

DESIGN | MAKE | PROTECT

A report on the open source maker and manufacturer response to the COVID-19 PPE crisis

Introduction





DESIGN | MAKE | PROTECT

- Open Source Medical Supplies & Nation of Makers teamed up to measure and report on the open source emergency maker response to COVID-19-induced medical supply shortages.
- Our goal is to spread this information and these best practices far and wide, and educate policymakers around the country about how best to coordinate and sustain their grassroots maker efforts.



Open Source Medical Supplies



- Founded on March 10, 2020 to help makers fight COVID-19
- Began as an open source ventilator project on Facebook
- Pivoted to become the "Open Source COVID-19 Medical Supplies"
 Group, and an effort to empower makers around the world with the info they needed to make supplies locally
- Became a 501(c)3 non-profit project hosted by RESOLVE and funded by Schmidt Futures, the Patrick J. McGovern Foundation, Toyota Research Institute, and private donors



Nation of Makers





- 501(c)3 non-profit organization, fiscally-sponsored by Strong City Baltimore
- Provided regular information updates, access to resources, PPE production funding, and calls to action via its network throughout the COVID-19 pandemic
- Co-producer of the weekly "Plan C" community show with Make:
 Community



Highlights







42,000+ Citizen Responders



1,878+
Individuals & Groups Tracked



86

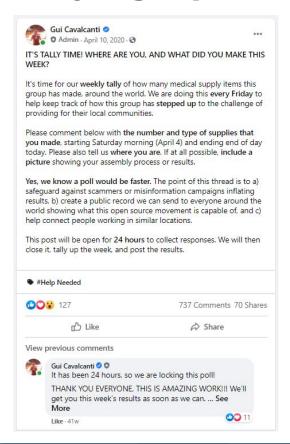
Countries with Local Response Efforts



93% Volunteers



Tallying Open Source Maker Production





Community Impact Survey

Are you reporting for an organization or for your own individual efforts? * I am reporting data for my entire group or organization I am part of a group but only reporting my personal data I am an individual maker reporting my personal data We are collecting data from both active and inactive groups. Are you currently producing PPE or medical supplies? * Organization's Facebook page or group URL: If different than above website link





Outline

- The Problem
 - The Causes
- The Citizen Maker Response
 - Who Produced Supplies
 - Critical Resources for Design and Production
- The Impact of the Response
- The Problem, Evolved
- Opportunities for Policy Reform



The Problem



PPE Shortages During a Pandemic



HHS clarifies US has about 1% of face masks needed for 'full-blown' coronavirus pandemic

PUBLISHED WED, MAR 4 2020-1:55 PM EST UPDATED WED, MAR 4 2020-3:12 PM EST



HARE **f** 🍠 in 🖹

KEY POINTS

 HHS clarified Wednesday that the U.S. has about 1%, not 10%, of the required respirator masks that would be needed if the COVID-19 outbreak were to erupt into a pandemic.

Source: CNBC

Prognosis

Hospital Workers Make Masks From Office Supplies Amid U.S. Shortage

'We're not getting new supplies and our stores are almost depleted.'

By Ben Elgin and John Tozzi

March 17, 2020, 8:17 PM PDT Updated on March 18, 2020, 5:45 AM PDT



Source: Bloomberg





Medical Supply Shortages During a Pandemic

IMPOSSIBLE CHOICE Only patients under 60 are getting ventilators in Italy as hospitals are overwhelmed by coronavrius crisis

Felix Allen

Mar 23 2020, 5:21 ET | Updated: Mar 23 2020, 10:02 ET





Practise social distancing



Self-isolate with cough or fever



Wash hands regularly

o 13

DOCTORS in coronavirus-ravaged northern Italy have been told to save ventilators for under-60s because of a desperate shortage, according to reports.

One medic said older patients are not being offered life-saving treatment as hospitals have been overwhelmed by thousands of critically ill sufferers.

Source: The Sun

A plea from doctors in Italy: To avoid Covid-19 disaster, treat more patients at home

By SHARON BEGLEY @sxbegle / MARCH 21, 2020

Reprints

"We are far beyond the tipping point," Nacoti and his colleagues write. With 70% of ICU beds reserved for critically ill Covid-19 patients, those beds are being allocated only to those "with a reasonable chance to survive," as physicians make wrenching triage choices to try to keep alive those who have a chance. "Older patients are not being resuscitated and die alone without appropriate palliative care, while the family is notified over the phone, often by a well-intentioned, exhausted, and emotionally depleted physician with no prior contact," they report.

Most nearby hospitals in the wealthy region are "nearing collapse while medications, mechanical ventilators, oxygen, and personal protective equipment are not available," the physicians write.

Other health care in northern Italy has come to a near-halt, they report: The system "struggles to deliver regular services, even pregnancy care and child delivery, while cemeteries are overwhelmed ... [V] accination programs are on standby."

Source: Stat News



New PPE Required To Protect Communities

CDC calls on Americans to wear masks to prevent COVID-19 spread

JAMA editorial reviews latest science, while case study shows masks prevented COVID spread

Press Release

For Immediate Release: Tuesday, July 14, 2020

Contact: Media Relations

(404) 639-3286

Americans are increasingly adopting the use of cloth face masks to slow the spread of COVID-19, and the latest science may convince even more to do so.

In an editorial published today in the Journal of the American Medical Association (JAMA), CDC reviewed the latest science and affirms that cloth face coverings are a critical tool in the fight against COVID-19 that could reduce the spread of the disease, particularly when used universally within communities. There is increasing evidence that cloth face coverings help prevent people who have COVID-19 from spreading the virus to others.

"We are not defenseless against COVID-19," said CDC Director Dr. Robert R. Redfield. "Cloth face coverings are one of the most powerful weapons we have to slow and stop the spread of the virus – particularly when used universally within a community setting. All Americans have a responsibility to protect themselves, their families, and their communities."

This review included two case studies out today, one from JAMA, showing that adherence to universal masking policies reduced SARS-CoV-2 transmission within a Boston hospital system, and one from CDC's Morbidity and Mortality Weekly Report (MMWR), showing that wearing a mask prevented the spread of infection from two hair stylists to their customers in Missouri.

Source: CDC



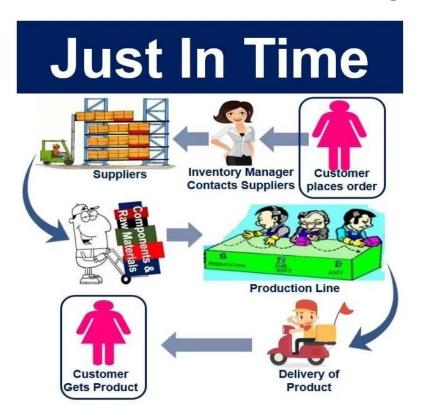


The Causes





Just-In-Time Inventory Management



"Most if not all of the medical products or protective-device companies in this country are operating at almost full capacity. That's the reality of today's economy; just-in-time delivery with no surge capacity."

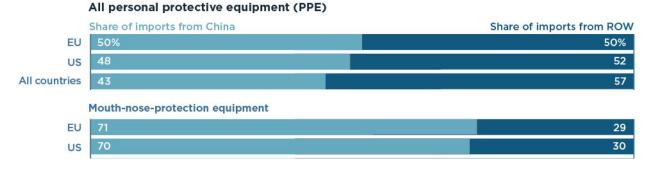
Michael Osterholm

Director of the Center for Infectious Disease Research & Policy Advisor on Biden Transition Team's COVID-19 Advisory Board

Source: Market Business News



Imported Medical Supplies



Source: Peterson Institute for International Economics

- 70% of the U.S.' mouth-nose PPE comes from China
- 48% of the U.S.' PPE generally comes from China
- China quarantined 760 million people at the start of COVID-19, shutting down all manufacturing right as exponential demand began



China & COVID-19

- January 11th, 2020:
 - China records its first death from COVID-19
- January 21st, 2020:
 - Virus detected in Japan,
 South Korea, and the U.S.
- February 15th, 2020:
 - China locks down over half of its own population and shutters factories

Half the Population of China, 760 Million, Now Locked Down



Volunteers disinfecting a housing complex in Taizhou, a city in China's Zhejiang Province that has had many coronavirus infections



Price Surges & Unavailability

	90-day supply (per million workers)	Unit price			Cost \$ million (per million workers)		
		Non- Pandemic	Pandemic	% Markup	Non- Pandemic	Pandemic	Savings
N95	14,050,662	\$1.27	\$5.90	465%	\$17.80	\$82.90	\$65.10
Surgical masks	18,101,324	\$0.05	\$0.55	1100%	\$1.40	\$15.50	\$14.10
Face shields	14,050,662	\$0.50	\$4.50	900%	\$7.00	\$63.20	\$56.20
Gowns	28,101,324	\$0.50	\$5.00	1000%	\$14.80	\$147.90	\$133.20
Shoe covers	28,101,324	\$0.11	\$0.12	109%	\$3.10	\$3.40	\$0.30
Exam glove pairs	126,455,958	\$0.04	\$0.12	300%	\$5.10	\$15.20	\$10.10

Source: <u>UC Berkeley Labor Center</u>





Price Surges & Unavailability

Abraar Karan ② @AbraarKaran · 2h Replying to **@**AbraarKaran

2/ "Steve Francis, a special agent in an investigatory division of the D.H.S., told me that the illicit P.P.E. market was so profitable that some transnational criminal organizations turned from smuggling humans and narcotics to moving masks."

Wow. #Covid19 #BetterMasks

Q

1 33

 \bigcirc

59

~

Source: New York Times

Logistics Failures

- Ocean shipping is now 400% more expensive than pre-pandemic levels
- Ocean containers and berths are sold out for months
- 75% of containers heading back to China are empty
- 50% of air freight flies on airlines; commercial flights dropped by as much as 90%



Airlines transporting cargo in empty seats (Freight Lines)



Multi-day-long line of tractor trailers at Pudong Airport (Freight Lines)





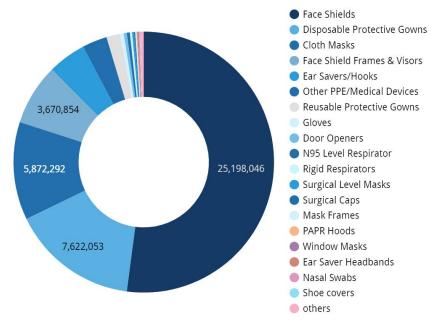
The Citizen Maker Response



Citizen Maker Response Overview

- 48.3 million units of supplies
- Market value of \$271M
- 52% face shields
- 16% isolation gowns
- 12% cloth masks
- Developed an entire medical design ecosystem, from masks, to gowns, to PAPRs, to ventilators, as communities needed new supplies

Maker Supply Production Breakdown

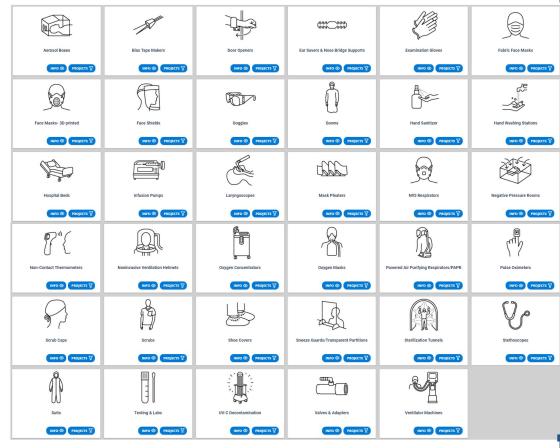


Source: OSMS and NoM Community Impact Survey data



Global Maker Design

- Hundreds of individual designs across dozens of supply categories
- Designed for processes ranging from scissors to injection molding
- Many new types of medical supplies, distributed manufacturing infrastructure, and PPE invented for the COVID-19 pandemic

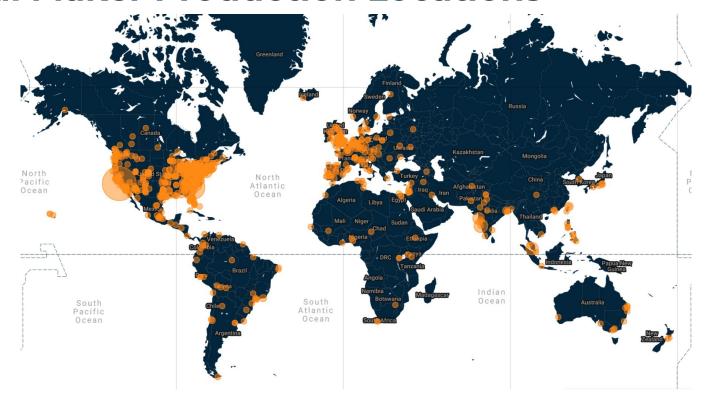


Source: Open Source Medical Supplies Project Library





Global Maker Production Locations



At least 42,000 people working in 86 countries

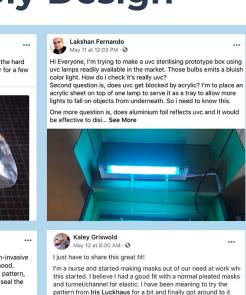




Realtime Open Source Medical Supply Design

- Large open source design forums featured 10,000 to 74,000 people working together to rapidly collaboratively design medical supplies
- OSCMS, Helpful Engineering, JOGL, ViralResponse, Prusa, NoM and others served as centralized focal points







tonight. I'll admit it was intimidating for a decent but novice sewer

reality, it was not hard at all with the steps broken down in the link

and only minor adjustments to wha... See More

Global Design Iteration







Prusa RC1Developed by Josef Prusa for the

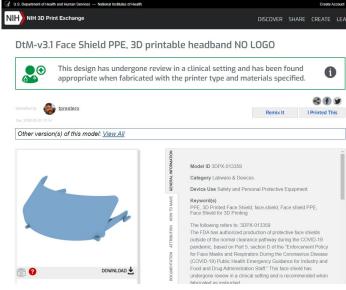
Czech Ministry of Health

March 16, 2020

DtM Shield, Derivative of the RC1

Developed by Tim Prestero of Design That Matters for the University of Washington Harborview Medical Center

March 19, 2020



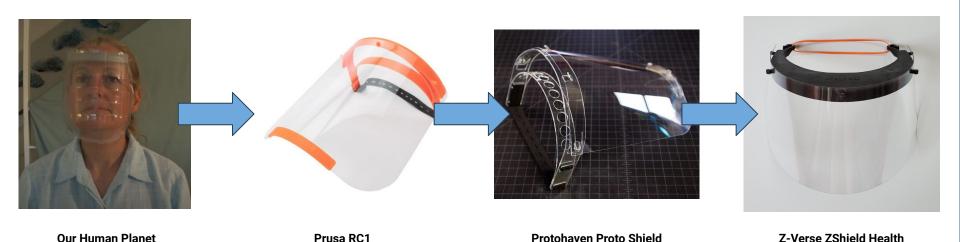
Listed on the NIH 3D-Print Exchange as appropriate for clinical settings

March 28, 2020



Design for Manufacturing

3D-Printed Face Shield



Laser Cut Face Shield

2-Liter Bottle Face Shield



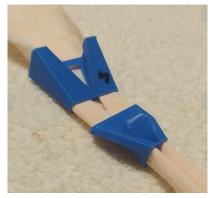
Injection Molded Face Shield

Novel Supply Designs



Ear Savers To Reduce Chafing From Masks





Mask Pleaters and Tape Folders To Increase Sewist Productivity



Intubation Boxes To Contain Aerosolized Virus





Medical Evaluation & Collaboration

- Clinicians participated in design processes like never before
 - Called makers to action to design and produce supplies
 - Formed partnerships between makers and hospitals
 - Developed new supplies themselves
 - Tested custom medical supplies for efficacy, and sometimes publicly supported certain designs
 - Provided demand data to makers



Government Participation

- FDA proved helpful and nimble for a government agency
 - Approved Emergency Use Authorizations for certain products (like face shields and intubation boxes) which helped alleviate liability concerns
- NIH hosted supply designs informally
 - Clinically reviewed designs in the NIH Print Exchange helped create trust in the maker movement broadly
- Some local and state governments worked directly with their maker movements to support them



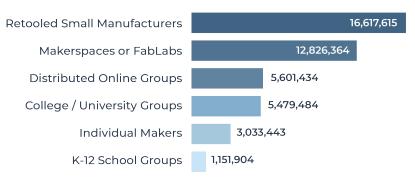
Who Produced Supplies



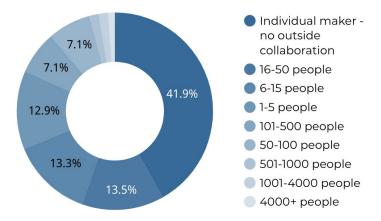
Types of Makers

- Retooled Manufacturers: 42%
- Makerspaces or Fab Labs: 22%
- Distributed online groups: 8.5%
- Universities & Colleges: 8.1%
- Individual Makers: 3.4%
- K-12 Schools: 1.2%
- 81.6% of responding groups had fewer than 50 people

Total Production by Maker Organization Type



Size of Organizations That Responded



Source: OSMS and NoM Community Impact Survey data



Retooled Manufacturers

- Small-to-medium-size manufacturers produced more supplies than any other maker category by:
 - Sharing high-volume medical supply designs early
 - Making tooling for high volume manufacturing equipment and refocusing production staff
 - Forming manufacturing partnerships
 with healthcare
- Notable examples include Kaas Tailored,
 Daniels Wood Land, Budmen, Z-Verse and others



JBC Technologies Producing Die-Cut Face Shields



Makerspaces

- Makerspaces played a pivotal role in the Citizen Maker Response by:
 - Being design hubs that could prototype supplies for healthcare institutions
 - Being manufacturing hubs capable of high volumes with existing equipment
 - Being distribution hubs for new supplies
 - Having memberships predisposed to both volunteerism and manufacturing
- Notable examples include Artisan's Asylum,
 Maker Nexus, MakerLab, Makelt Labs, Open
 Works and others



Artisan's Asylum Volunteers Making Isolation Gowns



Open Works Volunteers Assembling Face Shields





Distributed Manufacturing Groups

- New distributed online networks of fabricators produced significant quantities of supplies by:
 - Centralizing design decisions, coordination, and demand for supplies while distributing fabrication responsibilities
 - Aggregating enough manufacturing equipment via sheer volume of volunteers
- Notable examples include the M19
 Collective, Z-Verse, Illinois PPE Network,
 JOANN, Something Labs, and others



The M19 Makerspace Collective Producing Over 1M Face Shields



Individual Makers

- Individual makers were well-positioned to help their communities by:
 - Being responsive to the needs of healthcare workers, while sharing refined designs for those needs
 - Producing large numbers of helpful, simple supplies for communities
 - Remaining agile and being able to produce supplies for new communities quickly
- Notable examples include Dave O'Meara,
 Nicole Angell, Nick Franklin, and many
 others around the globe



Nicole Angell Sewing 2,350 Cloth Masks



Colleges & Universities

- Colleges and Universities were uniquely positioned to help the response by:
 - Having both makerspaces and hospitals on-campus or in-network
 - Having experienced faculty and staff that could cross departments
 - Being familiar with open source ethos, the need for testing, and production requirements
 - Having trained students on-hand
- Notable examples include the University of Wisconsin-Madison, Case Western Reserve University, and Modesto Jr. College



University of Wisconsin-Madison Makerspace's Badger Shield

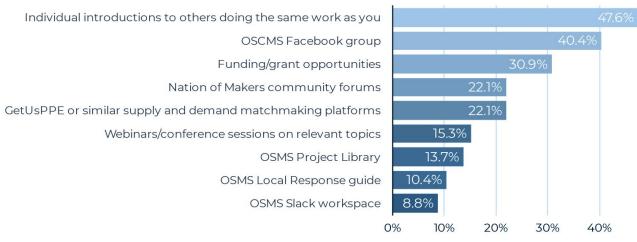


Critical Resources for Design and Production



Digital Resources

Breakdown of What Digital Resources Were Helpful to Makers



Source: OSMS and NoM Community Impact Survey data

 Makers valued introductions and networking to others doing similar work the most, whether individually or in specific forums Only 30.9% reported that funding and grant opportunities were helpful



Manufacturing Resources

- All makers had access to some form of fabrication equipment
- Most makers had access to a rapid prototyping toolset - 3D printing, sewing and laser cutting
- As the pandemic wore on, makers shifted to higher productivity processes that required investment in tooling

Manufacturing Equipment Utilized by U.S. Citizen's Maker Response

Manufacturing Process	% of U.S. Respondents Using Process
3D Printing	64.1%
Sewing	53.8%
Laser Cutting	37.6%
Die Cutting	10.6%
Vacuum Molding	9.3%
Injection Molding	6.6%
Die Casting	1.8%

Source: OSMS and NoM Community Impact Survey data



Funding & Donations

- Roughly half of makers had materials donated, and one third of makers were paid for supplies
- Most makers utilized their own money or networks to pay for supplies they were making
- Only 2.8% of makers received money from the government, though 24% reported creating partnerships with government
- 93% volunteer labor created \$271M
 worth of market value

Financial & Material Support For Maker Groups

	Support Type	% of Respondents
	Support Type	% of Respondents
	Materials Donations	47.8%
	Payment for Supplies	29.4%
	Crowdfunding Campaigns	23.8%
Ir	ndividual Donor or Foundation Grants	20.2%
,	Corporate Sponsorship	7.2%
	Government Funding	2.8%

Source: OSMS and NoM Community Impact Survey data



Funding & Donations

- Funding and support came from donors and corporate sponsorships
 - Get Us PPE created multiple maker-focused Grants to spur maker production of PPE such as hospital gowns and deliver to places in need
 - Coca Cola donated 100 metric tonnes of PETG plastic sheets for face shield production by makers
 - 3D print filament suppliers like
 MatterHackers and Keene Village
 Plastics donated material for PPE
 - Industrial suppliers like McMaster-Carr donated prototyping supplies



Source: GetUsPPE

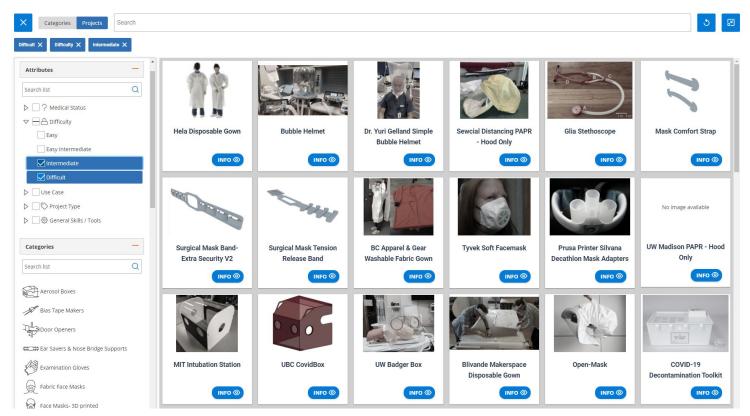


Source: The Coca Cola Company - "Face Shields to the Front Lines"





Design Repositories



Source: Open Source Medical Supplies Project Library

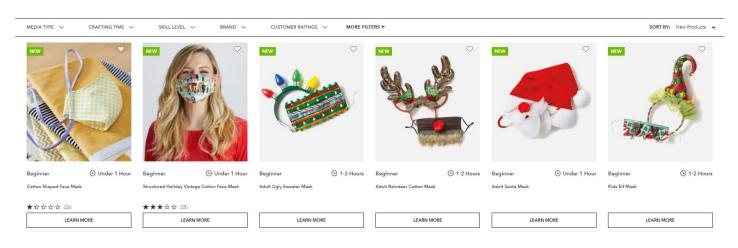




Design Repositories



face masks & coverings (146)



Source: JOANN Pattern Library





Design Repositories











Tracking and Mapping the Response

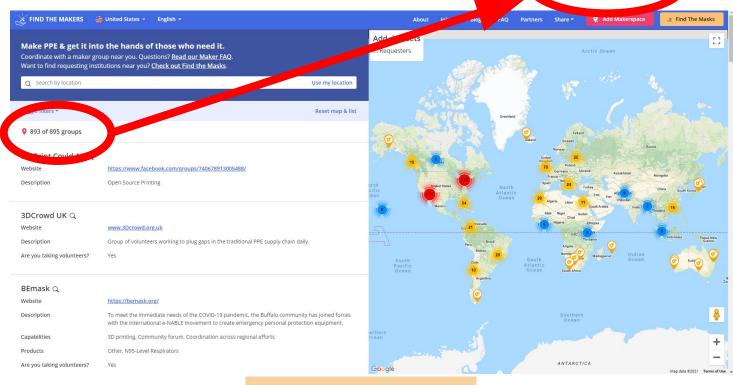
895 Groups

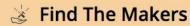






















Coalitions & National Organizations





Coalitions & National Organizations



OSMS

MAKER'S[™] ASYLUM

M-19 INITIATIVE











International COVID-19
Local Manufacturing
Information Network
(ICLMI)





The Impact of the Response







Source: Sean Zachary/OSMS British Columbia



Source: Ramses Galaz/GSE Biomedical



Source: Something Labs



Source: Ryan Finnigan/MakerLab



Source: Kevin Pineda/OSMS North Jersey



Source: David Rainosek





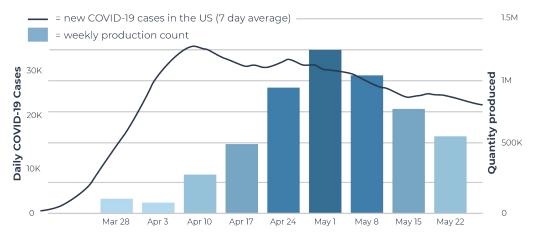
Where Makers Distributed Supplies

Distribution Locations		% of Respondents
1	Hospitals	76%
2	Individual medical professionals	72%
3	Senior housing/healthcare facilities	57%
4	Other medical clinics	54%
5	Non-profit/social service agencies serving low-income populations	50%
6	Miscellaneous essential workers	49%
7	Schools	46%
8	First responders	41%
9	Other	30%

Source: OSMS and NoM Community Impact Survey Data

Speed of Response

U.S. Maker Productivity vs. New U.S. COVID Case Rates, April-May 2020



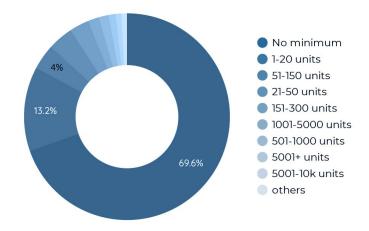
Source: OSMS Weekly Tally Data, 91-DIVOC

- Makers ramped production up within weeks of cases arriving in their region,
 while inventing supply designs from scratch
- 3M's production of N95 masks grew **42% in 16 weeks** from March to July, while maker output grew **653% in 5 weeks** of tallying a **50X faster growth rate**



Minimum Order Quantities

- As commercial manufacturers recovered, they could initially only service bulk orders from large institutions.
- Schools, secondary care facilities, homeless shelters, and the like could only place small orders.
- 92% of maker responders reported being able to fill orders smaller than 150 units.



Source: OSMS and NoM Community Impact Survey Data



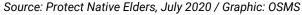
Helping Under-Resourced Communities

 Makers often specifically targeted under-resourced groups like Native Americans, low-income rural areas, and institutions like homeless shelters for direct support





Source: Raelynn Cachini



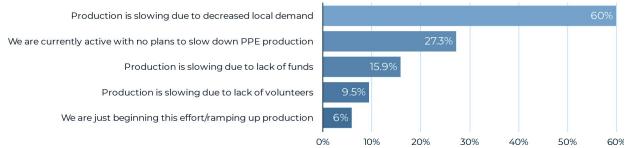
The Problem, Evolved



Status of Maker Responders - "Active"



Status of Active, Responding Maker Groups (Fall 2020)



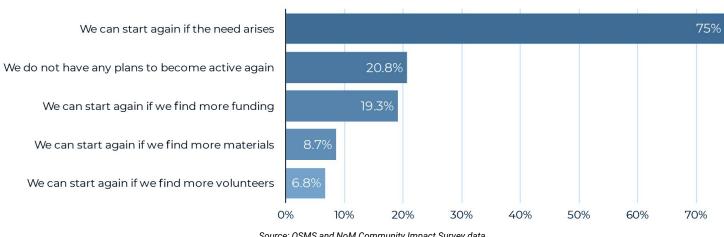
Source: OSMS and NoM Community Impact Survey data

- Starting in late May 2020, makers reported producing less because they're disconnected from demand, even though demand from small institutions is still strong.
- About 1/4 of still active groups were lacking funds or volunteers to keep up peak activity.



Status of Maker Responders - "Inactive"

Status of Inactive Maker Groups Regarding Future Production (Fall 2020)



- Source: OSMS and NoM Community Impact Survey data
- The majority of groups that stopped production felt that the local need was fulfilled, but are willing to start again when called upon.
- About 20% were lacking funding to continue; 9% materials; 7% volunteers



Continuing Demand

DEMAND

87,000,000+

pieces of PPE requested to fill need for just ONE WEEK

6,500,000+

pieces of PPE delivered to frontline workers by Get Us PPE

Top 3 most requested PPE items







PPE supply remaining data indicates urgent need



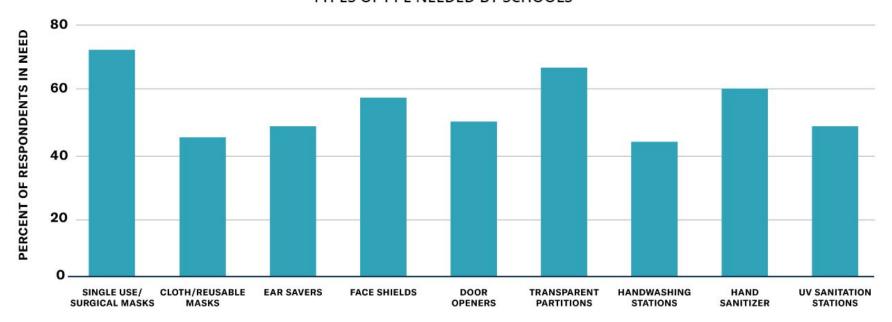
Source: Get Us PPE December Shortage Index





Continuing Demand

TYPES OF PPE NEEDED BY SCHOOLS



Source: Get Us PPE December Shortage Index



Opportunities for Policy Reform





"Now that we know that makerspaces can fill such a vital role... we need lawmakers to invest funds towards organizing these efforts and making sure they have the materials and support needed to ramp production back up when needed."

— Craig Farrington, Factory Two, Flint, MI



U.S. Government Involvement

- Direct U.S. Government involvement in the Citizen Maker Response was limited.
- 24% of U.S. based CIS respondents said they had created a new relationship with some government agency through their work.
- 2.8% received any government financial support (via grants or purchasing) for labor or supplies.

Two Key Questions

- 1. How can we build on the momentum of the Citizen Maker Response to COVID-19, creating structures that integrate makers into the U.S. domestic response to crisis, allowing makers respond to other critical challenges?
- 2. What specific policies and support—increased access to funding, raw materials, testing facilities, partnership with government entities—at the local, state, and federal level, can be developed to support and sustain the Citizen Maker Response?

Policy Recommendations



Formalize the Citizen Maker Response Network

- To plan for a greater national resilience and future disaster response, designers, prototypers, engineers, makers, local manufacturers and their facilities should be formalized, supported, funded, and leveraged as a distributed emergency innovation and manufacturing response network.
- Create a federally defined but state-activated network of facilities and volunteers—A U.S. Prototyping and Manufacturing Reserve (USPMR) or a "Maker Corps."

Fund and Incentivize the Citizen Maker Response

- Grant and capital improvement opportunities—especially for makerspaces, the central infrastructure of the Citizen Maker Response—are critical towards ensuring their capacity to respond in the future.
- Provide access to a federally-funded / local-match revolving, forgivable loan funds, and/or New Markets Tax Credits that offer resources for facility capital improvements and capacity building.
- Build channels for communication and compensation between Citizen Makers (individuals and groups) and city and state emergency response agencies.

Create a U.S. Digital Stockpile

- Create of a comprehensive library of open source medical supply "blueprints" — the U.S. Digital Stockpile - a repository of disaster response designs.
- The U.S. Digital Stockpile should be manufacturing-agnostic, involve a diversity of federal agencies and manufacturing institutes, include designs for low-resource environments, offer plain-language user guidance, and provide complete manufacturing requirements and testing guidance.

Increase Opportunities for Crowdsourced Citizen Maker Innovation

- Expand Challenge programs, as well as an expansion of other mechanisms such as hackathons for individual knowledge bearers to transfer innovation expertise to both private and public sectors.
- An additional mechanism to harness crowdsourced innovation could occur via a federal Maker-in-Residence Fellowship program, placing innovators into temporary positions within the federal, state or local government.

Streamline Pathways with Regulators and Testing Facilities for Open Source Designs

- The FDA should include dedicated staff to develop approval pathways for open source supplies and devices, and provide advance coordination of Emergency Use Authorizations aligned with Digital Stockpile designs and USPMR facilities.
- Incorporated into the new regulatory pathway involving the FDA and a USPMR should be the expectation that all testing facilities establish validation protocols and calibration tools for substantial testing equivalency, independent of geographic location.
- Additionally, a map of certified testing facilities, both independent and university-based, should be maintained as a resource in the Digital Stockpile.

Ensure Access to Raw Materials for PPE Production

 Domestic PPE raw material manufacturers should be identified and federally contracted (similar to the SBA bidding contract system) to constantly have a specified inventory available within a certain time frame.



Reduce the Burden of Liability

- Clarify the liability landscape for both medical institutions and the Citizen Maker Response at the beginning of the crisis.
- Utilize issuances such as the the Public Readiness and Emergency Preparedness (PREP) Act, which provides immunity from liability for claims of loss from countermeasures to diseases threats and conditions and covers entities and individuals involved in the development, manufacturing and distribution of such countermeasures.
- Use plain language guidance to increase awareness of policies that reduce the burden of liability on the Citizen Maker Response.

Facilitate New Distribution & Delivery Pipelines

 Create and incentivize new supply aggregators and distribution pipelines for domestic surge manufacturing.

Guarantee and Support a Domestic Market

- To increase national resilience to medical supply chain disruption, the U.S. Government must offer market subsidies and/or longer-term contracts to domestic manufacturers of PPE to ensure availability of high-quality and sufficient supply in pandemics and emergencies.
- Require all PPE for the Strategic National Stockpile be domestically manufactured.
- Promote a culture of willingness to pay more to fairly compensate for American labor.



Parting Thoughts





Thank You

We would have had nothing to write about without the willingness of individual responders to take the time to share their stories with us, and if makers and health care workers hadn't chosen to step up and take initiative when the pandemic began. **Thank you.**



Contact Information

Open Source Medical Supplies (OSMS)

- http://www.opensourcemedicalsupplies.org
- info@opensourcemedicalsupplies.org

Nation of Makers (NoM)

- http://www.nationofmakers.us
- info@nationofmakers.us

