

COVID-19 Update December 3, 2020

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1) EPIDEMIOLOGY UPDATE:

Worldwide to date: **Cases:** At least 65 million; **Deaths:** At least 1.5 million

United States to date: **Cases:** ~ 14 million; **Deaths:** ~ 300,000

Israel to date: **Cases:** ~ 340,000; **Deaths:** ~ 2,900

NYS to date: **Cases:** ~ 675,000; **Deaths:** ~ 34,500

Nassau County to date: **Cases:** ~ 62,000; **Deaths:** ~ 2,270

Current US Hospitalizations: ~100,000

Current NYS Hospitalizations: ~3,800 with over 718 in intensive care units; 66 deaths yesterday.

During the summer, the daily death toll in NY was in single digits; in April, death rates were nearly 800 a day. Long Island surpassed 1,000 new confirmed cases last week for the first time since late April.

Nassau County hospitals are seeing markedly increased hospitalizations and ICU admissions versus the summer, but Boruch Hashem nowhere near the horrific April / May numbers. All are actively updating surge plans, re-establishing COVID-19 isolation units, decreasing family visitation, and preparing for worsening numbers post-Thanksgiving and December holidays. *Hashem yeracheim.*

The Centers for Disease Control and Prevention announced on December 2nd that it has a shortened alternative to its recommended quarantine for people exposed to someone with COVID -19. While the CDC **still recommends a 14-day quarantine** as the best way to reduce the risk of spreading COVID-19, it issued two “acceptable” alternative approaches. The new guidance allows people with contact with a known COVID-19 contagious individual to leave quarantine after only 10 (instead of 14) days. Alternatively, they can stop quarantine after just 7 days if they receive a negative COVID-19 test result. Regardless of the length of quarantine, people MUST monitor their own symptoms for a full 14 days after an exposure.

Finally, one continued silver lining in this dark pandemic has been the minimal numbers of “flu” cases recorded so far this year in the Northern Hemisphere, paralleling what was seen during the winter months in the Southern Hemisphere.

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2) New Treatments

A couple of important quick news items worthy of dissemination.

Three new treatments received FDA emergency use authorization in the last few weeks.

- a) **Baricitinib** (brand name **Olumiant**), is an immune modulating drug used in the treatment of rheumatoid arthritis, that has been demonstrated to have **mild** benefit in combination with remdesivir in a very specific subset of hospitalized COVID-19 patients. However, it has not been tested against or used in combination with steroids, which have been proven to be significantly beneficial in such patients, and therefore at this time this medication has a very limited role.

- b) **Bamlanivimab**, a (single) monoclonal antibody made by Eli Lilly, and **Casirivimab / Imdevimab**, a dual monoclonal antibody “cocktail” produced by Regeneron, were approved for newly diagnosed COVID-19 positive patients with mild to moderate symptoms not requiring hospitalization or oxygen supplementation who are at high risk of progression to severe COVID-19 illness. This drug can only be given as an outpatient infusion (intravenous treatment over an hour) and in a setting that can address emergency treatment of anaphylaxis, the major (albeit rare, 1 in 425 incidence) complication that patients receiving this treatment might get. Only hospitals or very few ambulatory centers can provide this therapy. As appropriate, physicians involved in the management of such patients may consider referring them for potential monoclonal antibody infusion therapy. If such therapy is to be effective, it must be started early in the course of infection, as NO benefit (and potential harm) can occur if started too late.

- c) Numerous additional medications such as **fluvoxamine**, **ivermectin**, **interferon** and others have received some attention in the scientific and lay press, but none are currently routinely recommended (outside of a study setting) by Infectious Diseases societies and experts.

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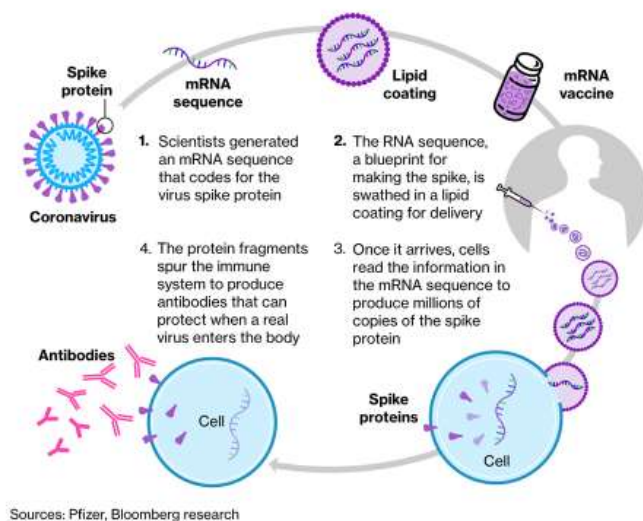
3) Vaccines

By far the most exciting subject of COVID-19 scholarship is the development and submission to the FDA of two mRNA COVID-19 vaccine candidates: one from Pfizer / BioNTech (BNT162b2) and one from Moderna (mRNA-1273).

What are mRNA vaccines?

This is a novel type of vaccine technology which I will discuss in great detail *motzei* Shabbos. A good picture is worth a thousand words – these two slides were produced by colleagues in the Sinai system. The efficacy and safety data for both are very impressive.

Novel Vaccine Technology



Additionally, data are being finalized from the AstraZeneca vaccine candidate AZD1222, and we expect the same in the near future from the Jansen (one of the pharmaceutical companies of Johnson & Johnson) vaccine candidate. Press releases have also been put out by the Russian government regarding the success of Phase 3 trials for their Sputnik 5 vaccine and they suggested that mass vaccinations would be rolled out in Russia in the coming weeks.

mRNA Vaccine Candidates: Double Blind Placebo-controlled trials

	Moderna (mRNA-1273)	Pfizer (BNT162b2)
Participants	30,000 US participants	43,661 international participants
Reported cases of COVID-19 after 7 days after second dose	196 cases with 185 in placebo group v. 11 in vaccine group	170 events with 162 in placebo group v. 8 in vaccine group
Patients in study developing Severe COVID-19	30 cases of severe disease - all in the placebo group	10 cases of severe disease with 9 in the placebo group
Efficacy	94.1%	95%
Safety (median of 2 months after 2 nd dose of half of the participants)	Localized injection site redness/pain, muscle and joint aches, headaches	Fatigue, headache
FDA Advisory Meeting	12/17/20	12/10/20

How and when these vaccine candidates will become available and actually utilized is still not final. The United Kingdom became the first western country to approve widespread use of the Pfizer / BioNTech COVID-19 vaccine earlier this week.

In the US, the Advisory Committee on Immunization Practices (ACIP), comprised of medical and public health experts, will develop recommendations for the use of COVID-19 vaccines in the civilian population. Their recommendations stand as public health guidance for safe use of vaccines and related biological products.

At its December 1, 2020 emergency meeting, the ACIP approved the following recommendation by majority (13-1) vote:

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program should be offered to both:

1) Health care personnel and

2) Residents of long-term care facilities.

The Centers for Disease Control and Prevention (CDC) sets the U.S. adult and childhood immunization schedules based on recommendations from the Advisory Committee on Immunization Practices (ACIP). The above ACIP recommendation has been adopted by the CDC Director.

The FDA advisory committee, made up of outside scientific and public health experts from around the country, will meet on December 10th to discuss the totality of the safety and effectiveness data of the Pfizer / BioNTech COVID-19 vaccine, and consider emergency use authorization for this vaccine. Final decisions on whether to authorize the vaccine for emergency use are made by the FDA. If approved, initiation of vaccines to healthcare workers will start as early as Dec. 15th. Two doses are required, at least 21 days apart. There are significant distribution, storage and reconstitution issues that need to be addressed but this will not prevent rapid rollout of this vaccine if approved.

The Moderna vaccine will be considered in an identical process at a December 17th meeting. Two doses are also required, given at least 28 days apart. There are also distribution and storage issues that will need to be addressed but likewise should not prevent rapid rollout of this vaccine if approved.

Indeed, this is a very exciting time, and I will discuss in detail the development process, medical and halachic decisions in taking the vaccine and the expected rollout on *motzei* Shabbos.

Have a safe wonderful Shabbos.