What Happened Last Week

The FDA issued one new EUA, no amendments to existing EUAs, and one new safety/policy communications in the past week:

- New EUAs (1):
  - Molecular (1): Roche Cobas Duo
- Safety Updates (1):
  - Vaccine Updates (1): FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

New & Noteworthy

Blockbuster movies and testing-company cutbacks: Must be summer

Barring unforeseen circumstances, it’s looking more and more like no new money for testing will be forthcoming from the federal government - and, as an inevitable consequence, testing companies are planning to shrink their workforces. One of the larger regional testing companies, Summer Bio, has already decided to shut its doors and will close their lab on July 30th.

Commentary: Summer Bio’s closure is particularly disappointing, as it was an automated, high-volume lab, providing testing at very competitive pricing for California schools. Clearly, when there is less demand, there eventually will be less supply. We understand that schools and businesses are reducing or eliminating testing. But is now the right time to stop testing and reduce capacity? Didn’t we watch this movie last summer? Eliminating testing programs and decreasing capacity did not turn out well for anyone - and created the unproductive boom and bust cycle. While we don’t expect an agreement in DC to fundamentally change the situation - and the US is clearly in a much better position, immunologically speaking, than it was this time last year - SARS-CoV-2 is not predictable. We’re crossing our fingers that Congress will see the value in continuing to fund testing and the virus does not mutate in new more virulent ways.

More data: Antigen tests detect the infectious

In past Newsletters, we have reviewed many papers that seek to define the right roles for antigen and PCR tests. A recent paper in Microbiology Spectrum evaluates the SD Biosensor Standard Q COVID-19 Ag test against PCR (pre Omicron), using live virus culture as the true gold standard for infectiousness.
The bottom line was that this antigen test showed 96% sensitivity compared with this viral-culture metric (and ~100% specificity). By contrast, the antigen test had a 41% sensitivity when compared with PCR instead of viral culture - implying that if you’re testing to find out whether someone is infectious or not, PCR has a 59% false-positive rate.

Commentary: This emphasizes the PCR over-diagnosis challenge, because PCR identifies as positive all those with any trace of virus. Most of this “false positive infectivity” is in individuals after they are no longer contagious. There is a potential early warning differential benefit for PCR over antigen during the 1–2-day ramp-up phase of infection, but few are actually tested in this short window, and even those that are rarely get the results in time to take precautions.

**Food for Thought**

*Update on COVID vs. flu*

The recent data (Thanksgiving 2021 through June 16, 2022) shows us that severe COVID is in decline at the moment - likely due to widespread prior immunity -even as the number of total cases continues to rise. If we compare the total number of COVID cases reported over the past two years to the number of influenza cases over the last two non-COVID seasons (2017/19), they’re neck and neck, with COVID at 86 million and flu at 91 million.

Important to note that hospital admissions for COVID overall (4.8 million) have been about 4x those for influenza (1.3 million), and COVID’s death rate overall (1 million people) has been 10x higher than flu’s (100,000 people). However, the new news is that COVID's death rate both as a percentage of cases and as a percentage of hospitalized patients is now - post Omicron BA.1/2 - in the same range as flu. See charts below.
Commentary: Folks, we’re trying to be stoic. There is no evidence that we are ever going to be rid of some variant of the SARS-CoV-2 virus, so we better learn to live with it and continue our social and economic lives. But living with it does not mean ignoring it. We have learned to live with other viruses through vaccination (e.g., measles, polio, smallpox). They now mutate infrequently, so vaccines are effective for life. Other viruses, particularly flu, have more dynamic mutation profiles, so we need annually updated vaccines. SARS-CoV-2 is still exploring mutation possibilities in a new host animal (us) and has not been infecting that host for long enough for us to reliably predict its future. The pace of mutations may slow down, creating only incremental flu-like viral fitness improvements (e.g., Delta), or another extreme variant may appear "out of nowhere" (e.g., Omicron). There is just no way to predict the future of this virus. So, we must remain fully prepared with surveillance (wastewater), easy and rapid diagnosis (point-of-care tests), and updated vaccines.

The Good News Is…
Long COVID less likely after Omicron than after Delta

A *Lancet* study that included over 97K patients concluded that the risk of Long COVID after infection with Omicron was roughly half the risk of Long COVID after infection with Delta. That risk still isn’t negligible: About 4.4% of post-Omicron patients in the study reported Long COVID symptoms, and 4.4% of Omicron cases worldwide is still a very large number of people. But it could have been a whole lot worse.

### Latest Monthly Capacity Estimates

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<th>Test Type</th>
<th>Jan '22</th>
<th>Feb '22</th>
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<th>April '22</th>
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<tr>
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*Based on published reports, company interviews, and proprietary analysis. Content and commentary represents the views of the editors alone and not their organizations. A collaboration between Health Catalysts Group & COVID-19 Response Advisors.*

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