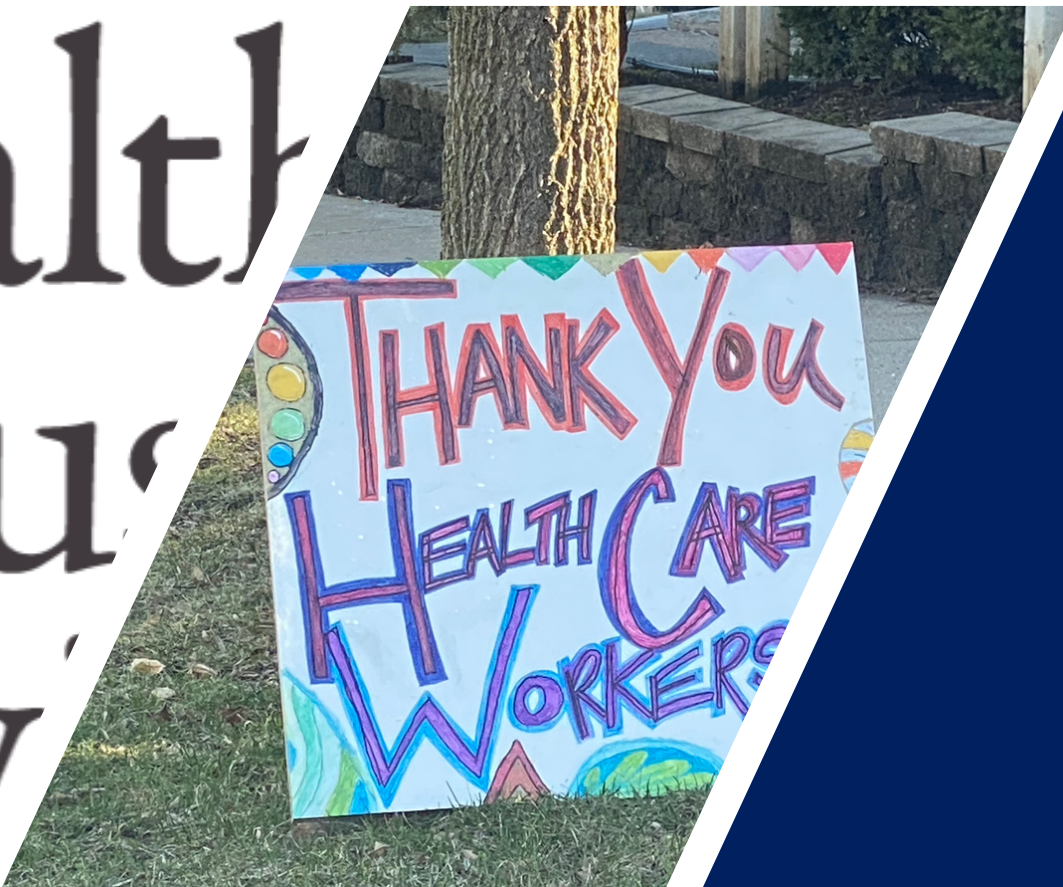




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Issue # 169
Thursday, September 24, 2020

COVID-19 Report

Highlights

- Clinical trials of vaccines
 - **With Johnson & Johnson's announcement of the launch of a Phase III clinical trial of its vaccine, this now become the largest Phase III clinical trial in the United States**
 - There are now four clinical trials in the United States (AstraZeneca, JNJ, Moderna and Pfizer, although the AstraZeneca trial remains paused here) and ten worldwide
 - JNJ set its **efficacy target (i.e., targeted infection risk reduction via the vaccine)** at 60%, consistent with Modern and Pfizer; AstraZeneca's is set at 50%
 - **JNJ has established 154 events or, infections at the completion point of its trial; AstraZeneca's is set at 150; Moderna at 151; and Pfizer at 164**
 - **Thus, after 154 infections among study participants, a determination is made of JNJ's vaccine efficacy**
 - The goal is that participants receiving the vaccine will have a 60% lower infection rate than those receiving the placebo
 - **Under FDA guidelines, a vaccine is considered effective so long as its efficacy is at least 30%**
 - **In this event, the vaccine could be approved for general use in the United States**
 - JNJ has not yet disclosed the number of interim analyses it plans; AstraZeneca plans 1; Moderna, 2; and Pfizer 3
 - **The initial interim analysis for Pfizer occurs after 32 infections; for AstraZeneca, it occurs after 75 infections; and for Moderna, after 53 infections**
 - **Thus, under the FDA's proposed evaluation guidelines, Pfizer's trial could be considered successful if, after 32 infections among participants, the infection rate for those receiving the vaccine is 50% lower than for those receiving a placebo**
 - **In this event, the company could then apply for Emergency Use Authorization (EUA) for its vaccine**
- State-By-State Scorecard
 - In today's report, we update our chart depicting infection, testing and fatality rates for each state and the District of Columbia
- **A new measure in this analysis is the ratio of tests to new cases for the previous 7-day period. The higher this ratio, the more effective the state's testing program. Vermont scores best on this measure, with 250 tests for every new case it detected. Maine is next at 191. By comparison, North Dakota detected a new case for every 4 tests it performed**
- **Several states reported high test-positive and new infection rates for the last 7-days, including: Alabama, Idaho, Iowa, Kansas, Missouri, Nebraska, North Dakota, South Dakota and Wisconsin**
- States reporting low test-positive and new infection rates include Connecticut, Hawaii, Maine, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, Ohio, Vermont and Washington
- New cases and infection rates in the United States
 - **We seem to be treading water in the U.S. with respect to new infections - they don't seem to spiking or declining; the new infection rate has remained relatively stable now for the past six days**
 - New cases yesterday were generally in-line with new cases on 3 of the past 4 Wednesdays (the Wednesday following Labor Day being an exception, with relatively low cases). New cases were significantly higher on Wednesdays in July through mid-August
- Hospital resource use due to COVID-19
 - **After seeing significant declines from mid-July peaks, inpatient and ICU census of COVID-19 patients have been relatively flat over the past week, with slight increases on each of the past three days. These remain, however, at 50-60% of their peak levels**
 - **Ventilator use continued to decline as a % of inpatient COVID-19 census; In March, 35% of patients were on ventilators; as of yesterday, this rate is just above 12%**
 - ER visits for COVID-19 like illnesses, pneumonia and shortness-of-breath have each steadily declined as a % of all ER visits. For COVID-19 like illnesses, this rate has dropped by nearly 1/2 since late July
- Deaths with the coronavirus
 - **The 7-day average in reported deaths fell yesterday for the ninth consecutive day**

As of yesterday, there were at least 147 potential vaccines in the pipeline:

- 92 under active investigation in animals
- 40 in safety trials
- 10 in large-scale efficacy tests
- 5 approved for limited use (none in the U.S.)

Pre-Clinical –
Vaccines not yet in clinical trial

92

Phase I –
Vaccines testing safety and dosage

26

Phase II –
Vaccines in expanded safety trials

14

Phase III –
Vaccines in large-scale efficacy tests

10

Limited –
Vaccine approved for limited use

5

Full –
Vaccine approved for full use

0

* - Source: "Coronavirus Vaccine Tracker", New York Times, Updated September 23, 2020
<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

There are now four Phase III clinical trials of a COVID-19 vaccine underway in the United States. JNJ is now the largest

Pfizer, JNJ and Moderna are targeting a 60% “efficacy” (i.e., reduction in infection risk); Astra-Zeneca is targeting 50% (WHO standard: 50%)

All four have established a threshold of a 30% risk reduction (95% confidence interval; consistent with FDA guidance)

Interim checkpoints are used to judge whether sufficient evidence (“events”, infections) is available to end a trial early. Astra-Zeneca has established a single interim checkpoint; Moderna, 2; and Pfizer, 4

COVID-19 Phase III Clinical Trial Protocols - United States

	Pfizer	Moderna	AstraZeneca	JNJ
Sample Size	44,000	30,000	30,000	60,000
Participants getting vaccine	15,000	15,000	20,000	30,000
Type of vaccine	mRNA	mRNA	Adeno v	Adeno v
Efficacy target	60%	60%	50%	60%
Lower 95% CI efficacy	30%	30%	30%	30%
Number of events at completion	164	151	150	154
Number of interim analyses	4	2	1	N/A
Number of events 1st look	32	53	75	20
Number of shots	2	2	2	1
Deep freezing required	Yes	Yes	Yes	No

Table: Eric Topol, MD • Created with Datawrapper

Interpretation: Pfizer’s “first look”, can occur after 32 infections among its participants. Using the FDA’s proposed evaluation criteria, the trial may be considered successful, if there is at least a 50% lower infection rate among participants receiving the vaccine versus those receiving the placebo. At that point, the company could apply for Emergency Use Authorization (EUA)

Pfizer’s trial would be complete after 164 infections among its participants. The trial may be considered successful, if there is at least a 30% lower infection rate among participants receiving the vaccine versus those receiving the placebo. At that point, the company could apply for full approval

State-By-State Comparisons (page 1 of 3):

Alabama, Idaho, Iowa and Kansas show high rates of new infections and test-positive %'s

Connecticut, D.C. and Hawaii report low new infection and test-positive rates

Connecticut and D.C. are most efficient in their testing (highest ratio of tests per new case identified)

State-By-State Comparisons

As of September 23

State	Cases per 1M Population	Deaths per 1 Million Population	Tests per 1M Population Past 7 days	Test-Positive % (7-Day Moving Average)	New Daily Cases Per 1M Population (7-Day M.A.)	Tests / New Case
Alabama	29,896	507	1,306	13.5%	177	7
Alaska	9,500	62	4,811	2.3%	109	44
Arizona	29,517	759	1,598	6.6%	106	15
Arkansas	25,509	407	2,986	9.1%	272	11
California	20,085	388	3,178	2.8%	90	35
Colorado	11,470	353	1,225	8.0%	99	12
Connecticut	15,752	1,261	3,826	1.2%	46	83
Delaware	20,293	646	1,487	5.9%	87	17
District Of Columbia	21,284	880	5,102	1.2%	62	82
Florida	32,029	634	1,144	11.2%	128	9
Georgia	29,030	638	2,006	7.1%	143	14
Hawaii	8,138	86	2,125	3.2%	75	28
Idaho	21,398	253	1,097	18.4%	211	5
Illinois	22,054	690	4,155	3.5%	147	28
Indiana	16,729	524	1,293	9.1%	117	11
Iowa	25,774	410	1,664	15.9%	276	6
Kansas	18,873	213	1,376	15.5%	225	6

State-By-State Comparisons (page 2 of 3):

Missouri and Nebraska show high rates of new infections and test-positive %'s

Maine, Massachusetts, New Hampshire, New Jersey, New Mexico and New York report low new infection and test-positive rates

Maine and New York are most efficient in their testing (highest ratio of tests per new case identified)

State-By-State Comparisons

As of September 23

State ▲	Cases per 1M Population	Deaths per 1 Million Population	Tests per 1M Population Past 7 days	Test-Positive % (7-Day Moving Average)	New Daily Cases Per 1M Population (7-Day M.A.)	Tests / New Case
Kentucky	14,041	252	6,279	2.4%	152	41
Louisiana	34,894	1,163	3,221	3.8%	117	27
Maine	3,828	104	4,660	0.5%	24	191
Maryland	20,000	645	1,634	4.9%	81	20
Massachusetts	18,414	1,345	2,233	2.1%	58	39
Michigan	13,053	702	2,956	2.7%	79	37
Minnesota	16,211	361	1,813	8.8%	159	11
Mississippi	31,591	964	4,031	4.0%	160	25
Missouri	19,388	339	1,866	12.9%	266	7
Montana	10,011	154	3,309	6.0%	198	17
Nebraska	21,601	239	1,635	12.7%	211	8
Nevada	24,771	505	1,038	11.4%	119	9
New Hampshire	5,876	322	1,130	2.1%	24	47
New Jersey	22,986	1,824	3,020	1.7%	52	58
New Mexico	13,253	409	2,748	2.1%	64	43
New York	24,942	1,706	4,445	0.9%	44	100
North Carolina	18,645	316	2,166	5.3%	115	19

State-By-State Comparisons (page 3 of 3):

North Dakota, South Dakota and Wisconsin show high rates of new infections and test-positive %'s

Vermont, Ohio and Washington report low new infection and test-positive rates

Vermont is the most efficient in its testing (highest ratio of tests per new case identified)

State-By-State Comparisons

As of September 23

State	Cases per 1M Population	Deaths per 1 Million Population	Tests per 1M Population Past 7 days	Test-Positive % (7-Day Moving Average)	New Daily Cases Per 1M Population (7-Day M.A.)	Tests / New Case
North Dakota	24,287	266	1,836	27.0%	496	4
Ohio	12,489	402	2,954	2.6%	77	39
Oklahoma	19,983	245	3,131	9.1%	284	11
Oregon	7,424	127	842	6.7%	56	15
Pennsylvania	12,226	636	980	6.3%	61	16
Rhode Island	22,697	1,040	1,858	5.9%	110	17
South Carolina	27,344	634	3,043	6.9%	210	14
South Dakota	21,691	228	1,692	22.4%	378	4
Tennessee	27,095	333	3,556	5.7%	201	18
Texas	25,920	534	2,173	10.2%	230	9
Utah	20,288	138	2,055	13.4%	275	7
Vermont	2,758	93	1,190	0.4%	5	260
Virginia	16,638	362	2,064	5.1%	104	20
Washington	11,299	273	1,204	3.7%	63	19
West Virginia	8,049	178	2,534	4.1%	105	24
Wisconsin	17,891	216	1,930	17.5%	324	6
Wyoming	8,667	86	1,240	12.0%	149	8

Table: Health Industry Advisor LLC • Created with Datawrapper

During the month of September, Israel has experienced a sharp increase in its infection rate (nearly 3x)

Bahrain saw its rate increase sharply but start to decline

Czechia has seen its rate increase by >5.6x

Brazil and Peru's rate have declined modestly

Highest Rate of New Daily Infections / Million: Countries > 1M Population

Trailing 7-Day Moving Average, As of September 23

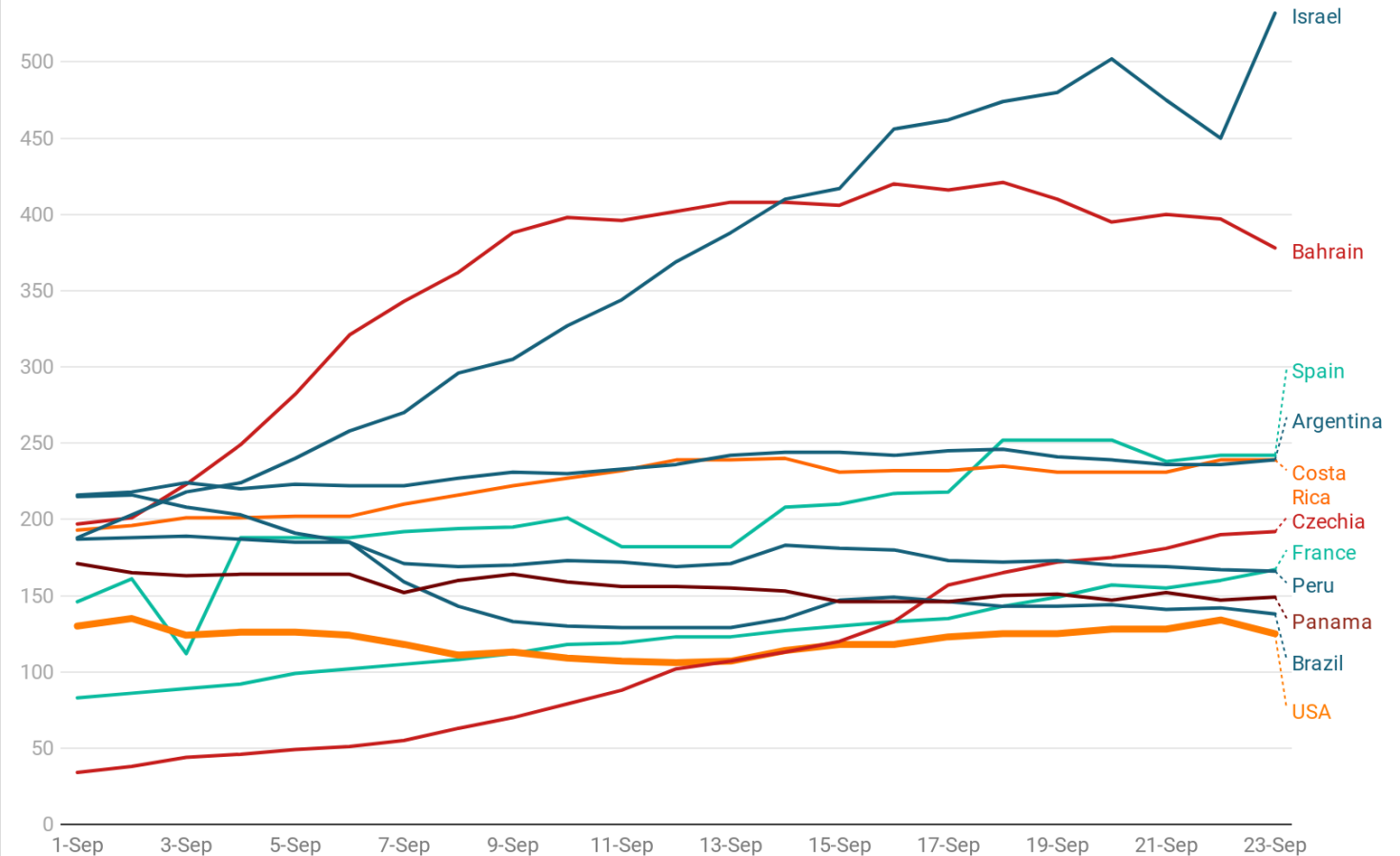


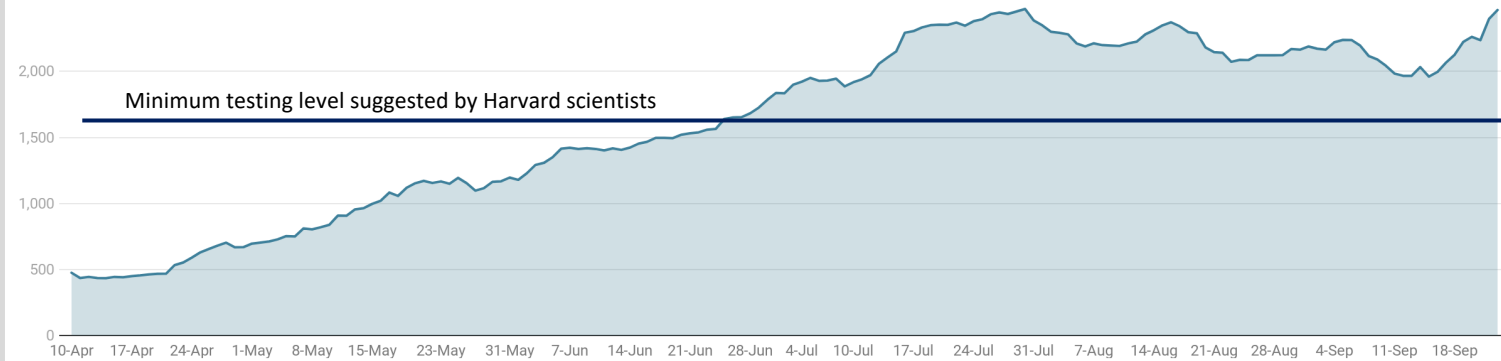
Chart: Health Industry Advisor LLC • Created with Datawrapper

7-day average daily test volume as of yesterday was second highest volume to-date; this rate has increased 24% week-over-week

The test-positive rate yesterday fell below 5% (4.7); the 7-day average test-positive rate is as low as it has been since June 27

Daily Tests Per 1 Million - United States

Trailing 7-Day Moving Average, As of September 23

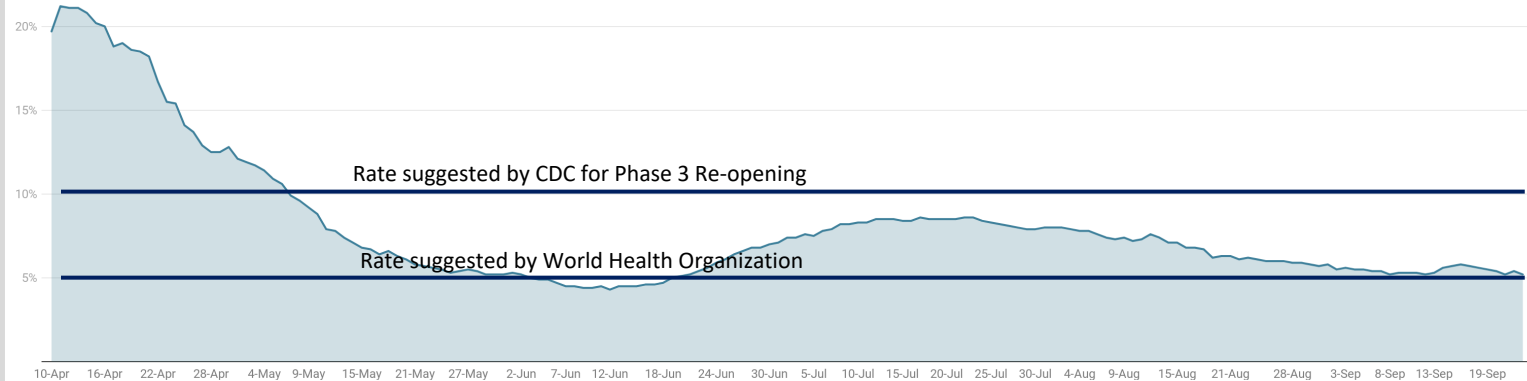


Health Industry Advisor LLC analysis

Chart: Health Industry Advisor LLC • Source: The Atlantic's Covid Tracking Project • Created with Datawrapper

Test-Positive Rate - United States

Trailing 7-Day Moving Average, As of September 23



Health Industry Advisor LLC analysis

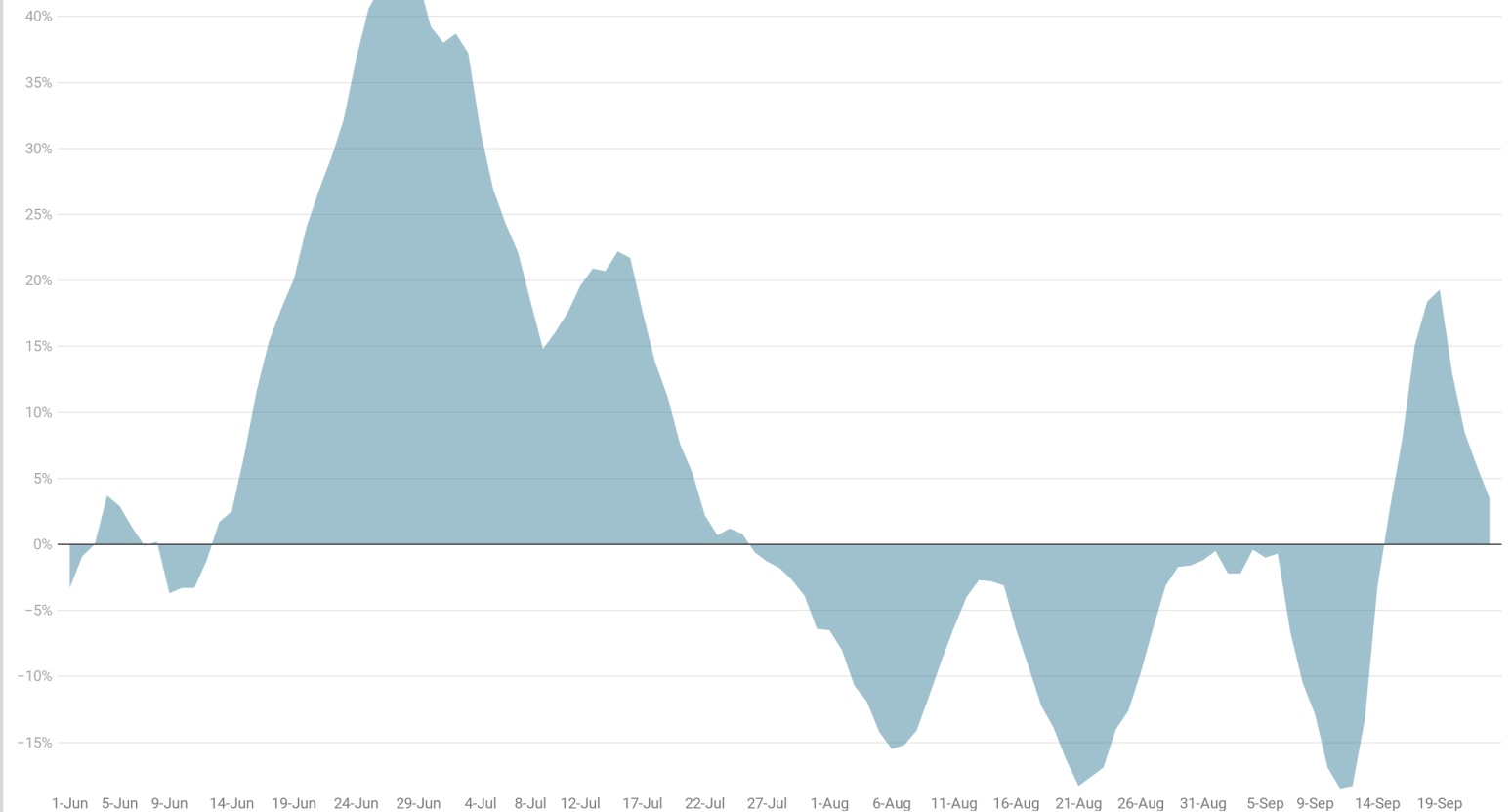
Chart: Health Industry Advisor LLC • Source: The Atlantic's Covid Tracking Project • Created with Datawrapper

Following a seven-week period of decline, new cases began increasing on a week-over-week basis one week ago.

Yesterday, this rate was up 3.5% versus a week ago (although the rate of increase has declined each of the past four days)

Week-Over-Week Change In New Cases

Through September 23



Health Industry Advisor LLC analysis

Chart: Health Industry Advisor LLC • Source: worldometers.info • Created with Datawrapper

Case growth:

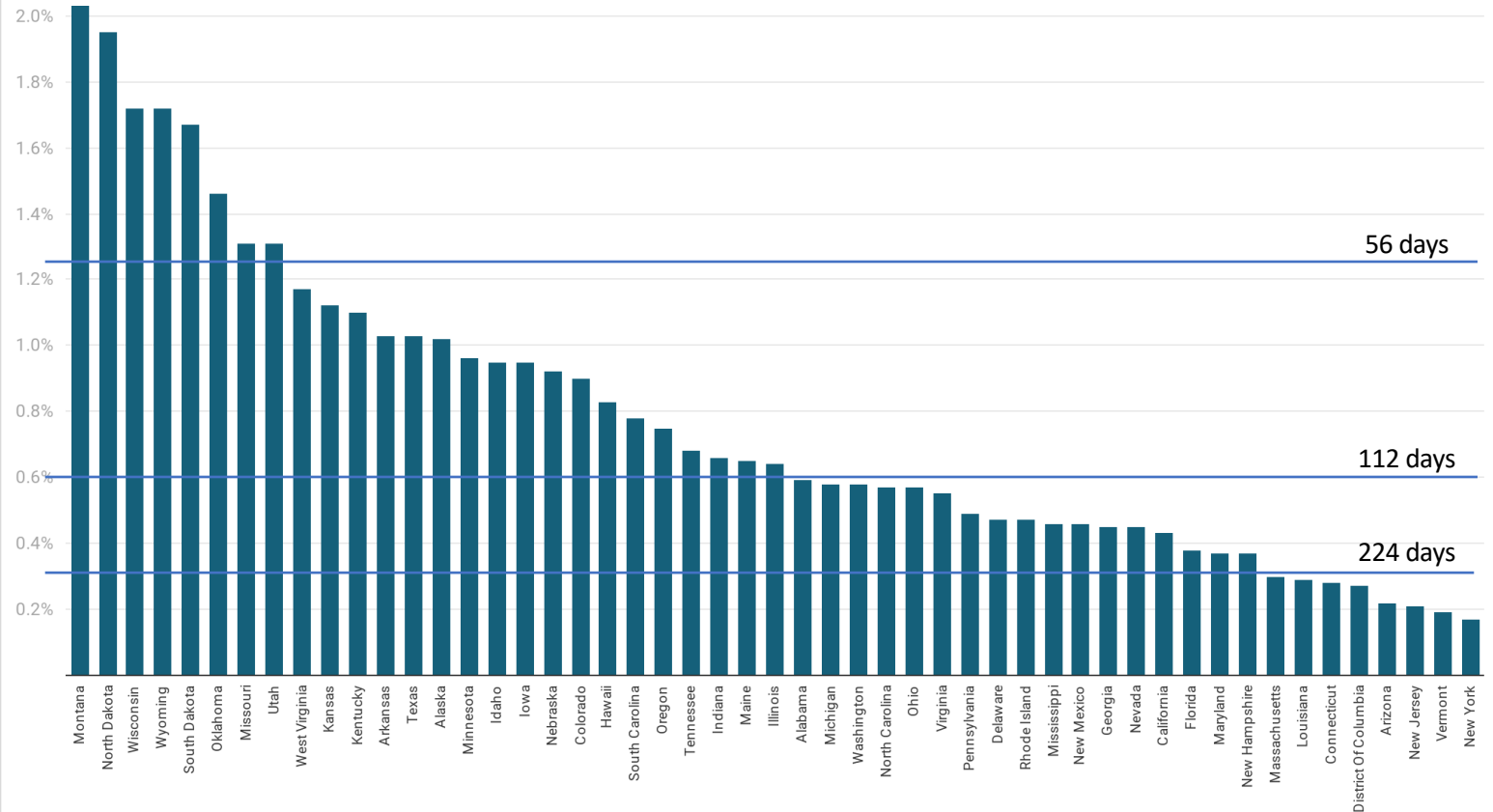
At current rates, cases are doubling every 34-35 days in Montana

Every 404 days in New York

Every 127-128 days for the United States overall

Growth Rate in Total Cases

Trailing 5-Day Moving Average, Through September 23



Health Industry Advisor LLC analysis

Chart: Health Industry Advisor LLC • Source: worldometers.info • Created with Datawrapper

Except for Labor Day week, new cases on recent Wednesdays have been relatively consistent (40-42K)

New Daily Cases

Through September 23

Wednesdays Highlighted

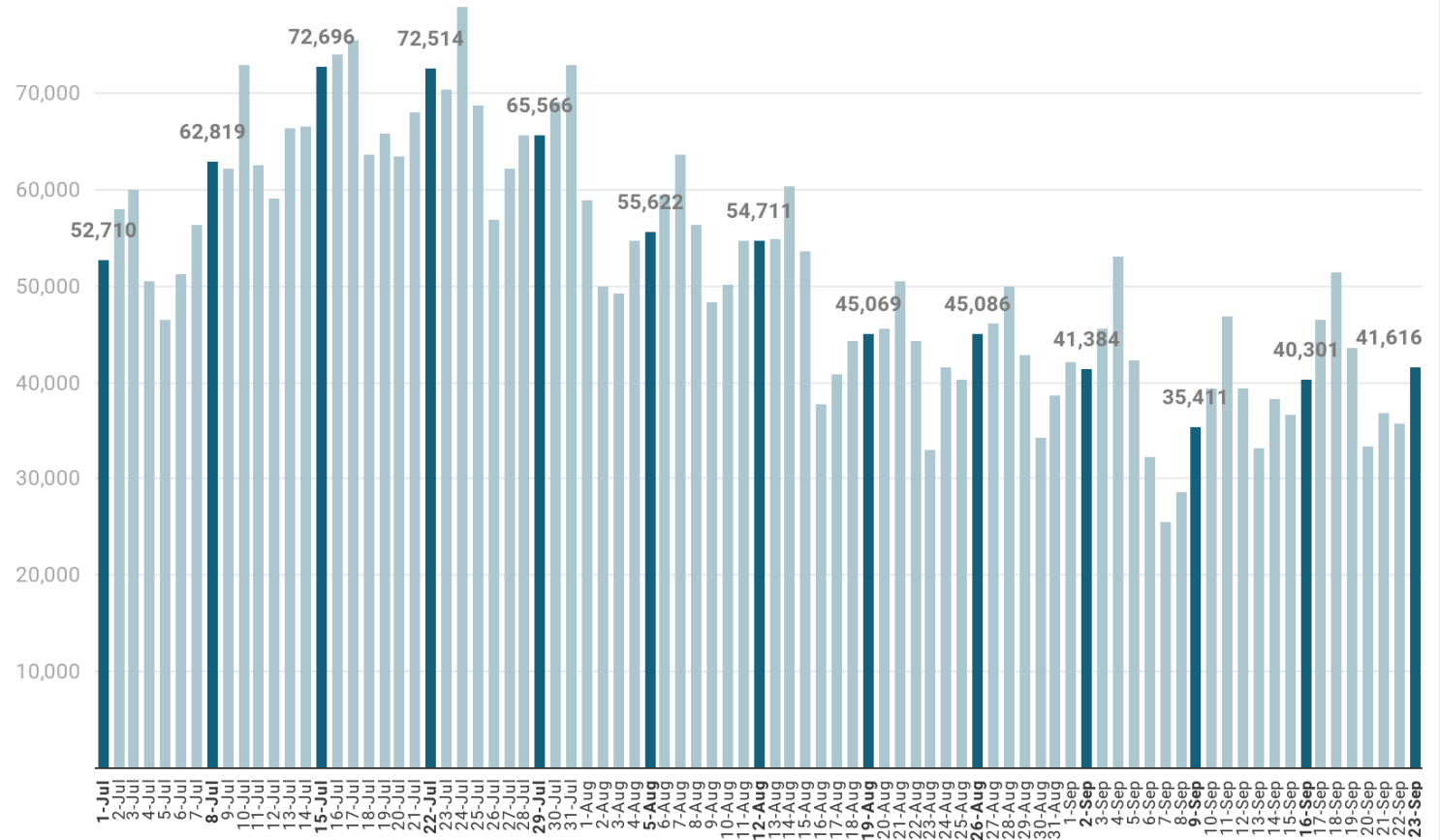


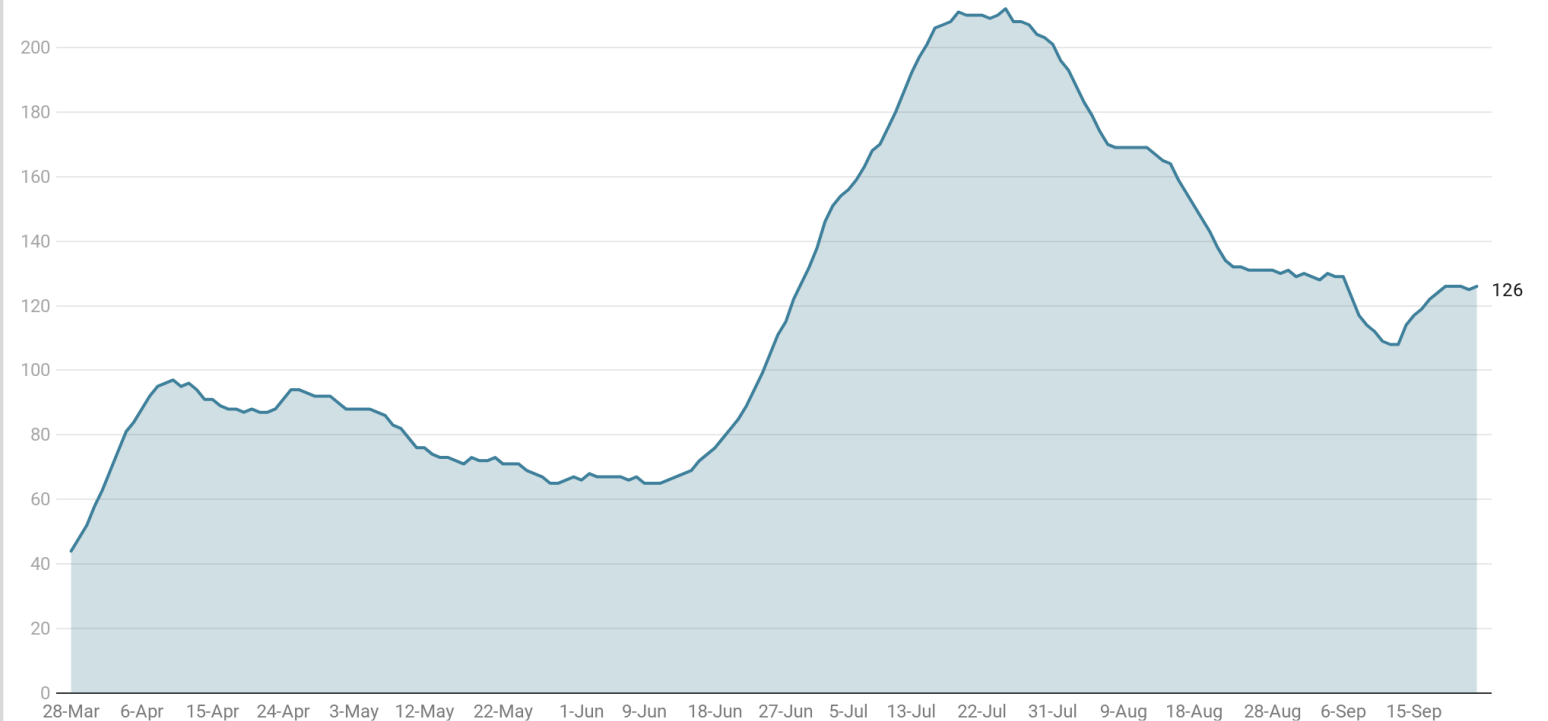
Chart: Health Industry Advisor LLC • Created with Datawrapper

New infections per capita in the U.S.* bottomed-out on September 12 then increased through the end of last week

The current rate has been essentially flat for the past six days

New Infections Per 1 Million Population - United States

Trailing 7-Day Moving Average, Through September 23



Health Industry Advisor LLC analysis

Chart: Health Industry Advisor LLC • Source: worldometers.info • Created with Datawrapper

* - 7-day moving average basis

Inpatient and ICU COVID-19 census have each increased for three consecutive days

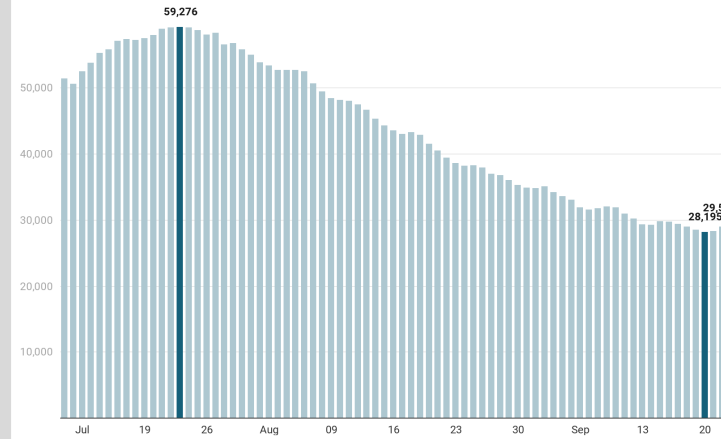
Ventilator use continues to decline as a % of patients

ER visits for COVID-19-like illness, pneumonia and shortness-of-breath as a % of all ER visits each have declined since early July

No discernable start yet to the impact of flu season

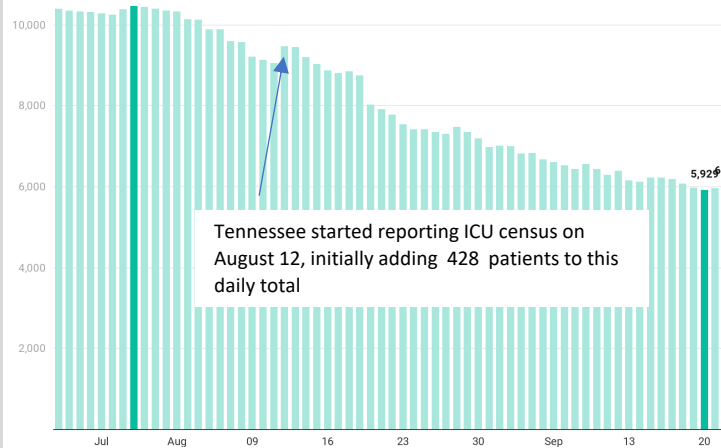
Hospital Census: COVID-19 Patients

As of September 23



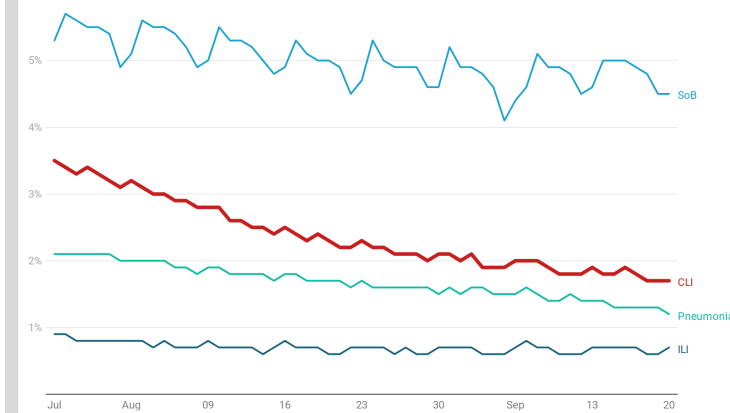
COVID-19 ICU Census

As of September 23



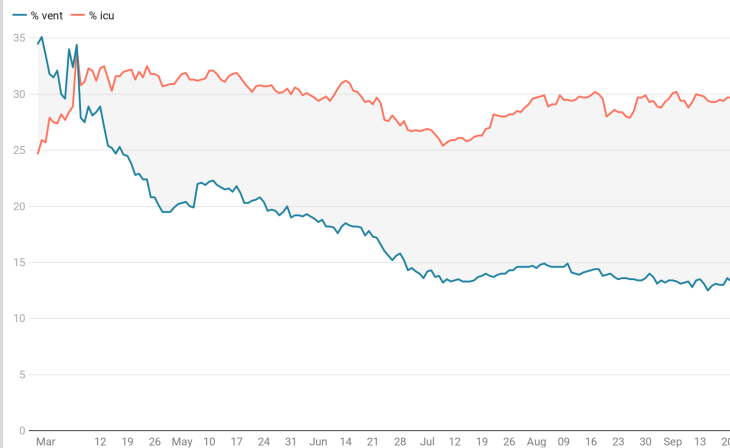
% of Emergency Department Visits for COVID-Like Illness (CLI), Influenza-Like Illness (ILI), Pneumonia & Shortness-of-Breath (SoB)

As of September 20



Severity of Hospitalized Patients

% of patients on ventilators and in the ICU, As of September 23



7-day average daily deaths have declined on nine consecutive days

Except for Labor Day week, there were fewer deaths reported on Wednesday than any other Wednesday in the past 10 weeks

Deaths Reported With Coronavirus in the U.S.

Trailing 7-Day Moving Average, As of September 23



Health Industry Advisor LLC analysis

Chart: Health Industry Advisor LLC • Source: worldometers.info • Created with Datawrapper

Newly Reported Deaths

Through September 23

Wednesdays Highlighted

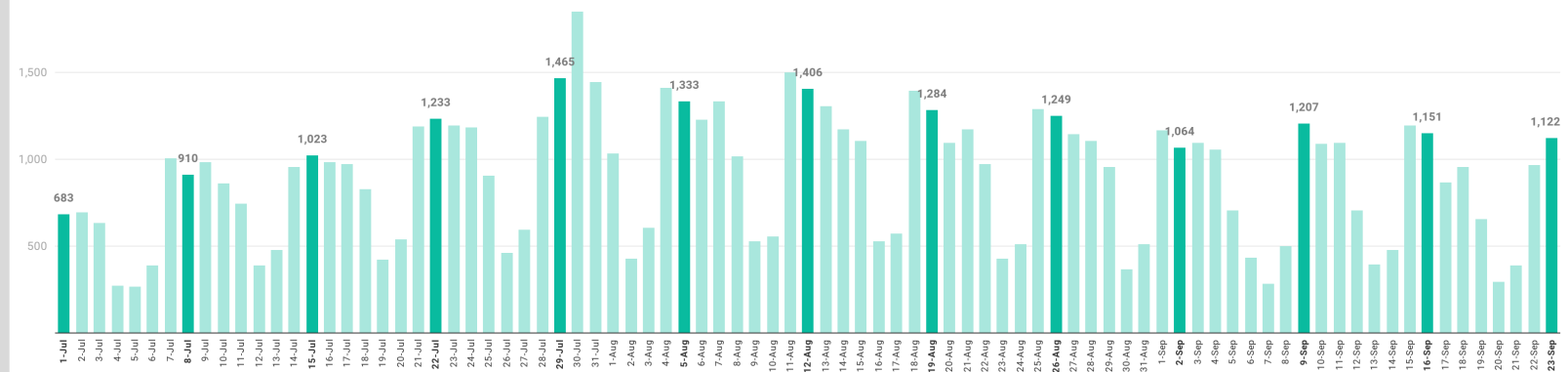


Chart: Health Industry Advisor LLC • Source: worldometers.info • Created with Datawrapper

Data Sources

The following data sources are accessed on a daily or weekly basis:

- The Atlantic's Covid Tracking Project: <https://covidtracking.com>
- Worldometers.info: <https://www.worldometers.info/coronavirus/>
- Centers for Disease Control, National, Regional, and State Level Outpatient Illness and Viral Surveillance
<https://gis.cdc.gov/grasp/fluview/fluportaldashboard.html>
- Centers for Disease Control, COVID-19 Laboratory-Confirmed Hospitalizations
https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html
- Centers for Disease Control, COVID Data Tracker <https://www.cdc.gov/covid-data-tracker/index.html#mobility>
- Institute for Health Metrics and Evaluation, COVID-19 estimate downloads
<http://www.healthdata.org/covid/data-downloads>
- New York Times, Covid-19 data <https://github.com/nytimes/covid-19-data>
- COVID-19 Data Repository by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University
<https://github.com/CSSEGISandData/COVID-19>
- COVID-19 Projections Using Machine Learning, <https://covid19-projections.com>