LAWRENCE
LIVERMORE
NATIONAL
LABORATORY

LLNL-TR-811868

Domestic Supply Chain of Medical Consumables Needed During COVID-19 Pandemic

E. S. Elton, E. B. Duoss, A. C. Tooker, C. M. Spadaccini

June 23, 2020

Disclaimer

This work performed under the auspices of the U.S. Department of Energy by Lawrence Livermore National Laboratory under Contract DE-AC52-07NA27344.

Lawrence Livermore National Laboratory

Domestic Supply Chain of Medical Consumables Needed During COVID-19 Pandemic

June 20, 2020

Eric Elton (Elton2@llnl.gov)
Eric Duoss (Duoss1@llnl.gov)
Angela Tooker (Tooker1@llnl.gov)
Chris Spadicinni (Spadicinni2@llnl.gov)
Lawrence Livermore National Lab

Report Prepared By:
Eric Elton

Disclaimer

Lawrence Livermore National Laboratory is operated by Lawrence Livermore National Security, LLC, for the U.S. Department of Energy, National Nuclear Security Administration under Contract DE-AC52-07NA27344.
LLNL-TR-811868

Overview

This report is an assessment of the availability, demand, and production capability of medical consumables needed to combat the COVID-19 pandemic. We focus here on the ability of the supply chain to increase production to meet demand during peak pandemic conditions. In addition, we report on domestic production efforts and supply chain issues, as well as the propensity of other countries to limit export of needed medical supplies to the United States.

In brief, the domestic supply chain and production capability vary greatly depending on the consumable. Some consumables, such as N95 masks or face shields, can likely be nearly fully supplied by domestic production, while other consumables, such as gloves or surgical masks, have little domestic production and thus will depend on imports to meet demand.

The assessment pulls primarily from published news sources and company press releases. As such, the demand and production numbers are not precisely known, and some degree of uncertainty exists in them. The total production capability is also often difficult to ascertain from these reports especially as other industries have begun to supplement existing supply chains. In addition, local conditions (including company financial decisions, local public health issues, and political aspects) can vary throughout the pandemic which will affect future production.

The report also pulls from estimates of demand and domestic production of some consumables compiled by the White House COVID-19 Supply Chain Taskforce (SCTF) presented by Rear Admiral John Polowczyk before a June 9, 2020 hearing of the Senate Homeland Security and Governmental Affairs Committee [1]. These numbers, where applicable, are likely to be more accurate than those found in public news sources since they are more directly tied to private companies' actual orders and actual production estimates, as opposed to publicly released estimates.

Finally, we note that other issues with the supply chain, including the production of raw materials, increase demand due to industries that have not previously used PPE now using it, and increased domestic production from non-traditional suppliers, make complete picture of a rapidly changing supply chain difficult to obtain. This report attempts to produce an accurate image of the supply and estimated demand, as understood by the authors who are not experts in the medical supply chain.

Assessment of Specific Medical Consumables Supply Chain and Domestic Production

N95 Masks

- Domestic production is increasing to nearly meet estimated demand by October
- International production is also up but may be limited by quality concerns

N95 masks are crucial to the protection of medical workers as they eliminate 95% of all particulate from the air. N95 masks are typically made from melt blown polypropylene which is then shaped with support materials into the masks. Masks must be manufactured in sanitary condition and meet

FDA approvals for medical use. The total demand for N95 masks is estimated at 160M masks/month in April.[1]

Domestic production of N95 masks is led by 3M Corporation, which produced ~30 million masks/month at its plant in Aberdeen, South Dakota. At the onset of the pandemic, 3M began to increase production, and is expected to triple production to ~96M masks/month by the end of the year [2,3]. The SCTF projects that total domestic production will total 140M masks/month by October. Combined with imports from the 3M production facilities in China, and efforts to reuse masks being led by Battelle, a total of 180M masks/month would be available [1].

International production of masks is also increasing, most notably in China. Although production is up, the strict standards for mask production are not always met and inferior product has been delivered. The rapid increase in demand and production makes verifying the mask quality and production conditions difficult or impossible [4,5] , as evidenced in early May by the FDA revoking the authorization of 72 of 86 masks producers in China for making inferior masks [6]. Along with increase demand, increase costs also occur [5,7].

Finally, the production of raw materials to make masks is a potential bottleneck that should be explored further. Mask producers in China have reported that they are having difficulty obtaining melt blown polypropylene [8]. It is unclear what the domestic production capability for melt blown polypropylene is, but a lack of raw materials would destabilize the supply chain.

Gowns

- Domestic production is not expected to be able to meet demand.
- Introduction of reusable gowns, if accepted by health care workers, could ease demand.

Gowns are worn to prevent aerosols and other droplets for landing on medical worker's clothing where the virus can be carried to other areas. Gowns must be watertight and fit tightly around the wrists and waist. They are typically single use items.

Domestic production of medical gowns is expected to reach 20M gowns/month by July [1]. As facilities to produce gowns are limited, domestic production may not increase much beyond that. For context, the total demand for gowns was almost 200M in April and is expected to remain similar through July. Hospital usage accounts for nearly 50% of the total demand [1].

The shortage of gowns has led the CDC to recommend moving to cloth gowns that could be laundered and reused [9]. Domestic production of these new type of gowns is not known, but it would be easier to ramp up than disposable plastic gowns due to a variety of raw material available. The SCTF predicts that with reusable gowns in use, the total demand for gowns will be able to be met in July [1], although the willingness and ability of health care systems to implement reusable gowns is unknown.

Gloves

- Nearly all gloves are made in Malaysia, which has limited production due to public health concerns
- Virtually no domestic production is available

Latex or nitrile gloves are a crucial part of PPE for medical workers. Nearly 2/3rds of all rubber gloves made in the world are manufactured in Malaysia [10–12]. There is virtually no domestic production capability for nitrile or latex gloves in the United States [1].

Glove trade groups in Malaysia estimate that demand for nitrile gloves is up by approximately 15% [10]. For public health reasons, staff in Malaysian factories have been limited to 50% of normal numbers, leading to reduced production [11,12]. Since there is no domestic production capability, the State Department leaned on Malaysian authorities to open factories and restore shipments [13].

Total demand for gloves is estimated to be 10B pairs/month in March, and to remain between 9B and 10B pairs/month through the summer [1]. Hospital demand accounts for approximately ½ of all demand. The big 6 distributers were able to meet the hospital demand for gloves through April, but fell short in May [1].

Face Shields

- Face shields are the easiest PPE to make, and can be easily reused if needed
- Non-traditional suppliers can likely work together to supply domestic demand

Face shields protect medical workers from large droplets expelled by patients. Demand for face shields increased nearly 8x to 8M shields/month in March. Notably, the big six distributors were able to meet demand through May [1]. Traditional domestic production capability has increased to about 1M shields/month.

Face shields are relatively easy to design and assemble but do require FDA or CDC approval for use in medical environments, although the FDA is not objecting to use of non-certified shields currently [14]. Thus, while it is relatively easy for other manufactures to quickly adapt to producing face shields, they may be difficult to place into use [15]. The SCTF estimates that non-traditional suppliers (such as universities, other companies, or independent maker groups) will be able to adapt and produce 6M to 8M shields/month, meeting domestic demand [1].

As face shields can be reused [16], the total demand should decrease as the pandemic progresses.

Nasal Swabs and Test Kits

- Domestic production of swabs and test kits are up, and likely to meet expected testing demands
- Other testing components (reagents, machines, labor) are more difficult to access

The ability to test for COVID-19 is crucial to effectively battle the pandemic. Specially designed nasal swabs, consisting of a plastic swab on the end of a long, flexible stick, along with proprietary chemicals are needed for complete test kits.

Domestic production of nasal swabs is increasing, and the largest domestic producer, Puritan, expects of produce 8M swabs per week [17]. Thermo Fischer expects to produce 5M testing kits/week [18]. Currently between 3M and 4M tests are conducted per week in the United States, with that number expected to double by the fall [19]. Notably, the percent of tests that are positive remains below 5% for most states, suggesting that current testing is adequate (the World Health Organization recommends keeping the percent positive to less than 5% to ensure that the data can accurately track how many actual infections there are) [20]. This suggests that domestic production of nasal swabs will be sufficient through the end of the year.

The ability to conduct a test is also limited by the availability of reagents, testing machines and technicians. Since each test developed has proprietary regents, we could not determine the supply of reagents (other than the 5M test kits/week shipping from Thermo Fisher). Similarly, we could not ascertain the supply of the machines needed to run the tests (typically PCR machines), although we note that these machines are typically expensive and difficult to obtain with short lead times. Finally, the availability of testing technicians may also limit the ability of testing to be increased. We did not perform any assessment of any labor shortages related to testing capability.

Ventilators and Intubation Consumables

- Total ventilator count will increase to 200k by the end of the year
- Ventilator consumables are more difficult to track

Ventilators are, of course, not consumable and remain functional for a long period of time and many patients. However, since their shortage attracted significant attention during the early pandemic in the US, we make a note of their production and demand here. It is difficult to ascertain the total domestic production numbers of ventilators since so many small and non-traditional manufacturers have been added to the supply chain recently. In terms of total numbers, the national stockpile is on track to have 100,000 ventilators in the supply by mid-July, and 200,000 ventilators by the end of the year [21]. Worst-case scenario projections from early April indicated that the US may need 20,000 - 50,000 ventilators at peak use [22]. Thus, a supply of 200,000 should be more than sufficient.

While ventilators themselves may not be of concern, consumables needed for ventilation may be. This includes tubing and breathing circuits, valves, filters, and other items needed for ventilation. Due to the complexity of the system, we could not determine the production of these elements.

Pharmaceuticals Needed for Intubation

- Pharmaceuticals needed for ventilated patients are in short supply
- Difficult to increase supply since process is aging and needs strict oversight

Intubated patients must be sedated to keep them from removing the ventilation tube. Typically, pharmaceuticals for this purpose are given via IV bags made from liquid suspensions of the needed drug [23]. Since March, the FDA has listed 17 drugs commonly used for intubated patients on its list of drugs in shortages, mostly due to issues with manufacturing capability [24,25]. Notably, these drugs are made using ageing and complex manufacturing processes that are not easily increased. Similarly, starting another production line would require significant time and capital investment (about a year) [23]. Thus, it is unlikely that production will be able to increase to meet demand, and alternative forms of delivery or alternative drugs must be found [25].

Consumables Needed for Vaccine Deployment (needles, syringes, vials)

- Potential demand likely to be held in Strategic National Stockpile by the end of the year

Ideally a vaccine for COVID-19 will be developed and will need to be deployed rapidly. The Strategic National Stockpile is on track to have 400M to 700M of each of these consumables by the end of the year [26]. This would be enough to have a single set for the entire US population.

These numbers are roughly in line with what individual companies are reporting. For example, the Department of Health and Human Services signed contracts on May 1 for 320M syringes and needles [27]. Corning and SiO2, two leading glass vial makers in the United States, have also signed contracts for increased production of glass vials [28]. Notably, SiO2 says that their contract would require 120M vials per month to be produced by November. The government has also issued contracts to scale up production of pre-filled syringes, to be ready when a vaccine is viable [29].

Given the time needed for vaccine development, with proper planning it appears that these consumables will not be in high demand when a vaccine arrives.

Issues Surrounding Importing Medical Supplies into the US

In general, there has been little opposition to the movement of medical supplies between countries thus far in the COVID-19 pandemic. However, that does not mean future issues will not arise. We foresee several possibilities that may affect the availability of medical consumables in the United States. First, other countries may limit or shut down manufacturers due to public health concerns, as was done in Malaysia (with gloves [11]) and more broadly in China. The US would need to diversify the supply chain to avoid the shutdown of any one region exerting a large control on the total availability of medical consumables. Perhaps the most potent example is Malaysia, which supplies 66% of the world's rubber gloves.

Second, companies or countries could refuse to allow export of medical supplies. This could be accomplished through outright refusal to export, or through rapidly changing the requirements for export thus effectively limiting the ability of companies to export or import items. One example of this is China which has changed requirements for export of N95 masks and other supplies to ensure quality leading to delays in shipments to the US [30,31].

Finally, issues with transportation between countries, either through closed borders or limited transport options would also limit the import of medical consumables. One example of this is the need for the US to directly airlift supplies from Italy [32] and China [33] during March and April 2020.

Although not widespread, previous incidents suggest that some countries may limit exports through either of these pathways. Issues would need to be resolved through diplomatic channels and would likely take valuable time to resolve during a crisis. The impact of any country refusing to export supplies can be mitigated by diversifying production to other regions whenever possible.

References

[1] Polowczyk, John. *White House COVID-19 Supply Chain Task Force Report*. The report slides can be downloaded at: https://www.hassan.senate.gov/download/fema-ppe-and-supply-chain-document
[2] "How 3M Plans to Make More Than a Billion Masks By End of Year." *Bloomberg*, 25 Mar. 2020. https://www.bloomberg.com/news/features/2020-03-25/3m-doubled-production-of-n95-face-masks-to-fight-coronavirus
[3] "3M to Triple Monthly U.S. Production of N95 Masks to 96 Million." *Pioneer Press*, 8 May 2020. https://www.twincities.com/2020/05/07/3m-to-triple-monthly-u-s-production-of-n95-masks-to-96-million/
[4] "'It's Fraud': Con Artists Tap Booming Demand for China Medical Supplies." *South China Morning Post*, 20 May 2020. https://www.scmp.com/economy/china-economy/article/3085215/coronavirus-face-masks-ventilators-fake-certificates-pushed
[5] "Newsom Says 150 Million N95 Masks Will Arrive after BYD Earns Federal Approval." *Los Angeles Times*, 9 June 2020. https://www.latimes.com/california/story/2020-06-08/byd-earns-federal-approval-for-n95-masks
[6] "US Pulls Permission for Chinese Masks Found Defective." *AP NEWS*, 8 May 2020. https://apnews.com/d9150d44512a9a46edb671c031e2047b
[7] "3M Files Lawsuit Against Merchant Selling Masks on Amazon for 18 Times List Price." *Wall Street Journal*, 8 June 2020. https://www.wsj.com/articles/3m-files-lawsuit-against-merchant-selling-masks-on-amazon-for-18-times-list-price-11591642637
[8] "Masks, Gowns like 'Gold Dust' in China's Chaotic Markets as Supplies Run Low." *South China Morning Post*, 25 Apr. 2020. https://www.scmp.com/economy/china-economy/article/3081470/coronavirus-chinas-mask-gown-markets-chaos-shortages-vital
[9] "Coronavirus Disease 2019 (COVID-19) Infection Control Guidance." *Centers for Disease Control and Prevention*, 18 May 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
[10] "Top Supplier Malaysia Sees No Quick End to Shortages in $8 Billion Gloves Industry." *Reuters*, 4 June 2020. https://www.reuters.com/article/us-health-coronavirus-malaysia-gloves-idUSKBN23B105
[11] "Now The World's Hospitals Are Running Out of Vital Rubber Gloves." *Bloomberg*, 26 Mar. 2020. https://www.bloomberg.com/news/articles/2020-03-26/the-world-could-run-out-of-gloves-as-plants-curbed-in-lockdown
[12] "Coronavirus Healthcare Workers Need Medical Gloves but the World's Top Producers Have Cut Capacity." *Fortune*, 24 Mar. 2020. https://fortune.com/2020/03/24/coronavirus-healthcare-workers-medical-gloves/
[13] This fact was disclosed by Rear Admiral Polowczyk during the Senate Hearing on Procurement and Distribution Strategies in Response to Coronavirus Pandemic held by the Senate Homeland

Security and Governmental Affairs Committee. The approximate time in the video of the hearing is 1:50:00. The full video of the hearing and partial transcripts is available here: https://www.c-span.org/video/?472884-1/senate-hearing-procurement-distribution-strategies-response-coronavirus-pandemic

[14] "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)." *U.S. Food and Drug Administration*, 26 May 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health

[15] "Boston Partnership Leverages Local Manufacturing to Quickly Produce Reusable Face Shields." *EurekAlert! From AAAS*. https://eurekalert.org/pub_releases/2020-06/cp-bpl061820.php. Accessed 19 June 2020

[16] "Personal Protective Equipment (PPE) Directory and Guidelines." *Mount Sinai Health System*, 10 June 2020. https://www.mountsinai.org/files/MSHealth/Assets/HS/About/Coronavirus/MSHS-COVID-19-PPE-Practices.pdf

[17] "Maine Company to Double Production of Virus Testing Swabs." *AP NEWS*, 30 Apr. 2020. https://apnews.com/b199d0e370447f43bff5e3ae815b262e

[18] "Thermo Fisher to Produce Millions of Coronavirus Diagnostic Tests." *STAT*, 14 Mar. 2020. https://www.statnews.com/2020/03/14/thermo-fisher-to-produce-millions-of-coronavirus-diagnostic-tests/

[19] "US Historical Data." *The COVID Tracking Project*, https://covidtracking.com/data/us-daily. Accessed 18 June 2020

[20] "Track Testing Trends." *Johns Hopkins Coronavirus Resource Center*, https://coronavirus.jhu.edu/testing/tracker. Accessed 18 June 2020

[21] "Becoming 'King of Ventilators' May Result in Unexpected Glut." *AP NEWS*, 10 May 2020. https://apnews.com/e08621567fd8758c89b0c5aed5ac5d72

[22] See the estimates for ventilator usage on April 5, 2020, by the Institute for Health Metrics and Evaluation. Data can be downloaded here: http://www.healthdata.org/covid/data-downloads

[23] "Special Report: COVID Deepens the Other Opioid Crisis - a Shortage of Hospital Painkillers." *Reuters*, 9 June 2020. https://www.reuters.com/article/us-health-coronavirus-opioids-specialrep-idUSKBN23G1GM

[24] "FDA Data Shows Numerous Drugs in Shortage, Including a Leading Antidepressant." *USA TODAY*, 10 June 2020. https://www.usatoday.com/story/news/2020/06/10/coronavirus-and-fda-drug-shortage-list/5330491002/

[25] "FDA Moves to Ease Shortages of Drugs for Covid-19 Patients on Ventilators." *STAT*, 20 Apr. 2020. https://www.statnews.com/pharmalot/2020/04/20/fda-compound-pharmacies-covid19-coronavirus-drug-shortages/

[26] This quantity was disclosed by Rear Admiral Polowczyk during the Senate Hearing on Procurement and Distribution Strategies in Response to Coronavirus Pandemic held by the Senate Homeland Security and Governmental Affairs Committee. The approximate time in the video of the hearing is 43:00. The full video of the hearing and partial transcripts is available here: https://www.c-span.org/video/?472884-1/senate-hearing-procurement-distribution-strategies-response-coronavirus-pandemic

[27] "Pandemic's Next Medical Shortage? Vaccine Needles, Syringes." *Bloomberg Law*, 7 May 2020. https://news.bloomberglaw.com/health-law-and-business/pandemics-next-medical-shortage-vaccine-needles-syringes

[28] "Inside the US Government's $347 Million Plan to Fight the Global Glass Vial Shortage Ahead of a Coronavirus Vaccine Rollout." *Business Insider*, 22 June 2020. https://www.businessinsider.com/coronavirus-vaccine-glass-shortage-operation-warp-speed-corning-sio2-2020-6

[29] "Finding a Coronavirus Vaccine Is Hard. Getting It to People Is a Whole Other Problem." *CNN*, 12 June 2020. https://www.cnn.com/2020/06/11/business/vaccine-glass-vials-coronavirus/index.html

[30] "China Imposes More Checks on Mask Exports to Ensure Quality Control." *Reuters*, 10 Apr. 2020. https://www.reuters.com/article/us-health-coronavirus-china-masks-idUSKCN21S141
[31] "Millions of Masks and Coronavirus Test Kits Are Sitting in Warehouses and Can't Reach the US Because of New Chinese Policies." *Business Insider*, 18 Apr. 2020. https://www.businessinsider.com/millions-masks-coronavirus-tests-stuck-in-warehouses-chinese-export-restrictions-2020-4
[32] "HHS, DOD Coordinate International Airlift of COVID-19 Supplies." *HHS Press Release*, 20 Mar. 2020. https://www.hhs.gov/about/news/2020/03/20/hhs-dod-coordinate-international-airlift-of-covid-19-supplies.html
[33] "White House-Led Airlift of Urgently Needed Medical Supplies Arrives in New York." *Reuters*, 29 Mar. 2020. https://www.reuters.com/article/us-health-coronavirus-trump-airlift-idUSKBN21G0LB