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Distributed Manufacturing of Open-Source Medical Hardware for Pandemics

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Abstract:

Distributed digital manufacturing offers a solution to medical supply and technology shortages during pandemics. To prepare for the next pandemic, this study reviews the state-of-the-art for open hardware designs needed in a COVID-19-like pandemic. It evaluates the readiness of the top twenty technologies requested by the Government of India. The results show that the majority of the actual medical products have had some open source development, however, only 15% of the supporting technologies that make the open source device possible are freely available. The results show there is still considerable work needed to provide open source paths for the development of all the medical hardware needed during pandemics. Five core areas of future work are discussed that include: i) technical development of a wide-range of open source solutions for all medical supplies and devices, ii) policies that protect the productivity of laboratories, makerspaces and fabrication facilities during a pandemic, as well as iii) streamlining the regulatory process, iv) developing Good-Samaritan laws to protect makers and designers of open medical hardware, as well as to compel those with knowledge that will save lives to share it, and v) requiring all citizen-funded research to be released with free and open source licenses.

Keywords: pandemic; influenza pandemic; open source; open hardware; COVID-19; COVID-19 pandemic; medical hardware; open source medicine

1. Introduction

Pandemics stress critical infrastructures and hospitals can be particularly challenged [1–5]. For example, the coronavirus disease 2019 (COVID-19), has overwhelmed our medical infrastructure at the regional level, increasing mortality rates in many regions [6,7]. Developing nations are particularly vulnerable [8]. For example, in India, the government's ability to obtain needed supplies is under an extreme challenge [9]. Even in the relatively wealthy U.S. [10], however, hospitals are overwhelmed as epicenters of the disease pass tipping points [11,12]. This lack of critical infrastructure and supplies results in higher mortality due primarily to the volume of patients [13–15]. The health care systems have the technology and staff to care for some patients, but not the volume of patients observed during surges brought about by a rapidly-spreading virus. Traditionally, these challenges were met with two strategies: first, by pre-planning and stockpiling equipment, supplies and medication [16–22], and second, by using policies equivalent to the American Defense Production Act, which allows the President to direct private companies to produce equipment needed for a national emergency [28–30]. Unfortunately, as shown during the COVID-19 pandemic, the stockpiles are often insufficient [23–25], in part because of the high costs associated with maintaining the stockpiles [26,27]. The second approach is complicated by intellectual monopolies [31–33] that entangle global value chains [34] for critical medical supplies [35,36] that slow the ramp rate of production. In some cases, companies good-naturedly free their intellectual

monopolies during a pandemic and make technologies available for everyone to use [37]. Other companies threaten lawsuits for reverse engineering components of their systems [38], or even block critically-needed testing [39], which directly prevents lives from being saved (i.e. is indirectly responsible for killing people). Even if most of the primary equipment or supply companies act with good will, however, the access to the rights and supply chains of enabling technologies (e.g. the precursors to drugs or the microchips for medical devices) as well as the lack of full documentation make it challenging, if not impossible, to implement a rapid scale-up of production in the face of a global pandemic [40,41]. In addition, during a global pandemic, there is a conflict of interest between countries, which inhibits the global supply chains (e.g. export bans of medical equipment) [42–45]), as well as in-fighting for medical supplies within countries, states, and hospitals [46].

With this context in mind, it is illuminating to consider the ongoing transition observed in the nature of manufacturing. There is growing evidence of a fundamental change in the nature of manufacturing from the traditional large-scale, centralized, long lead-time, forecast-driven production to a distributed manufacturing paradigm, where manufacturing is small-scale, decentralized, rapid, autonomous and geographically-proxemic to the consumer [47]. Distributed manufacturing refers to a cloud-based manufacturing system [48] where designs are manufactured close to the consumer, but normally by third-party companies [49]. Additive manufacturing, for example, is dominated by the open source release of the self-replicating rapid prototyper [50,51] class of 3-D printers, and is currently deployed at the highest volumes throughout the globe [52]. This distributed manufacturing is already upsetting global value chains [53] and supporting a domestication of supply chains [54]. Technological maturation of a number of enabling digital manufacturing technologies has allowed for a new, and even more radical, approach to mass-scaled distributed manufacturing, where consumers fabricate their own products [55–61], from toys [62–64] to high-end scientific tools [65–75]. In this model, open source hardware designs, ideally made with free and open source software [76–78], are shared freely on the Internet, downloaded and then manufactured on site, normally for substantial economic savings [79]. This concept can be applied to medical supply shortages [80–83] and there are already examples [84–93] and calls for open source development of medical devices [94–97]. There is substantial evidence that funders, which invest in open source design for medical equipment can expect large rates of return as products can then be fabricated for little more than material costs [95,98–100].

This approach of leveraging open source hardware to combat global pandemics appears promising [101], but there are unanswered questions about the current viability and the maturation of the open source design for manufacturing supplies and medically-required technologies. To determine the effort and trajectory needed to apply this new method of manufacturing of medical supplies to fight a pandemic, this article evaluates the medical supplies to fight COVID-19 requested by the Ministry of Micro, Small and Medium Enterprises for the Government of India [102]. Each technology is analyzed for availability of free and open source designs, as well as availability of open source manufacturing methods or equipment to fabricate the components of the primary requests. The results are discussed in the context of the technical research required to make this method viable, and the policies that would enable distributed manufacturing to provide a solution to the manufacturing of supplies and devices for future pandemics.

2. Materials and Methods

Thirty-nine medical supplies were listed as needed by the Government of India [102] during the COVID-19 pandemic, and in this study the most critical twenty are evaluated. First, for each request, the existing Internet and grey literature is reviewed for open source projects and designs. For each request, it is determined if a design is available that is completely free and open source hardware (FOSH). A designation of FOSH indicates that the designs are licensed using an open source hardware license [103] such as the CERN Open Hardware License (OHL) v1.2 [104] and the TAPR Open Hardware License (OHL) [105]. Likewise, the technologies may be in the public domain. The documentation of the design can be under an open license as well, such as GNU General Public License (GPL) v.3 [106] and the Creative Commons Attribution-ShareAlike 3.0 [107], or again in the

public domain. For projects that use software, these also must use free and open source software (FOSS) licenses [108]. In addition, to achieve full FOSH status, the practical details need to be available for the medical supplies and devices. This includes possessing accessible designs that are freely accessible source files such as bill of materials (BOM), computer aided design (CAD) files, as well as production files (e.g. STL files for 3-D printing) for mechanical designs as well as printed circuit board (PCB) layouts and other electronic design files, list of tools and production machines required, wiring diagrams, firmware and software, as well as assembly, operation and calibration instructions. If full FOSH documentation is not available but there are some basic designs, the request is denoted as POS for partially open source. Finally, for those requests for which there are no free and open source alternatives, the request is denoted 'Closed'. The final results are tabulated and color coded for clarity, where dark green indicates FOSH completed, light green indicates FOSH with near full documentation, yellow means POS, orange indicates some open source tools are available, but primary plans are closed, and red means Closed technologies.

Similarly, the building-block technologies needed to fabricate each of the devices is evaluated. For simple technologies, these are evaluated completely. For complex devices, however, such as the glucometer, the complexity of developing each part (e.g. PCB components) far exceeds the scope of this paper and only general evaluations are presented. In all cases, the designs are evaluated to determine if they can be completely digitally manufactured, ideally from locally-sourced waste products. In some instances, using distributed recycling and additive manufacturing (DRAM) [109–114] is possible as the technologies (open source granulator [115], pelletizer [116], and recyclebot (an automated device to make filament for fused filament fabrication-based material extrusion 3-D printing) [117–119]) are already mature for pure polymers [109,120–125] and complex plastic packaging, blends and composites [126–130]. In addition, direct material extrusion of waste is now possible for additive manufacturing [113,131–136]. Utilizing widely-dispersed waste material as building blocks would ensure wide accessibility of the approach for providing medical technologies.

3. Results

The documentation to obtain FOSH is substantial and most projects were not able to meet the rigorous requirements, as shown in the results below for each of the top 20 requested medical supplies from the Indian government during the COVID-19 pandemic. It should be noted, that the patent literature was not included in the analysis because of lack of practical utility, although many patents are no longer in force and a database is available to find inactive patents [137].

3.1. Ventilators

A recent review of open source ventilators was completed in the midst of the COVID-19 pandemic [138] which found that the peer-reviewed and vetted systems [139–143,143–145] lacked complete documentation and the “open source” ventilator systems that were documented [146] were either at the very early stages of design (often without a prototype) and lacked testing, or only had basic testing. This is changing rapidly with AmboVent releasing all plans [147], and there are several projects like the OxyGEN [148], an automated manual ventilator, being tested that appear to be at or near the point of production for use in hospitals. Many of the designs, particularly in the open source community, relied on an Arduino [149–151], which is an open source microcontroller, but many of the core components have no open source equivalent, such as the valves and methods of producing pressure. Although it should be noted that for this specific technology, there is concern about aerosolizing virus with these systems, and thus they are a potential threat to health-care workers [152] without appropriate safety precautions. Thus, appropriate personal protective equipment (PPE), high-efficiency particulate air (HEPA) and negative pressure rooms can also be considered required associated equipment. There is discussion about CPAP (continuous positive airway pressure) being a better alternative noninvasive treatment [153,154]. This device is identified as POS/Closed, but, as of this writing, there is significant international development occurring in this space, so this may change rapidly because of the critical nature of ventilators in treating COVID-19 patients.

3.2. Alcohol based hand-rub

For hand sanitizer to be effective, the U.S. Centers for Disease Control and Prevention (CDC) reports that it must contain at least 60% alcohol content [155]. The World Health Organization has provide a detailed guide for local production of hand-rub formulations [156], as does the Appropedia Foundation [157]. Knowledge of alcohol production is widespread and glycerol and hydrogen peroxide are both widely available, but detailed validated instructions would assist open source production.

3.3. Face shield (eye, nose & mouth protection)

Several 3-D printable designs for face shields were created during the COVID-19 pandemic [158–160]. They involve a printed component, a clear plastic sheet, and in some cases, bands. Other designs can simply be cut from the plastic sheets themselves, and were released on Creative Commons licenses [161]. Such PPE is widely used throughout the world [162,163]. The entire device could be fabricated using open source tools and meet its function from plastic waste using readily available RepRap-class 3-D printers and recyclebots.

3.4. N95 Masks

Due to the global shortage of N95 masks during the COVIND-19 pandemic, there was significant effort placed in finding alternatives. Several designs were made available that could be 3-D printed [164–166] and then would use cut up pieces of commercially manufactured filter materials or alternative materials [167]. Southworth has also made available plans to fabricate an N-95 substitute using HEPA filters [168]. More work is necessary to develop open source methods of manufacturing the active filter material, as well as more reliable and deployable methods of testing.

3.5. Latex single use gloves (clinical)

Although the process for fabricating latex gloves is well established [169], there does not appear to be an open source process or projects for fabricating latex gloves.

3.6. Reusable vinyl / rubber gloves (cleaning)

Similar to latex gloves, there does not appear to be an open source project focusing on manufacturing reusable vinyl or rubber gloves. As these materials are thicker, it is possible to consider laser welding gloves from sheets of the material using plastic welders [170] and then automate cutting them out using any number of open source laser cutters [171–174].

3.7. Eye protection (visor / goggles)

Although a wide range of open source frames for glasses have been designed including 3-D printable self-adjustable glasses [58], those meant as safety glasses or goggles are only crudely modeled and untested. There is, however, a substantial collection of open source face shields being designed, 3-D printed or manufactured/assembled and used during the COVID-19 pandemic as discussed in Section 3.3.

3.8. Protective Gowns / Aprons

There is a robust open source sewing community that shares patterns (e.g. Free Sewing that made a face mask pattern available for the COVID-19 pandemic [175]) and open source pattern design software like Seamly2D [176]. In addition, patterns for gowns and aprons are available. None, however, appear focused on medical needs, nor have the materials available to lay people been tested (as with mask materials) to see how they perform in medical environments.

3.9. Disposable thermometers

Disposable thermometers are based on a chemical system by varying the ratio of two organic chemicals, which are completely soluble in each other while having different melting points. Thus, the melting point of the mixture can be adjusted anywhere between the two end points of the two chemicals. Work has been done in the open source appropriate technology community [177,178] on such active thermometers in the past to make water pasteurization indicators (WAPI) for solar water pasteurization [179–182]. There does not appear to be any efforts to make open source disposable thermometers in the open source medical community, but work on 3-D printing microfluidics with a number of technologies appears to be a promising route [183–191].

3.10. UV tube light for sterilization

UV radiation can be used to inactivate microorganisms by causing DNA damage and thus interfering with DNA replication [192,193]. It has been shown to be effective at disabling coronavirus [194,195]. There are already detailed open source designs for a programmable and low-cost ultraviolet room disinfection device [196], which could be adapted for use in a pandemic. There is a clear need and promise of using UV radiation to extend the life of PPE during a pandemic [197] and developing a distributed manufactured system to sterilize hand-held or sized objects appears to be possible. There are currently no plans available, however, to manufacture the core components (either UV tube lights or UV LEDs), which are the critical components of such devices.

3.11. Medical masks (surgical / procedure)

The same limitations and opportunities as were discussed in Section 3.4 are present for both surgical and procedure-based medical masks. Although, it should be noted, that the requirements for these masks are less stringent than for the N95 masks [198], which would make meeting a specification more easily obtained with widely-available materials. Dato et al., have discussed the use of T-shirt material to act as a simple respiratory mask [199] and there is evidence that home-made masks decrease viral exposure and reduce probability of infection [167,200].

3.12. Detergent / Disinfectant

Recipes for ‘homemade laundry detergent’ that are as effective as commercial detergents are wide spread and can be made for significantly lower costs (50% less or more) than proprietary formulations [201]. DIY recipes normally contain a mixture of borax (sodium borate), washing soda and bar soap along with non-active ingredients to add a pleasant odor; but can be made without borax [202]. Such DIY laundry detergent would be expected to remove coronavirus, as it contains soap (just like washing hands). Thus, such recipes would be expected to be effective for disinfecting medical clothing, but a study is needed in this area. Similarly, there are numerous open source resources for fabricating the main ingredients: soap (e.g. [203]) and washing soda (e.g. [204]).

3.13. Single use towels

Similar to Section 3.8, the know how to make a disposable towel is widespread and the pattern is unnecessary due to its simplicity, but detailed guidelines of acceptable materials have not been developed. Unanswered questions include: Can rags cut to shape and sterilized be sufficient? Does the material need to be autoclavable? Can rags made of different materials be color-coded representing utility for different functions in the hospital?

3.14. Biohazard bags

Biohazard bags are generally fabricated from 1.5 mils (0.038mm) to 2 mils (0.05mm) thick polypropylene plastic, which can be sterilized with steam. California law is specific about the mechanical properties of a biohazard bag [205], which must pass the tests for i) tear resistance of 480 grams in both parallel and perpendicular planes with respect to the length of the bag, following the American Society for Testing Materials (ASTM) D1922, “Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin

Sheeting by Pendulum Method" [206], and for impact resistance of 165 grams, following ASTM D1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method," [207]. Biohazard bags often generally have bold visuals printed on them signifying decontamination use and some jurisdictions specify a color. Similar to Section 3.6, open source laser welders/cutters could be used to manufacture bags from raw materials, but future work is needed to determine if there are other mass-manufactured bags (i.e. garbage bags) that could be repurposed during a pandemic.

3.15. Wheel Chair

A well-established literature has developed around the need for low-cost open-source wheel chairs made with PVC pipe, CNC laser cut wood, constructed around inexpensive outdoor lawn chairs, and cut plywood [208–210]. The Hu-Go [211], Kigali Chair [212], and the TooWheels [213] are all open source wheelchairs that could be fabricated in makerspaces and fab labs. There are also open source wheelchairs meant for off-road (e.g. more challenging) conditions like the SafariSeat [214], that could be used for rural clinics, but are meant for use by healthy people. In addition to the normal advantages of open hardware, including cost and customizability, ease of repair is a substantial benefit of open wheel chair designs [215]. As the materials are very diverse with which any of the myriad open source wheelchair designs can be made, the manufacture of the components is also deemed readily accessible. It should be pointed out, however, there is a clear opportunity for developing open source versions of patient chairs on casters for patient transport within hospitals using common maker techniques and tools.

3.16. Glucometer with strips

Meehan has developed an open source universal glucometer that can use test strips from any supplier [216], which includes all software, electronic design files and mechanical designs for a 3-D printed case. Gluco, is another open source glucometer based on an Arduino Uno and the e-Health Shield [217]. There has been some work on printing a low-cost glucose test strips on paper [218], but more work is needed in this area, as well as perhaps the more promising development of open source, non-invasive tests.

3.17. Medicine

This request is too broad to adequately analyze, but there are substantial efforts like Open Source Pharma, which hopes to be the "Linux of drugs" [219] (in reference to the free and open source Linux operating system which dominates super computers, the cloud, smartphones and embedded systems [220–222]). Already, open source methods have been developed to specifically target neglected tropical diseases like malaria [223–225]. The open source biotechnology and drug discovery are becoming more established because of the ability of open source collaboration to accelerate discovery [226–230]. An open source pharma roadmap has been established to improve i) efficiency, ii) quality of research, iii) relevance of research, and iv) encourage a wider participation by the scientific and patient communities [231]. Far more work is needed, however, to develop a range of open source drugs for all relevant diseases as well as the methods to manufacture them.

3.18. IV Fluid -DNS

DNS IV fluid is used to correct salt depletion and hypovolemia (decreased volume of blood in circulation) with a supply of energy. Each 100mL of DNS IV fluid is made up of sterile water with 5.0 g of dextrose anhydrous and 0.90g of sodium chloride [232]. The materials and formula are well known and accessible, but the manufacturing method is not. As only a few facilities make IV fluids, when Hurricane Maria struck Puerto Rico, home to a key manufacturer, it created a critical shortage throughout the whole world [233]. Some have contended that there is not a simple solution to this problem [234], however, the development of clear distributed manufacturing/sterilization methodologies and the use of other types of fluid containers and digitally-manufactured quick connects could provide a range of solutions to this and other IV fluid shortages. Extreme care must be made to ensure that the methods do not introduce further disease into patients that would use it.

3.19. IV Fluid -Dextrose

Dextrose IV fluid is used as a basic fluid to provide some calories and can also be used to administer various drugs. It is also often used to prevent or treat dehydration. It is available in concentrations of 5%, 10% and 25% where each 100mL of sterile water contains 5.0g, 10.0g and 25.0g of dextrose, respectively [235]. Similar to request in Section 3.18, the materials are known, but a method to mix the components, sterilize the solutions and contain them using low-cost, widely accessible manufacturing methods needs further development.

3.20. Hard-frozen Gel Packs

There are a plethora of low-cost methods to fabricate frozen gel packs, which do not demand special equipment, including filling a freezer or ziplock bag with i) corn syrup, ii) dish soap, iii) combination of vodka and water, iv) diaper with water and alcohol, vii) sponge with water, v) salt water, vi) loose change, and viii) rice grains [236]. The latter two methods can even utilize a cloth bag. Only modest effort would be needed to identify the lowest-cost and most accessible materials for a given location.

3.21. Summary of Results

Figure 1 summarizes the status of open source development of India's top twenty requested medical supplies and their method of manufacture of components during the COVID-19 pandemic. As can be seen from Figure 1, whereas the majority (75%) of the actual medical products have had some inroads into open source development, the methods of manufacture and the base materials are 70% closed. For the core supplies or devices, forty percent are open source now and another thirty-five percent are within range of being developed with a concentrated effort. On the other hand, for the supporting technologies that make the open source device possible, only fifteen percent have support.

Device	OS Base Device Status	OS Manufacture of Components Status
1. Ventilators	POS	Closed
2. Alcohol based hand-rub	FOSH	FOSH
3. Face shield (eye, nose & mouth protection)	FOSH	FOSH
4. N95 Masks	FOSH	Closed
5. Latex single use gloves (clinical)	Closed	Closed
6. Reusable vinyl / rubber gloves (cleaning)	Closed	Closed
7. Eye protection (visor / goggles)	POS	Closed
8. Protective Gowns / Aprons	Closed	Closed
9. Disposable thermometers	Closed	Closed
10. UV tube light for sterilization	FOSH	Closed
11. Medical masks (surgical / procedure)	FOSH	Closed
12. Detergent / Disinfectant	FOSH	FOSH
13. Single use towels	FOSH	Closed
14. Biohazard bags	FOSH	POS
15. Wheel Chair	FOSH	FOSH
16. Glucometer with strips	FOSH	POS
17. Medicine	Closed	Closed
18. IV Fluid -DNS	FOSH	Closed
19. IV Fluid -Dextrose	FOSH	Closed
20. Hard-frozen Gel Packs	FOSH	FOSH

Figure 1. Summary of open source development status of India's top 20 requested medical supplies and their method of manufacture of components during the COVID-19 pandemic.

4. Discussion

4.1 Diversity of Solutions Needed

The list of products requested by the Indian government during the COVID-19 pandemic can be roughly regarded as in the order of perceived need. So open source designers could focus their attention on the top of the list first to be most effective, while ensuring it is in areas they have experience either in the specific supply, device or the method of manufacture. This has certainly occurred organically with request 1: an open source ventilator. Despite the massive efforts underway, however, fully documented and tested systems that can be deployed and manufactured in a range of contexts remain elusive (why and how to overcome this in the future will be discussed in Section 4.2-4.4). Open hardware designers should not stop their efforts as open designs are made available for the specific project they are focusing upon. This is because myriad methods of solving the problem will ensure that these life-saving devices or supplies can be manufactured throughout the world.

A good example of this that has occurred in the past is with technology further down on the list of Indian's priorities; number 35, which is the syringe pump. An open source syringe pump library was developed that can be customized for any syringe using a scriptable CAD (OpenSCAD) and 3-D printed from waste plastic and driven wirelessly with a Raspberry Pi [237] and open source software [238]. These and their variants (e.g. using an Arduino [239]) and other types of open source syringe pump controllers have been developed [240] to allow for multi-syringe devices [241] or different sizes [242], and to help different applications in biotech [237] and DNA labs [69], and those with feedback that enable even more sophisticated control [243,244]. Ideally such technical diversity could be realized for all of the supplies and technologies needed to combat a pandemic.

Having a great diversity of solutions relying on different materials and approaches will ensure the greatest possible coverage because if only one approach is validated, the core components could quickly become unavailable during a global pandemic, as all nations race to fabricate the devices for their own populations. In addition, as in the COVID-19 pandemic shipping and global supply chains can become disrupted, so being able to fabricate medical hardware from local supplies becomes important. Thus, whenever possible, open hardware designers of medical equipment for pandemics should consider multiple approaches and tools for fabrication of their device, as well as alternate materials. This is particularly prescient with respect to materials. As it should be pointed out, not all of the materials are at as advanced of technical state for DRAM as plastic, which was heavily favored as the solution for many of the requests shown in Figure 1. Substantial effort should be made to move open source DRAM for metals, ceramics and semiconductors.

4.2 Protecting Laboratories, MakerSpaces, and Fabrication Facilities During 'Shelter in Place'

Looking at the results in Figure 1, the complexity of the requested device or supply does not appear to be an indicator of a fully open source design. Supplies like gel-packs that have frequent home-based/consumer use have myriad solutions posted and tested by many all over the world. These are simple to construct and have many substitutable materials. Even complex medical devices, like a wheel chair, also have myriad designs, primarily because of the need in the developing world for low-cost substitutes. Some simple supplies, however, like latex gloves, do not have available open source solutions, nor complex devices like ventilators. These results can in part be explained by access to technologies at home to fabricate them. So, for example, numerous types of open source face shields (Section 3.3) are available because they can be fabricated from readily available clear plastic sheets and a simple print from a desktop 3-D printer. Open source fused-filament-based 3-D printers are now widespread and there is a general ethos of sharing in the community as witnessed by the exponentially growing number of free designs [79] in repositories like YouMagine, MyMiniFactory, GrabCAD, Thingiverse, Cults, Pinshape, TurboSquid, Prusaprinters, CGTrader, 3DExport, Free3D, and the NIH 3D Print Exchange. As people had these fabrication facilities available at home and access to the plans on the Internet, it is now common for them to make face shields for their local hospitals.

Complex devices, however, which had not previously had substantial open hardware development and that require facilities beyond the confines of a typical maker home, have been far more challenging to complete than under normal circumstances. During a pandemic, many universities are closed first as potential hosts of “super spreaders”, and after shelter in place orders are put in place, most makerspaces, fab labs, machine shops, manufacturers and university labs are shuttered. This limits innovation velocities. Shelter in place that is necessary to slow the spread of the pandemic not only hampers development of new technology, but can also slow manufacturing as more open hardware is designed, tested, vetted and approved for widespread deployment, makers will need access to their equipment to make it. In some cases, makers can get requisite permissions to use their facilities again as long as strict social distancing rules are maintained [245]. To avoid this situation occurring in the future, however, policies should be instituted to have mixed use makerspaces. This means that whenever possible, superusers or those that maintain the equipment in the various types of makerspaces should be ‘in residence’ or facilities adapted to make them as such during a pandemic. Instituting such protocols varies in the degree of challenge, depending on federal, state, and institutional rules and laws. As the risk to human life to not have full access to fabrication and development equipment is so large, efforts should be made to adjust rules and laws to prepare for the next pandemic.

4.3 Streamline Regulatory Processes

Any medical equipment to be used on humans, even during a pandemic, must, to the greatest extent possible, be proven to do more good than harm (and ideally no harm). Studies to enable medical hardware to become approved by the medical authorities of most developed countries is complex. For example, any studies involving testing on humans needs institutional review board (IRB) approval, which alone could take months at the university level. For example, a recent study by Hall et al. found the initial IRB review took 2 to 4 months, with expedited and exempt reviews requiring less time with medians of 85 and 82 days, respectively [246]. The full board reviews had a median of 131 days, but some went up to 296 days! This obviously is a major impediment to rapid research and development. During a pandemic, where, for example, there was an exponential rise of cases and preventable death due to lack of supplies in Italy [247], any such lengthy delay is unacceptable.

If the device is to be used or manufactured in regulated areas, there are numerous challenges to making medical devices [248]. For example, studies in the U.S. needed to enable open hardware to be used clinically would need an Investigational Device Exemption (IDE) to allow for a non-FDA approved device. This is only a temporary approval and the complete device would need actual FDA approval for legal deployment unless the laws are temporarily changed or suspended during a pandemic. In the case of the U.S., the FDA has, for example, altered enforcement policies during the pandemic [249] and made emergency use authorization (EUA) for a number of technologies [250], both made in the U.S. and imported [251]. Similar regulatory roadblocks are in place in other nations and would need to be removed/improved to have a clear method that allows for rapid response and deployment of needed medical supplies and technologies during a pandemic.

4.4 Develop a Good-Samaritan Law for Protection of Makers and Designers of Open Source Medical Hardware

During the current and potential future pandemics, there is a need to limit liability on the part of the designers, makers and users (e.g. medical professionals) of open source medical hardware. Substantial future work is needed in this area, but one approach could be to expand Good-Samaritan laws. In general, Good-Samaritan laws legally protect those who give reasonable assistance to others, whom they believe to be injured, ill, in peril, or otherwise incapacitated [252,253]. This legal protection is intended to reduce barriers for one person to help another because of potential liability or prosecution for unintended negative consequences. These types of protections are critical to reduce barriers to companies and individuals to release all of their designs, which would allow others to replicate in other locations. These laws can be instituted in such a way so as to provide as much protections as possible for patients and their care givers from harm. This is challenging and will involve substantial thought and careful implementation.

Laws could also directly help the release of documentation on known life-saving technology. One way to do this is to use an expanded version of the good Samaritan laws. Often these laws *require* people to aid others who are exposed to grave physical harm if there is no risk for the rescuer. For example, in Finland, there is an explicit “general duty to act” and “engage in rescue activities according to [one’s] abilities” [254]. Thus, the Finnish rules include a principle of proportionality, which requires more of professionals than of laypersons. The Finnish Criminal Code section 15 (578/1995) stipulates “A person who knows that another is in mortal danger or serious danger to his or her health, and does not give or procure such assistance that in view of his or her options and the nature of the situation can reasonably be expected, shall be sentenced for neglect of rescue to a fine or to imprisonment for at most six months.” When we apply this Finnish logic to engineers and companies that design and make medical equipment, the results are interesting. Such parties have knowledge that, if shared, would save lives, and, if not shared (or not released with a usable open source license), there is reasonable assurance that people will die unnecessarily. Is that ethically or morally defensible? If not, it would appear that these designers and companies should be compelled to share the artificial construct of “intellectual property (IP)” that would save others, and be held criminally liable for not doing so under such legal logic. When analyzed in this way, the current global shortage of a wide-range of proprietary products call into question the entire IP system. It is intuitively obvious that if proprietary designs were shared for the articles in Figure 1, shortages would be reduced and lives would be saved. Others might argue that without the IP protections in place, innovations may not have occurred. There is a long-simmering debate in the literature on the efficacy of IP laws to even drive innovation at all [31–35,255,256]. Many studies have concluded that IP law simply gets in the way of innovation in a wide range of fields and creates artificial (socially constructed) scarcity [31–35,177,257,258]. There are now well-established and successful business models based around open source technology (both software and hardware) [100,259–262], so the protests of intellectual property defenders grow progressively more feeble, and the case for weakening patent rights is strong [263]. The shortage of supplies and technologies analyzed in this study appear to support these claims. If widespread, completely open source products, along with their methods of production, are available, shortages are not. This hypothesis could be tested using the results of this study, as, for example, it would appear that face shields will become less critical than N95 masks, despite the initial ranking from India, because both the device and the method are open source and thus a wide array of makers can fabricate them and make them available to the hospitals.

4.5 Require All Citizen Funded Research Be Released Freely Under Open Source Licenses

As this review has shown, there is still considerable work needed to provide open source paths for the development of all the medical hardware needed during a pandemic. It is clear that such designs should be made open source so that everyone the world over can benefit from them. Including both the core products and their components, nearly half of the list of evaluated needs for India are closed and proprietary. Yet, much of the development of these technologies were funded by various governments. This is a problem, because the IP system is centered on laws that exclude others from using an invention. Is it tolerable for citizens to be excluding from using technologies they funded?

There are many examples of this particular problem, but perhaps the most egregious currently-relevant example is the number 1 request of ventilators on the list from India for the COVID-19 pandemic. In the U.S., federal research money was invested in private companies to specifically develop this life-saving technology to prepare for just such a pandemic as is occurring now [264]. Public funds were given to a company, Newport, to create a low-cost ventilator, yet the project stalled as Newport was acquired by Covidien, and no ventilators were ever delivered. Both “government officials and executives at rival ventilator companies said they suspected that Covidien had acquired Newport to prevent it from building a cheaper product that would undermine Covidien’s profits from its existing ventilator business.” [264]. Then, Covidien was in turn purchased by Medtronic. Interestingly, Medtronic just obtained a substantial amount of positive press for providing a temporary permissive license for a ventilator and providing some design files [265]. After inspection of the initial release, although many files were included, both software and CAD files were not apparent. This obviously limits the ability of anyone to replicate the device without Medtronic’s direct assistance. Medtronic may release all files and help as many fabrication facilities as possible build their design until all of the global demand for ventilators is met. Or, they may not, as they have

already done more than all of the other ventilator vendors have to date. All of the other commercial ventilator companies have this same choice. To prevent the lives of the world's citizens from being held ransom for the profits of such companies for any life-saving device or supply in the future, all government-funded research could have a requirement for free and open source licensing. This could be done similarly to how there are a growing number of science funders that demand open access for research they fund [266].

5. Conclusions

To prepare for the next pandemic and assist in solving critical shortages for the current COVID-19 pandemic, this study reviewed the readiness of the top twenty technologies requested by the Government of India. The results show that the majority of the actual medical products have had some open source development; however, only a tiny fraction of the supporting technologies were freely available that make the open source device possible. The results show there is still considerable work needed to provide open source paths for the development of all the medical hardware needed during pandemics. The results of this investigation show there are five core areas of future work needed to provide the global community with an 'open source' insurance policy of a collection of vetted and tested freely available designs and methods of manufacture for needed medical technology. To enable this potential source of increased security for the world, the technical development of a wide-range of open source solutions for all medical supplies and devices is needed. Policies are needed to protect the productivity of laboratories, makerspaces and fabrication facilities during a pandemic to enable such products to be fabricated when the need arises. These products need to be safe, but there is also a need for streamlining the regulatory process. Lawyers can help as well as technologists by developing Good-Samaritan laws to protect makers, designers and users of open medical hardware, as well as to compel those with knowledge that will save lives to share it. Finally, it is 2020 and all of the needed technologies are relatively well-known by scientists and engineers, yet unavailable in the quantities needed. Requiring all citizen-funded research to be released with free and open source licenses in the future will prevent such artificial scarcity from needlessly allowing people to die.

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