Laboratory Outreach Communication System (LOCS) Call

Monday, February 26, 2024, at 3:00 P.M. ET

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **ISO 35001:2019 - Biorisk Management for Laboratories and Other Related Organizations Standard**
  - Folasade Kembi, CDC Division of Laboratory Systems
- **Mpox Update**
  - Christina Hutson, CDC Division of High-Consequence Pathogens and Pathology
- **Mpox Reporting Update**
  - Shaw Gargis, CDC Division of Regulatory Science and Compliance
- **Early Detection and Surveillance of the SARS-CoV-2 Variant BA.2.86**
  - Anastasia Lambrou, CDC Coronavirus and Other Respiratory Viruses Division

About DLS

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

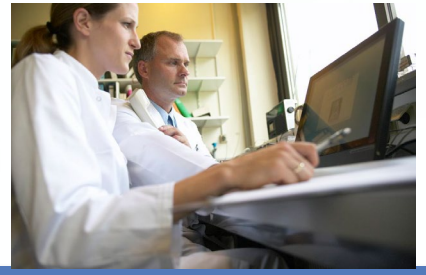
Four Goal Areas

Quality Laboratory Science

- Improve the quality and value of laboratory medicine for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



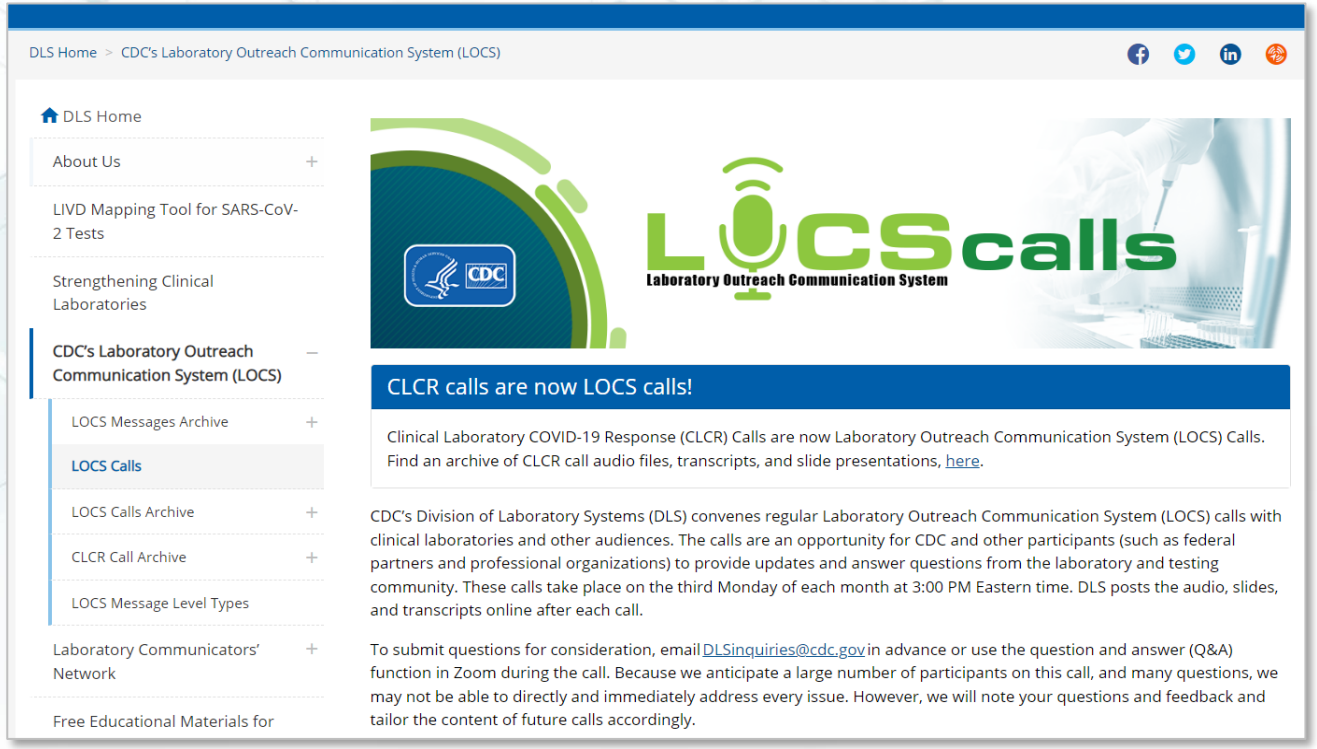
Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories

Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

LOCS Calls



On this page, you can find:

- LOCS Call information
- Transcripts
- Slides
- Audio Recordings

https://www.cdc.gov/locs/calls

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

OneLab **Summit**

REGISTER **NOW!**

OneLab **Summit**

Thrive: People. Planning. Preparedness.

APRIL 16-18, 2024

A THREE-DAY VIRTUAL LEARNING EVENT

CREATED FOR LABORATORY PROFESSIONALS WHERE ATTENDEES WILL:

- Increase their knowledge of laboratory training development tools and practices
- Gain insights from the clinical and public health laboratory community's success and resilience
- Collaborate and connect with CDC and laboratory education and training peers

REGISTRATION **IS LIVE**! https://reach.cdc.gov/onelabsummit

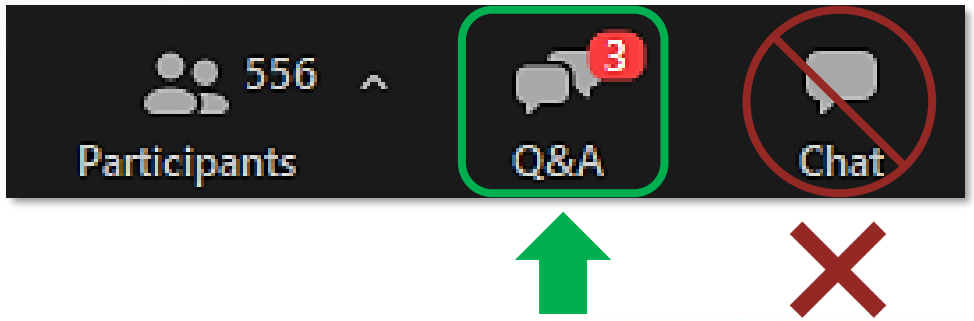
DLS ECHO Biosafety Program

- Upcoming sessions:
  - **February 27** - A Stepwise Process to Improve Biorisk Management Systems
  - **March 26** - Leadership: Roles, Responsibilities, and Authorities
  - **April 30** - Planning: Developing and Achieving Biorisk Management Objectives
- For questions, contact DLSbiosafety@cdc.gov

www.cdc.gov/safelabs/resources-tools/echo-biosafety.html

How to Ask a Question

- **Using the Zoom Webinar System**
  - Click the **Q&A button** in the Zoom webinar system
  - Type your question in the **Q&A box** and submit it
  - Please do not submit a question using the chat button



- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Access to the International Organization for Standardization (ISO) 35001:2019 Biorisk Management

LCDR Folasade Kembi, PhD
Division of Laboratory Systems
Quality and Safety Systems Branch

February 26, 2024

International Organization for Standardization (ISO) 35001:2019 Biorisk Management

CDC's Division of Laboratory Systems (DLS) is offering free access to the **ISO 35001:2019 - Biorisk Management for Laboratories and related organizations** for clinical and public health laboratories

ISO 35001:

- ISO 35001 defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials.
- The standard applies to laboratories or organizations that work with, store, transport, and/or dispose of hazardous biological materials.
- The offer is currently limited to interested laboratories and organizations within the United States.

International Organization for Standardization (ISO) 35001:2019 Biorisk Management

Process Overview:

- Select a point of contact responsible for biorisk management (e.g., Laboratory Director, Biosafety Officer).
- Point of contact email DLSBiosafety@cdc.gov
  - Name and physical address of the institution
  - Name and work e-mail address
  - Role in the organization
- DLS notifies the approved point of contact with details on how to access the standard.

DLS supports the enhancement of biorisk management in laboratories and encourages your institution to participate.

For questions, contact DLSBiosafety@cdc.gov

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Mpox Update

Christina L. Hutson, PhD, MS
Division of High-Consequence Pathogens and Pathology
Poxvirus and Rabies Branch

These slides were shared during the call but are not available for public distribution.

Mpox Virus and Federal Select Agent Program Regulations

Shaw Gargis, PhD

Associate Director for Science (Acting)

Division of Regulatory Science and Compliance (DRSC)

2/26/2024

Mpox Regulatory Language

- §73.3 HHS select agents and toxins

  (b) HHS select agents and toxins:

  Monkeypox virus (Mpox)

  (d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

  12) Any South American genotypes of Eastern Equine Encephalitis Virus and **any West African Clade of monkeypox virus provided that the individual or entity can identify that the agent is within the exclusion category.**

Select Agent Regulations and Mpox Virus

- Currently, there are two clades of Mpox virus:
  - Congo Basin clade (Clade I) and West African clade (Clades IIa and IIb).
  - For the 2022 U.S. Mpox Outbreak, laboratory testing indicated that the outbreak was associated with the Clade IIb of the Mpox virus.
- Mpox virus is regulated as an HHS-only select agent [42 CFR 73.3(b)] and entities that possess, use, or transfer this agent must comply with the HHS Select Agent and Toxin Regulations [42 CFR 73] (“the regulations”) unless there is an applicable exemption or exclusion

Diagnostic Specimen Exemption

- **Diagnostic Specimen Exemption:** The regulations provide that clinical or diagnostic laboratories or other entities that possess, use or transfer an HHS select agent contained in a specimen presented for diagnosis or verification will be exempt from the requirements of the regulations for such agent if the entity,
  1) reports the identification of the agent to the Federal Select Agent Program (FSAP) and other authorities as required by law,
  2) secures the select agent after identification, and
  3) transfers or destroys the material, in accordance with 42 CFR 73.5(a).

- This exemption would apply to material that has been identified as being or containing Mpox virus, but the clade has not been determined or the clade has been determined to be Congo Basin clade (Clade I).

Regulatory Status of Materials

- An entity may retain this material if registered with FSAP and approved to possess Mpox virus.

- FSAP regulates material that has been identified as being or containing a select agent. Therefore, identifications of *Orthopoxvirus* that are presumptive identifications of Mpox virus, are not considered select agents by FSAP until identified to be Mpox virus or another select agent.

Regulatory Status of Material

Test result	Subject to the select agent requirements?
Non-variola *Orthopoxvirus*	No
Mpox virus clade undetermined (using a generic Mpox assay)	Yes
Mpox virus Clade I (Congo Basin clade)	Yes
Mpox virus clade II (West African clade)	No

www.selectagents.gov

CDC Contact Information
Division of Regulatory Science
and Compliance
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070

Early Detection and Surveillance of the SARS-CoV-2 Variant BA.2.86 — Worldwide, July–October 2023

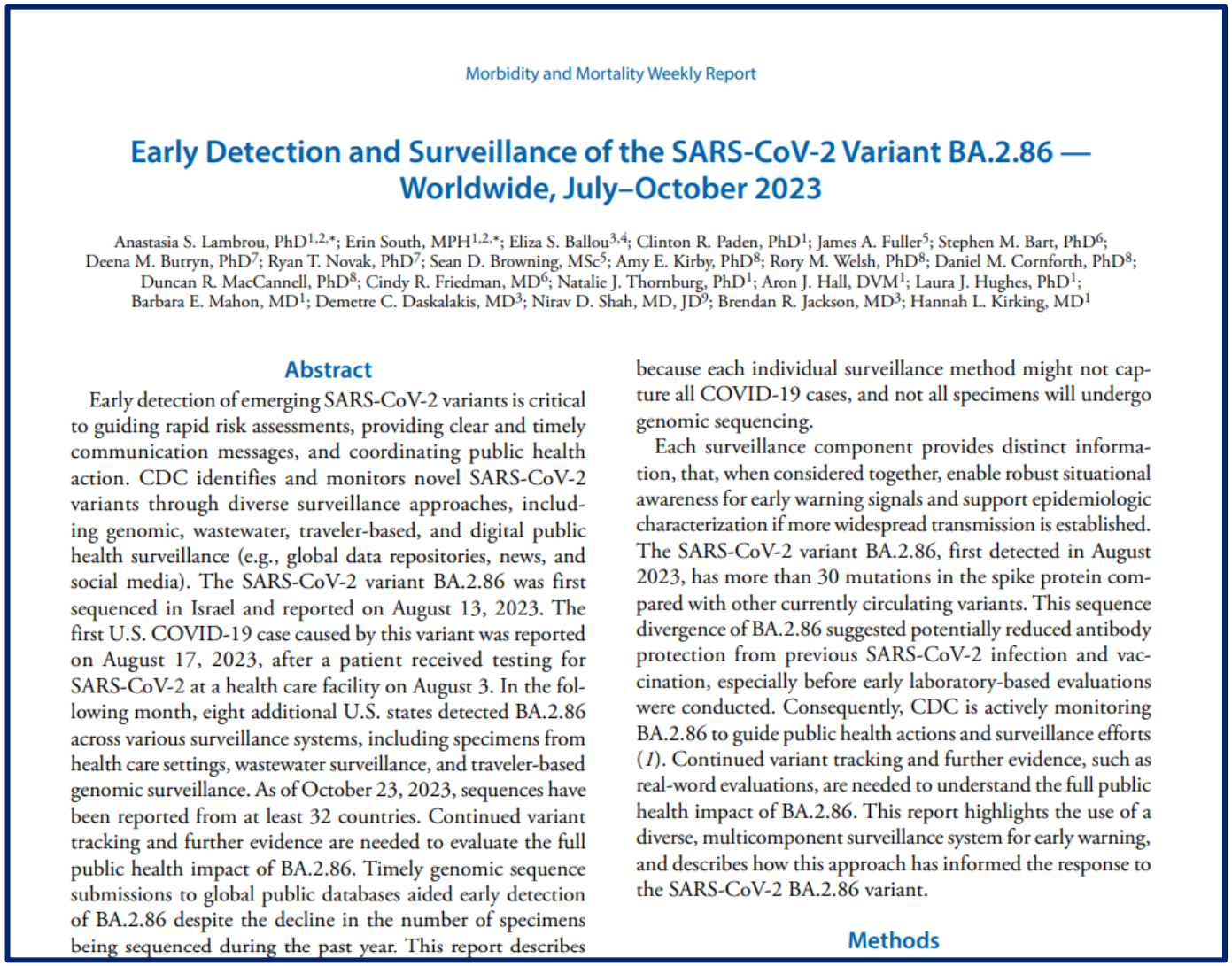
Erin South, MPH, Anastasia Lambrou, PhD, Hannah Kirking, MD

Centers for Disease and Control and Prevention

February 26, 2024

Outline

1. Background
2. Methods
3. Results
4. Public Health Action
5. Discussion
6. Preparedness Implications
7. Questions & Discussion



Morbidity and Mortality Weekly Report

Early Detection and Surveillance of the SARS-CoV-2 Variant BA.2.86 — Worldwide, July–October 2023

Anastasia S. Lambrou, PhD[1,2,*]; Erin South, MPH[1,2,*]; Eliza S. Ballou[3,4]; Clinton R. Paden, PhD[1]; James A. Fuller[5]; Stephen M. Bart, PhD[6]; Deena M. Butryn, PhD[7]; Ryan T. Novak, PhD[7]; Sean D. Browning, MSc[5]; Amy E. Kirby, PhD[8]; Rory M. Welsh, PhD[8]; Daniel M. Cornforth, PhD[8]; Duncan R. MacCannell, PhD[8]; Cindy R. Friedman, MD[6]; Natalie J. Thornburg, PhD[1]; Aron J. Hall, DVM[1]; Laura J. Hughes, PhD[1]; Barbara E. Mahon, MD[1]; Demetre C. Daskalakis, MD[3]; Nirav D. Shah, MD, JD[9]; Brendan R. Jackson, MD[3]; Hannah L. Kirking, MD[1]

Abstract

Early detection of emerging SARS-CoV-2 variants is critical to guiding rapid risk assessments, providing clear and timely communication messages, and coordinating public health action. CDC identifies and monitors novel SARS-CoV-2 variants through diverse surveillance approaches, including genomic, wastewater, traveler-based, and digital public health surveillance (e.g., global data repositories, news, and social media). The SARS-CoV-2 variant BA.2.86 was first sequenced in Israel and reported on August 13, 2023. The first U.S. COVID-19 case caused by this variant was reported on August 17, 2023, after a patient received testing for SARS-CoV-2 at a health care facility on August 3. In the following month, eight additional U.S. states detected BA.2.86 across various surveillance systems, including specimens from health care settings, wastewater surveillance, and traveler-based genomic surveillance. As of October 23, 2023, sequences have been reported from at least 32 countries. Continued variant tracking and further evidence are needed to evaluate the full public health impact of BA.2.86. Timely genomic sequence submissions to global public databases aided early detection of BA.2.86 despite the decline in the number of specimens being sequenced during the past year. This report describes because each individual surveillance method might not capture all COVID-19 cases, and not all specimens will undergo genomic sequencing.

Each surveillance component provides distinct information, that, when considered together, enable robust situational awareness for early warning signals and support epidemiologic characterization if more widespread transmission is established. The SARS-CoV-2 variant BA.2.86, first detected in August 2023, has more than 30 mutations in the spike protein compared with other currently circulating variants. This sequence divergence of BA.2.86 suggested potentially reduced antibody protection from previous SARS-CoV-2 infection and vaccination, especially before early laboratory-based evaluations were conducted. Consequently, CDC is actively monitoring BA.2.86 to guide public health actions and surveillance efforts (*1*). Continued variant tracking and further evidence, such as real-word evaluations, are needed to understand the full public health impact of BA.2.86. This report highlights the use of a diverse, multicomponent surveillance system for early warning, and describes how this approach has informed the response to the SARS-CoV-2 BA.2.86 variant.

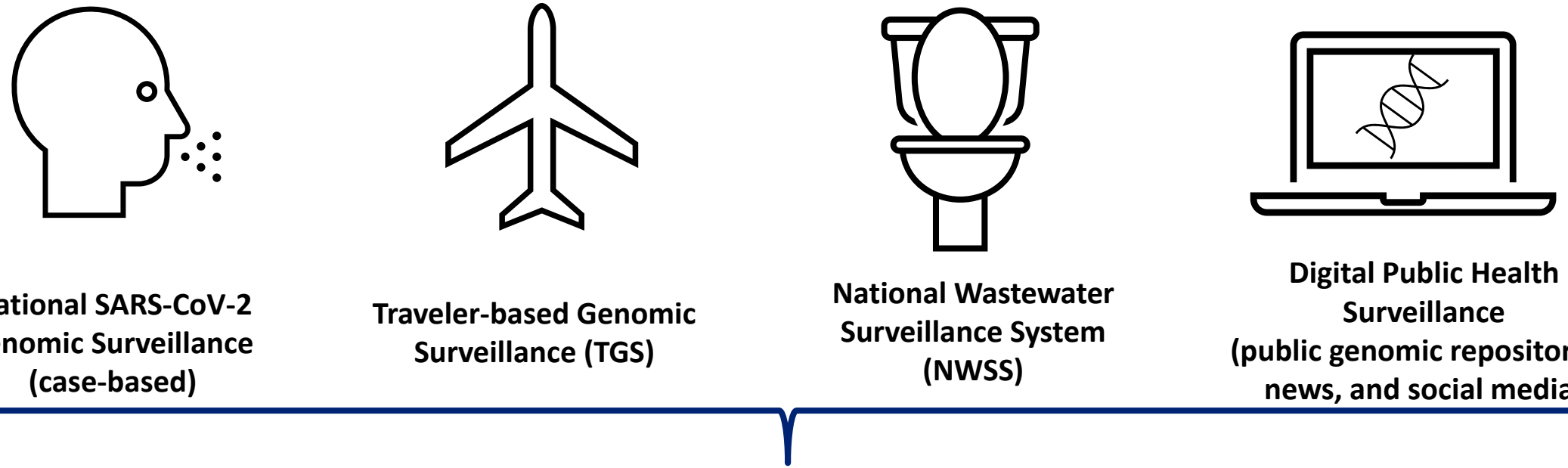
Methods

https://www.cdc.gov/mmwr/volumes/72/wr/mm7243a2.htm

Background

Introduction

- CDC uses a multicomponent surveillance approach to track emerging SARS-CoV-2 variants globally and in the United States.



BA.2.86 Background

- First detected in August 2023
- >30 mutations in the spike protein compared with other circulating variants which suggested potentially reduced antibody protection
- CDC is actively monitored BA.2.86 to guide public health actions and surveillance efforts
- Continued tracking and real-word evaluations are needed to understand the full public health impact

Study Objectives

1. Describe how multicomponent surveillance and genomic sequencing were used in real time to track the emergence and transmission of the BA.2.86 variant.

2. Outline the early detections of the BA.2.86 variant and surveillance mechanisms.

3. Monitor the national and global spread of the BA.2.86 variant.

Methods

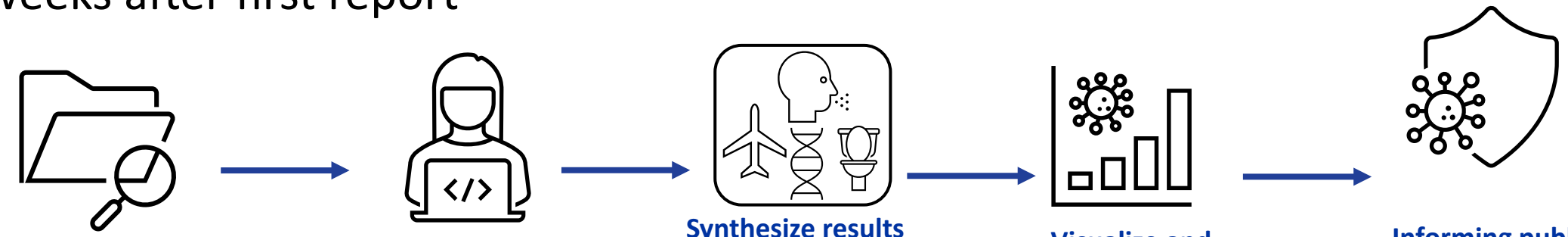
Surveillance System Data Components

- **National SARS-CoV-2 genomic surveillance**
  - Multiple sources of U.S. human respiratory virus specimen data from cases
- **Travel-based Genomic Surveillance (TGS)**
  - Human sampling at U.S. international airports, six major U.S. international airports*
- **National Wastewater Surveillance System (NWSS)**
  - Sewershed samples that service 40% of U.S. population
- **Digital Public Health Surveillance**
  - Global digital repositories (NCBI SRA**, GISAID***), news media, social media, global-event based and public health partner reports

*Los Angeles (LAX), Newark (EWR), New York (JFK), San Francisco (SFO), Seattle (SEA), and Washington D.C./Dulles (IAD) airports
**National Center for Biotechnology Information's Sequence Read Archive
***Global Influenza Surveillance and Response System

Methods

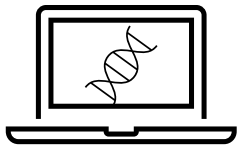
- BA.2.86 reports from Digital Public Health Surveillance collected and confirmed by CDC team
- Sequences in public databases were collected and examined daily from NCBI SRA and GISAID
- Data were analyzed using descriptive statistics and used for geographic and temporal mapping
- Detailed analyses conducted on the BA.2.86 sequences reported within first two weeks after first report



Results

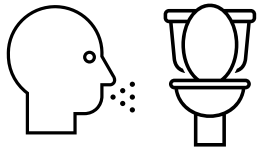
BA.2.86 Early Detection: Key Dates & Findings

Report Date



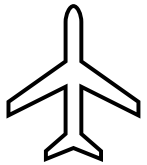
August 13

Israel reported first global BA.2.86 case.



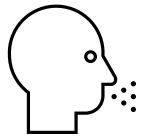
August 17

United States reports first and second detections: 1) wastewater detection (Ohio) and 2) respiratory specimen genomic surveillance detection (case in Michigan).



August 21

Traveler-based genomic surveillance reports from a BA.2.86 detection in a sample from a TGS participant traveling from Japan arriving at Dulles International Airport



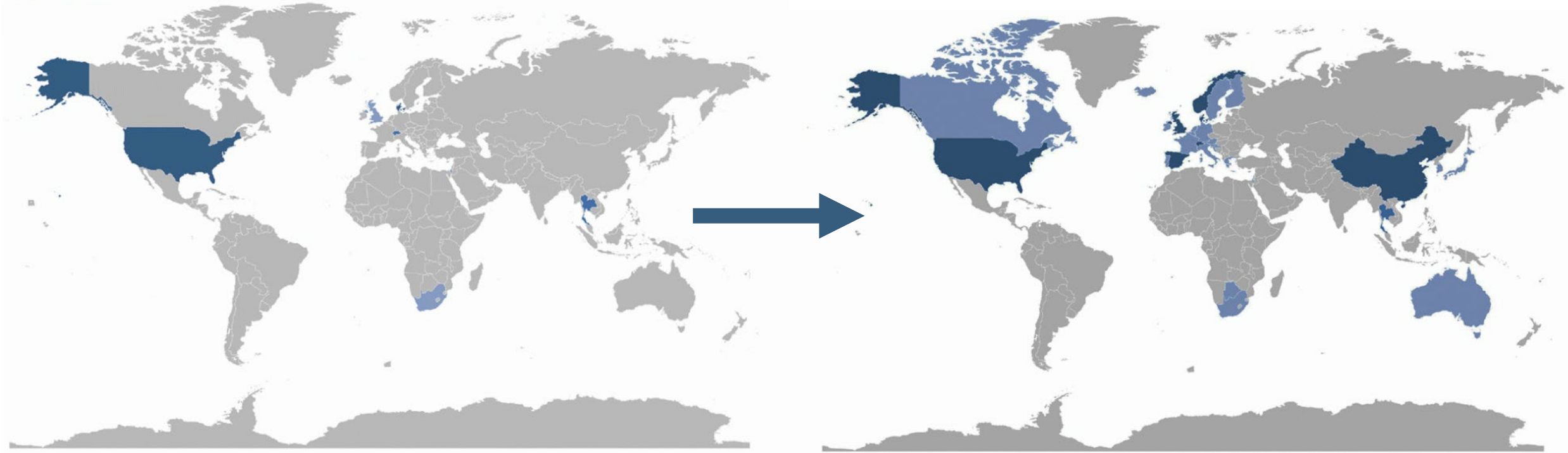
August 26

Ohio reported a case from a patient sample collected on July 29. The patient had been in the same area where the first wastewater detection was reported 9 days earlier.

Tracking BA.2.86 Emergence

August 26, 2023

October 23, 2023

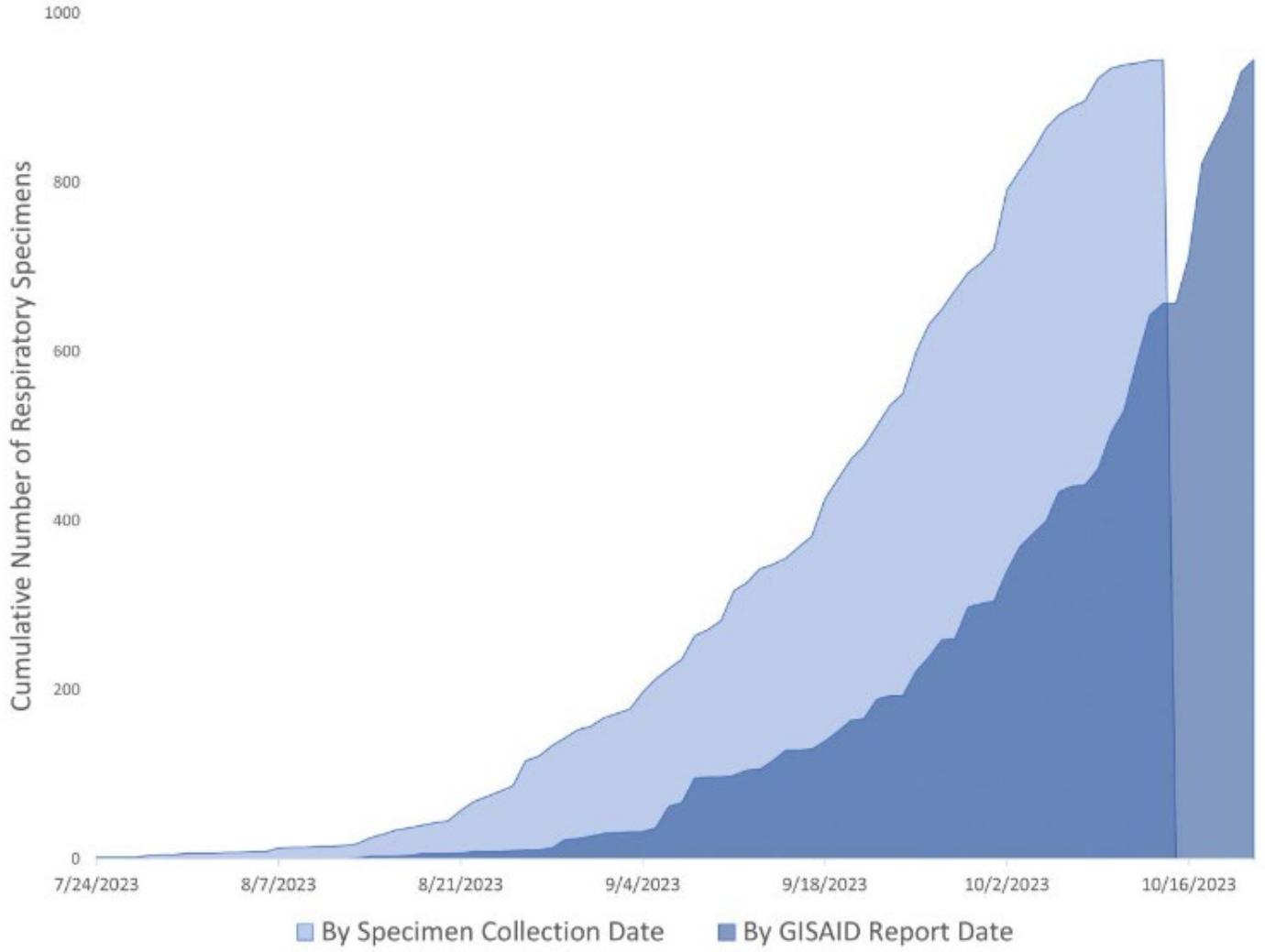


Respiratory Specimens

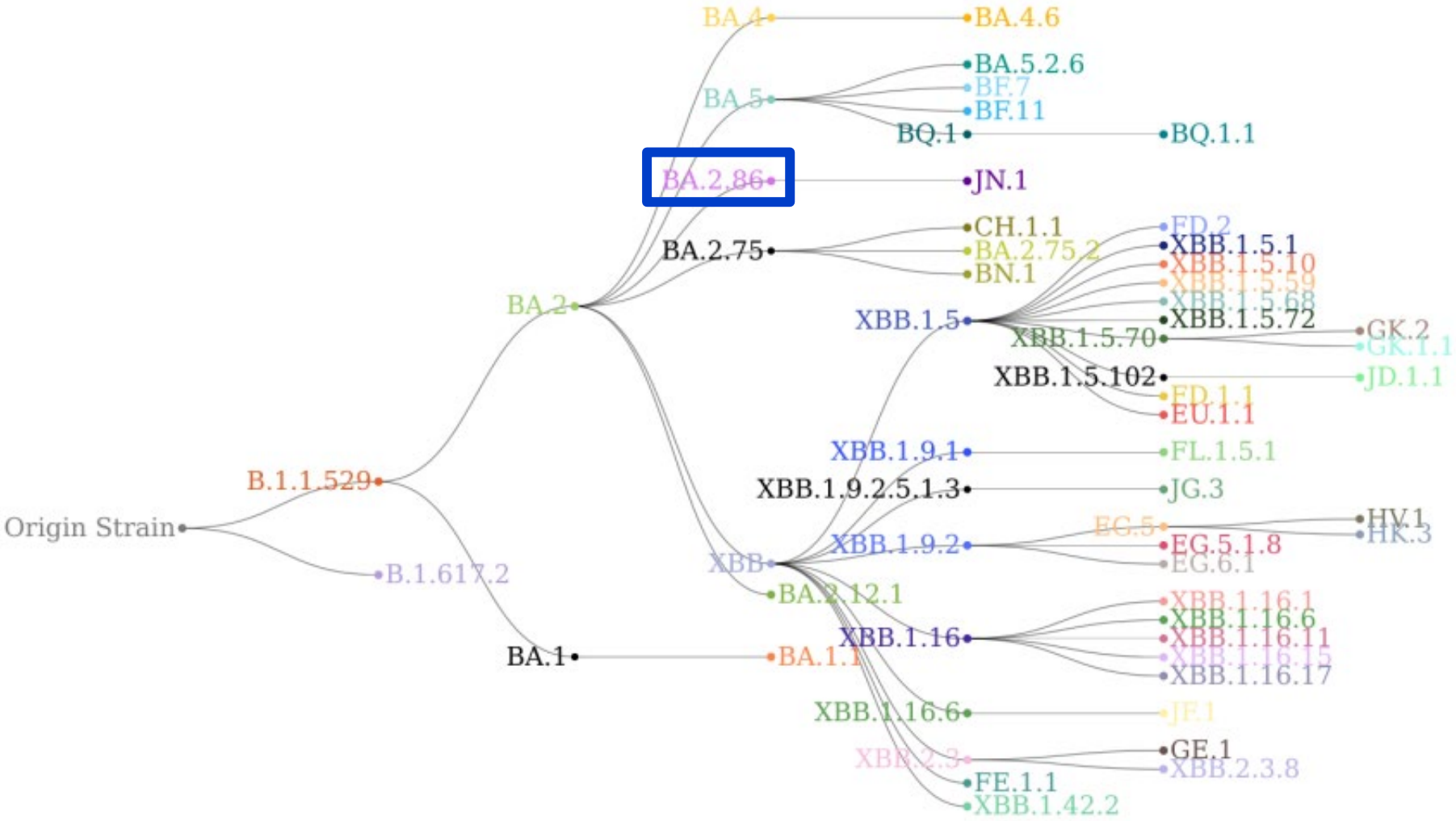
Wastewater Samples

Both Respiratory and Wastewater Samples

Time Between Human Specimen Collection and Report into Public Databases

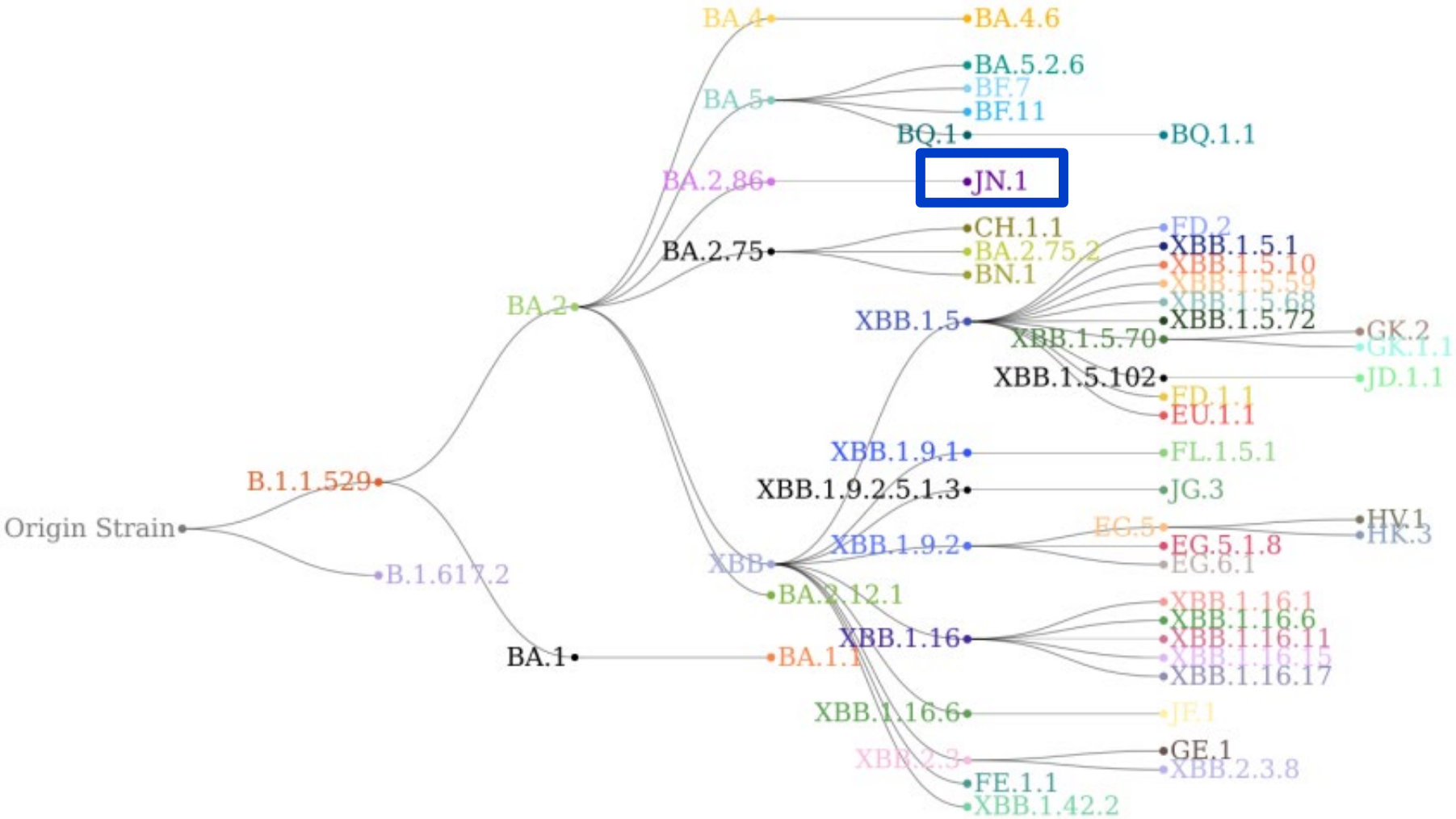


SARS-CoV-2 Omicron Variant Diversity: BA.2.86



https://covid.cdc.gov/covid-data-tracker/#variant-proportions

SARS-CoV-2 Omicron Variant Diversity: JN.1

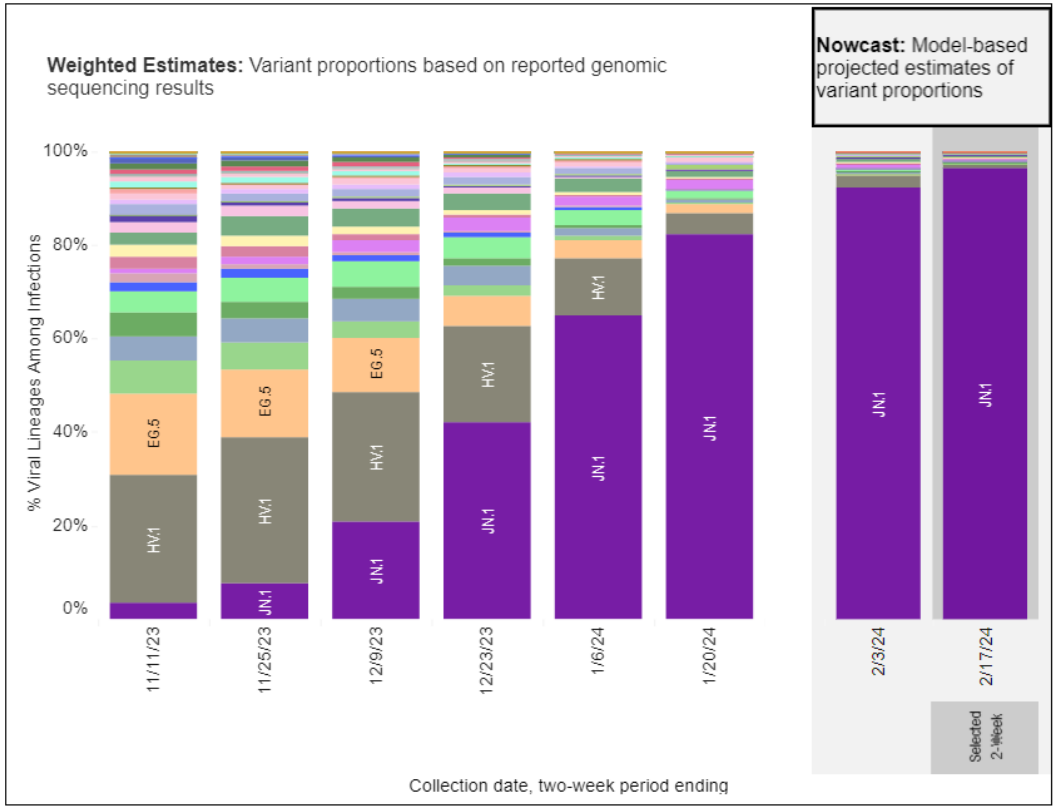


https://covid.cdc.gov/covid-data-tracker/#variant-proportions

BA.2.86 Update Since August 2023

Weighted and Nowcast Estimates in United States for 2-Week Periods in 10/29/2023 – 2/17/2024

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.



Nowcast Estimates in United States for 2/4/2024 – 2/17/2024

USA

WHO label	Lineage #	%Total	95%PI
Omicron	JN.1	96.4%	94.9-97.4%
	HV.1	1.0%	0.8-1.2%
	JG.3	0.6%	0.4-0.7%
	BA.2.86	0.5%	0.3-0.6%
	XBB.1.16	0.0%	0.0-0.0%
	GK.2	0.0%	0.0-0.0%
	XBB.1.5	0.0%	0.0-0.0%
	CH.1.1	0.0%	0.0-0.0%
	EG.6.1	0.0%	0.0-0.0%
	XBB.1.5.68	0.0%	0.0-0.0%
	XBB.1.16.1	0.0%	0.0-0.0%
	XBB.1.9.2	0.0%	0.0-0.0%
	XBB.1.16.17	0.0%	0.0-0.0%
	XBB.1.5.72	0.0%	0.0-0.0%
Other	Other*	0.1%	0.0-0.1%

USA

WHO label	Lineage #	%Total	95%PI
Omicron	JN.1	96.4%	94.9-97.4%
	HV.1	1.0%	0.8-1.2%
	JG.3	0.6%	0.4-0.7%
	BA.2.86	0.5%	0.3-0.6%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed.
\# While all lineages are tracked by CDC, those named lineages not enumerated in this graphic are aggregated with their parent lineages, based on Pango lineage definitions, described in more detail here: https://www.pango.network/the-pango-nomenclature-system/statement-of-nomenclature-rules/.

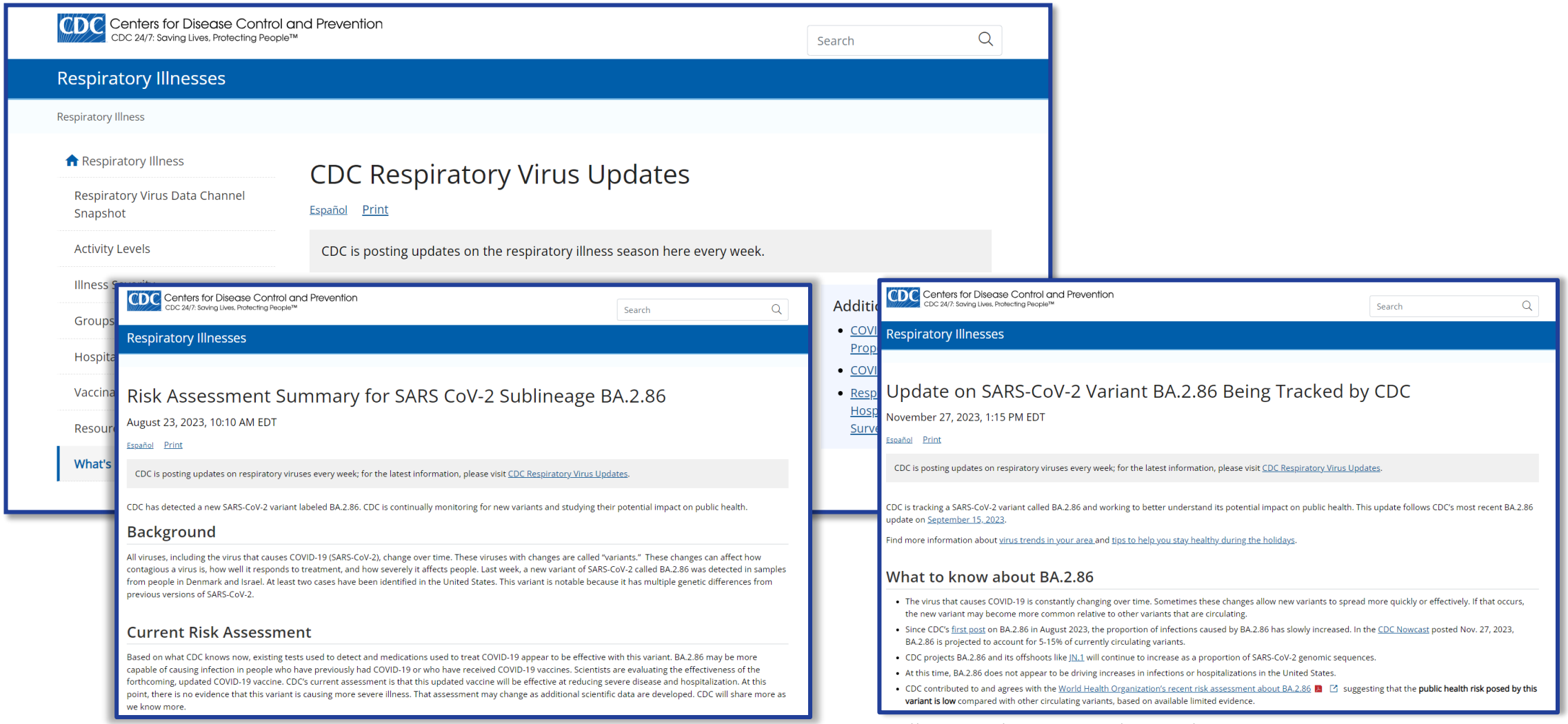
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Public Health Response

Public Health Response

1. **Rapid risk communication**
   - CDC weekly Respiratory Virus Updates and public health partner debriefs
2. **Viral isolation and characterization**
   - Collaborations between sequencing laboratories and CDC
   - Residual virus samples were shared with CDC laboratories for isolation, early characterization, and laboratory-based neutralization studies to better understand potential immune escape
   - High-quality, rapidly generated BA.2.86 sequences facilitated the understanding of its geographic distribution and aided early laboratory-based and computer-modeled studies predicting immune escape
3. **Cross-coordination for public health action**
   - Within agency and public health partner collaboration, data sharing, and risk assessment

Public Health Response – *Rapid Risk Communication*



https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant.html

https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant-update-2023-11-27.html

Discussion

- Despite decreased SARS-CoV-2 sequencing, U.S. genomic surveillance systems detected BA.2.86, a novel SARS-CoV-2 lineage circulating at very low levels
- Using multiple surveillance systems, integrating genomic sequencing, can successfully enhance early detection, tracking, and characterization of emerging SARS-CoV-2 variants
- Early detection of variants enable timely risk assessment, resource mobilization, communication, and public health action
- SARS-CoV-2 variants continue to emerge, and it is critical to continue to monitor their circulation and impact

Limitations

1. Varied levels of geographic, epidemiologic, clinical, and demographic information
2. Manual data gathering methods in digital public health surveillance are resource-intensive
3. Global genomic surveillance is limited by the lag time between specimen collection and reporting, impacting real-time actionability
4. Lacking standardized methods for genomic sequence data in public repositories, especially apparent for wastewater
5. Data quality, reporting, and aggregation standards are needed for multicomponent pathogen genomic surveillance

Implications for Public Health and Preparedness

- BA.2.86 highlighted the importance of early detection through multicomponent surveillance
- Addressing timeliness, individual system limitations, and increasing cross-coordination would strengthen this approach
- Maintaining multipurpose surveillance systems require sustained resources but could be used for early warning of known and novel public health threats

Future Directions

- Innovations in pathogen testing and genomic sequencing, capacity building, and reporting systems
  - Leveraging private sector help with more affordable, targeted, and sustainable surveillance products
- Continuous, automated data scraping for early warning signs
- Shortening lab reporting lag time from specimen collection to reporting results
- Tools to synthesize and integrate diverse early detection, genomic, epidemiologic, clinical, and other data
- Deployment of multiple innovations to strengthen early warning, preparedness, and response will be critical

Questions?

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Next Scheduled Call

Monday, March 18
3 PM - 4 PM EDT

https://www.cdc.gov/locs/calls

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https://www.instagram.com/cdcgov

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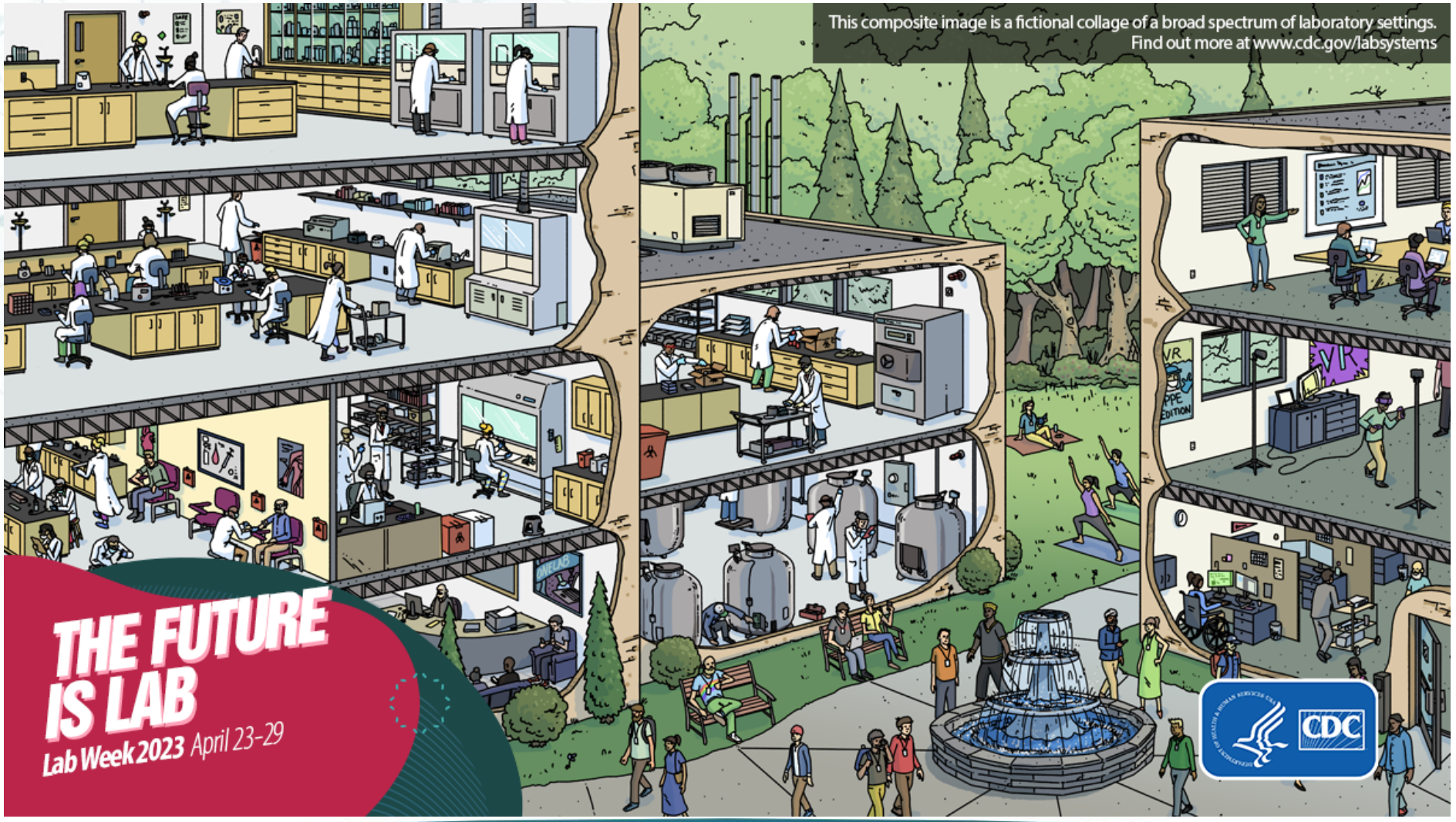
Thank You For Your Time!



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