PreScouter

Manufacturing challenges of critical COVID-19 medical equipment and how the industry is responding

Research Support Service

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PRESCOUTER

Intelligence Brief Question

What are the challenges in meeting the manufacturing demand of medical equipment caused by COVID-19 and how are industries responding?

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Executive Summary

The COVID-19 pandemic has brought to light many of the holes that exist in government and business processes, as described below:

1. The COVID-19 pandemic has very clearly shown that most of the world is lagging in outbreak readiness. Even though there have been reports and warnings in many scientific journals about an impending SARS-like disease, very few countries actually took early action.

2. Not maintaining localized supply chains, and instead concentrating the bulk of the manufacturing in China, caused a domino effect in the collapse of global supply chains for many industries in many countries. This caused undue rationing of essential medical supplies between both patients and healthcare professionals.

3. The distribution of critical PPE and medical equipment was not controlled, leading to wastage of these products on people who are not healthcare professionals.

In this report, we discuss the product shortages faced by the healthcare workforce, the impact on globalized supply chains due to impositions of strict government restrictions, and the unique manufacturing challenges for these products, as well as how industries are meeting those challenges.

What is the SARS-CoV-2 virus?

Introduction

What is the SARS-CoV-2 virus?

SARS-CoV-2 is a positive-sense single-stranded RNA virus from the severe acute respiratory syndrome–related coronavirus species.

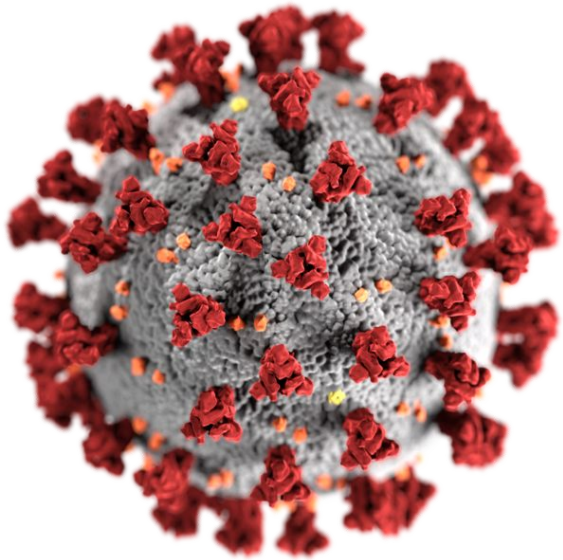
It emerged in China in December 2019, in a wet market of Wuhan.

Early studies demonstrated that SARS-CoV-2 binds a **membrane receptor** called human angiotensin converting enzyme 2 (hACE2).

hACE2 is expressed in different organs, such as the **lung, heart, kidney, and gastrointestinal tract.**

Once the virus binds and enters the host cell through the receptor, it **bypasses the host cell mechanisms and replicates**.

Cellular damage results either from the **virus that controls the host cell's mechanisms** or the **immune cells that kill the infected host cells, resulting in massive cell death**.



Introduction

What are the current treatment options?

There is no approved treatment for COVID-19. The current standard of treatment is to manage symptoms. Several existing and new therapies are being investigated for treatment and prevention of COVID-19.

Many of the world's major pharma and biotech companies have answered the call for a treatment with several antiviral drugs, vaccines, immunotherapies, and even cell therapies currently being developed.

One of the most promising drugs has been the antiviral drug **Remdesivir** from Gilead - initially developed for the Ebola virus. The drug has shown good antiviral activity against single stranded RNA viruses such as coronaviruses, inhibiting virus proliferation.

Some of the companies currently working on a vaccine or therapy for COVID-19.

Product and equipment shortages experienced by healthcare providers

Medical products that are in shortage

The items that are currently in short supply for healthcare providers can be divided into the following three categories:

Personal protective equipment (PPE)[3]: surgical masks, appropriate facial respirator masks, powered air purifying respirators (PAPRs), examination gloves, safety goggles, face shields, protective suits and gowns;

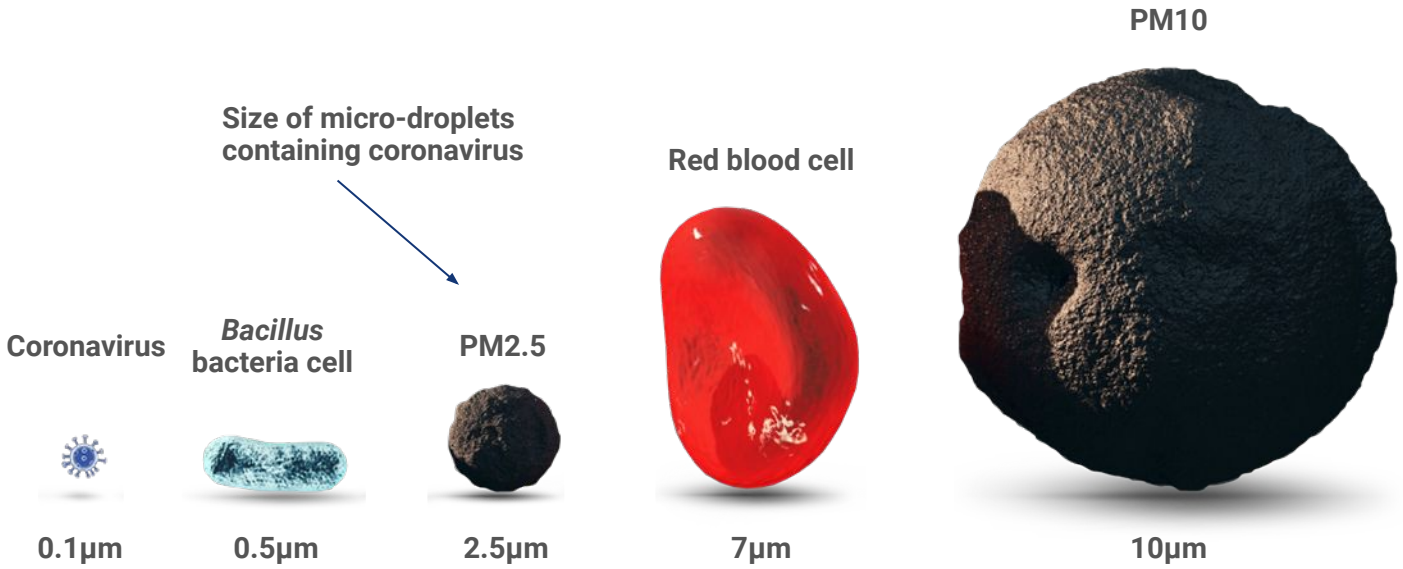
COVID-19 testing swabs and kits[4]: nasopharyngeal and throat swabs, used for the PCR based nucleic acid amplification test (NAAT), and blood sample collection-based anti-SARS-CoV-2 antibody detection tests; and

Medical treatment equipment[5]: critical care ventilators.

Medical products that are in shortage

Face Masks / Respirators

Masks which bear the classification FFP1, FFP2, FFP3, N95, and N100 can all filter out particles ≥0.3 microns. These are the first line of defense against the airborne viruses in micro-droplets released by infected patients. (It should be noted that the droplet size—not the virus itself—is the important number when talking about filtering capabilities.) In contrast, wearing a surgical mask does nothing to protect the wearer from incoming viruses, but it does dramatically reduce the amount of airborne micro-droplets[6] that an infected individual can spread. Hence, masks and respirators along with hand sanitizers were depleted from the local markets due to panic buying by the general public. This resulted in a large number of masks being used by healthy individuals, often without proper knowledge of ensuring a proper fit and airtight seal to prevent influx of virus particles.[7]



Medical products that are in shortage

Face Masks / Respirators

The filter capacity of different types of masks and respirators.

RESPIRATOR STANDARD	FILTER CAPACITY (removes x% of all particles that are 0.3 microns in diameter or larger)
FFP1 & P1	At least 80%
FFP2 & P2	At least 94%
N95	At least 95%
N99 & FFP3	At least 99%
P3	At least 99.95%
N100	At least 99.97%

The products that are in shortage

Face Masks / Respirators

Without enough PPE, healthcare professionals are forced to ration and in extreme cases even reuse masks, following their government's regulatory guidelines on how to use PPE in conventional, contingency, and crisis scenarios.[8] Unlike other PPE that can be disinfected and reused (such as PAPRs, safety goggles, face shields, protective suits and gowns), respirator masks cannot. This, in addition to being exposed to multiple infected patients per shift, translates into a significantly higher rate of respirator mask consumption.

RESPIRATORS CANNOT BE DISINFECTED AND REUSED.

As it stands, in Asia, China itself has a domestic demand of 60 million masks[9] a day and this is set to rise to 400 million if each healthcare worker is provided with multiple masks per shift. In North America, the USA is projecting a demand of 300 million to 3.5 billion masks over a year[10] if the pandemic goes unchecked. In Europe, France has ordered 1 billion masks[11] from China, and the WHO has already shipped 500,000 units of PPE supplies to countries receiving its support.[12]

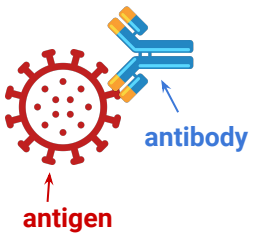
The products that are in shortage

COVID-19 Testing Kits

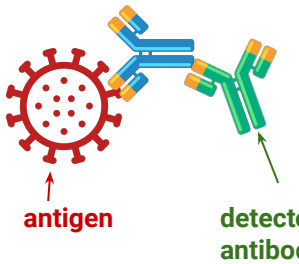
There are two types of testing kits:

Antigen tests: This test is also known as nucleic acid amplification test (NAAT) or a molecular diagnostic test. It involves collecting tissue samples using nasal and throat swabs. This test indicates if the person is currently infected. The swabs are sent to a pathology laboratory, which results in typical **turnaround times of up to 2 days**.

Antibody tests: This test is also known as a serological test, and looks for antibodies which are produced as a result of an infection. This test indicates if the person is or has been previously infected. As this is usually a point-of-care (POC) test, the **turnaround times are typically 15–20 minutes**.



In response to SARS-CoV-2 infection, the body produces antibodies that bind to antigens on the virus particle.



Detector antibodies stick to anti-SARS-CoV-2 antibodies and cause a reaction. This means someone has or had the infection.

The products that are in shortage

COVID-19 Testing Kits

There are a few issues causing shortages of these tests.[13]

The first is that, apart from countries like the USA, Singapore, South Korea, China, and Germany, most **lack extensive diagnostic manufacturing capabilities**. Indeed, even these countries have relied on importing large quantities of tests from China, many of which have been determined to be unfit for use.

This highlights a second problem, namely the low accuracy of the tests in terms of both specificity ("false positives") and sensitivity ("false negatives"). But the main issue was that there were just **not enough pathology labs** to process all the swab collections for the antigen tests, and simply **not enough chemicals and reagents** to do sample processing.

New upcoming rapid tests, although promising, cannot be deployed without validation. Hence, broad testing remains unfeasible.

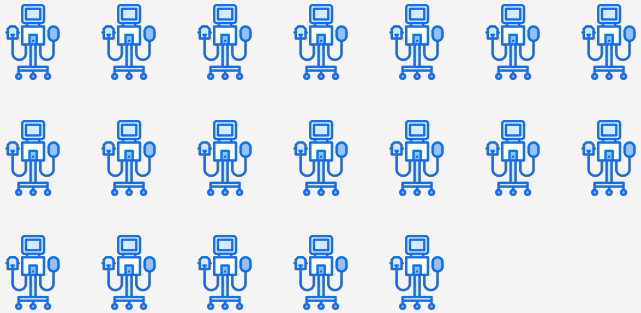
The products that are in shortage

Ventilators

This equipment is used for providing care to patients in intensive care units. Hence it falls under the critical care equipment category; therefore governments stock these items in their inventory accordingly.[14] But with the massive influx of critically ill COVID-19 patients who end up requiring respiratory support, there are simply not enough units **to support all the patients**. This has already led to one unit being shared among two patients in Italy, with some even suggesting that **sharing among up to four patients could occur in the near future**.[15,16]

In response to this, governments are scrambling to **purchase more ventilators** from abroad and asking domestic manufacturers to contribute towards fulfilling the demand for ventilators. It is projected that at the outbreak's peak almost **960,000 patients** will be in need of ventilators in the USA, while there are **only about 200,000** available at present.[17-19]

200,000 ventilators are currently present in the USA



It is projected that 960,000 patients will need ventilators at the peak of the outbreak

The products that are in shortage

Given the shortage of all these critical items, the question that emerges is, **WHY CAN'T COUNTRIES SIMPLY MANUFACTURE MORE**?

Manufacturing faces a number of complex challenges, which are discussed in the following sections.

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What are the challenges faced by companies that manufacture these equipment?

Manufacturing Challenges

The various challenges faced by manufacturers of PPE, testing kits, and ventilators companies can be summed up into three main issues:

1. Collapse of global raw material supply chains
2. Scaling challenges due to complex manufacturing processes
3. Strict manufacturing regulations for PPE, testing kits, and ventilators

Manufacturing Challenges

Collapse of Global Raw Material Supply Chains

N95 or equivalent mask production has been hit the hardest, with the collapse of its global raw material supply chain.

The N95 mask is essentially made of 4 components[1]:

- Outer layer (non-woven polypropylene),
- Filter layer (non-woven polypropylene, melt blown),
- Support layer (modacrylic), and
- The inner skin contact layer (non-woven polypropylene).

China contributes towards **70% of those filter layer exports**, with the rest sourced from India, Japan, South Korea, Malaysia, Italy, and France.

Countries like Vietnam and South Korea, which manufacture and export masks using the crucial antimicrobial particulate filter layer, have been suddenly hit with **raw material shortages**. This is due to domestic shortages in the raw material-supplying countries, in addition to the implementation of strict export and lockdown restrictions.

This shortage has resulted in countries hoarding what supplies they have left and even stopping the export of manufactured masks and raw materials.

Manufacturing Challenges

Collapse of Global Raw Material Supply Chains

China previously supplied 40–50% of the world's demand for masks, but now it is importing them from Vietnam, Indonesia, Kenya, and Tanzania.[3–6] Usually, the countries that import raw materials to manufacture masks also import the equipment that is used to manufacture those masks. Now, with the halt on export of these machines as well by countries like China, any possibilities of expansion of domestic manufacturing capacity to meet the demand has also effectively been extinguished.

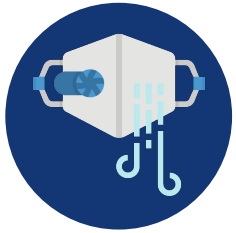
In addition to raw material shortages, countries can't expand their domestic manufacturing capacities as the export of these machines too, by countries like China are also now stopped.

This reverse flow of raw materials, machines, and finished masks has left many countries dependent on overseas manufacturing hubs, and without enough masks and respirators even for their domestic healthcare workers.

Manufacturing Challenges

Scaling Challenges Due to Complex Manufacturing Processes

The mass manufacture of N95 and equivalent respirators and ventilators pose their own unique challenges due to various complexities in the manufacturing processes that prevent rapid scale-up of production.



N95 and Equivalent Respirators: The crucial non-woven polypropylene component of the mask—which provides the protection from viruses through filtering particles ≥0.3 microns—is made from a process called "melt blowing". Manufacturers with this capability are largely concentrated in China. American respirator manufacturers **stopped producing N95 masks** in the early 2000s, due to heavy litigation-related costs and the presence of cheaper foreign alternatives.[7] This led to a significant scale-down of domestic production capacity. Even in China the production of N95 masks is limited to **only 200,000 daily** as compared to 20 million surgical masks daily.[8]

In the current pandemic situation, China and other raw materials-supplying countries have stopped exporting in order to cater to their own dramatically increased domestic demands.

Manufacturing Challenges

Scaling Challenges Due to Complex Manufacturing Processes

The mass manufacture of N95 and equivalent respirators and ventilators pose their own unique challenges due to various complexities in the manufacturing processes that prevent rapid scale-up of production.

Ventilators: The **VOCSN multifunction ventilator**[9] is currently in high demand in the US. This unit consists of five separate devices working in unison, including an oxygen source, critical care ventilator, cough assist pump, hospital grade suction unit, and nebulizer to deliver medication. Hence, each unit requires **700 individual parts** to build, some of which are sourced from countries like India where the factories are shut down due to quarantine and lockdown implementations.[10]

Although, this all-in-one device is excellent for emergency deployments, it is proving difficult to scale up production[11] as there can be no compromise on the manufacturing quality. MedTech companies like Ventec Life Systems typically have manufacturing capabilities set to around 250–1000 units each month, but this has to be **scaled up to at least 200,000 a month** if the country's demands are to be met. They simply lack the manpower and scale up capabilities which are common among automobile manufacturers.

Manufacturing Challenges

Scaling Challenges Due to Complex Manufacturing Processes

The mass manufacture of N95 and equivalent respirators and ventilators pose their own unique challenges due to various complexities in the manufacturing processes that prevent rapid scale-up of production.

3D printing challenges: Under normal circumstances, manufacturing a new product on an assembly line requires **extensive retooling**.[12] This process may take months of valuable time while the outbreak spreads, but still companies are pivoting to meet these needs as much as they can.[13] To bridge this gap, 3D printing has emerged as a potential solution to **fulfill immediate need** for multiple types of medical equipment components and PPE.

Formlabs, with its farm of 250 printers, is manufacturing **100,000 nasal swabs per day**.[13,14] They are presently working on 3D printing other categories of parts including test kits, ventilators, respiratory masks (adapters), facial shields, surgical masks and respirators (seen in the table in the following slide). But the crucial challenges they face is that the medical equipment they produce **needs to meet FDA standards** and gain clinical approval. Until they meet this quality constraint, their products cannot be deployed.[15]

Manufacturing Challenges

Scaling Challenges Due to Complex Manufacturing Processes

Formlabs' response to COVID-19[13]

CATEGORY	COMPONENT	CLINICAL PARTNER/TESTER	CLINICAL STEPS	CURRENT STATUS	WHAT'S NEXT
Test Kits	Nasal swabs	USF Health, Northwell Health, Tampa General Hospital	Emergency IRB approval, PCR test pass, ID sign off and pathology	In production	Scaling production at hospital partners and Formlabs' facilities
Ventilators	Tubing splitter (1 to 2, 3, and 4 patients)	Northwell Health	Passed lab testing with standard tubing	Awaiting final files and clinical protocols	Files and instructions made available later this week
Respiratory Mask (adapted)	Snorkel or scuba mask conversion to PPE	Several hospitals; MasksOn.org	Lab testing	Lab testing	Additional lab testing
Facial Shield	3D printed frame	Several hospitals	Successful printing. Clinical fit varies by organization.	Designs are available. Please coordinate with local health organizations.	Continual monitoring of approved designs
Surgical Mask and Respirators	N95 respirators and masks	Several hospitals	Successful printing. Clinical fit failure.	Temporality on hold	N/A (See below)

Manufacturing Challenges

Strict Manufacturing Regulations for PPE, Testing Kits & Ventilators

The critical shortage of essential medical equipment has given rise to multiple COVID-19 design challenges all over the world. This has spurred many DIY designs from individuals and companies, who don't necessarily understand the stringent clinical standards that are required to be met for a seemingly simple product like an N95 mask, much less a far more complex device like a critical care ventilator.

Use of such products will put both patients and healthcare providers at severe risk, and may even increase spread of the contagion due to a false sense of protection. Hence, regulatory bodies all over the world are cautiously specifying standards for non-healthcare manufacturing companies and DIY designers, keeping in mind the status of the pandemic spread.

This is reflected as **Emergency Use Authorizations (EUAs)**, which should not be confused with full-fledged FDA approval.[16]

An EUA product is barely validated and not rigorously tested as an FDA-approved product, so appropriate caution must be exercised.

Manufacturing Challenges

Strict Manufacturing Regulations for PPE, Testing Kits & Ventilators

The CDC has provided prioritizing strategies for the use of facemasks during conventional, contingency, and crisis capacites. As most healthcare workers are in contingency or crisis scenarios, it is paramount that non-healthcare manufacturers strictly adhere to FDA standards to prevent distribution of faulty products. A brief description of the use of face masks in these scenarios are:

1 Conventional Capacity

- The face masks are to be used in accordance with product labelling, and in adherence to local, state, and federal requirements.

2 Contingency Capacity

- Face masks for visitors are to be removed from public areas.
- Extended use of face masks is to be implemented.
- Face masks are restricted to healthcare professionals, and patients are asked to use cloth barriers to cover their nose and mouth.

3 Crisis Capacity

- Face masks are to be used beyond the manufacturer designated shelf-lives during patient care activities.
- Limited re-use of face masks is implemented.

Manufacturing Challenges

Strict Manufacturing Regulations for PPE, Testing Kits & Ventilators

The relaxation of regulations is reflected in the manufacturing of the following essential medical equipment.

PPE: The FDA[17] advises that 3D printing medical devices, accessories, components, and parts during the COVID-19 pandemic should follow the CDC recommendations[18] to optimize the use of such PPE according to the conventional, contingency, and crisis situations.

Ventilators: Recently, FDA regulations[19] have been relaxed to allow for more non-healthcare companies, universities, and DIY inventors to rapidly put out more ventilators on the market. This allows for companies like Tesla to **repurpose car parts** to design their own ventilators.[20-22]

In the UK, **Dyson**, a company primarily involved in the manufacturing of fans and vacuum cleaners, has worked on its own prototype ventilator design called **CoVent** to meet a provisional order from the NHS for 10,000 units.[23,24] However, due to lower-than-expected demand and potential regulatory challenges, the **NHS opted instead to scale up production of "proven" devices supplied by Ventilator Challenge UK**, a consortium from across the aerospace, automotive and medical sectors.[25,26]

Manufacturing Challenges

Strict Manufacturing Regulations for PPE, Testing Kits & Ventilators

COVID-19 testing kits: Antigen- or PCR-based tests usually have a turnaround time from a few hours to a couple of days. As a solution to this, recently, rapid antibody tests have begun receiving authorizations from regulatory bodies. As these tests provide results in as little as 10 minutes they enable a **point-of-care diagnostic method**. This allows for greater testing numbers, identification of persons at earlier stages of infection, and prevention of spread of the disease by asymptomatic people.

CTK Biotechs's OnSite COVID-19 IgG/IgM Rapid Test. Source: CTK Biotech

Abbott's ID NOW COVID-19 test. Source: Abbott.

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How are industries coming together to mitigate these shortages?

How Are Industries Coming Together?

The shortage of medical supplies is mainly being met by manufacturing industries stepping up in what has been likened to a wartime effort.[1] Automobile manufacturers like GM and Ford have historically heavily helped with wartime manufacturing by transforming their assembly lines to manufacture trucks, tanks, and airplanes. Hence, it is not surprising that the **Defense Production Act**[2] was invoked in the US to spur these companies to manufacture ventilator parts in collaboration with medical device companies.

3M is using "surge capacity" to expand production of N95 masks amid the pandemic, aiming to make one billion masks in 2020.

On the other hand, PPE and related raw material manufacturing companies like 3M had built "**surge capacity**" (extra idle machines) into their manufacturing plants around the world as a response to the overwhelming mask shortages during the SARS outbreak of 2002-03, almost 2 decades ago. They are currently running at surge capacity.[3]

How Are Industries Coming Together?

Automobile and Healthcare Industry Partnerships

Companies that manufacture healthcare equipment have the expertise to develop products, but they lack the scale-up capabilities of automobile manufacturers. Car manufacturers also have multiple components that are similar to those in ventilators, such as fans and motors in their **seat cooling systems**.[4] This is where multiple partnerships between these two industries is leading to rapid scale-up operations. We highlight several key partnerships below.

How Are Industries Coming Together?

Automobile and Healthcare Industry Partnerships

General Motors–Ventec Life Systems: GM has deployed **1000 workers** to scale up production of Ventec's VOCSN ventilators to 10,000 units per month, and scale up further as needed. They are also currently manufacturing 50,000 masks per day and have plans to scale up to **100,000 masks** per day, subject to the availability of raw materials.[5]

Ford–GE Healthcare–Airon Corp: This collaboration aims to manufacture 50,000 of Airon Corp's Model A-E ventilator by early July, and maintain capabilities to continue manufacturing 30,000 units per month as needed. Ford has set manufacturing targets of 1500, 12,000, and 50,000 units by the end of April, May, and July 4th, respectively. This will hopefully achieve the **100,000 units target goal** set by the US government. Airon currently manufactures 3 units per day. This will be boosted by Ford's production capabilities to 7200 units per week.[6]

How Are Industries Coming Together?

Automobile and Healthcare Industry Partnerships

Ford–3M: Using Powered Air-Purifying Respirators (PAPRs) is an alternative solution to the shortage of N95 masks. Unlike N95 masks, PAPRs have reusable HEPA filters, which are supplied by 3M in this collaboration while the air flow systems and fans are being provided by Ford based on their seat cooling technology.[4]

Others: **Toyota** has been focusing on stamping, printing, and assembling face-shields and visors.[7] They are continuing efforts to find a partner to manufacture ventilators and are ready to manufacture masks. **Hyundai** on the other hand has donated 65,000 COVID-19 RT-PCR tests developed by **Seegene Technologies**, to expand drive-through testing practices in the US.[8] Finally, **Mercedes** has offered its 3D printer services.

How Are Industries Coming Together?

PPE and Raw Materials Manufacturers

PPE and related raw material manufacturers are stepping up their production using surge capacity as described below.

3M

N95 masks production has been boosted to 100 million per month globally, using surge capacity in addition to leveraging their localized supply chains which protected them against both manufacturing machines and raw material shortages respectively. They aim to push annual production to 2 billion masks.[9]

ExxonMobil

The monthly production of the raw materials polypropylene and isopropyl alcohol has been boosted by 1000 and 3000 tonnes, respectively. This is enough to manufacture 200 million masks or 20 million gowns (from polypropylene), and 50 million bottles of hand sanitizer (from isopropyl alcohol).[10]

Honeywell

After retooling their plants, they plan to manufacture 20 million N95 masks in the US by mid-May.[11]

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What can be done to prevent such shortages in future outbreaks?

Preventing Future Shortages

The Steps That Need to be Taken

Experts concur that in order to prevent the repeat of such a critical scenario, the following steps can be taken to minimize the impact in the event of another outbreak.

1. Prepare a nationwide scalable outbreak readiness plan to function at three levels: conventional, contingency, and crisis levels.
2. Localize a significant part of the manufacturing of critical medical products, and place emphasis on sourcing raw materials locally.
3. Promote awareness and education among the general public in order to prevent the creation of artificial shortages as a result of hoarding behavior.
4. Develop new technologies in preparation for future pandemic outbreaks.
   For example, 3D printing has proven to be a valuable resource in rapid prototyping of products when immediate retooling of assembly lines has not been possible. Industries should consider investing more in 3D printer farms to enable rapid responsiveness to market demands.

ABOUT THE AUTHORS

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Charles is a Senior Project Architect and Technical Director of the Healthcare & Life Sciences Practice at PreScouter. He is responsible for ensuring that our clients' innovation needs in this space are being addressed by overseeing PreScouter's teams of Advanced Degree Researchers. He has managed projects covering all stages of innovation in the biomedical space, from emerging academic research through preclinical and clinical development of therapeutics and medical devices, to implementations of products in clinical settings. As an academic, he developed integrated microscopy–computational systems for high-precision quantification of the behavior of individual bacterial cells. Charles graduated with a BA in Physics, Molecular and Cellular Biology, and Spanish from Vanderbilt University, then earned his PhD in Biophysical Sciences from the University of Chicago before working as a Postdoctoral Scholar at Purdue University.

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Naveen is a medical technology professional with a deep interest in new and emerging technologies and their impact on businesses. He is passionate about understanding his clients' needs and guiding them towards technology solutions which are a perfect fit. He is also a science communicator and has consulted for pharmaceutical research clients, medical technology companies, and for PreScouter. Being of an entrepreneurial mindset he worked as a co-founder of two medical device start-ups in the areas of sports injury rehabilitation and mental health. He is experienced in managing intellectual property, drafting investigators brochures and ethics applications for clinical trials, and navigating regulatory guidelines to maintain compliance levels of medical devices. During his PhD, he developed expertise in the synthesis and use of electrically conductive nanomaterial inks to manufacture wearable biosensors, which resulted in a patented invention, garnering interest from Johnson & Johnson Innovation and 3M. He holds a PhD in Chemical Engineering from Monash University, Australia.

Next Steps

SOME POSSIBILITIES THAT PRESCOUTER CAN OFFER FOR CONTINUATION OF OUR RELATIONSHIP

- COMPETITIVE INTELLIGENCE
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- TECHNOLOGY & PATENT LANDSCAPING
- MARKET RESEARCH & ANALYSIS
- TRENDS MAPPING
- REVIEW BEST PRACTICES
- PATENT COMMERCIALIZATION STRATEGY
- DATA ANALYSIS & RECOMMENDATIONS
- ACQUIRE NON-PUBLIC INFORMATION
- SUPPLIER OUTREACH & ANALYSIS
- CONSULT WITH INDUSTRY SUBJECT MATTER EXPERTS
- INTERVIEWING COMPANIES & EXPERTS

WE CAN ALSO DO THE FOLLOWING

- ✔ **CONFERENCE SUPPORT:** Attend conferences of interest on your behalf.
- ✔ **WRITING ARTICLES:** Write technical or more public facing articles on your behalf.
- ✔ **WORKING WITH A CONTRACT RESEARCH ORGANIZATION:** Engage with a CRO to build a prototype, test equipment or any other related research service.

For any requests, we welcome your additional questions and custom building a solution for you.

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