Twitter Thread by Amy Maxmen, PhD



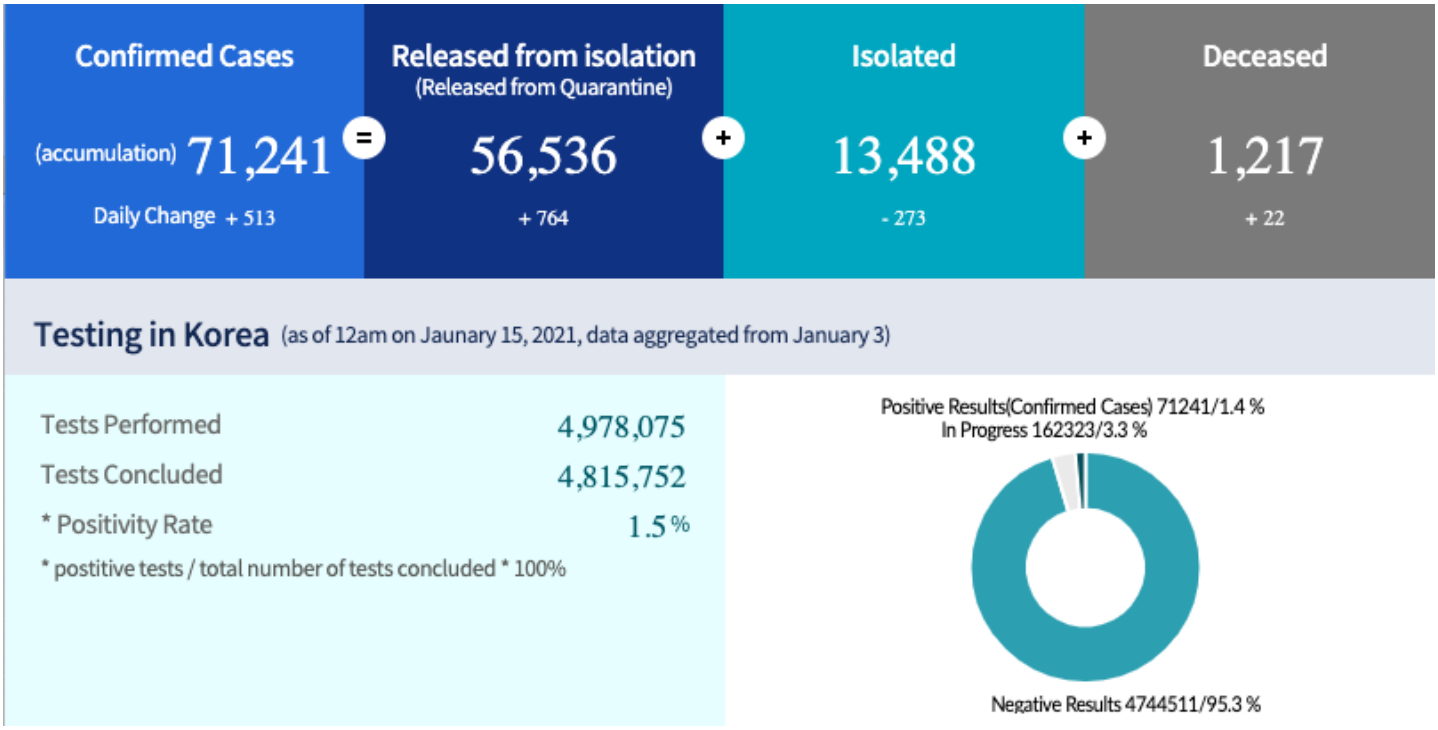
Amy Maxmen, PhD
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Azar just released a delusional, alternative history of Covid testing in the US. I'm mad because our testing failures allowed this outbreak to blow-up. We can't fix our system if we ignore where it is broken. I suspect @PublicHealth agrees.

My fact-check on remarks @HHSGov ■

"It is indisputable that the United States has built the most extensive testing system and strategy of any major country," says Azar.

False. Several countries have had percent positivity ~1% whereas US has never been below 5% and is >10% today. Refs KCDC & USA @JohnsHopkins



"The federal government got out of the way of test development in safe and sensible ways," says Azar.

False. In Feb, CDC & FDA blocked labs from testing as the disease spread exponentially. I broke this story■■& wrote more

like it as the year wore on. https://t.co/5zbGfZaSry

Azar defends questions about why the CDC refused an early German test vetted & distributed by WHO, by saying it was ‘unapproved’ & beneath us.

False. Top US researchers in my stories vetted several tests as early as Feb,& found that the one recommended by WHO was ideal.

When you hear people ask why the U.S. didn’t use “the WHO test,” it’s worth knowing that there was no such thing. The WHO had not developed or cleared a test. Rather, it had contracted with a German test maker to produce an unapproved set of primers and a mix of reagents, which the WHO then sent to dozens of low-income countries that either didn’t have the lab capacity to make the primers, didn’t have easy access to the reagents they’d need, or both.

It was, in essence, the same as the CDC test or any other test being used at the time around the world. It lacked any form of regulatory approval, as the WHO did not put any products through its process until April, and European countries do not hold such diagnostics to the same regulatory standards we did at the time.

The same goes for South Korea’s commendable scale-up of testing. It was largely one South Korean private sector manufacturer that developed specific primers and the right mix of reagents, and started performing tests just like the CDC was—but on a larger scale, without the unfortunate mistakes that occurred in CDC’s manufacturing of the testing kits they eventually distributed to other public health labs.

Azar refuses to concede that other countries handled Covid better. He attributes Koreas success to less travel, invasiveness & private sector.

False. Korea's gov't marshaled the private sector & tracing success was largely from hiring tons of tracers. https://t.co/Ad1D1kpd6Q

Here's a nugget of truth. The FDA held back academic labs from testing, and have been unclear. Researchers testing like @srikosuri @UrnovFyodor may be interested in this part of the discussion.

Achieving the right balance of speed and safety in these regulatory decisions is always a difficult task. But FDA was not transparent that they had actually raised the standards on these labs. Labs complained to us throughout February that they found the EUA criteria perplexing and challenging, which made a great deal more sense if it had been clear that FDA was imposing a wholly new and unprecedented requirement.

These labs were slowed down in part because they weren't accustomed to actually submitting EUAs or any kind of applications to FDA. Remember that the Obama Administration had backed down from its assertion of jurisdiction over LDTs, so these labs had never learned how to deal with FDA's device center and its requirements. They were told reams of data would be required, and even directed, in at least one case, that it be submitted in hard copy—at a time when every hour of every day counted.

The standards were hardly pro forma, too. The FDA, for instance, required five validations be run of a test, requiring five viral samples—at a time when, in early February, barely five cases of the virus had been confirmed in the United States.

When you combine FDA's lack of clarity about what they were asking of labs, and the independence traditionally accorded to FDA regulators, it took time to undo this morass. A partial resolution came on February 29: We agreed with FDA leadership that they would allow labs to start using tests they had developed, as long as they also submitted a completed EUA application within 15 days.

Azar asserts "There is a myth out there that, if only we'd had a superior testing system, we simply could have caught any cases and isolated them."

False (except for it being simple). Any outbreak specialist tells you that early days matter most. That's THE time for containment.

I need to get back to work but the speech goes on. I'll try to return to this later. In the meantime, here's my piece with @jefftollef about testing failures and why they matter so much. https://t.co/7pL6SzLvNc