COVID-19 Research Activities

There are more than 40 approved COVID-19 research studies most of which are chart reviews and surveys. There are also a number of studies that need blood samples from COVID patients and this has also been approved.

The following is limited to interventional trials:

**Remdesivir** is an antiviral that was developed by Gilead. It was the first antiviral to be used clinically. The final data hasn’t been published, but it appears to be of some benefit and has been approved by the FDA. We have been using it as part of a trial and then as part of compassionate use. The drug will soon be available for routine clinical use. The price is not been released. Given that the indications are that the benefit may be limited it may be replaced by some of the newer agents.

**Plasma Infusion therapy.** The idea was that giving plasma from patients who had survived infection would be beneficial and this is part of a very large clinical trial. Whether the antibody that is present in the plasma is actually protective is uncertain. This is an important issue because development of a vaccine will depend on the type of antibody that is produced and the jury is still out on this although vaccine trials are going to begin shortly (see below). At GW it was hard to see any benefit. It may be that this needs to be given very early in the course of the disease, perhaps even prior to the development of clinical illness.

**Active Clinical Trials at GW.**

**IMAB.** This is a monoclonal antibody against GMCSF. The pulmonary complications of COVID-19 appear to be similar to ARDS. ARDS is mediated by white blood cells. It is noteworthy that ARDS is very rarely seen in septic neutropenic patients. This is given to patients who appear to be deteriorating.

**Selinexor.** This is an antiviral which is being given to patients in early disease. Given that many patients are doing well, it may be difficult to show that this drug is effective unless it is given to a large number of patients.

**Regeneron** has developed a monoclonal antibody directed against the virus. There are 2 protocols. The first one is for outpatients who are diagnosed in the ED or in the tent. They will be infused in the negative pressure room in the MFA. These individuals will be met at the side door, masked and walked directly to the room. They will not be in the waiting room. After the infusion, they will be escorted to Munson Hall where they will stay for two days and be monitored by our staff. The second protocol is for selected inpatients who do not meet criteria for other studies.
Awaiting final approval are a few other studies.

**Novartis** has a monoclonal antibody that blocks IL-1β and IL-18 for patients with pneumonia, but not on mechanical ventilation. The criteria for enrollment are slightly different from that of the IMAB study.

**Ibrutinib** is a BTK inhibitor with potential antiviral activity in patients who have infiltrates on their x-ray, but do not have severe oxygen requirements. This may compete with Selinexor, but the number of patients who are to be enrolled is small.

**Interferon lambda.** A pegylated form of interferon lamda will be given to patients who have been evaluated in the ED and are being sent home. The theory is that this agent will reduce the colonization of the COVID-19. All of the monitoring of these patients will be done through telemedicine and home swabbing of their nose. This will compete with the regeneron trial, but the number of patients that we are seeing and sending home will be more than enough for both studies.

**Vaccine Trials**

**Moderna.** The moderna vaccine trial has been approved and is scheduled to begin in the MFA the second week of July. This is the RNA vaccine that has received so much publicity. This is a 2 year study with a 30,000 patient recruitment. At GW we plan to recruit 500 patients. A major consideration is to recruit individuals over the age of 65.

There are other vaccine studies for which we have been approached, but we are holding off accepting until we get the Moderna study off the ground.

**Pending site selection**

**Regeneron.** A subcutaneous injection of two monoclonal antibodies for health care workers and first responders. We have not heard from Regeneron if we are to be a site for this study.