Coronavirus and the vaccines

Dear Maplewood residents, families, staff and friends,

The coronavirus pandemic has caused devastating human, social and economic loss. The national mortality exceeds 300,000 and the global mortality is over 1.4 million. COVID-19 infection can be asymptomatic, cause mild disease, or be life-threatening, and often in unpredictable ways. It is primarily an airborne infection spread through respiratory droplets, which if severe, can lead to Adult Respiratory Distress Syndrome (ARDS), but can also be transmitted through touching, stool contamination, and potentially other body fluids. Advanced infection can lead to pneumonia, acute kidney injury, blood clots, stroke, cardiac disease and other debilitating and lethal complications. One out of twenty people who are infected with COVID-19 develop symptoms that last longer than eight weeks (sometimes termed long COVID) and 2% have symptoms which persist longer than twelve weeks. The case fatality ratio is difficult to ascertain as it varies by location and time period, but it has generally been calculated between 0.5% and 2% at present in the US. It is true that the incidence is significantly higher as many have contracted coronavirus without being diagnosed, and perhaps, if asymptomatic, even without their knowledge. The actual mortality is likely also higher than reported and there is the concept of "excess deaths" that are indirectly related to COVID because of limited hospital capacity or people's reluctance to seek medical care during the outbreak.

Part of the solution has always been to find safe and effective vaccines against this illness. Fortunately, the first coronavirus vaccine has been approved by the FDA (Pfizer-BioNTech) and a second is likely to follow (Moderna) quickly. Both these vaccines are mRNA technologies, a novel methodology, although it has had been explored with other illnesses prior to this application. It has relative benefits of productivity and safety. Full phase 3 studies were done for both vaccines with 43,000 participants in the Pfizer study and 30,000 in the Moderna study. Both these companies applied to the FDA for Emergency Use Authorization (EUA). The only limitation preventing full licensing was lack of long-term (6 mos. to 2 years) safety data. Due to the urgency of the pandemic this was weighed against the necessity of diminishing transmission and illness in the near term. The large majority of known complications of vaccines occur in the first six weeks post inoculation and the FDA did require at least two months of safety data after the second vaccination for more than 50% of the trial enrollees.

The vaccine can diminish the severity of the coronavirus in at least two ways. Firstly, on an individual basis, it can decrease the likelihood of symptoms, and perhaps more importantly limit the occurrence of severe disease. Whether it will prevent all viral shedding is presently unknown. The second benefit is it may diminish spread in the community leading to a potential for "herd immunity" (where the number of resistant individuals suppresses the disease to the point that those who are unvaccinated also have a decreased likelihood of contracting the

condition). The degree to which this is successful will not be fully known prior to widespread administration.

Unfortunately, no medical intervention is 100% risk-free. The vaccines have mild and sometimes moderate adverse effects. These include redness and swelling at the injection site, fatigue, headache, chills, muscle and joint pain, and rare allergic reactions. Fortunately, the majority of these are quite short-lived. There've been no serious long-term side effects to date.

Each vaccine application is looked at carefully by the FDA and its expert advisory groups. On December 11, 2020 the agency approved the Pfizer vaccine.

Please consider carefully whether the coronavirus vaccine is in the best interest for you or your loved one, as well as the greater community. Circumstances can differ, but it appears in the vast majority of cases that the benefits far outweigh the risks. Please contact me with any questions and I would be happy to discuss them with you.

Sincerely,

Douglas W. Keene, MD, MPH

Medical Director

Maplewood Nursing Home

FDA Action on Vaccines:

https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

Pfizer Fact Sheet for Recipients and Caregivers:

https://www.fda.gov/media/144414/download