

THE ALCIVAX

Alcimed examines the changes in the vaccine industry both good and bad, and speculate which changes might be permanent.

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Edition #25 - 18 Sept 2020

The Need for Speed

The vaccine industry takes on average 5-10 years to develop a vaccine for a new pathogen, but the pandemic has condensed that time frame to 5 to 10 months. Is this good or bad for the vaccine industry? What changes have occurred in the industry to make this happen? Are the changes positive or negative for the industry? Are they permanent? All questions worth asking.



Upfront Public Investment

The rapid acceleration of vaccine development timelines has been largely aided by public funding, creating the potential for adapting to the pandemic model of vaccine development as outlined in the New England Journal of Medicine. This allows for much of the preparation for clinical trials, such as assay development to overlap with early clinical trials and large scale manufacturing to begin ramping up as soon as a vaccine candidate exits Phase 1 trials. Normally, each step is done linearly to reduce invested costs. But as government agencies have provided funding for R&D, running clinical trials and investing in the expansion manufacturing capacity, have eliminated the financial risks of full scale production to ensure that vaccines are ready for full scale distribution on approval. It is unclear whether elements of this funding will remain available for non-pandemic vaccines in the future, without which it is reasonable to presume that vaccine developers will retreat back to the previous linear timelines.



New Payment Models

Due to the necessity of being able to distribute a COVID vaccine as soon as possible, the 5 major vaccine front runners have been able to pre-sell their full production capacity to governments all over the world. Moderna, for example has received over \$2.4 B in public funds for COVID-19 vaccine development. These guaranteed purchase models are also used as an incentive for other medical necessities, such as the development of new antibiotics. The current estimates for bringing a new drug/vaccine to market stands between \$1.3-\$2.8 B depending on the post approval costs. By this estimation, Moderna has entirely covered their go to market expenses through government funds. This does not entitle those investors to free vaccine. It does provide them with a discounted vaccine (\$12/dose US vs. \$35/dose elsewhere).

Moving forward, it would be good to continue to allow pre-purchase agreements for potential vaccines to shorten the time to full scale production, though tiered payments to provide for only unnecessary manufacturing costs should the vaccine fail trials would prevent governments for paying full price and not receiving a vaccine in the end.



Under a Microscope

Government pre-purchase agreements have allowed for a larger degree of public pressure to be exerted on vaccine manufactures during the clinical trial period, but it has also allowed for to the politicization of vaccine approval and distribution times, raising safety concerns over accelerated timelines and creating an antagonistic relationship between developers and political figures. After a case of transverse myelitis was reported as an adverse event in the Astra Zeneca trial, the trial was suspended for an ad hoc safety review and are set to resume this week. To create greater transparency, Pfizer and Moderna have released their trial designs to the public prior to the completion of trials, signaling an unprecedented move toward gaining the public trust.

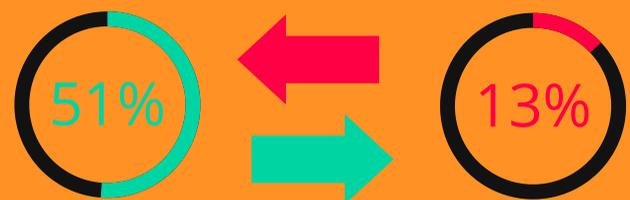


Global Inoculation

According to the G20 finance and health ministers, providing an "equitable and affordable" vaccine against SARS-CoV-2 is the key to overcoming the current pandemic and crucial to supporting global economic recovery, in a statement released this week. A detailed plan for achieving this will be submitted and discussed at the upcoming G20 summit in October.

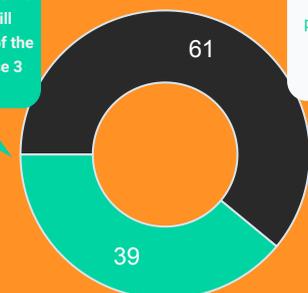
Oxfam International released an analysis of the COVID-19 vaccination global outlook. The current situation, as described in the study, suggests we have a long way to go in vaccinating the world and bringing an end to the active phase of the pandemic.

The Current Outlook



51% of promised COVID-19 vaccine doses are currently promised to 13% of the world's population.

Vaccinating even 39% prior to 2022 will require that all 5 of the vaccines in Phase 3 succeed.



61% of the world's population won't have access to a vaccine until at least 2022.

The Cost of Global Vaccination

1%

of the projected cost of the COVID-19 pandemic on the global economy would cover the cost of providing a vaccine for everyone on earth.



Global Manufacturing

Supply details have already been released for 5 of the 9 front runners (AstraZeneca, Gamaleya/Sputnik, Moderna, Pfizer and Sinovac) for a COVID-19 vaccine.

5.94 B

doses based on current capacity

5.3 B

doses have already been sold locking up the bulk of supply

Vaccines for the Developing World

49%

of the manufacturing capacity is promised to the developing world including India, Bangladesh, China, Brazil, Indonesia and Mexico among others.

Included in the current developing world supply is the deals between AstraZeneca and the Serum Institute of India for production of vaccine for local production and distribution as well as licensing rights for Brazil's Fiocruz for at least 100 million doses. The Serum Institutes total annual manufacturing capacity is 1.5 billion, which may be the key to providing a larger % of the world's population vaccine sooner if other licensing agreements can be reached.

Despite early hopes of COVID vaccine distribution beginning in fall of 2020, the CDC currently projects widespread distribution of vaccine 2nd quarter of 2021, assuming that it can get the \$6 B of funding needed for distribution.

WHO, SAGE, & COVAX

As late stage development on COVID vaccine continues to progress, the WHO is already working on distribution plans through its Strategic Advisory Group of Experts on Immunization or SAGE. The individual country response so far has pushed toward vaccine nationalism, where countries pre-buy enough vaccine to cover their entire nation. The WHO is advocating for a different approach.

"The first priority must be to vaccinate some people in all the countries, rather than all the people in some countries," WHO Director-General Dr. Tedros Adhanom Ghebreyesus said in Geneva on Friday. "Vaccine nationalism will prolong the pandemic, not shorten it."

The global distribution plan involves the utilization of the COVID vaccine accelerator program or COVAX, which will allow for pre-purchase vaccine to cover 30% of a countries population from one of the many COVAX production facilities. Participating countries are seperated into self-funding countries, who can afford to pay the \$1.60 per dose price while also providing funding for countries who can not afford to pay for their own vaccine needs. COVAX facilities meet the following needs:

COVAX facilities:



Image Credit: Gavi

1. Produce early doses for clinical studies
2. Scale up to industrial scale before clinical trials begin
3. Scale-out products in different countries to expand capacity
4. Stockpile vaccines in bulk
5. Monitor products in trail to anticipate failures
6. Switch to successful products if failures occur

Some On & Off World Perspective on the Current State of Affairs

Is it time to move to Venus?



Image Credit: Joe Heller

The UK's The Guardian



Image Credit: Chappatte Der Spiegel

The Vaccine Narrative

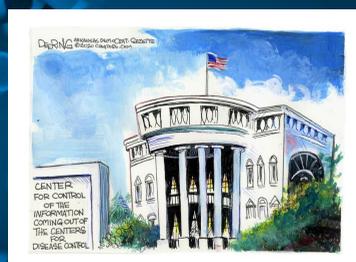


Image Credit: John Derring

Get Your Flu Shot!



Image Credit: DaveGranlund.com



Do we have a Flu problem?

Respiratory co-infections are common, and can be responsible for poorer clinical outcomes, such as increased likelihood of lung scaring, longer recovery times, higher rates of mortality. As flu season approaches for the US and Europe, experts are beginning to speculate on whether seasonal flu will exacerbate the current COVID pandemic.

The first struggle is diagnostic. The onset of symptoms are highly similar between COVID and the flu but the patient pathways are very different. The need for antiviral therapy and hospitalization need to be anticipated with a correct diagnosis. To this end, LabCorp is in the process of developing combined COVID/Flu testing kits.

The second concern is the long road to recovery for COVID patients. Over 50% of COVID patients suffer from lasting fatigue, whether experiencing mild or severe symptoms. While no explanation is currently available, lingering immune suppression from COVID would make people more susceptible to seasonal flu.

The good news is that current COVID social distancing has largely kept flu infections down this year in countries, such as Australia already well into flu season. Pfizer is also launching trials for a new antiviral against SARS-CoV-2, PF-07304814, which may serve as a combination therapy with remdesivir. Though as cases rise again in Europe for a second wave, and no lockdown plans, the situation will need to be closely monitored.



All joking aside

German football teams are world renowned for racking up large scores, such as the 7-1 victory against Brazil in the 2014 World Cup Semis. But COVID has upped the bar with a 37-0 victory by a local German football club at a 1 goal/2 min rate. The losing team only fielded 7 players that adhered to social distancing practices during the game after learning that their opponents had been exposed to COVID-19.

A Zoom collaboration between rival breweries in Scotland and Germany resulted in the creation of the worlds strongest beer. Called Strength in Numbers, the beer is 57.3% alcohol, beating out Schorschbräu's 57% Schorschbock for the title. A single beer retails for £28.95 and current stocks have already sold out online.

COVID's impact on German recreation continued this week after an American, who refused to quarantine, went on a Bavarian pub crawl. Nearly 700 people were exposed to COVID in a single night and the resort where the super spreader works has been closed for two weeks.