A Statewide Voluntary Movement Addressing the Shortage of Medical Supplies During the COVID-19 Pandemic

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During the COVID-19 pandemic, a shortage of personal protective equipment compromised efficient patient care and provider safety. Volunteers from many different backgrounds worked to meet these demands. Additive manufacturing, laser cutting, and alternative supply chains were used to produce, test, and deliver essential equipment for health care workers and first responders. Distributed equipment included ear guards, face shields, and masks. Contingent designs were created for powered air-purifying respirator hoods, filtered air pumps, intubation shields, and N95 masks. (*Am J Public Health*. 2021;111(9): 1595–1599. https://doi.org/10.2105/AJPH.2021.306364)

During the early stages of the COVID-19 pandemic, the rapid spread of severe acute respiratory syndrome coronavirus 2 via aerosolized particles as well as the high demand for and limited reusability of medical equipment led to a shortage of personal protective equipment (PPE) and compromised patient care and provider safety.[1,2]

INTERVENTION

An ad hoc group of stakeholders and volunteers came together to design, validate, manufacture, and distribute PPE for health care workers and first responders.

PLACE AND TIME

This Colorado-wide initiative began in March 2020 and was consolidated as Make4Covid. A digital community was created using Mighty Networks (Mighty Software, Palo Alto, CA) and Slack (Slack Technologies, San Francisco, CA) channels. Private donations from individuals, foundations, businesses, and state grants were accepted via the https://make4covid.co homepage. A total of $316 400 was used for raw materials and fabrication costs (61%); specialized design, testing, and prototyping services (30%); professional fees and services (8%); and gifts to volunteers (1%). Notably, the bulk of logistics and shipping were provided in-kind, warehouse spaces were donated, and additional materials were supplied in-kind by both individuals and organizations.

PERSON

After a core interdisciplinary group spearheaded the project, a broader coalition of more than 100 partner organizations bundled their efforts and connected through the make4covid.co Web site. As of this writing, this group has grown to more than 2200 volunteers (Figure 1).

PURPOSE

With the temporary closure of production facilities and the disruption of supply chains during the pandemic, these local efforts enabled the procurement of scarce supplies through creative problem solving, and philanthropic efforts served to offset costs for recipients.

IMPLEMENTATION

Sewing machines, 3-D printers, and laser cutters located across a network of more than 500 homes, small businesses, public schools, libraries, and university labs were used to produce face shields, cloth masks, and ear guards at scale. Designers and clinicians evaluated and

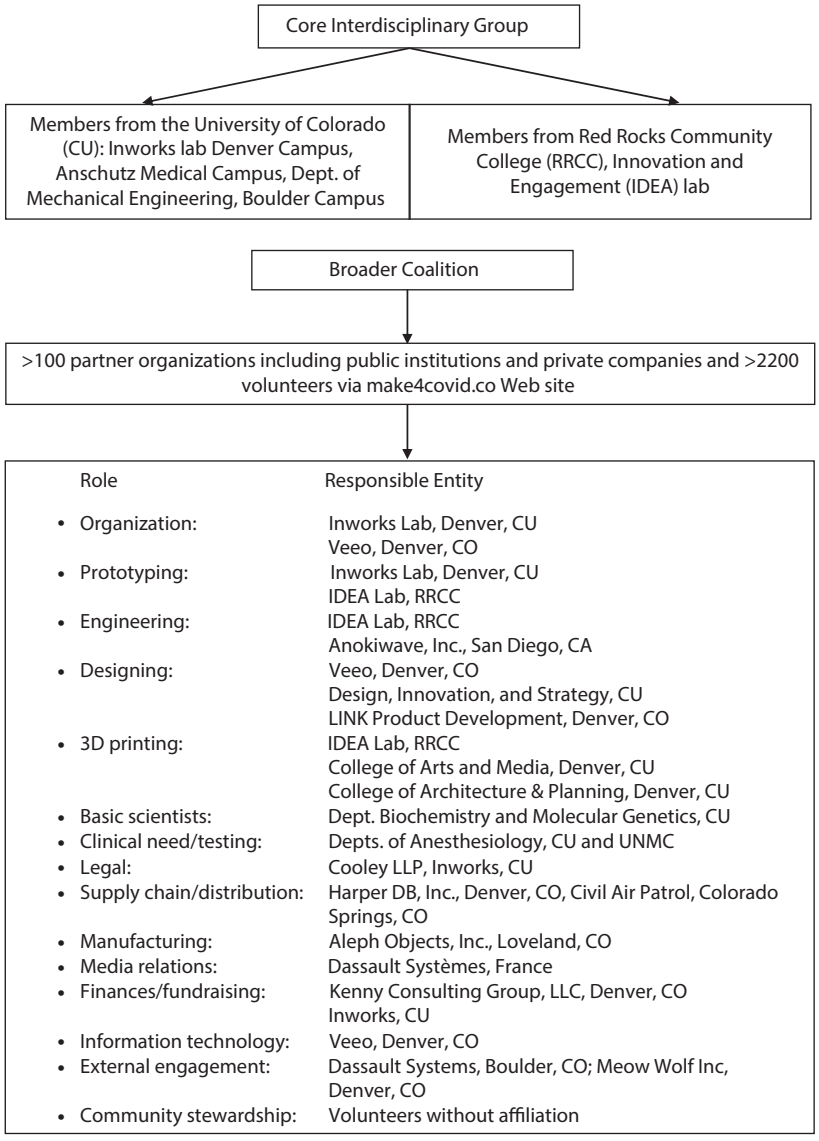

FIGURE 1— Key Stakeholders of Make4Covid.co, Which Designed, Validated, Manufactured, and Distributed Essential Equipment for Health Care Workers and First Responders in Hospitals, Nursing Homes, and Schools: United States, 2020

Note. LLC = limited liability company; LLP = limited liability partnership.

adapted open-source designs. Two experienced medical designers used an extended network of contacts available from the greater Make4Covid community to bring working prototypes on location and asked users targeted questions. Qualitative review with hospital staff included several prototypes across multiple products and involved fit tests across diverse staff to assess ergonomics, breathability, stability, and coverage. Novel or complex products, such as powered air-purifying respirators (PAPRs) and intubation shields, were brought on-site for mock procedures. Products were tested weekly or at critical points in the design and were revision controlled to ensure appropriate iterative changes. Qualified designs were published on a "Start Making" page for distributed production. Once approved, legal counsel for adherence to emergency use authorizations was sought. This process continued after publication, and meaningful revisions to designs were made over time following similar mechanics. In addition to qualitative analysis and codevelopment with clinicians, products were tested quantitatively whenever feasible.

Strict sanitation guidelines were followed in all participating locations.

Because many of the makers did not have a background in sanitation, guidelines included redundant sanitation methods through commonly available cleaning products (e.g., rubbing alcohol) at each step in the distribution chain. In addition, in-person contact was kept to a minimum, and, when unavoidable, Centers for Disease Control and Prevention guidelines were followed to prevent transmission between volunteers.

A network of volunteers and nonprofit transport organizations packaged and delivered PPE to recipients. Collection points were established at partner locations, and a hub-and-spoke model was used to consolidate products at a central location. The State Emergency Operations Center supported the effort, allowing the Civil Air Patrol to provide logistical support for collection, quality control, and distribution. A group of skilled makers provided technical support through recurring video meetings and were instrumental in translating quality control feedback to the entire network. The same group provided agile, short production runs of customized face shields to meet specialized needs in dental and emergency medicine.

Additionally, intubation shields, novel mechanical ventilators, ventilator connectors, reusable N95 respirators, PAPR hoods, and filtered air pumps were designed and prototyped using a combination of the distributed manufacturing network and traditional manufacturing techniques such as injection molding.

Legal counsel specializing in medical products assisted in meeting Food and Drug Administration (FDA) emergency use authorizations and crafting usage waivers. Local medical device manufacturers assisted in material selection and clean room assembly of PAPRs and N95 prototypes. The N95 respirators were iteratively tested to the National Institute for Occupational Safety and Health (NIOSH) equivalent standards at the State of Colorado's emergency testing facility.

In preparation for an anticipated ventilator shortage, a novel ventilator prototype using industrial high-speed valve technology was pilot tested in a swine model.

EVALUATION

Facilities in desperate need of vital equipment were provided with 127 866 pieces of PPE (Table 1). This ensured the safety of patients, health care workers, teachers, and schoolchildren. A dashboard was publicly available at the Make4Covid Web page specifying the number of delivered PPE, volunteers, partners, and weeks in operation.

TABLE 1— Delivered Personal Protective Equipment (PPE) and Recipients of PPE Served by Make4Covid.co: United States, 2020

	No. or No. (%)
PPE deliveries	
Face masks	12 426
Adult size	7 839
Child size	4 587
Face shields[a]	91 687
Complete face shields	78 314
Replacement of clear shields	13 373
Upgrades	
Visors	1 428
Padding	574
Sewn back straps	6 178
Ear savers	23 773
Total[b]	127 886
PPE recipients	
Clinics, medical offices	84 (22)
Home care, assisted living, nursing homes, hospices	61 (16)
Dental practices	55 (14)
Hospitals, medical centers	47 (12)
Education, schools	27 (7)
First responders: police, corrections, fire, EMS	18 (5)
Government, emergency response, health departments	19 (5)
Community organizations, underserved areas	26 (7)
Native American aid	3 (1)
Essential workers	43 (11)
Total	383

Note. EMS = emergency medical services.

[a]The total number of face shields delivered includes complete face shields and replacement of clear shields but excludes upgrades for face shields.
[b]Total number of PPE components delivered includes face masks, face shields, and ear savers but excludes upgrades for face shields.

ADVERSE EFFECTS

Before taking advantage of these resources, health care entities had to account for several issues. For example, demand for PPE needed to be anticipated. Second, products procured through nonstandard sources needed to be assessed for compliance with applicable regulatory policies.[3] A particular challenge was procuring filter media that met NIOSH standards consistently. This material requires specialized machinery and technical knowledge to create, putting it outside the network's fabrication capabilities. Despite multiple accepted purchase orders with reliable manufacturers of N95 media, governmental authority overrode each attempt. Attempts to validate filter media from two new domestic manufacturers identified unacceptable variations of filter performance. Although the products met many of the levels of protection required, the lack of reliable filter media prevented N95 respirators and PAPR pumps from meeting all requirements under the prevailing emergency use authorizations and NIOSH standards. Prototypes of novel mechanical ventilators have been tested on test lungs and animal models but would require clinical trials and FDA emergency use authorization if ventilators became scarce. Another logistic issue involved distributing equipment to more rural areas in need, which made the operation highly dependent on nonprofit aviation organizations such as Angel Flight West and Civil Air Patrol.

SUSTAINABILITY

Novel local production infrastructure developed during the COVID-19 pandemic could be used for health care emergencies in the future when complex supply chains collapse and national response programs are overwhelmed.[4] Laser cutting and 3-D printing, also known as additive manufacturing, proved to be innovative production solutions for medical equipment made from commonly available materials and could, therefore, be used in upcoming health care challenges. Out of necessity, institutional and private manufacturers created alternate approaches to conventional mechanical ventilation methods during this pandemic, such as supplies enabling ventilatory splitting or designing alternative ventilators.[3] Although mostly tested in experimental settings, these emerging techniques could become crucial for future pandemics caused by airborne pathogens.[5] Lastly, the production of reusable instead of disposable parts, which can then be sanitized chemically or sterilized by ultraviolet radiation,[1,3,6,7] is currently being tested by organizations such as Make4Covid and could become a more sustainable solution to depleted inventories of medical equipment and for environmental protection.

PUBLIC HEALTH SIGNIFICANCE

Volunteer-driven programs similar to Make4Covid.co have been essential for the health care community on state and national levels.[3,6] There is no question that without these efforts, many more health care providers and patients would have been infected and could have died. AJPH

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because no human participants were involved in this report.

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