

## Coronavirus Daily Report 9.4.20

### Main Findings

#### Highlights

- **Many countries in Europe (Denmark, Czech, Austria, Spain, Belgium, and Finland) and so is Iran**, announced their intentions to **ease lockdown and restrictions**.
- Two German biotech companies, **BioNTech** and **CureVac** (partnered with **Pfizer**), which develop vaccines against **COVID-19**, warned the EMA and the FDA that the current outline in which clinical trials are being held (3 phases) is delaying the development of vaccines that are planned to start trials in the next few weeks.
- Screening of over 7,000 blood donations in China revealed 4 cases of blood units contaminated with SARS-CoV-2 RNA. During the time of the donation, all donors were asymptomatic.

### 1 - Drug Development and Clinical News

#### 1.1 Clinical Trials and Drug Development

- **FUJIFILM Toyama Chemical**, which manufactures the drug **Favipiravir** (commercial name Avigan), has announced a phase **3 trial to evaluate the efficacy and safety of the drug in COVID-19 patients**. The drug is marketed and approved in Japan as an antiviral treatment against the influenza virus.
- Clinical trials evaluating the efficacy of **hyperbaric oxygen therapy chambers (treatment with high pressure hyperbaric- oxygen ) in COVID-19 patients** are planned to start in the US.
- **Invivo Pharma** has received FDA approval to begin clinical trials of **INO-4800, a DNA based vaccine**, and initiated phase 1 study, which will include up to 40 healthy volunteers in the US.
- The British company, **Izana Bioscience**, has announced the initiation of a clinical trial of the drug **Namilumab** in COVID-19 patients, which is currently in late-stage clinical development for the treatment of rheumatic diseases.
- The **Israeli** company, **RedHill Biopharma**, has initiated clinical trials evaluating the antiviral drug **Opaganib**. The treatment was initially given in Israel through a compassionate use program, and in Italy, it was given to 160 COVID-19 patients with life-threatening symptoms.

#### 1.2 Prominent Scientific Publications

An Italian article explaining how one should deduce from the "4S" theory for surge capacity (which includes staff, stuff, structures, and systems) on the management during the present pandemic was published.

Among the key points are the recommendation to **mix specialized with non-specialized staff during the early stages of the surge** (due to the fact that some staff members will be infected), the recommendation to register inventory and order additional equipment in advance as soon as possible, and recommendations for the reconfiguration of the hospital and for the needs of the system.

### 1.3 Diagnostics

- **Microsoft**, partnered with Adaptive Biotechnologies, is developing **an AI-based tool, aiming to generate immune response data using collected blood samples from diagnosed or recovered COVID-19 patients.**
- Two Israeli companies, Hylabs and Daniel Biotech, reported the development of **a new testing technique that doesn't require the use of a key reagent which is currently at a shortage in Israel and could be used for tens of thousands of tests.**

## **2- Regulation and public policy**

### 2.1- Ease of restrictions- Several countries declared their intention to ease restrictions-

- **The first step in easing the lockdown in Denmark will be reopening of day-care centers and schools** on April 15<sup>th</sup>.
- **Czech government agreed on reopening part of the shops and open-air sports activities as of Thursday**, with more restrictions to be eased after Easter.
- **Austria plans to reopen non-essential stores next week**, after reaching a downward trend in new infections growth rate. The government will extend the requirement to wear face masks in supermarkets, public transportation, and reopened shops.
- **France, Spain, Belgium, and Finland intend to gradually ease the lockdown and the restrictions.** Denmark and Belgium are considering splitting classes and the school week, to allow for better social distancing.
- **Iran will ease some social-distancing restrictions from April 11<sup>th</sup> and allow "low-risk" business activity to resume**, as the number of new daily reported cases continue to decline.

### 2.2- Recurrent outbreaks after lockdown ease and patients monitoring- **Slight surge of new patients in China, mostly imported-** Beijing reported on April 6<sup>th</sup> of 39 new coronavirus cases; 38 imported cases and one domestic. However, on April 7<sup>th</sup> **China reports zero daily deaths** for the first time since January. Furthermore, **China and Hong Kong strengthened restrictions on foreign arrivals.**

### 2.3- Wide-scale testing and its effect on patients number-

- Vox news site reports that the **CDC has begun serological testing of people living in outbreak hotspots who haven't been diagnosed.** In later phases, representative samples of people living across the country and health care workers will also be tested.
- **The Netherlands** plans to expand the daily coronavirus testings. At the same time, Sanquin blood bank will test 7,000 blood donors and local health boards **will screen 6,000 people in order to estimate the prevalence of infected people.**

#### 2.4- Medical supply production-

- James, Fisher & Sons company launched a design of a **non-invasive ventilator prototype**. Upon UK government approval, the company **will be able to produce 2,000 ventilators a week**.

#### 2.5- Reports on lacking in medical equipment

- New York is using refrigerator trucks to store **bodies that accumulate rapidly for funeral directors**. A local funeral home manager estimates that his homes are currently handling three **times more bodies than normal**.
- Principal deputy general inspector published a review on **hospitals' experiences and challenges responding to the COVID-19 pandemic in the US**. The main challenges mentioned were patients' testing, staff safety and lack of PPE, human resources, hospital beds, and negative pressure rooms.
- [EMA](#) and the pharmaceutical industry established a system, the i-SPOC system, to **facilitate fast interaction on shortages between industry and the EU Executive Steering Group**. This way, Each pharmaceutical company will report directly to EMA anticipated shortages or current shortages of critical medicines used in the context of COVID-19.
- **FDA changes its enforcement policy for electronic thermometers and infusion pumps in order to help ensure its availability.**

2.6- Hospitals and health care systems- National COVID-19 Convalescent Plasma Project, which includes doctors and researchers from 34 centers in 17 states in the US, has published a public appeal **for confirmed COVID-19 patients and patients who suffered from relevant symptoms to donate blood for COVID-19 therapy development**.

2.7- Civilian population coping with the restrictions- **A rise in domestic abuse worldwide, an increasing number of mental health incidents that are being reported to police, and lack of social care staff.**

2.8- New applications and platforms- Facebook partnered with Carnegie Mellon University to launch a survey for health researchers to track COVID-19 spread. **The survey will be used to help health systems plan where resources are needed.**

### **Detailed findings**

#### **1 - Drug Development and Clinical News**

##### 1.1 Clinical trials and drug development

- [FUJIFILM Toyama Chemical](#), which manufactures the drug **Favipiravir** (commercial name Avigan) has announced a phase **3 trial to evaluate the efficacy and safety of the drug in COVID-19 patients**. The drug is marketed and approved in Japan as an antiviral treatment against the influenza virus.
- Two German biotech companies, **BioNTech** and **CureVac** (partnered with **Pfizer**), which develop vaccines against **COVID-19**, [warned](#) the **EMA and the FDA that the current outline in which clinical trials are being held (3**

**phases) is delaying** the development of vaccines that are planned to start trials in the next few weeks.

- Clinical trials evaluating the efficacy of **hyperbaric oxygen therapy chambers (treatment with high pressure hyperbaric- oxygen ) in COVID-19 patients** are planned to start in the US. The advantage of this treatment is that the oxygen dose given is able to reach very high values (20 folds the standard).
- **Invivo Pharma** has received FDA approval to begin clinical trials of **INO-4800, a DNA based vaccine**. The company, funded by the Bill Gates foundation among others, initiated phase 1 study which will include up to 40 healthy volunteers in the US.
- The British company, **Izana Bioscience**, has announced the initiation of a clinical trial of the drug **Namilumab** in COVID-19 patients. **This treatment will be given through a compassionate use program** and will take place in two medical centers in Italy. The drug is a monoclonal antibody, which is currently in late-stage clinical development for the treatment of rheumatic diseases.
- The **Israeli** company, **RedHill Biopharma**, **has initiated clinical trials evaluating the antiviral drug Opaganib**. The treatment was initially given in Israel through a compassionate use program, and in Italy, it was given to 160 COVID-19 patients with life-threatening symptoms. The drug is being simultaneously investigated in oncology trials, however, the company focuses on gastrointestinal diseases.
- **Ridgeback Biotherapeutics** company has developed an antiviral drug called **EIDD-2801, which demonstrated promising results in preclinical animal studies, and has received FDA approval to start clinical trials**. The researchers published the study results on April 6<sup>th</sup> in the journal *Science Translational Medicine* and the permission to carry out the clinical trial was received on April 7<sup>th</sup>.
- **A clinical trial evaluating the use of fibrinolytic** (Tissue Plasminogen Activator- tPA) on COVID-19 patients has been initiated in the US. A team of researchers from Beth Israel Deaconess Medical Center is examining the efficacy of the drug in light of publications and proposed theories that arose concerning the pro-thrombotic mechanism of the disease.
- **LSU Health Shreveport** Department of Medicine in Louisiana, USA, collaborated with the Massachusetts General Hospital and the University of Alabama-Birmingham in an **international study examining the efficacy of inhaled Nitric Oxide in COVID-19 patients with lung damage caused by the disease**.
  - To note, according to Dr. Daniel Martin's experience, a consultant in critical care and a senior lecturer from the UK, combination treatment of NO and prostacyclin inhalation may improve the patient's condition.

## 1.2 Prominent Scientific publications

- **Detection of SARS-Co-V-2 RNA in blood donations in China**- Since the 25th of January, all blood donations were screened for the presence of viral RNA due to the emerging concern of transmission through plasma components. To note, 2,430 donations were tested in real-time, and 4,995 donations were tested retrospectively. A total of **4 cases of blood donations were found to be**

**contaminated with viral RNA. During the time of the donation, all donors were asymptomatic.**

- Lessons from Italy- an [article](#) explaining how one should deduce from the “4S” theory for surge capacity (which includes **staff, stuff, structures, and systems**) on the management during the present pandemic in light of their poor experience. Key points to emphasize:

1. Staff- specialized staff members (ED, ICU, infectious disease) constitute the bottleneck. **It is advisable to mix specialized with non-specialized staff during the early stages of the surge** (due to the fact that some staff members will be infected). In addition, the staff will become tired quickly- it is best to plan **short shifts with recovery time**.
2. Stuff- there is a need for huge amounts of equipment- it is recommended to pre-order large amounts and organize additional emergency stock. With problematic equipment- especially oxygen-related and ventilators- register inventory and order additional equipment in advance as soon as possible.
3. Structure- reconfiguration of the hospital-
  - Evacuating negative pressure rooms for the use of COVID-19 patients.
  - Organizing delivery rooms and surgery theatres to contain negative pressure.
  - Increasing the imaging department and facilities in the hospital.
  - Organizing different departments for the care of patients in various disease intensity levels.
  - **Identifying regions in the facility to be converted to sites of care- outpatient clinics, converting operating theatres into intensive care units, while maintaining the effort of centralizing the patients in the facility in order to minimize the amount of staff needed.**
  - The 2019-nCOV testing activity should be available 24/7 in order to prevent delay in diagnosis
  - **Triage area outside the ED, a clear and unequivocal triage protocol.**
  - Forbidding visitations.
  - In the case of autopsy- in a negative pressure room, full PPE.
4. System
  - A clear command chain.
  - A clear communication strategy with relatives and caregivers.
  - Allow patients to keep in touch with their loved ones through mobile phones.
  - **Psychological support for patients and staff.**

### 1.3 Diagnostics-

- Microsoft, partnered with Adaptive Biotechnologies, is developing **an AI-based tool, aiming to generate immune response data using collected blood samples from diagnosed or recovered COVID-19 patients.**
- Promega has received FDA approval for the marketing of a **ready-to-use reagent mix** called **GoTaq® Probe 1-Step RT-qPCR**. The company's reagents are also currently incorporated in 15 COVID-19 diagnostic tests produced by other global diagnostic manufacturers.
- Hylabs together with Daniel Biotech [reported](#) (article in Hebrew) the development of **a new testing technique that doesn't require the use of a key reagent which is currently at a shortage in Israel**. They also mention that if the current prototype succeeds, **the alternative could be used for tens of thousands of tests.**

### 1.4- Reports regarding technological developments

- Alyn Hospital has developed a device called [CoughSync](#), which **produces artificial cough** in ventilated patients, and by doing so **decreases the need for suction and the exposure of healthcare providers** to aerosols. The device is currently evaluated for the approval of its use in China.
- Several countries in Asia began using an **Israeli developed robot, Temi**, that can execute a number of actions that **minimize the contact needed between patients and healthcare providers.**

## **2- Regulation and public policy**

### 2.1- Global adaptations of restriction measures

- According to Reuters news agency, **Denmark's prime minister announced the country's plan to reopen daycare centers and schools** on April 15<sup>th</sup> as a **first step to ease the lockdown**.
- Another report stated that the **Czech government agreed on reopening part of the shops and open-air sports activities as of Thursday**, with more restrictions to be eased after Easter.
- **Austria announced plans to reopen non-essential stores next week**, after reaching a downward trend in new infections growth rate. The government will also extend the requirement to wear face masks in supermarkets, public transportation, and reopened shops.
- According to the Financial Times, **additional countries in Europe, such as France, Spain, Belgium, and Finland, plan to gradually ease the lockdown and the restrictions**. Spain, for example, imposed a ban last month on all non-essential work which would be lifted after Easter. Denmark and Belgium are considering splitting classes and the school week, to allow for better social distancing.
- According to Bloomberg news agency, **Iran will ease some social-distancing restrictions from April 11 and allow "low-risk" business activity to resume**, as the number of new daily reported cases continue to decline.

## 2.2- Recurrent outbreaks after lockdown ease and patients monitoring

- **A slight surge of new confirmed COVID-19 cases in China, mostly imported-** Beijing reported on April 6<sup>th</sup> of 39 new coronavirus cases; 38 imported cases and one domestic.
- However, on April 7<sup>th</sup> **China reports zero daily deaths** for the first time since January. Furthermore, **China and Hong Kong strengthened restrictions on foreign arrivals** due to the growing number of imported and asymptomatic cases.

## 2.3- Wide-scale testing and its effect on patients number

- Vox news site reports that the **CDC has begun serological testing for people living in outbreak hotspots who haven't been diagnosed**. In later phases, representative samples of people living across the country and health care workers will also be tested. The tests are developed by Cellex.
- **The Netherlands plans** to expand coronavirus testing carried out daily. At the same time, Sanquin blood bank will test 7,000 blood donors and local health boards **will screen 6,000 people in order to estimate the prevalence of infected people**. The results of that project, due to the end of the month, will help officials decide on further actions.
- According to the Star news site, **the Nation of Brunei will conduct random COVID-19 tests for foreign workers**, after the latest statistics showed that 25 out of 135 confirmed cases detected in the country were of foreigners, including some foreign workers in the sultanate.

## 2.4- Medical supply production

- **James, Fisher & Sons** company launched a design of a **non-invasive ventilator prototype**. Upon UK government approval, the company **will be able to produce 2,000 ventilators a week**.
- **Bauer Hockey** company, a hockey equipment manufacturer, is **shifting its resources to distribute face shields** for medical staff.

## 2.5- Reports on lacking in medical equipment

- CNA news agency **reports** that New York is using refrigerator trucks to store **bodies that accumulate rapidly for funeral directors**. A local funeral home manager estimates that his homes are currently dealing with **three times more bodies than usual**.
- Principal deputy general inspector has published a **review** on **hospitals' experiences and challenges responding to the COVID-19 pandemic in the US**. **Key points** from the review:
  - Most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe.

- Hospitals are **lacking supportive equipment** such as infusion pumps, medical gas systems, and food, as well as human resources, beds and negative pressure rooms.
- Hospitals described they were unable to keep up with the testing demands due to a shortage of complete testing kits, which led to delay in treating the patients. The report also criticizes **extended waits for COVID-19 test results, frequently 7 days or longer.**
- Shortage of face masks, partly due to unnecessary use and purchasing from unauthorized sources.
- In order to mitigate the supply chain of medicines in a coordinated manner, the [EMA](#) and the pharmaceutical industry established a system, the i-SPOC system, to **facilitate fast interaction on shortages between industry and the EU Executive Steering Group.** This way, Each pharmaceutical company will report directly to EMA anticipated shortages or current shortages of critical medicines used in the context of COVID-19.
- FDA changes its enforcement policy for [electronic thermometers](#) and [infusion pumps](#) in order to help ensure availability.

## 2.6- Hospitals and health care systems

- The Lancet journal [reviewed](#) the **Fangcang shelter hospitals** which started in China. The review covers three key characteristics: **rapid construction, massive scale, and low cost**, and it focuses on five essential functions: **isolation, triage, basic medical care, frequent monitoring, and rapid referral, and essential living and social engagement.**
- The Guardian daily newspaper [reports](#) that **Britain's supermarkets received data regarding vulnerable patients as part of the government's effort to help prioritize deliveries to those most in need. Data must be deleted** when the coronavirus crisis is abated in order to keep the patient's privacy.
- National COVID-19 Convalescent Plasma Project, which includes doctors and researchers from 34 centers in 17 states in the US, has published a [public appeal for positive COVID-19 patients and patients who suffered from relevant symptoms to donate blood for COVID-19 therapy development.](#)

## 2.7- Civilian population coping with the restrictions

- The New York Times [reports](#) on a **rise in worldwide domestic abuse cases.** In that context, the UN chief [urged](#) all governments to take action and improve this situation.
- According to the [Independent](#) newspaper, there is an **increasing number of mental health incidents that are being reported** to the police during the lockdown and a **very early indication of an increase in suicide attempts and suicides.** Mental health and social care services are short in staff because of the outbreak.

## 2.8- New applications and platforms

- [Facebook](#) partnered with Carnegie Mellon University to launch a survey for health researchers to track COVID-19 spread. **The survey will be used to help health systems plan where resources are required.** The project will start in the US, and if the results are helpful, similar surveys will be available in other parts of the world.
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