January 15th, 2021

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

As vaccines are shipped across the country, there are two scenarios, those who are waiting in line for hours to get it and those who are refusing to take it. Read on to find out what is behind these two major opposing views. Click on this link to read "To Take or Not to Take the Vaccine?"

As the Stay-at-Home Advisory continues due to a second surge in COVID-19 cases, many people may feel further isolated from family, friends and colleagues which could lead to medical issues. Find out how Fostering or Adopting a Pet During a Pandemic can alleviate some of those issues. Click on this link to find out more.

For a list of activities to do with your family or for yourself over the holidays, click on

Newport Mansions, MFA, Isabella Stewart Gardner Museum or a virtual tour of Greece all at your fingertips to enjoy from your home.

Missed my articles, on "How to Deal with Uncertainty" click here.

If you need a little inspiration or something to make us laugh to get us through this difficult time, click on the "Inspiration" link to give yourself a few minutes to relax and enjoy the music from the Berklee School of Music in their song "What the World Needs Now," other inspirations and ending with Celine Dion and Josh Groban with "The Prayer".

Please read on for other current news in the Table of Content below. The next newsletter will be published on February 15th, 2021.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
BioMarketing Insight

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Join my mailing list

Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Marketing Strategies

Scenario Planning - for more information, email me.

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

We Will Get Through It Together

A Little Bit of Humor Helps Too

I like to thank Carol, Joan, Denise, and Sharon for forwarding these inspirations to me to share with you.

Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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Another Crisis is Brewing

I am pleased to announce that my article "Another Crisis is Brewing" has been published in the European Biopharmaceutical Review's October 2020 issue. To read this article click

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BioProcess International

Save the Date: BioProcess International Conference: September 21-24, 2020, Virtual Conference

I am pleased to announce that I delivered a presentation at the BioProcess International Conference on September 22, 2020 at 2:20pm under the Speed from Gene to Market Track. The title of my presentation was "Aligning the R&D and Marketing Target Product Profile (TPP) to Achieve R&D and Commercial Success". To see the full agenda, click here. To see a list of speakers at the conference, click here.

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Fun Activities for You and Your Family

advantage in visiting museums virtually around the world, Disney World virtual tours, the Grand Canyon and other National Parks, Newport Mansions, MFA, Isabella Stewart Gardner Museum or a virtual tour of Greece all at your fingertips to enjoy from your home.

Tour a National Park, 32 parks to choose from in the comfort of your home.

Take a 360 degree virtual tour of Disney World. We are all kids at heart.

If you like museum, take a virtual tour of museums around the world.

Boston's famous virtual tour of the Museum of Fine Arts.

Another Boston's famous virtual tour of Isabella Steward Gardner Museum.

If you haven't been to the Newport Mansions, your virtual tours are here.

If you have never been to Greece, you want to click on the Greece Virtual Tour.

And of course, there is the good old fashion board games to play with your family and friends virtually.

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TO TAKE

Or NOT TO TAKE

To Take or Not to Take the COVID-19 Vaccine?

On December 11th, 2020, Pfizer and BioNTech received an Emergency Use Approval (EUA) from the FDA for their vaccine and people were thrilled. Everyone had been anxiously waiting for a vaccine in hopes of getting back to some form of normalcy once majority of the people got vaccinated.

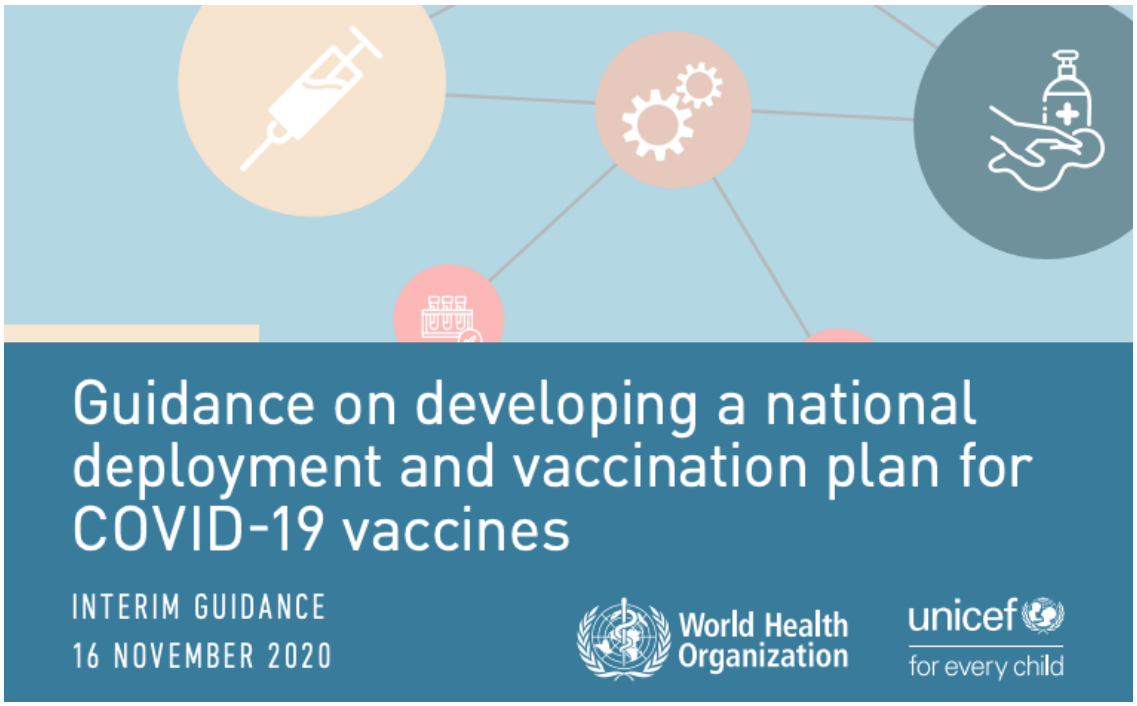
Immediately after Pfizer received their EUA, vaccines were shipped across the country. Shortly after Pfizer/BioNTech received their EUA, Moderna received their EUA on December 18th, 2020. With two vaccines being approved, the goals was to vaccinate 20 million people in December.

However, by December 23rd, only a little over a million people were vaccinated. There were three (3) main reasons why vaccination uptake can stall:

1) Due to lack of leadership from Trump, there is no national vaccination plan, guidance or support. Therefore, there is no advance planning or consistent planning across States, Cities or Town. Majority of the State and local officials are probably looking for guidance;

2) Concerns about the safety of the vaccine considering how quickly the vaccines were developed and long-term consequences; and

3) Not paying attention to the logistics or details for a vaccination plan. It is extremely important to identify all the vulnerabilities where things can fall through the cracks and



#1 - Lack of a National Vaccination Plan

There is a need for a National Vaccination Plan where a Vaccination Coordinator group has a comprehensive plan on how the distribution of the vaccine will be rolled out. This includes coordinating with vaccine manufactures to ensure that there is enough vaccine to vaccinate everyone at a timely matter, getting it to the various institution, prioritizing who will be vaccinated first, who will be responsible and where people will be vaccinated and the list goes on.

Rick Bright, MD, Biden COVID-19 Advisory Board gave an overview on what needs to be done once President-elect Biden takes office. He advocated a multi-communication platforms in reaching out to all communities to ensure everyone is informed on what needs to be done to reach the goal of getting everyone vaccinated. He emphasized an "all hands

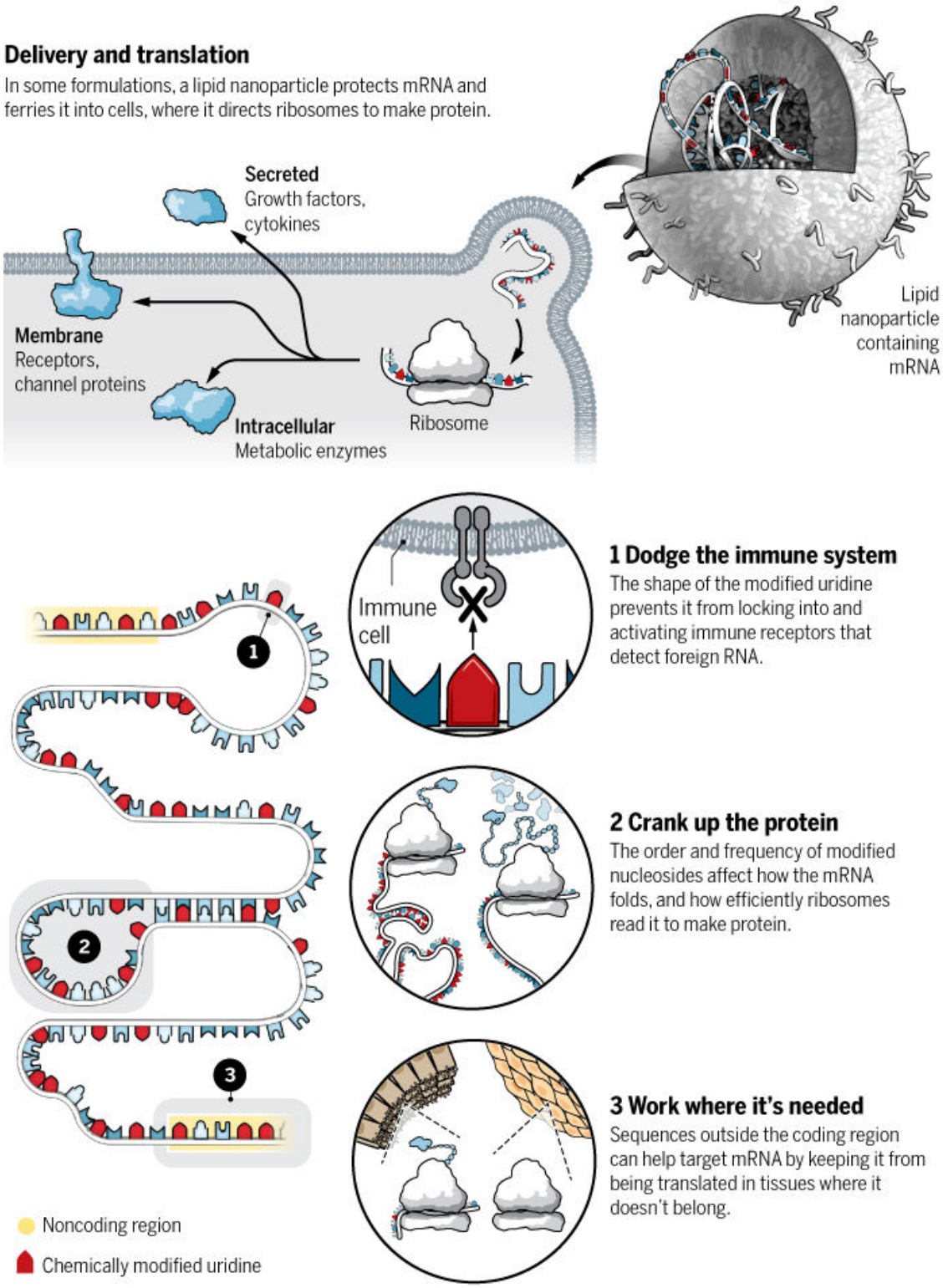
Bright also proposes a National Testing Strategy which I assume will entail testing everyone. By testing everyone whether one is symptomatic or asymptomatic will help to identify who needs to be isolated in stopping the spread of the virus. In addition, isolation must be reinforce and monitored to stop the spread of the virus.

To accurately identify those who are infectious, we need to understand which tests (PCR, antigen or antibody) are appropriate (PCR - indicate infectious today), and the frequency of testing as contract tracing will not identify all those who were exposed. Bright mentioned, there needs to be protocols to ensure layers of protection, it's not just testing. In addition, asking for advance funding from congress to hire and train staff is paramount in carrying out this strategy.

#2) Is the Vaccine Safe?

Safety is the biggest obstacle to overcome both short-term and long-term. A vaccine can be available, but if 80% of the population is not vaccinated, herd immunity will not be achieved and the virus will continue to infect people.

Questions have come up as to whether the vaccine is safe because it was developed in such a short period of time compared to the traditional method. Both Pfizer and Moderna have messaging RNA (mRNA) as their platform to develop their vaccine. Messaging RNA is not new, in fact, research has been done for over two decade. "A lot went into the mRNA platform that we have today," says immunologist Akiko Iwasaki at the Yale School of Medicine in New Haven, Connecticut, who has worked on nucleic-acid vaccines — those based on lengths of DNA or RNA — for more than two decades.



Source: sciencemag.org

The COVID-19 experience will almost certainly change the future of vaccine science, says Dan Barouch, director of the Center for Virology and Vaccine Research at Harvard Medical

making vaccines, such as by using messenger RNA (mRNA), have been validated by the COVID-19 response, he adds. “It has shown that the development process can be accelerated substantially without compromising on safety.”

Pharma/biotech companies and the FDA will not compromise on safety or efficacy in receiving or granting FDA approval respectively. The FDA's number one concern is safety and will not compromise on this even with an EUA. They maybe a little lenient with the efficacy but stead fast on safety in a Pandemic. Dr. Fausi mentioned that he would be happy with a vaccine that has 50% efficacy. Fortunately Pfizer and Moderna have a 94% and 95% efficacy respectively. The FDA doesn't want any backlash if a product is perceived to be or is not safe. The public will chastise the FDA and demand how the FDA could allow this to happen and why they were not doing their job in keeping the public safe.

Pharma/Biotech companies will certainly make sure the product is safe because their reputation is on the line. These companies are experts in developing and launching a safe and efficacious product. If they have a product that is perceived to be unsafe, any product they launch subsequently will not be looked upon favorably. All people will remember is that one product that was not safe.

If I was offered the vaccine today, I would take it. However, I will have to wait until the general population is vaccinated and rightly so as the people who are at the greatest risk should be first.

mRNA is becoming so attractive that a number of other companies are investing in this technology. Sanofi has deals with BioNTech and Translate Bio, CureVac has deals with Sanofi, Eli Lilly, and Boehringer Ingelheim and most recently Bayer.

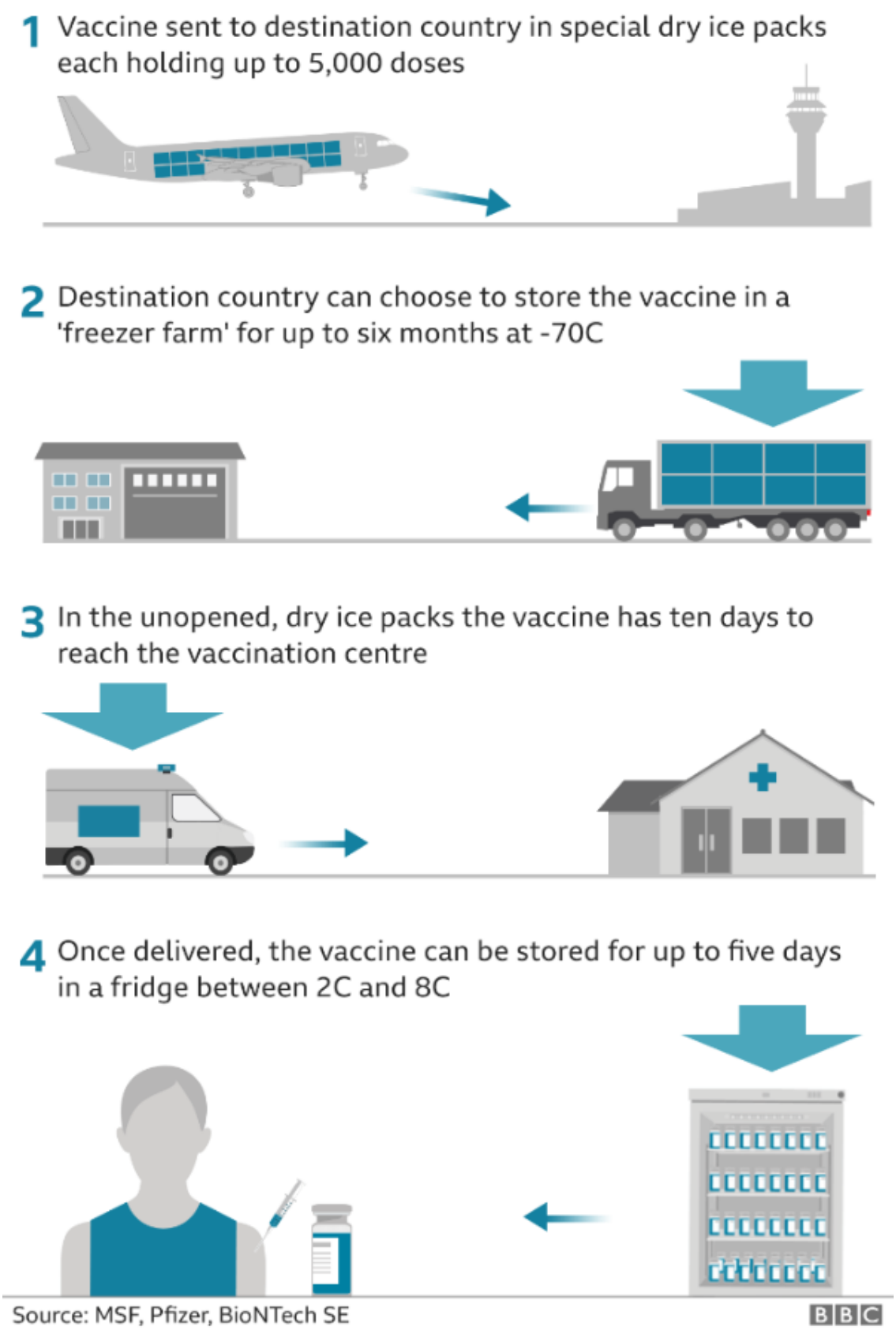
As for long-term safety? No one can predict the long term effect of a vaccine and one could wait 10 years to see if the vaccine is safe, but what is the alternative? According to the Nightly News, in the greater Los Angeles area, **one person is dying every 6 minutes**. As of this writing, there is close to 400,000 deaths in the US and more than 20 million people who tested positive for COVID-19 and growing exponentially especially with this new variant that is more contagious. Many have been hospitalized and even if they do recover, many have long-term residual effect from the virus that could be debilitating.

One can't wait 10 years to determine the long-term consequences. We may not be around in 10 years at the current rate of infections and deaths.

There are a number of vaccines that are being developed behind Pfizer and Moderna listed below in Table 1 and the type of platform they are using. We need all these companies vaccine to be approved if we are going to vaccinate 80% of the world to

Platform	Attributes	Doses	Vaccine Candidate (Manufacturer)
mRNA	Fast development speed; low- to-medium manufacturing scale	2	BNT-162b2 (Pfizer, BioNTech); mRNA-1273 (Moderna)
DNA	Fast development speed; medium manufacturing scale	2	INO-4800 (Inovio)
Viral vector	Medium development; high manufacturing scale	1 or 2	AZA-1222 Ad5-CoV (AstraZeneca; Oxford University); Ad26.COV2.S (Johnson & Johnson)
Protein subunit	Medium- to-fast development; high manufacturing scale	2	NVX-CoV2373 (Novavax)

delivery chain



#3) Logistics in getting the vaccine "into the arms of the people" quote from

Logistics are also very important because it is the details that will determine the success or failure of a vaccination plan. It is similar to Launching a New Product for those who have been involved with a product launch. One has a overall Launch Plan, but there are many details to consider in ensuring a successful launch.

Here are some of the major things one has to consider:

1) Medical Records - since all the vaccines require two doses, there must be a system in place to ensure that each patient is contacted, get the first dose and then contacted again for the second dose at the designated time (i.e. two weeks or one month later).

2) Inventory - a system must be in place to ensure that when the patient is due for the second dose, there is enough vaccine available. Since the vaccine comes in a multi-dose vial, it is hard to reserve a vial for individual people. Recently, it was reported that instead of 5 doses to a vial, sometimes there are six doses. This requires noting the lot number for each patient in case one need to go back to that particular lot number.

3) Storage - The Pfizer vaccine needs to be stored at -94 degrees while the Moderna vaccine can be stored in a regular freezer. This means, special freezer are need for the Pfizer vaccine but not for the Moderna vaccine. For smaller community hospitals or non-hospital settings, this is an added cost which they may or may not be able to afford. Pfizer's vaccine can be stored in a refrigerator, but it has to be used in five (5) days. This can also create confusion among the healthcare professionals.

Because there is two different storage requirements, one has to have a system to ensure that the Pfizer vaccine is not stored in a regular freezer and the Moderna vaccine is not accidentally storage in a special freezer because we don't know if the Moderna vaccine will be viable at a temperature that is too cold.

For better convenience, the vaccines that are approved later maybe able to be stored in a regular refrigerator and possibly at room temperature. Therefore, a system must be in place to ensure that each company vaccines is stored at the appropriate temperature at various institutions.

4) Dosing - since one institution may receive multiply company vaccines, a system need to be in place to ensure that if the patient receives a Pfizer vaccine for the first dose, they receive a Pfizer vaccine for the second dose. One can't interchange vaccines especially if the vaccine has a different technology platform (see Table 1).

Since each company vaccine has their own dosage amount (i.e. 1 cc for one vaccine, 3 cc for another), one has to have a system to ensure that the correct amount is administered.

for stretching the vaccine supply and said people who are speculating about the possibility of making do with just one dose or cutting doses in half are misinterpreting the data.

"We have been following the discussions and news reports about reducing the number of doses, extending the length of time between doses, changing the dose (half-dose), or mixing and matching vaccines in order to immunize more people against COVID-19," said FDA Commissioners Dr. Stephen Hahn and Dr. Peter Marks, who heads FDA's vaccine division.

"These are all reasonable questions to consider and evaluate in clinical trials. However, at this time, suggesting changes to the FDA-authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence. Without appropriate data supporting such changes in vaccine administration, we run a significant risk of placing public health at risk, undermining the historic vaccination efforts to protect the population from COVID-19," they added.

If the second dose is delayed, it is unknown what percent of immunity will be achieved since it is outside the protocol of the clinical trials. Generally, if the dose is delayed the immunity is lower, how much lower is unknown.

6) Side effects - as we have seen with other vaccines like the two dose shingle vaccine, people who have a moderate to severe reaction to the first dose may not want to come back for the second dose. If people don't receive their second shot, we don't know whether they will have enough immunity to avoid being infected. According to the FDA, people need both dosages. A plan needs to be in place to convince these people to come back in for the second shot.

From a marketing perspective, because compliance is so important for a drug or vaccine to work, one of the goals in bringing a vaccine to market is to have a one dose shot with minimal side effects in a normal situation. To achieve this goal is harder from and R&D perspective and would take longer to develop. With COVID-19 pandemic, the goal was to get a vaccine out as quickly as possible.

But now, one has to work really hard to overcome these challenges. It's very difficult to convince a person who doesn't want the second shot to take it. This is the reason why marketing come in with a marketing target product profile (TPP) simultaneously with the R&D TPP. The Marketing TPP will influence the R&D TPP to be able to compete in the marketing and be better.

7) Administering the vaccine - to perform mass vaccination, a plan is needs to have a work-flow outline in getting people in and out as efficiently as possible. This includes a large enough venue to accommodate the number of people that needs to be vaccinated

pads, etc) to perform the vaccination and ample vaccine.

With any mass event, auxiliary personnel is also needed to make sure the work-flow is moving smoothly and orderly, plus the requirement dictated by the town. As demonstrated here, it take a lot of planning and coordination with a lot of people to have a successful vaccination program.

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Closing Thoughts

The key to a successful vaccination program is advance planning both at a high level and in the details as outlined in my newsletter. Countries such as Israel have been successful in quickly vaccinating their citizens because they started planning early and been vaccinating their citizens since Dec. 19th.

To date, and with a new lockdown in place amid a surge in coronavirus cases, around 1.59 million people in Israel (of a population of 8.6 million) have received their first vaccine shot, according to Our World in Data.

By contrast, the U.S. has given the first inoculation to 5.9 million people (with a population of around 331 million), the U.K. has vaccinated 1.3 million (of 66 million) and just 45,000 people in France have received their first shot (population: 67 million).

These are the reasons why Israel has been so successful:

1) "First of all … plan in advance. Be prepared, have a big informational campaign and get the trust of the people, that's on one side," Dr. Boaz Lev, who chairs the advisory

2) "Then, create a good flow of vaccines, a good flow of people … with a good administrative background so that you can register them and they know when to come for their next jab. So there's a variety of things involving planning ahead basically, and having it rolled out so it flows."

3) Israel has a public health care system which requires everyone to belong to one of four health care maintenance organizations (or HMOs) that operate a bit like Britain's National Health Service. Vaccine supplies were distributed to these HMOs who in turn have deployed them to their respective members.

The US has a lot of health care systems and unless each healthcare system has its own vaccination site, this is more difficult. And how does one track those that don't have insurance or are homeless. Massachusetts is setting up field vaccination site to vaccinate the masses, but it's harder to control the inventory and record keeping of each person.

4) Israel's health care system is highly digitized, so everyone receiving the vaccine is registered with the health ministry. In the US, due to HIPPA and each healthcare system having their own network and not accessible to other network, one can't access people's medical records from one central location. Tremendous amount of planning is needed to overcome this obstacle.

5)Israel has been success because they implemented a lockdown while vaccinating their citizens. A lot of US citizens would never accepted or abide to the lockdown.

Countries that have implemented a lockdown have been success in containing the spread of the virus. The only reason that some countries had a resurge of the virus is because they may not have locked down long enough or open up too quickly without further testing, isolating those that may be infectious particularly with multiple people in households and cleaning everything thoroughly before opening up again within their own country.

In order for the US to control the spread of the virus, we need to shut down the country down for 3 week, the virus can't spread if it can't replicate from human to human. Then we need to test everyone to ensure that people are not positive and if they are, they need to be isolated and monitored in a government facility like they do in other countries and in some states like Hawaii for 14 days and not released until they are negative.

In the meantime, since scientist have discovered that the virus can survive up to 28 days on some surfaces. We need to thoroughly clean all surfaces before we can open up offices, restaurants etc. While this is being implement, people still need to wear mask, social distance and wash their hands for a short time until it is determined that everyone is

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.
