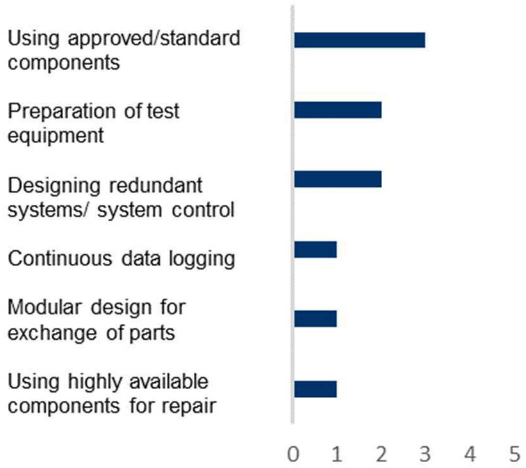


Figure 21: Best practices in reliability testing

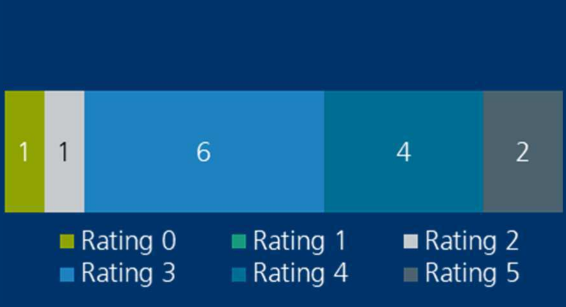
To guarantee durability, the use of approved and tested components was often mentioned. In addition, designing redundant systems (for critical functions) and modular systems was seen as an advantage for reliability. The systematic preparation of test equipment and continuous data logging during testing were also best practices when testing.

COVID-19 suitability

Suitability of the device to be used during the pandemic

Rating descriptions and interview statistics

0. In design phase or not listed
1. Operates with supplemental oxygen
2. Pressure or volume control or both
3. Positive end-expiratory pressure (PEEP)
4. Sophisticated alarm capability and sanitizability of all patient contact points
5. Meets British RMVS standards or any similar national standards



Challenges

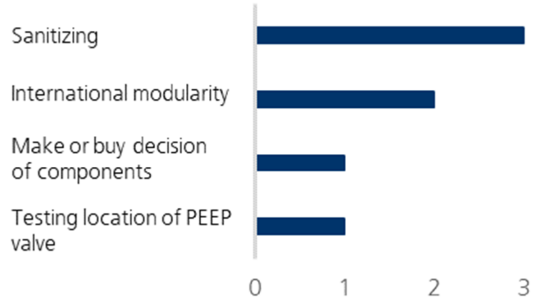


Figure 22: Challenges in COVID-19 suitability

The challenges in this category were limited to specific project issues. However, it is important to note that it is a challenge to develop products which are so modular that they can be adapted across the globe. For example, replacing certain non-available parts with another.

Best practices

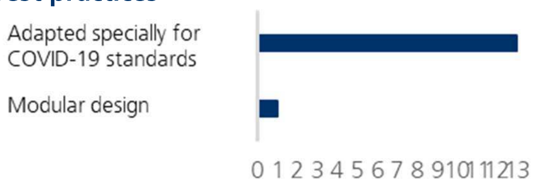


Figure 23: Best practices in COVID-19 suitability

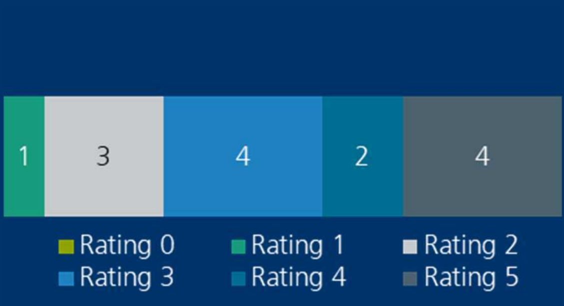
The challenges here were limited due to the widely available standards and requirements for COVID-19 suitable medical devices. Hence, the projects considered these national standard and emergency approval requirements from the very beginning of the projects. However, as mentioned before the growing knowledge on COVID-19, does make the development volatile.

Clinician Friendly

User-friendliness of device for clinicians or professionals

Rating descriptions and interview statistics

0. Unknown controls
1. No controls
2. Breath rate and volume control, standard ports
3. Breath rate, volume and pressure control easy to set, standard ports, clear external labelling graphically and in the language of choice
4. Alarms easy to set and understand; wholesale replication of an existing UI or conformance to a TBD UI standard
5. Data logging, informative, easy control, battery backup. No training needed in normal operation



Challenges

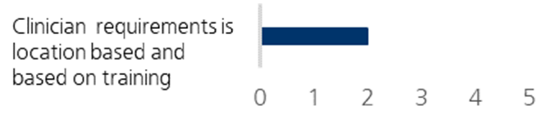


Figure 24: Challenges in clinician friendly

The challenge here was to consider and work with clinican requirenments across the globle. The fact that the parameters to be displayed on the user interface (e.g. volume vs. pressure) was dependent on the doctors training and on the location the devices were used in.

Best practices

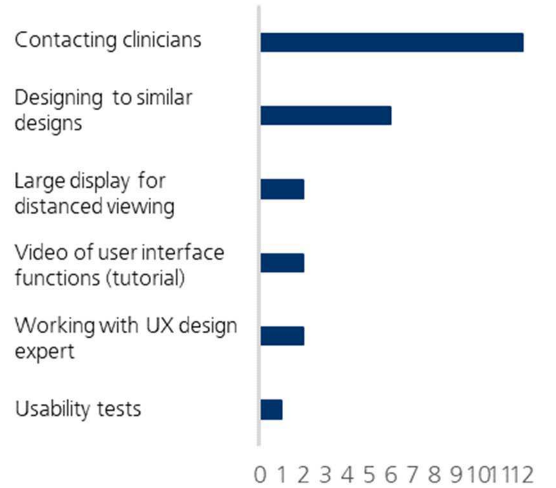


Figure 25: Best practices in clinician friendly

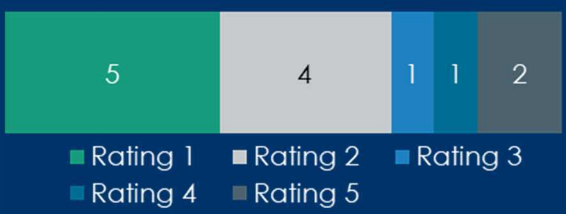
Working closely in contact with end-users, here the clinicians was clearly the best practice. Including UX (user experience) experts and conducting usability study also helped in designing better for the end-user. Using similar designs which already exist as reference was also a common practice. Improving the ease of use by using large displays and providing video tutorials were also mentioned.

EMC testing

Electro-magnetic compatibility testing

Rating descriptions and interview statistics

1. In design phase, not listed, tested, or addressed
2. EMC requirements have been considered for functional design
3. Risk assessment for EMC is conducted
4. EMC testing is being conducted
5. EMC testing passed and certification obtained



As seen in the interview statistics on the left side, the one missing project partner stated no need of EMC testing since the developed device has no electronic parts. Therefore, this project will not be considered for this category. Some projects used already EMC tested components, due to which some of them are not considering execution of a complete system EMC test at all. Whereas, some of them are planning to consider it in the near future. One project aims for CE certification in which EMC testing is a part, but this will just take place at the end of the project. Another project was handed over to a manufacturer and hence the further development difficult to observe. Altogether, the results are mainly at the lower end of the evaluation scale. Independently of project decisions on EMC testing, many participants also indicated missing experience in this area which seems to be the greatest challenge here.

Challenges

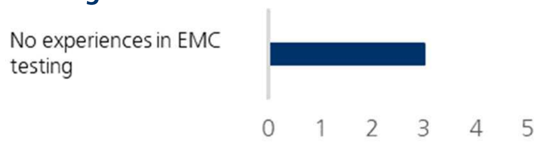


Figure 26: Challenges in EMC testing

Best practices

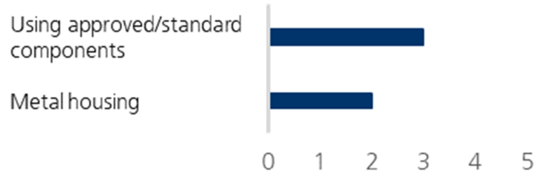


Figure 27: Best practices in EMC testing

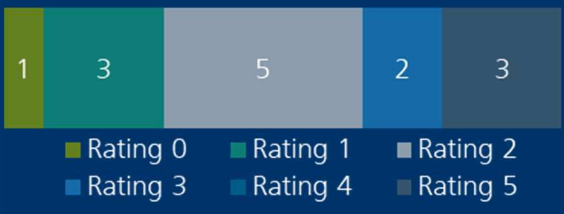
Best practices for EMC testing was to use already EMC tested and approved components. Usage of metal housing was also mentioned as an advantage.

National approval agency/ EU approvals

Status of national approvals

Rating descriptions and interview statistics

0. Not listed, tested or addressed
1. Not seeking approval
2. Not yet applied for approval
3. Applied for approval
4. Denied first round of approvals
5. Approval passed and certification obtained



Challenges

Figure 28: Challenges in national approval agency

National approval processes are challenging as they are financially intensive and time consuming. In addition, dealing with national agencies during the crisis was not easy. Further, even if an openly sourced product receives approval, it is unclear how the liability is taken care of.
Another mentioned point was unclear business models, since the future of projects is not very clear, some communities do not want to manufacture and sell the ventilators themselves. Hence, approvals are not yet considered or do not come to question at all.

Best practices

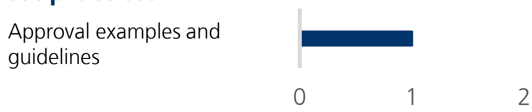


Figure 29: Best practices in national approval agency

A project team stated that referring to approval examples and guidelines from other projects helped them in this category.

Out of the three projects rated with a five, two of them received national approvals. One team applied and received approval by themselves, another teams design received approval through a private company which further worked on the design. One other project works in a location which does not need approvals and can be immediately used on the patients due to the dire situation there.

Usage in field

Use of device in professional area or in field

Rating descriptions and interview statistics

1. Not deployed
2. Sold or sent for use in hospital
3. Feedback provided by the doctor or physician with improvement suggestions
4. Feedback provided by the doctor or physician with only positive comments
5. Used on a patient or patients successfully

Challenges

Challenges here could not be mentioned due to two aspects. On the one hand, many projects are not in a stage to allow any field usage on patients. In addition, all the projects mentioned that their devices are recommended for use only during emergency situations. The ratings provide insights about how many projects were able to receive feedback based on testing of devices or during in field usage. On the other hand, it is unknown if anyone in the open source community has reused a design, manufactured and used the device. Albeit a couple of them have possibilities to count number of downloads of the project, they do not have any indicators if the project really has been built or even further, receive feedback on quality or effectiveness.

Best practices

Figure 30: Best practices in usage in field

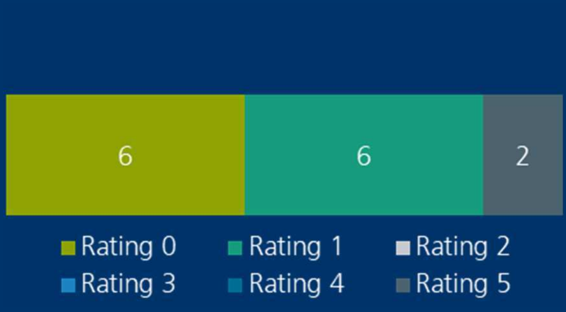
Best practices for projects to be used in the field are to have continuous contact with experts using the product throughout its lifecycle. So that the product is made according to their needs and works as desired.

Financing

Raising finance for the project

Rating descriptions and interview statistics

0. Not listed, addressed or research-only device
1. Blocked by need for investment
2. Financing secured for 100 units
3. Financing secured for 1000 units
4. Financing secured for 10,000 units
5. Sufficient investment secured



Challenges

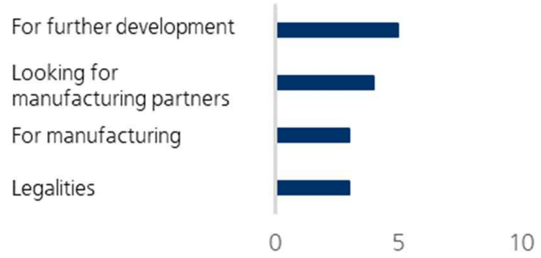


Figure 31: Challenges in financing

Financing/private forking raised questions about the balanced distribution of intellectual property rights in the project. Although finding financing partners for open-source projects is the greater challenge in the first place. Many of them are looking for manufacturing partners to collaborate with to manufacture large quantities.

Best practices

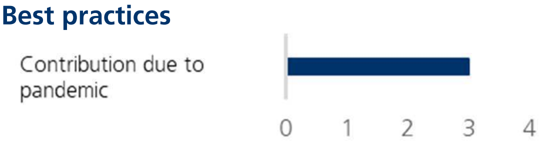


Figure 32: Best practices in financing

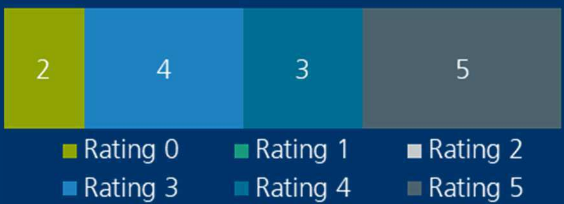
Due to the topicality and urgency of COVID-19, the motivation to contribute in such projects is currently very high. Some projects did receive funding to carry out the development of ventilators.

Manufacturability

Ability to manufacture in large quantities

Rating descriptions and interview statistics

0. Insufficient plans to duplicate a single unit
1. Bill of Materials (BOM) clear
2. 2D parts, 3D parts, code, all clearly documented
3. Electrical schematics and air circuit schematics clear. PCBs if any present and documented. Wiring, if required, fully documented
4. Basic instructions and special instructions present. Documented in language of choice, preferable more than one. Basic description of "smoke tests" and simple quality assurance present
5. Either evidence of BOM availability in units of 1000, or supply-chain flexibility of parts suggesting same. Detailed quality assurance plans present



Challenges

Figure 33: Challenges in manufacturability

Difficulties in manufacturability are the availability of certain medically approved parts. Also, the project participants have troubles considering pricing or supply chain development and management at larger scale.

Best practices

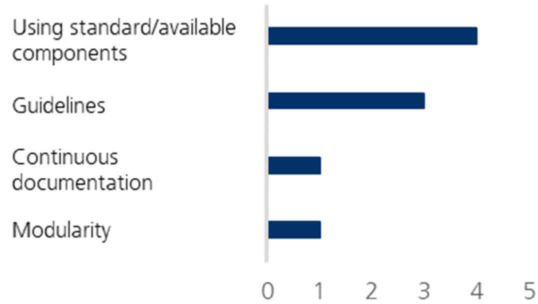


Figure 34: Best practices in manufacturability

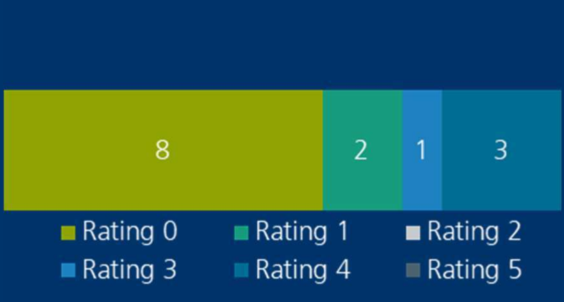
Manufacturability of large quantities can be well assured by using standard and widely available components. Also following guidelines, continuous documentation and designing for modularity were mentioned to be advantageous.

Units produced

Number of units manufactured

Rating descriptions and interview statistics

0. Not listed, addressed or prototype stage
1. Manufacturing planning in progress
2. Manufacturing facility is setup
3. Manufacturing is in progress
4. More than 25 pieces manufactured
5. More than 500 pieces manufactured



Challenges

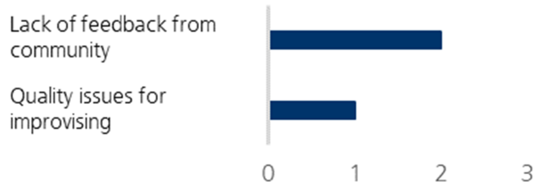


Figure 35: Challenges in units produced

As already mentioned, some projects have the possibility to count the number of downloads of a project, but receive little to no response about products manufactured by others across the world. However, some community members do contact and inform the main project owners about rebuilding such devices. Quality issues were also mentioned as a challenge because people tend to improvise when components or facilities are not available. In addition, not following the instructions fully or lack of certain instructions/tests also lead to quality issues. Most of the units produced by the projects were prototypes. Only a few managed to manufacture final prototypes in amount of 25 to 100 ventilators. Some projects are in talks with private companies to manufacture their designs.

6 Recommendations

In this section, each category is further discussed as to how the desired states in the future can be look like for each of them. In addition, recommendations are provided for each of them to achieve the best possible outcomes. As shown in Figure 36, in this report the current state and challenges faced (section 5) were analyzed and some best practices from the interviews were found. The gaps or challenges faced can be overcome with certain solutions. These are also discussed in this section.

Figure 36: Fit-gap approach followed [JUA04]

6.1 Openness

Open-source hardware is closely linked to the degree of openness of the project data. The ideal behind it is to document in an open manner, which enables collaborations across the world [OPE12].

To achieve high level of openness, some suggestions are:

- to choose the suitable license for the project,
- document continuously across the various lifecycle phases of the project and
- use templates or structured projects as reference [WIK20]

Some suggestions from the interviews involved including technical writers in the team to document and publish data in an open manner.

With respect to the hardware-specific issues (such as patent infringement or liability issues) regarding open-source medical projects suitable licenses such as CERN can be used to protect the inventor/designers. In addition, providing disclaimers which indicate the prototypical or emergency use nature of the project can help with the issues.

6.2 Buildability

In this category the aim is to have a complete (software and hardware) and transparent documentation of the project. As this forms the basis for the project to be successfully reproduced by another team anywhere on the globe.

As the availability of resources varies across the globe, and during the pandemic the supply chain is highly strained, the buildability is affected. Also, the needed equipment for reproducing can vary in the community.

To tackle these challenges designing for modularity is a solution [KAM02]. In the pandemic, the challenge of restricted supply chain was well known to many teams, hence this was considered from the beginning of the project as a requirement. The projects were developed to integrate standard components and interfaces. In addition, commonly available machines/tools and 3D printing machines were considered to manufacture parts in large quantities and with higher speeds. A suggestion from one of the interview participant was to conduct a fit-gap analysis on what components or machines are available in their target regions, so that the products can be developed to include this flexibility in design.

6.3 Community support

The advantage of working in an open manner is to involve and work with a large, active and open community. However, managing such a community can often be a challenge. Some recommendations to manage community are:

- providing the contributors with contribution guides [JÉR17],
- having clear communication channels to separate the types and topics of discussion and
- contacting and involving experts for certain collaborative work.

In the projects interviewed, involving medical experts and the end users from the beginning helped streamline the development of the ventilators.

6.4 Functional and Reliability testing

Testing is an integral part of hardware products. Especially in the field of medical devices functional and reliability testing are important. In the case of ventilators tests for pressure and volume limits, breath rate control, alarms, multiple modes and oxygen mixing are some of the tests which need to be successfully conducted. In addition, ventilators also have to be tested for a longer period to determine its reliability. Some of the challenges were finding test facilities, equipment and procedures.

A recommendation from an interview partner was to develop centralized hardware facilities for open-source hardware testing as the acquisition costs of test equipment can inhibit the testing process. In addition, sharing testing procedures and protocols can also reduce the effort put into designing the tests. Using standardized testing procedures also saves time and costs.

For reliability testing, developing the product to enable efficient data logging and failure detection is advantageous to determine the root cause of failure.

6.5 COVID-19 suitability

To develop a COVID-19 suitable device, certain specifications should be met. Hence, consideration of such requirements is essential from the beginning of the project. In the use case of ventilators many emergency national standards/ authorities were established (such as British RMVS standards and Emergency Use Authorization) [MED20], [FDA20]. The interviewed projects considered these guidelines from the beginning. However, as the knowledge of the disease changed across the development process, this led to changes in requirements. Here the ability to be flexible and working with modular solutions presented advantages.

6.6 Clinician friendly

The hardware developed should be user friendly for the end users. For the ventilators the engineered device has to be:

- easy to use,
- familiar to what the end users are used to and
- use it with minimum training hours

In the current pandemic situation, the clinicians have less time than usual to get used to the new devices. Hence, some of the ways to address this is to:

- design similar to existing familiarized devices
- involve clinicians from the beginning of development
- conduct periodic usability tests or meets
- develop manuals that are easy to use and understand
- develop short videos and graphics as training materials
- consider the language and location-based needs based on the target areas.

6.7 EMC testing

When multiple electronic devices are used in a certain vicinity, it is important to ensure that they do not disturb the working of each other. This is especially critical when they find themselves in a hospital room, where the patient is often in close contact with them.

In case of ventilators, they are often developed with electronic components which need to pass Electro-magnetic compatibility tests to be certified for approvals.

Considering the EMC tests as a requirement in the early development phase and assessing risks through the development process can be advantageous.

6.8 National approvals

Medical devices are a part of a highly regulated market, because they are critical devices used on humans. Hence, obtaining national approval is a necessity before marketing for use on patients.

Applying for approvals is a time-consuming process, it is important to consider it throughout the lifecycle. However, there is a lack of clarity on what has to be considered when. In Figure 37 a developed guideline on what has to be considered in which phases is shown. This can help in better planning the product development and thus aid in the approval process.

In the open source world, if an approved design from an organization is remade by another organization, the approval does not hold good for the other. Hence, the approval process has to be reinitiated. In such cases the documentation and the experience of the origin community when shared makes it easier and quicker for the other organizations to work on their approvals.

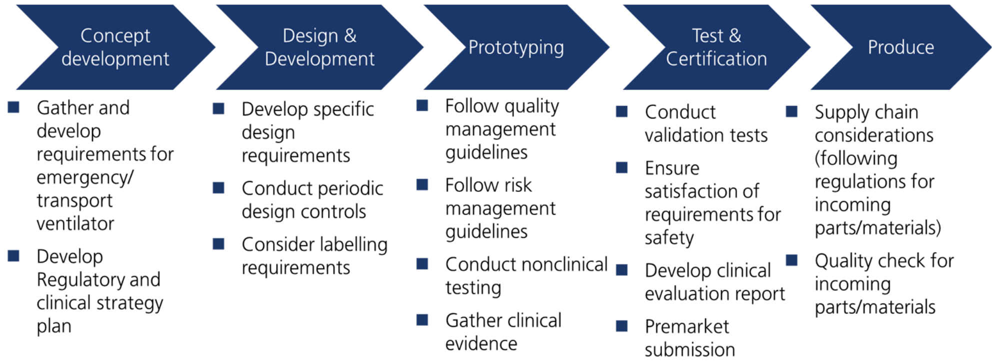


Figure 37: Regulations in life cycle

6.9 Manufacturability

As already touched upon in buildability, open-source projects reach a global audience. Hence, it is important to document all the necessary hardware and software models, bill of materials, schematics and instructions. In addition, it has to take into account the demand and supply aspect. Especially in the pandemic, the disruption in the supply chain have to be considered and accordingly designed to be mass produced.
Based on the communities target locations the following practices can be advantageous:

- research about commonly available parts
- research about number of parts available or manufacturable based on demand
- using commonly available manufacturing processes
- working with standard interfaces and formats
- working with multiple manufacturing facilities (including fablabs, makerspaces, etc.) to ramp up production
- assuring quality of production through defined and documented procedures

7 Conclusion

This study provides insights into the experiences of open-source projects during the pandemic. Especially focusing on developing ventilators. The aim of the study was to analyze the effectiveness of such projects. Through the collaboration with Public Invention the initial list developed by them was further enhanced and re-evaluated using the information available online. In addition, through interviews a deeper insight was gained into some projects. This threw light on best practices and challenges faced by these projects.

One main interest of the study was to analyze the effectiveness of open collaboration in projects. Since effort in community management rises with open collaboration it would be useful to see the impact it has on project results. As the interview sample is quite small to see certain trends, all the CVL projects are used for this analysis. Indicators for open collaboration are here the criteria openness and community support. Before this, a few remarks will be added on the interpretation of the data for reasonable consideration of the results. After this, the evolution of the criteria with increasing openness and community support is presented and described followed by the interpretation of possible influences of criteria.

The first thing to note is that the final evaluation naturally took place after the interviews, as other projects were already in later stages of development. A comparison of the sample and CVL projects (as it was done before the selection of projects) at the end of the research, including basic data, is also shown in Annex A1. A more comprehensive comparison by dividing the projects in groups based on their average rating led to the identification of an outlier. Further detail of this consideration is in Annex A2. In summary, it should be noted that the development of the sample, taking into account the distribution of averages, continues to show good representational tendencies.

To provide a clearer picture of the projects considered for the comparisons the criteria with zero rating were eliminated as stated earlier. This was applicable for the categories listed below. In addition, the number of open projects are also indicated. Hence the concluding statements derived are based on this limited and varied data per category.

- Functional testing (87 projects, 69 open projects)
- Reliability testing (38 projects, 36 open projects)
- COVID-19 suitability (96 projects, 81 open projects)
- Clinician friendly (101 projects, 83 open projects)
- National approvals (60 projects, 39 open projects)

The correlation of openness with other criteria is shown in Figure 38. The average rating of the criteria community support, buildability, COVID-19 suitability, clinician friendly, functional and reliability testing seem to rise with increasing openness. A slight rise can also be seen in the other criteria, but since it is just light and rather unsteady these criteria seem not to be influenced by the factor openness. When interpreting the diagram, the distinction between non-open (rating one) and open (rating greater one) projects must be taken into account.

Clearly it makes a difference in criteria rating if a project is open or not open (as to see in Figure 38). Non-open projects must be evaluated very cautiously with regard to the insufficient open information to be assumed. For open projects, the trend here shows positive impact for projects with a well-prepared objective (which comes with rising openness as it is defined here). Particularly noteworthy, the relatively strong increase in buildability. Also the increasing community support, as criterion under investigation, is attributed to the dedication to project collaboration, which is assumed to grow with affinity of project members to openness. Well and openly documented projects, enable better opportunities for collaboration.

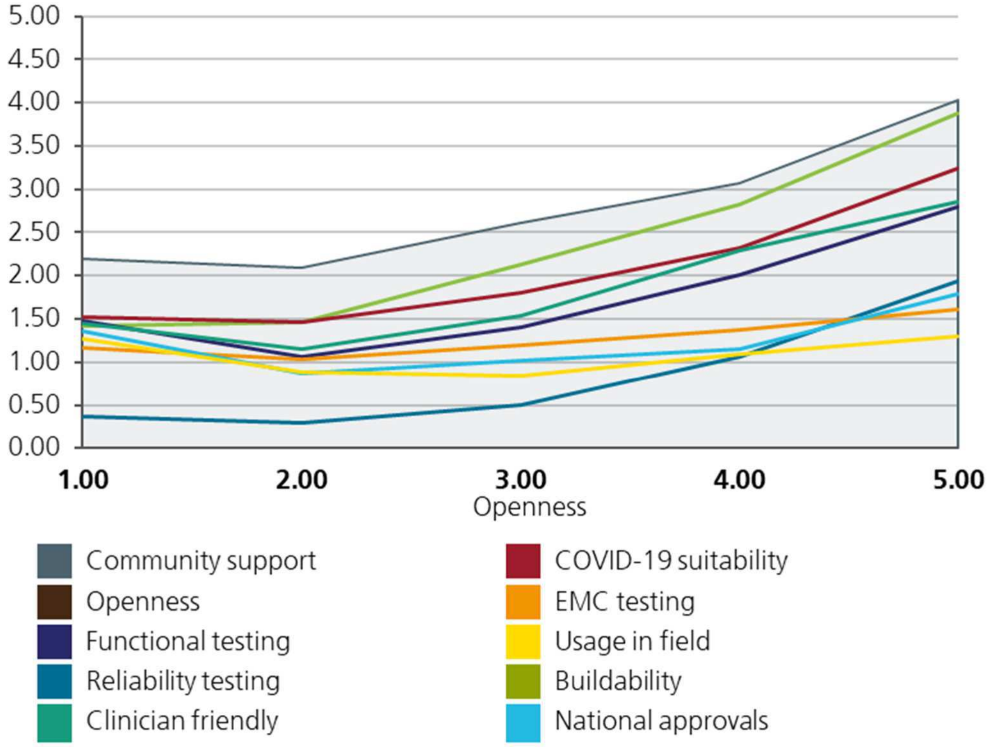


Figure 38: Correlation between Openness and other criteria

Especially the buildability of a project plays a major role as criterion in this research. This is defined in such a way that a high value reflects such a well thought-out and iterated design that people from outside the project across the globe can reproduce it. However, due to the accessibility or the unrecognizable topicality of documentation, a lower value cannot be conclusively concluded as to the insufficiency of a project. Nevertheless, complete and open documentation (which is a core of openness) leads to a rise in buildability.

Figure 39 shows, there is a positive correlation between buildability and functional testing criteria as well as the features COVID-19 suitability and clinician friendly. The graph also indicates, highly buildable projects have gone through testing activities, making the design further suitable for the needs. A well-documented and structured project can ease the testing process. The unsteady course of the reliability testing although suggests that there are also other influences or difficulties.

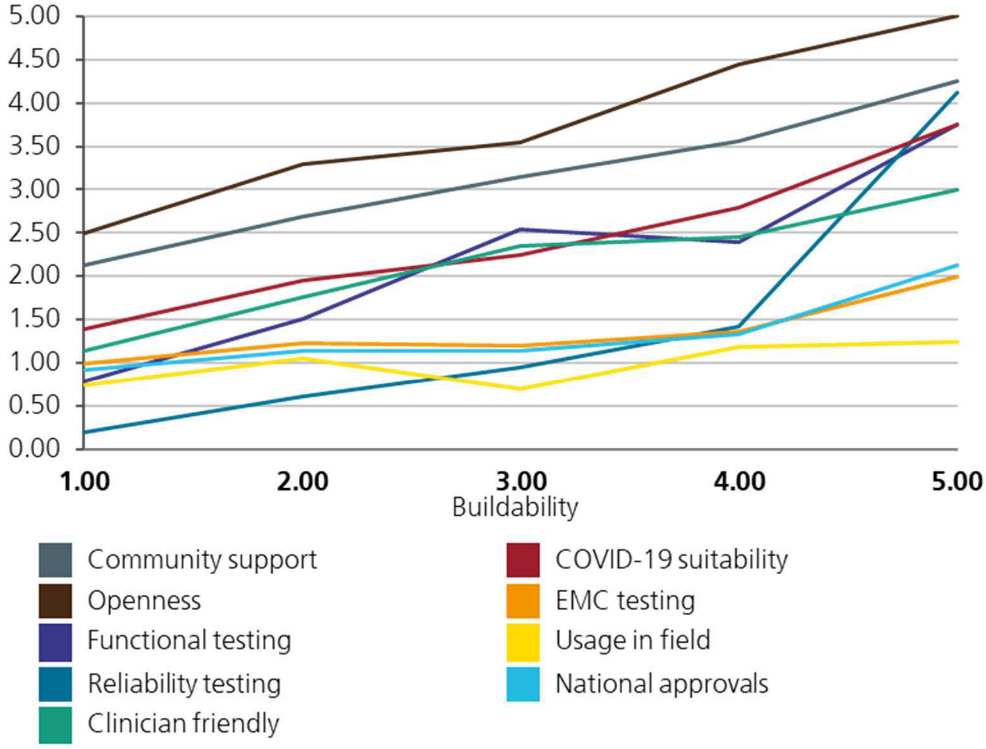


Figure 39: Correlation between buildability and other criteria

Figure 40 shows a rather mixed field. This suggests the difficult terrain of OSH development in the medical field. The diagram suggests a correlation with national approvals (and also reliability testing), which is very likely and logical, but this assumption has to be handled very carefully for the underlying dataset. Since many projects have not reached this state yet, or just want to develop devices for the emergency case, there is very limited amount of data for usage in field with rating greater than 1 (exactly 7 projects). Rating 4 in the diagram is also just an interpolation between ratings 3 and 5 since there are no projects with rating of 4 in the dataset at all. So, from the data, a conclusion is logical thought. As it is understandable and reasonable that if a specified approval on a topic is reached, such a project is more likely - or even only then - to be used in practice, especially in medical field.

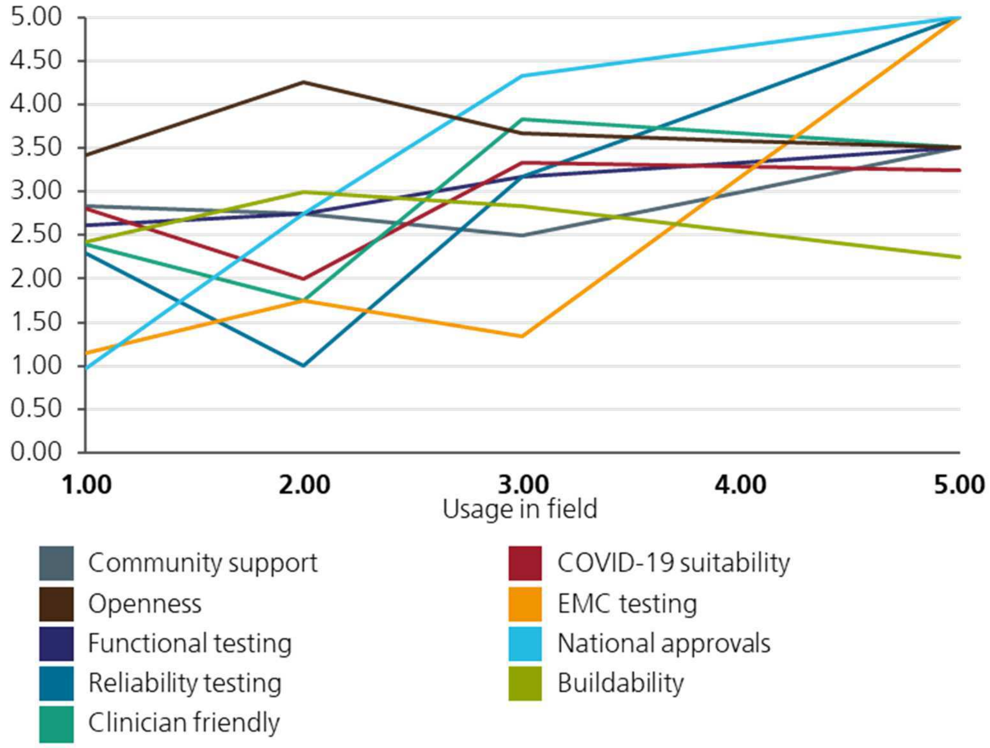


Figure 40: Correlation between usage in field and other criteria

The limitations of this analysis are the closed projects which are difficult to evaluate here because of the missing information. The chosen criteria are not exhaustive, but provide an initial insight into the OSH projects. The ratings of the projects that were not interviewed were done mostly with information from the online sources. Since there was no elimination of influences between multiple variables on each other (e.g. Design of experience) the interpretation of results is based on practical, common real life experience. Nevertheless, for open projects, where people with diverse experiences meet, community support and openness seem to support good results. Social aspects of teamwork motivate people to work further on the project.

The study also showed that through open-source projects it is possible to design, develop, approve and manufacture complex medical devices. The ratings in the criteria such as buildability and national approvals show that projects were reproduced and some already did meet the medical requirements for approvals. There has also been an increased documentation of knowledge associated with such projects to be accessed from anywhere in the world. In addition, the projects also considered the lack of a stable supply chain and worked with common and locally available resources as shown by the criterion manufacturability. The community was able to react to the pandemic with innovative solutions. Especially in the field of personal protection equipment's such as face masks and shields, many open-source solutions were used by end customers [RIC20], [VIC20]. However, in the case of ventilators which are more complex and are used directly on patients until now there was no evidence of direct use on patients. This can also be attributed to the decrease in demand for ventilation due to the other treatments which are available, and that the supply chain of established companies slowly recovered. Nevertheless, this study highlights the positive impact and achievements of open-source projects as well as the gaps which need to be filled. The gaps are important topics to be addressed by research and development in order to boost the results of open-source hardware projects in the future. This might come into great help in case another wave of the pandemic spreads across the world.

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Annexure

A1. Comparison of the selected projects and the CVL at the end of the project

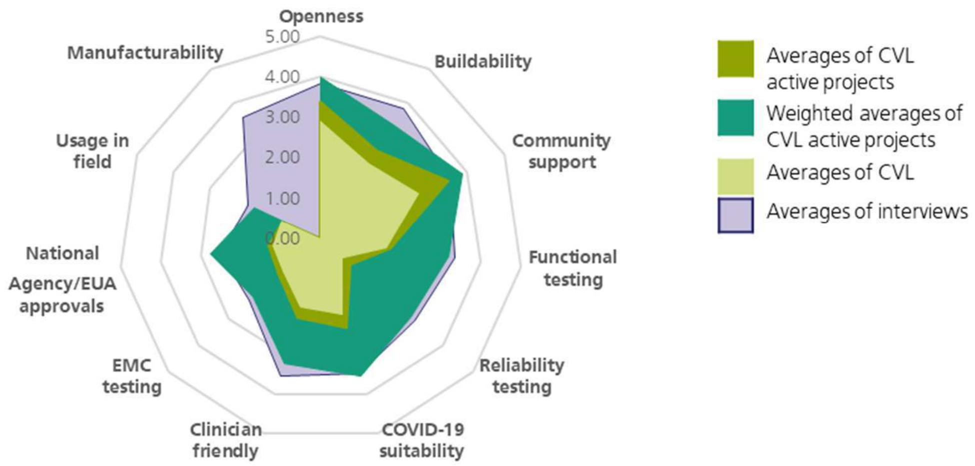
In this annexure, the averages of the selected projects and the averages on the CVL at the end of the project are compared. At the end of the interviews, the total number of projects in CVL was 138. Out of those, 109 were open (openness rating two and higher) and 29 were non-open projects. The number of inactive projects were 58. The overall average of all projects (average of all criteria ratings) in the CVL was of value 1.75 (out of 5), while the sample considered for the interview had an overall average of 3.2. Excluding unresponsive projects, the overall rating of the CVL rose to 2.02. Also here, the rating ratio of the projects was to be considered. The following table (Table 2) shows the ratio at the end of the project.

Table 2: Ratio of rated projects at the end of OPEN.Effect

	Interview sample	COVID19-vent.list	
		active	all
High rating	14%	1%	3%
Middle rating	57%	7%	10%
Low rating	29%	91%	88%

This results in a new comparison of averages. To see is an alignment of the averages of the comparisons from the beginning to the end of the project. This indicates that projects mature in similar ways to the chosen sample of projects. Also, the graph shows that the differences in averages can be mainly explained by the selection and distribution of projects in the sample (rating ratio).

Figure 41: Comparison of averages



A2. Comparison of different rated averages

A further comparison of averages gives more insights to the discrepancy between CVL and interviews averages. Looking at Figure 42, it becomes clearer the interviews are a quite representative sample of the CVL for mid and high average rated projects, recognizable by the large overlapping areas. Already to see in Figure 42 (b), there is special interest in criteria EMC testing and usage in field to look at. Additionally to Figure 42 (c), reliability testing adds as challenging criterion. Also of particular interest for this research is the criterion manufacturability since it represents the entry point for the ventilator for real world usage. Other than overall high and mid averaged rated projects, lower in average rated projects show not quite the congruency in contrast (Figure 42 (c)). Although low in average, one project exceeds the average rating in seven criteria and also scores well in two of the four above named challenging criteria (usage in field and EMC testing, cf. dotted line in Figure 42 (c)) and is rated, albeit not best, rather high in manufacturability. This involves a non-open project of a company unrelated to complete medical devices. Therefore general project work experience and resources for development can be assumed. Their low scoring criteria national approvals, community support and reliability testing can be attributed to the chosen business model. They only intended to design and develop a ventilator for emergency use with parts that the company manufactures. Hence, they themselves were not interested in mass manufacturing the ventilators, but wanted to encourage other manufacturers to use develop ventilators using their readily available parts. Taking this outlier out of rating changes the characteristics of the low average interview to be more similar to the low average projects in the CVL but the overall picture just changes slightly. This is due to the ratio of the number, and thus the weighting on average, of high, middle and low rated projects, as explained in A1.

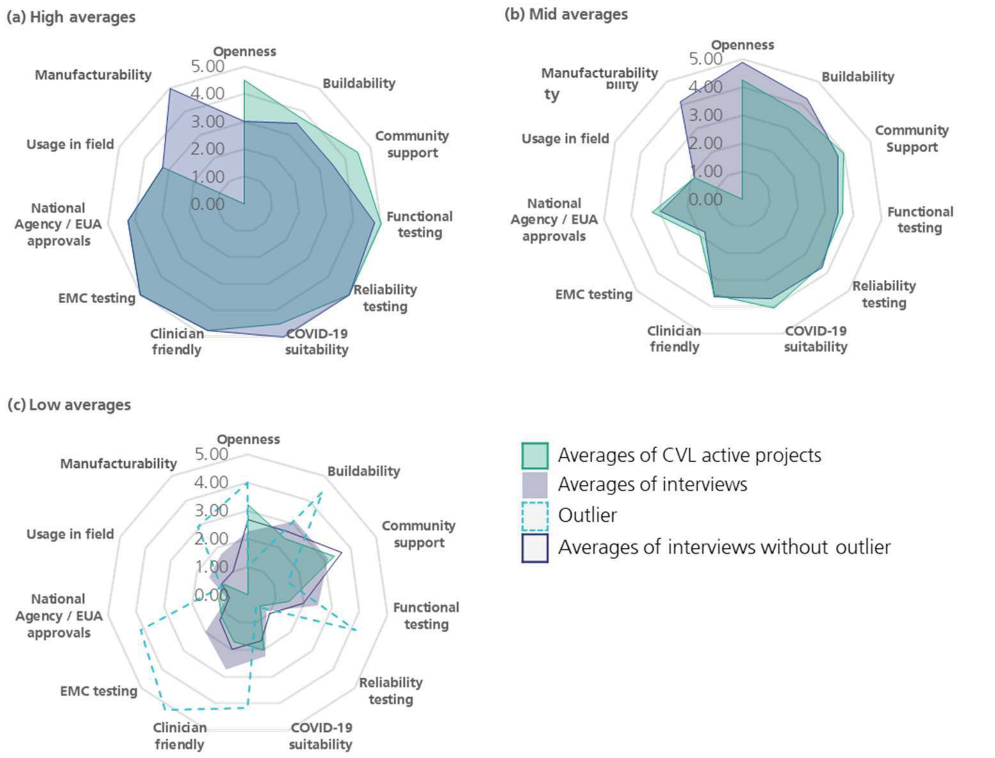


Figure 42: Comparison of averages

A3. Criteria growth of the interviewed projects

For a deeper and more complete analysis of deviations, it also has to be considered that many projects were evaluated at different times of the year and that not all progress is documented online, hence they probably will be in further stages at the moment since. To get an idea of rate of maturity of the interviewed projects the average ratings at the beginning and to the end of this study are compared in Figure 43. The overall rating rose from 2.52 to 3.2, about 27% increase (percentages indicate the growth in the category rating).

Due to the manifold influences on the development of a project such as experience of project members, effectivity of collaboration, social aspects etc. it is not suitable to apply the same growth or weighted growth on the population. Since the CVL projects are also updated on regular basis, many of the projects have different dates of last update. Also the ratings in the CVL projects are mostly based on the documentation of the projects available on the internet or sometimes based on direct communication with the projects themselves. Should interim results not be published because they are still being revised, this is consequently not reflected in the rating of the CVL. Therefore it is difficult to estimate a weighted growth factor for the averages here.

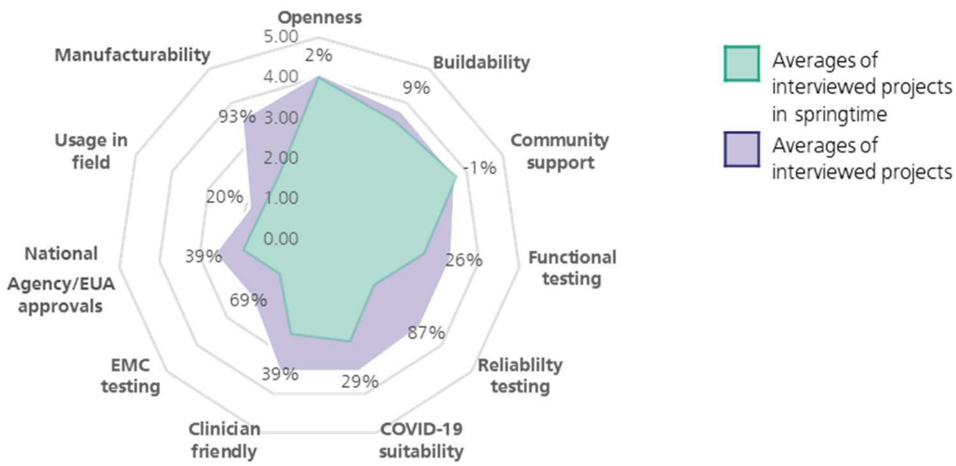


Figure 43: Development of the interviewed projects

In conclusion, it can be noted, that trends in the different ratings of the sample and population are – with reasonable consideration of outliers – similar.