

Near Real-Time Surveillance of RSV to Support Clinical Trial Enrollment Strategies in ConquerRSV

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BACKGROUND

- Respiratory syncytial virus (RSV) is a common seasonal virus¹ that can affect people of all ages and is an important cause of severe lower respiratory tract disease (LRTD) in older adults and those with certain underlying health conditions²
- No vaccines are currently approved to prevent RSV-associated acute respiratory disease or RSV-LRTD, although a novel mRNA-based RSV vaccine, mRNA-1345, is currently under investigation in an ongoing, case-driven phase 2/3 pivotal vaccine efficacy trial in adults aged ≥ 60 years (ConquerRSV; NCT05127434)
- Preventive measures enacted during the height of the COVID-19 pandemic led to a disruption in the normal seasonal patterns of RSV³
 - The risk of initiating a pivotal RSV vaccine efficacy trial during these disruptions can be reduced by conducting geographically granular and near real-time surveillance of RSV
 - By leveraging near real-time surveillance data, we developed a strategic enrollment plan for the ConquerRSV study in adults aged ≥ 60 years across 22 countries, including the United States

OBJECTIVE

- To describe RSV seasonality in the United States from June 2016 to December 2022 using laboratory surveillance data

METHODS

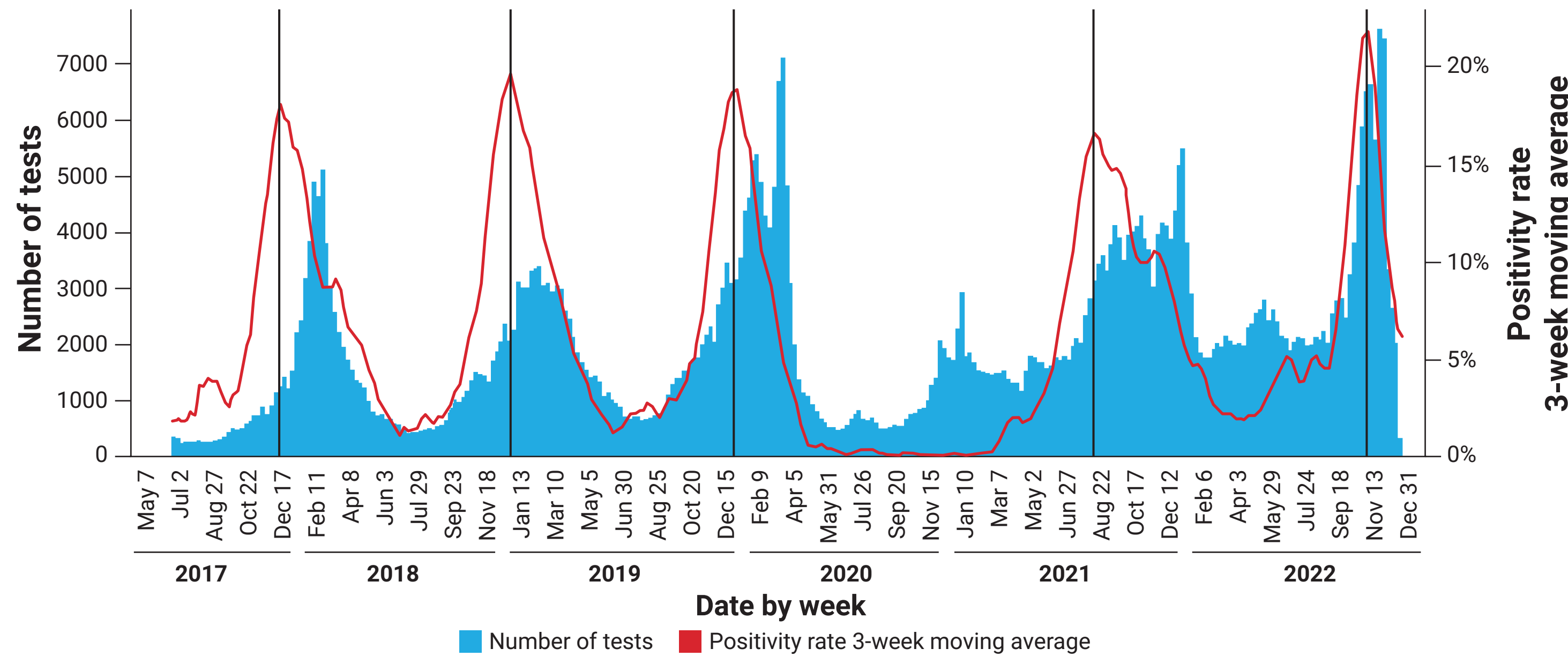
- This was a descriptive study that leveraged Amazon Web Services Data Exchange to collect weekly near real-time data in 2022 and historical data as available from various healthcare database vendors such as Quest, Ovation, and Health Catalyst using a cloud-based data warehouse (Redshift) that consolidates all data into a uniform format, following which, data are visualized using Tableau
- A common data model was developed to centrally combine data collected from independent populations throughout the United States, which included various levels of geographic indicators, including (as feasible) US Department of Health and Human Services (HHS)⁴ region, state, metropolitan statistical area, and 3-digit ZIP code
- Eligible healthcare database vendors had populations meeting the following requirements: included individuals of all ages with RSV reverse-transcriptase polymerase chain reaction (RT-PCR) testing data; included data from 2022 with no more than a 1- to 2-week lag
 - RSV positivity trends were plotted over time using a 3-week moving average

RESULTS

RSV Test Count and RSV Positivity Rate

- From June 17, 2016, through December 24, 2022, there were 995,414 RT-PCR tests performed and 56,925 positive results for RSV in the United States
- Before the start of the COVID-19 pandemic (January 2020⁵), nationally, consistent, seasonal RSV winter peaks were observed in December or January (Figure 1)
 - However, during the pandemic, there was no RSV season in 2020; in 2021 and 2022, RSV peaks occurred in August and November, respectively

Figure 1. Total Test Count and RSV Positivity Rate From May 2017 to December 2022

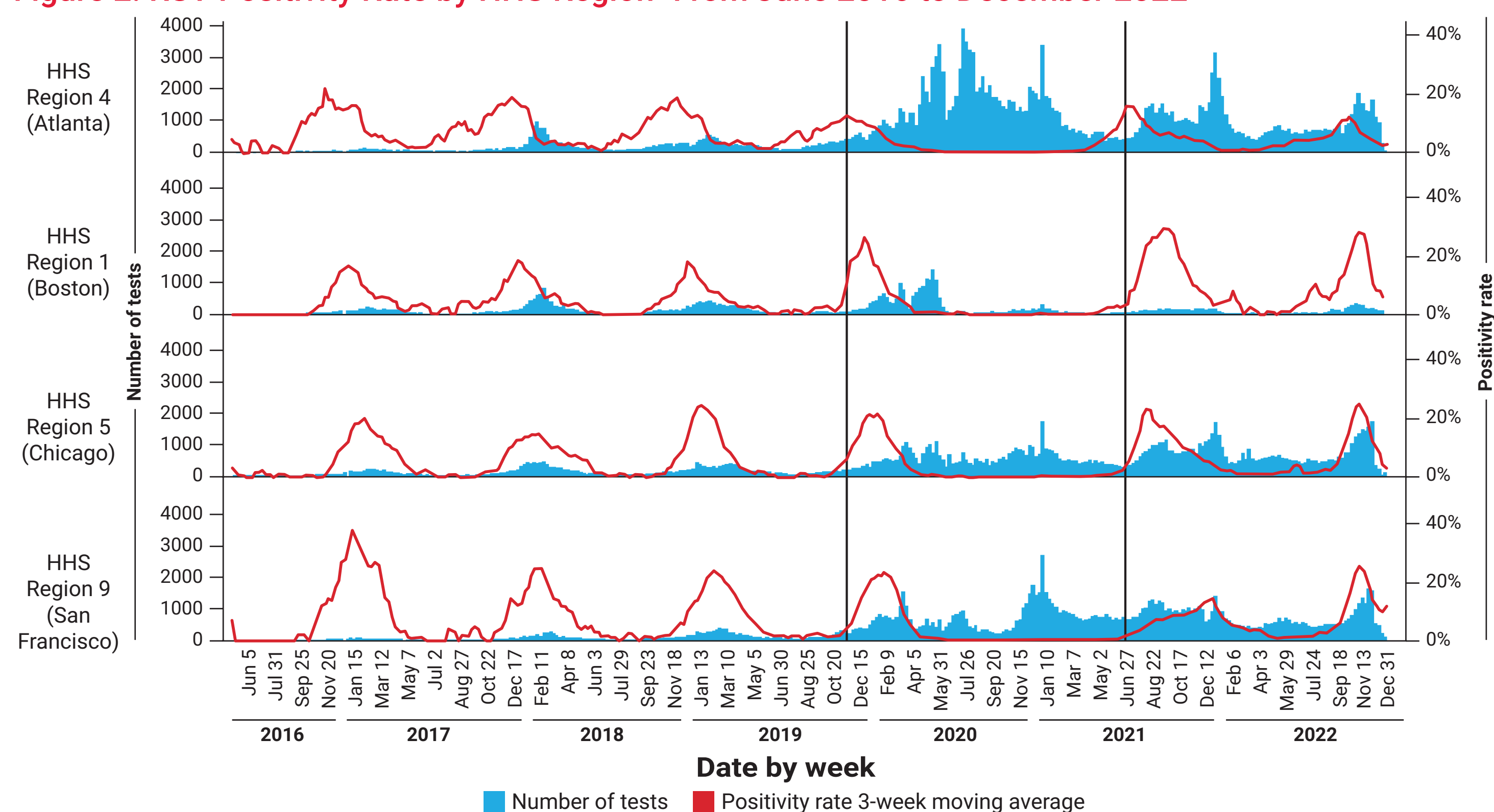


RSV, respiratory syncytial virus.

Regional Variation of RSV Activity

- During both pre-pandemic and pandemic periods, regional variation was observed, with the RSV season peaking first in the south east of the United States (HHS region 4) both in November 2019 and June 2021; this was followed by peaks in states in the north and west of the United States (Figure 2)

Figure 2. RSV Positivity Rate by HHS Region⁴ From June 2016 to December 2022



RSV, respiratory syncytial virus.

⁴US Department of Health & Human Services (HHS) regional offices: region 1 (Boston) includes Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont; region 4 (Atlanta) includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee; region 5 (Chicago) includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin; region 9 (San Francisco) includes Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau.⁴

CONCLUSIONS

- Developing internal surveillance systems for vaccines targeting pathogens with uncertain or seasonal variations can guide enrollment strategies in large pivotal efficacy trials and ensure that a timely source of data is available throughout the enrollment period
- Implementation of optimal enrollment strategies may ensure maximum potential benefit for participants and accelerate trial timelines in case-driven studies, which may be especially important when there is an unmet medical need for a disease with a substantial health burden (i.e., RSV)

ABSTRACT PLAIN LANGUAGE SUMMARY

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References

- Li Y, et al. *Lancet Glob Health*. 2019;7:e1031-e1045.
- Centers for Disease Control and Prevention. RSV in Older Adults and Adults With Chronic Medical Conditions. <https://www.cdc.gov/rsv/high-risk/older-adults.html>
- Zheng Z, et al. *JAMA Netw Open*. 2021;4(12):e2141779.
- US Department of Health and Human Services. About HHS. <https://www.hhs.gov/about/index.html>
- Centers for Disease Control and Prevention. CDC Museum COVID-19 Timeline. <https://www.cdc.gov/museum/timeline/covid19.html#:~:text=January%2030%2C%202020&text=This%20is%20the%20first%20recorded,of%20cases%20up%20to%20seven>

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Disclosures

CAP, HC, CP, and AE are employees of Moderna, Inc., and hold stock/stock options in the company.