

What to Expect for Penn's COVID-Era Spring Semester

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Agenda

- Vaccine Update Harvey Rubin
- Public Health and COVID Dashboard Update Benoit Dubé
- Spring Semester Testing Mark Dingfield
- Testing Compliance Jennifer Pinto-Martin
& Jeffrey Rowland

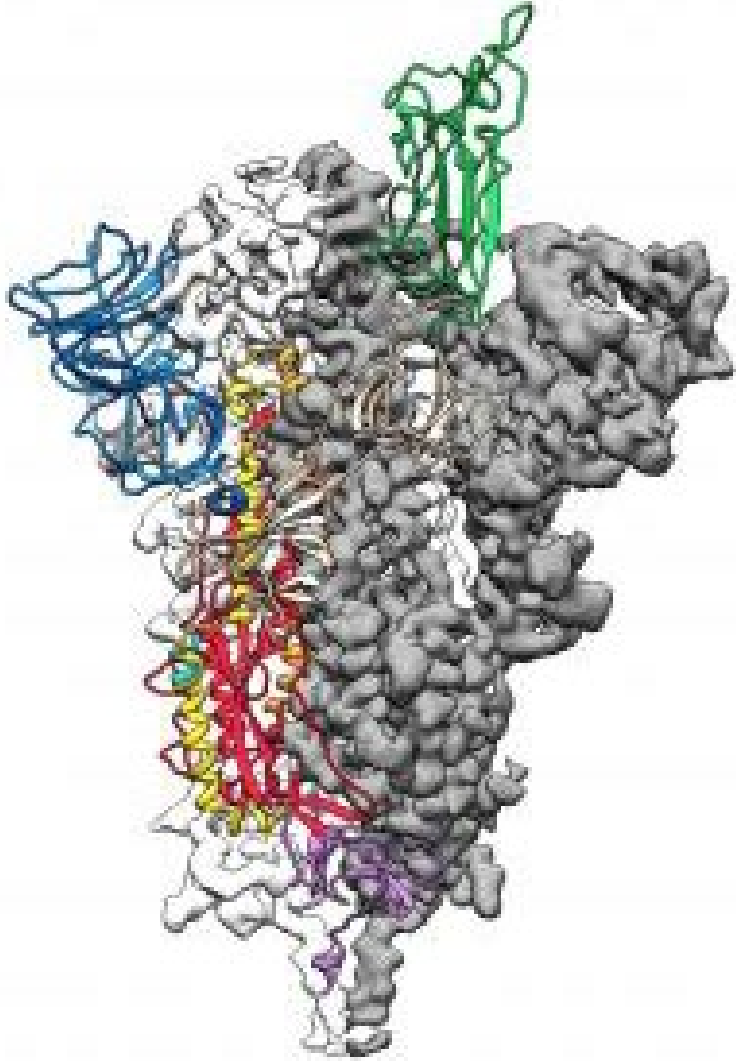


Vaccine Update

*Harvey Rubin, MD, PhD, Professor of Medicine,
Infectious Disease, Perelman School of Medicine*



Vaccine Update



- The atomic-level structure of the SARS-CoV-2 spike protein in its prefusion conformation. The receptor binding domain, the part of the spike that binds to the host cell, is colored green.
- *Credit: Credit: UT Austin, McLellan Lab*



Vaccine Update: Questions

- Is the Vaccine Safe?
- Are we endorsing the vaccine?
- Must staff and students be vaccinated to return to campus?
- Can you mix and match vaccines?
- If I don't want to get the vaccine now, can I get it later?
- I have symptoms after injection—can I come to work?
- When am I considered immune?
- How long does immunity last?
- Can I be vaccinated if I've already been infected?
- Should I be vaccinated if I've already been infected?
- Can I stop distancing and masking?
- What if get really sick from the vaccine?



Vaccine Update: Penn's COVID-19 Vaccine Advisory Group

Purpose: bring together experts from various specialties to advise on the best approach for prioritizing the administration of the vaccine to patient staff and providers

- Apply Ethical Principles to Penn Medicine's Policies
 - Maximize benefits and minimize harm
 - Mitigate Health Disparities
 - Promote Justice
 - Promote Transparency
- Points to consider:
 - Limited vaccine supply, who should be in the 1st tier for vaccination
 - How will we message information to staff
 - How will we address vaccine hesitancy be handled
 - How will vaccine storage and distribution be managed
 - What are the logistics for administration



Vaccine Update

National Adult and Influenza Immunization Summit

COVID-19 Vaccine information from NAIS Webinar (9/9/20)

Manufacturer	Vaccine Technology/Type	Storage Requirements	Doses	Handling + Administration	Self-Reported Timeline of Release	Fed Govt Contract
Pfizer/BioNTech	mRNA vaccine (2 dose series)	Distributed at -70 °C Stable for 48 hrs: 2-8 °C Stable for up to 10 days in shipping box if dry ice is maintained	5 doses/vial Minimum order: 975-1,000 doses	Mix with diluent on site		100 mill doses by end of 2020 + optional purchase of 500 mill doses
Moderna	mRNA vaccine (2 dose series)	Storage/transport (manufacture → distribution center): -20 °C At point of care (distribution → administration location): 2-8 °C in normal refrigerated conditions	10 doses/vial Minimum order: assume 100 doses	No dilution or special handling on site	500 mill – 1 bill doses annually	100 mill doses + optional purchase of 400 mill doses
NOVAVAX	Prefusion spike protein with co-formulated with adjuvant (2 dose series)	Storage at 2-8 °C Handling at room temp: 25 °C Very stable under stress conditions, will utilize standard cold chain	10 doses/vial Minimum order: assume 100 doses	Co-formulated with adjuvant. No mixing required.		100 mill doses by February 2021
INOVIO	INO-4800 DNA vaccine (2-dose series)	Stable at 25 °C for >1 year, 37 °C for >2 months In buffer, 2-8 °C for >5 years	10 doses/vial Minimum order: assume 100 doses	Injection + Collectra device use to create immune response	100 mill doses in 2021 200+ mill doses in 2022	

Vaccine Update

National Adult and Influenza Immunization Summit

COVID-19 Vaccine information from NAIS Webinar (9/9/20)

MEDICAGO	Plant-based vaccine (2-dose series)	Stable at 4-8 °C	10 doses/vial Minimum order: assume 100 doses	1 dose of product + 1 dose of adjuvant Mixed on site	Phase 3: December 2021	
Sanofi Pasteur #1	Recombinant vaccine (2-dose series)	Storage 2-8 °C for product and adjuvant Administration: 25 °C	10 doses of product/vial 10 doses adjuvant/vial Minimum order: assume 100 doses	Recombinant vaccine product + adjuvant Mixed on site.	2021: 1 billion doses	100 mill doses + optional purchase of 500 mill doses
Sanofi Pasteur #2	mRNA vaccine (2-dose series)	Storage at -20 °C	Minimum order: assume 100 doses		90-30 mill doses annually	
Janssen (+ Johnson & Johnson)	2-dose series	Storage at 2-8 °C	5 dose/vial Minimum order: assume 100 doses		EUA: Jan-March 2021	
MERCK #1 (V590)	Live vaccine, single dose			IM (intramuscular) or OM (oral mucosal)		
MERCK #2 (V591)	Live vaccine, single dose	2-8 °C stable presentation No storage information yet				

Vaccine Update: Complex Landscape

- One vs. two dose series
- Products not interchangeable
- Strict timeline for second administration
- Vaccine efficacy and adverse event profile in different populations
- Cold-chain requirements
- Not trialed in children and pregnant women
- Socially distanced vaccination practices
- Communication and education to counteract vaccine hesitancy
- Some high-risk groups for COVID-19 may distrust public health



Vaccine Update: Latest from PDPH

- EUA for Pfizer anticipated around December 10
- Vaccine will ship on December 14th
- Advisory Committee on Immunization Practices endorses HCWs and Nursing Residents for first wave of vaccination
- ACIP to meet quickly again after EUA
- Administration can begin on December 16th
- Six institutions in the City will receive the first allocation
 - HUP (for PPMC)
 - Einstein
 - CHOP
 - Jefferson
 - Temple
 - PDPH (for PAH)
- Weekly supplies will follow; we will be instructed on orders
- Administer the entire supply; no holdback for second shot
- CDC provides second dose
- We will continue to vaccinate our workforce until we finish
- May be able to finish clinical workforce by late February 2021



Vaccine Update: Storage and Distribution

- Pfizer vaccine will arrive first
 - 21-day interval to second dose; Range 19-23 days
 - -70C storage
- Moderna EUA 12/17; Shipping shortly thereafter
 - 28-day interval to second dose; Range 24-32 days
 - -20C storage remains stable for up to six months
 - Stable at 2° to 8°C (36° to 46°F) for 30 days
 - Stable at room temperature for up to 12 hours

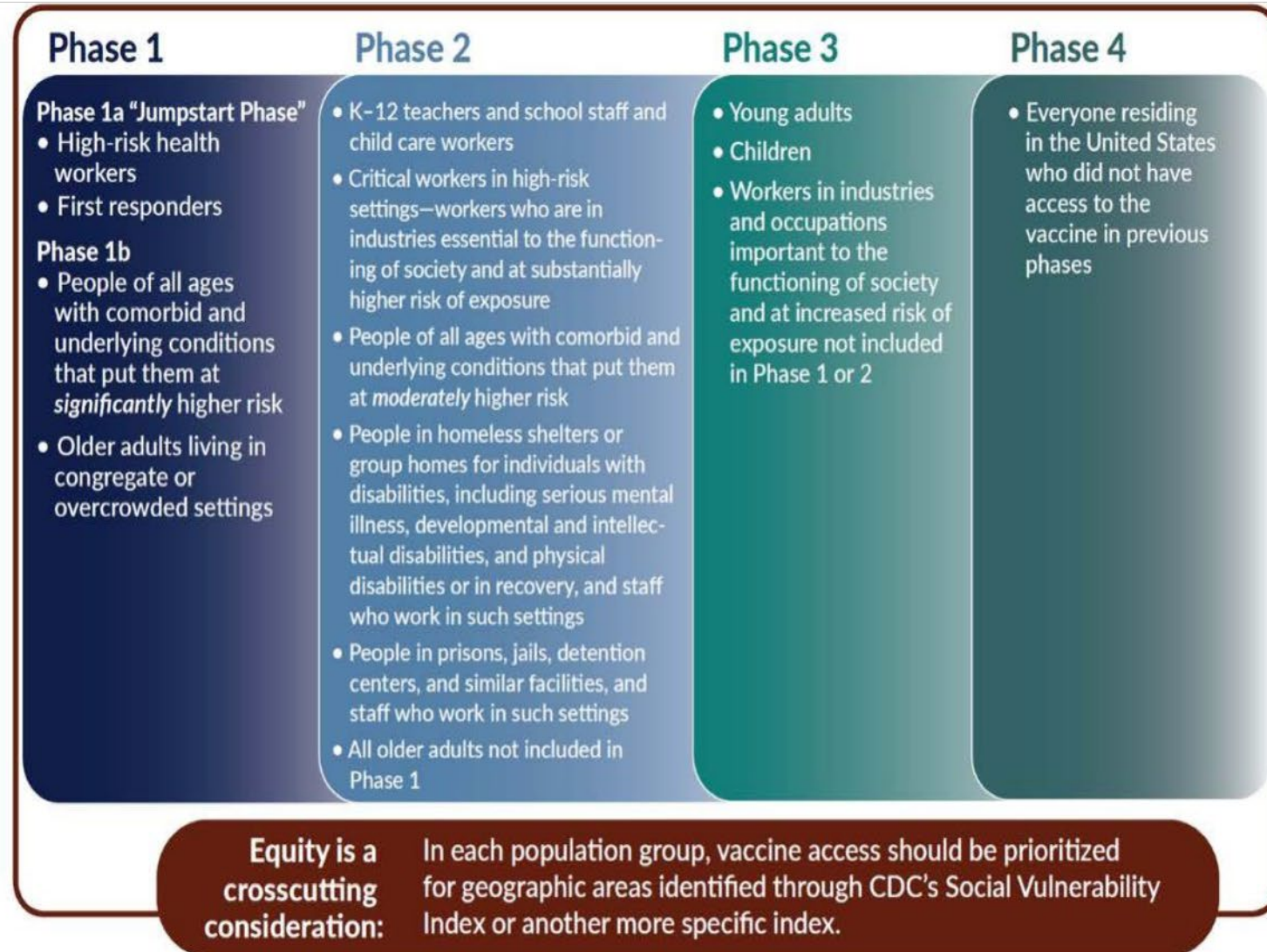


Vaccine Update: Prioritization of Staff/Providers: 1A

- First priority status to staff who work directly with patients in emergency situations and have a higher risk of exposure to patients whose COVID-19 status is unknown.
- List will be expanded as more vaccine doses become available.
- CDC's Advisory Committee on Immunization Practices endorsed health care workers and residential facilities for Phase 1A.
- Includes clinical/non-clinical staff working in the following high-risk areas/departments seeing a large portion of patients with unknown COVID-19 status:
 - Emergency Departments – including security personnel, EVS assigned to the area, transport, radiology techs, etc.
 - Labor & Delivery and PEC units
 - Trauma Team – provider teams, and those present in the trauma bay
 - Organ Transplant retrieval teams – onsite to collect the organs
 - COVID-19 testing sites
 - Home Health



Vaccine Update: New Guidance Documents



Vaccine Update: Essential Workers: 1B

- Agricultural workers
- Childcare workers
- Construction workers
- Education workers
 - Public/private school teachers
 - Higher education workers
- Financial services workers
- Food preparation/servers
- Grocery store workers
- Healthcare workers not included in Phase 1-A
- High-volume retail workers
- Maintenance/janitorial workers
- Meat production workers
- Pharmacists
- Public safety/first responders
 - Police
 - Fire-EMS
 - Correctional officers
- Streets Department
 - Sanitation workers
- Telecommunications workers
- Transportation workers
 - SEPTA
- Utility workers
 - PECO
 - PGW
 - Philadelphia Water Department
- Employees working in congregate residential settings (i.e., shelters, senior housing, etc.)



Vaccine Update: Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020 FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

Local site reactions and systemic solicited events after vaccination were frequent and mostly mild to moderate.

The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%);

Severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1 and were generally less frequent in adults ≥ 55 years of age ($\leq 2.8\%$) as compared to younger participants ($\leq 4.6\%$).

Among adverse events of special interest, which could be possibly related to vaccine, lymphadenopathy was reported in 64 participants (0.3%): 54 (0.5%) in the younger (16 to 55 years) age group; 10 (0.1%) in the older (> 55 years) age group; and 6 in the placebo group.

The average duration of these events was approximately 10 days, with 11 events ongoing at the time of the data cutoff.

Bell's palsy was reported by four vaccine participants. From Dose 1 through 1 month after Dose 2, there were three reports of Bell's palsy in the vaccine group and none in the placebo group. This observed frequency of reported Bell's palsy is consistent with the expected background rate in the general population.



Vaccine Update: Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020 FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

A total of six deaths occurred in the reporting period (2 deaths in the vaccine group, 4 in placebo).

In the vaccine group, one participant with baseline obesity and pre-existing atherosclerosis died 3 days after Dose 1, and the other participant experienced cardiac arrest 60 days after Dose 2 and died 3 days later.

Of the four deaths in the placebo arm, the cause was unknown for two of them, and the other two participants died from hemorrhagic stroke (n=1) and myocardial infarction (n=1), respectively; three deaths occurred in the older group (>55 years of age).

All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate.



Vaccine Update: Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020 FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

The frequency of non-fatal serious adverse events was low (<0.5%), without meaningful imbalances between study arms.

The most common SAEs in the vaccine arm which were numerically higher than in the placebo arm were appendicitis (0.04%), acute myocardial infarction (0.02%), and cerebrovascular accident (0.02%), and in the placebo arm numerically higher than in the vaccine arm were pneumonia (0.03%), atrial fibrillation (0.02%), atrial fibrillation (0.02%) and syncope (0.02%).

Appendicitis was the most common SAE in the vaccine arm. There were 12 participants with SAEs of appendicitis; 8 in the BNT162b2 group. Of the 8 total appendicitis cases in the BNT162b2 group, 6 occurred in the younger (16 to 55 years) age group and 2 occurred in the older (>55 years) age group (one of the cases in the older age group was perforated). One of the 6 participants with appendicitis in the younger age group also had a peritoneal abscess. Cases of appendicitis in the vaccine group were not more frequent than expected in the general population.



Public Health Overview & COVID Dashboard Update

*Benoit Dubé, MD, Associate Provost
and Chief Wellness Officer*



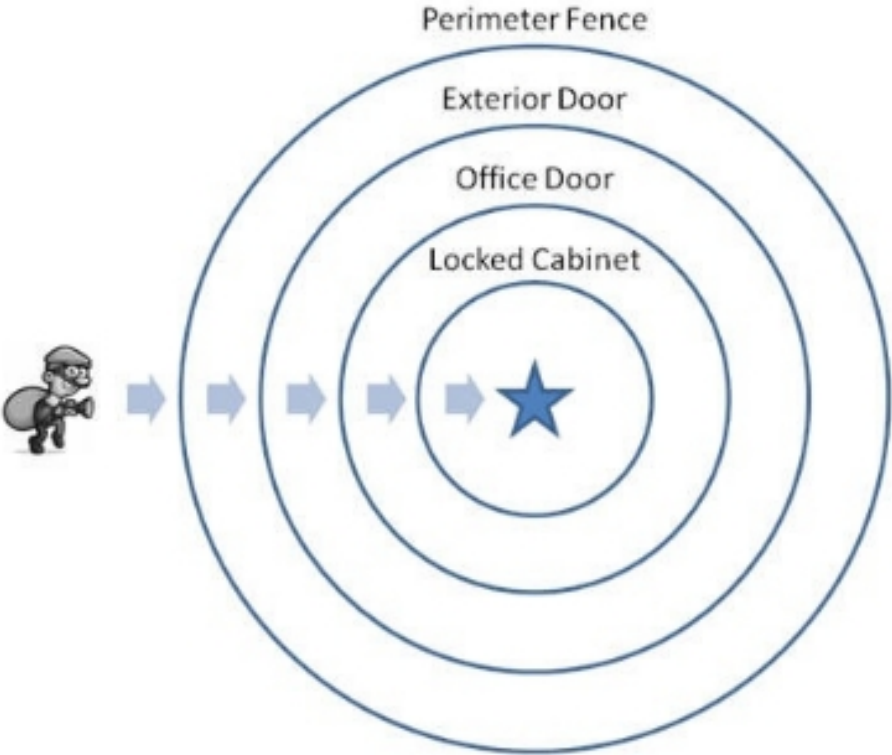
Public Health Guidance



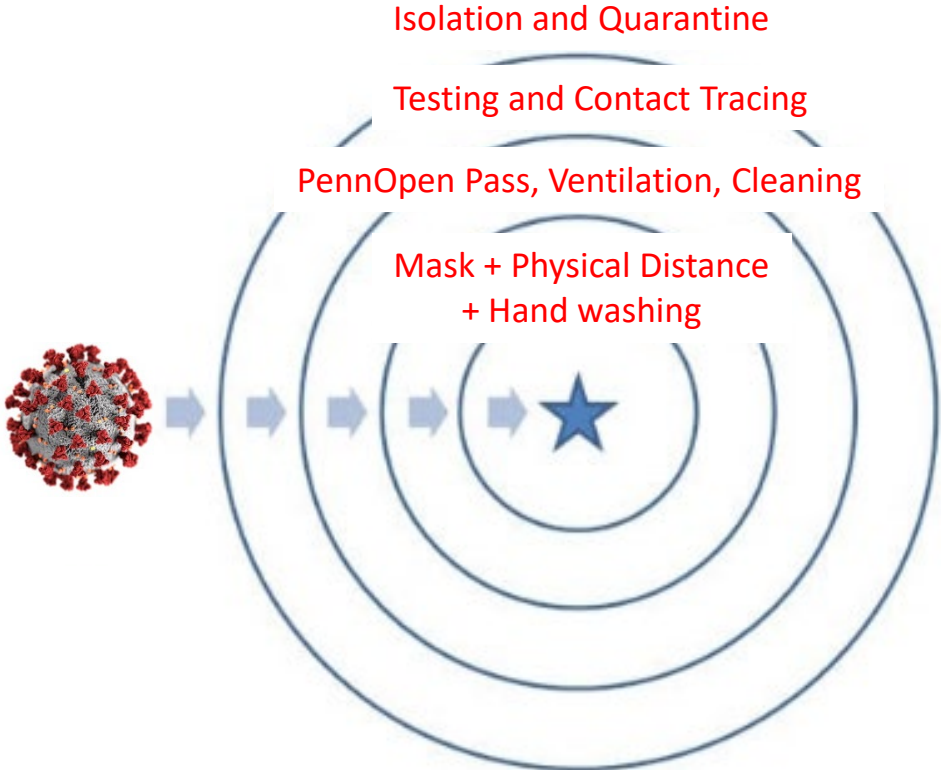
- To create a safe environment and bring even more students, faculty, postdocs and staff on campus this Spring, Penn continues to promote the 3 W's:
 - Wear a Mask
 - Watch Distance
 - Wash Hands
- Along with our testing strategy, there has been a multidimensional, campus-wide effort to ensure the proper safety precautions have been instituted, including:
 - Maintaining proper distancing of work/gathering spaces on campus
 - Implementation of PennOpen Pass
 - Following CDC guidance for cleaning & disinfecting
 - Assessment of ventilation system conditions
 - Contact tracing process
 - Isolation and quarantine plans for those on campus
 - Launch of @COVIDPenn social channels on Instagram and Twitter as a source of public health guidance and Q&A

Public Health Guidance

Security Layers



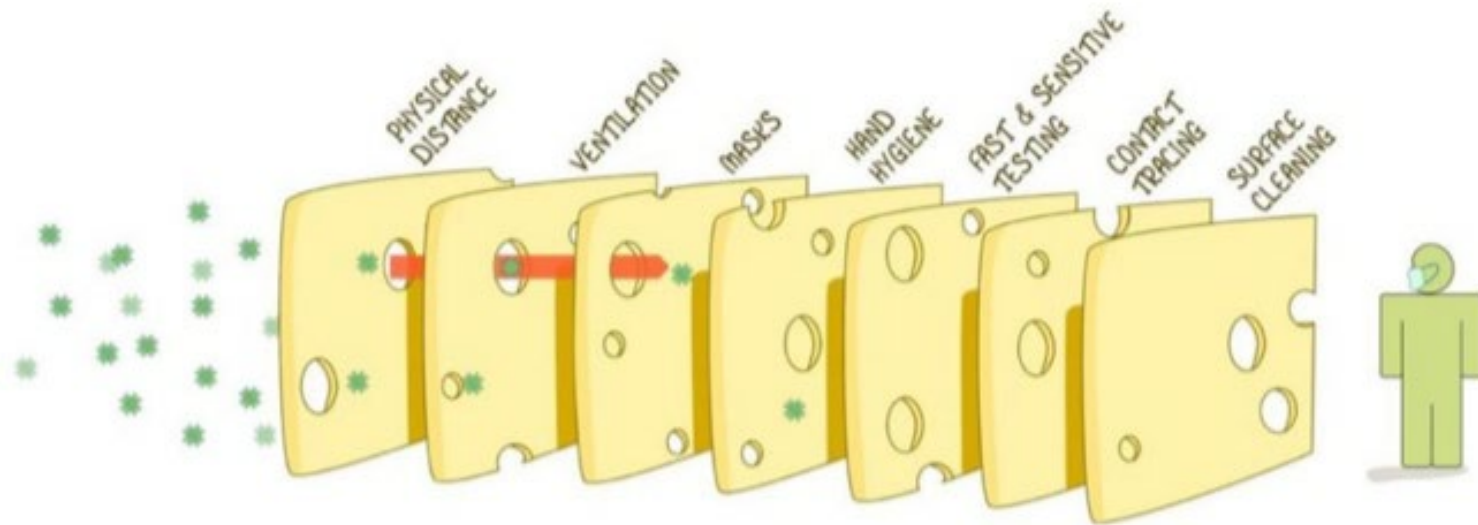
Public Health Layers



Public Health Guidance

THE SWISS CHEESE RESPIRATORY VIRUS DEFENCE

RECOGNISING THAT NO SINGLE INTERVENTION IS PERFECT AT PREVENTING SPREAD



EACH INTERVENTION (LAYER) HAS IMPERFECTIONS (HOLES).
MULTIPLE LAYERS IMPROVE SUCCESS.

JAN DE THACKER
VIRIOLOGYDOWNUNDER.COM
DERIVED FROM @SKETCHPLANATOR
BASED ON THE SWISS CHEESE MODEL OF ACCIDENT CAUSATION, BY JAMES T REASON, 1990
VERSION 1.3
UPDATE: 12OCT2020

Public Health Guidance: Testing

- **Screening Test**

- Intended to identify COVID-19 positivity even if there are no symptoms or known exposure. Screening testing is a critical part of our overall public health efforts to monitor the positivity rates of COVID-19 in our University community.
- Saliva PCR

- **Diagnostic Test**

- Intended to identify COVID-19 when there is a reason to suspect that an individual may be infected, such as having symptoms or suspected recent exposure, or to determine resolution of infection. PennOpen Pass will continue to help those who need testing based on symptoms or a notification of exposure to COVID-19.
- Nasal PCR

COVID-19 Dashboard

- The work behind the University's dashboard is informed by our profound respect for the impact our public health initiatives have on the health and safety of the Penn community.
- Data are available by undergrad, grad, and total students, as well as faculty, postdocs, staff and other affiliates.

Most Recent Week <i>11/29/2020 - 12/5/2020</i>		
3,511 Total Tests	107 Total Positive Results	3.05% Total Positivity Rate
1,197 Screening Tests	4 Screening Positive Results	0.33% Screening Positivity Rate
313 Symptomatic & Contact Tests	58 Symptomatic & Contact Positive Results	18.53% Symptomatic & Contact Positivity Rate

COVID-19 Dashboard

Choose a Population

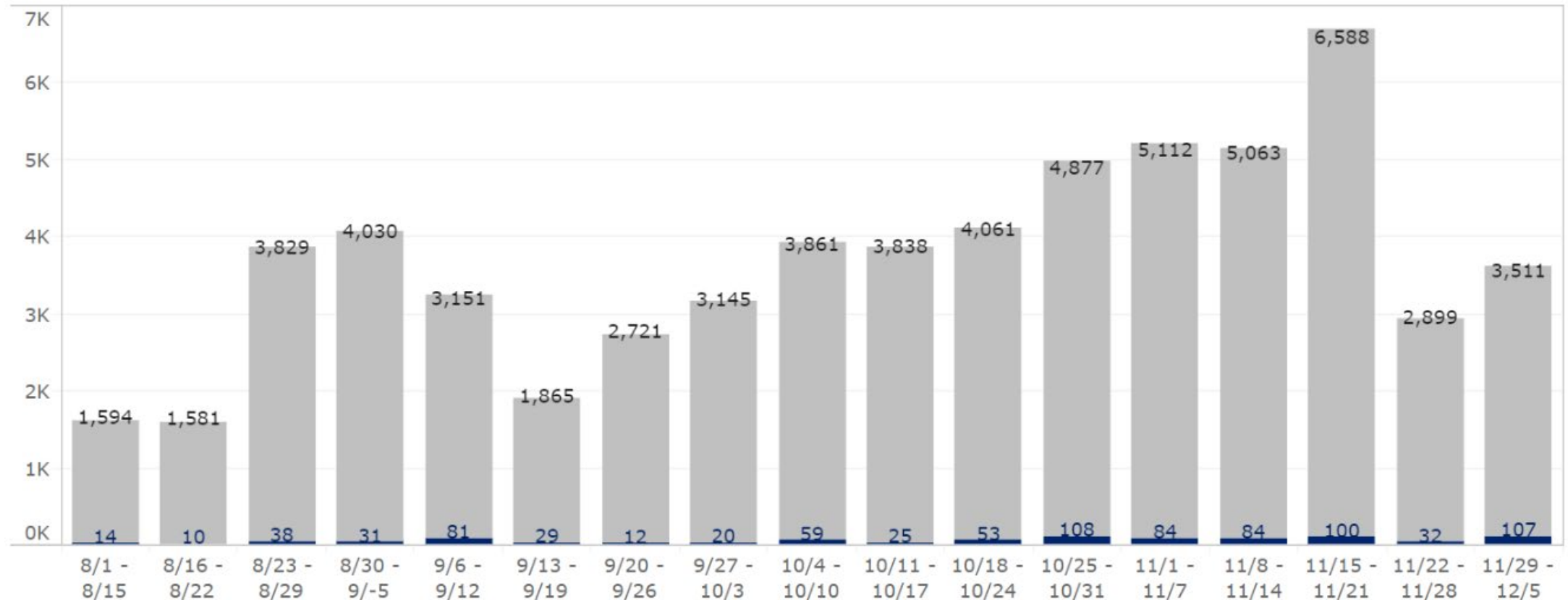
Total

Tests and Positive Cases by Week

Total

Tests

Positive Results



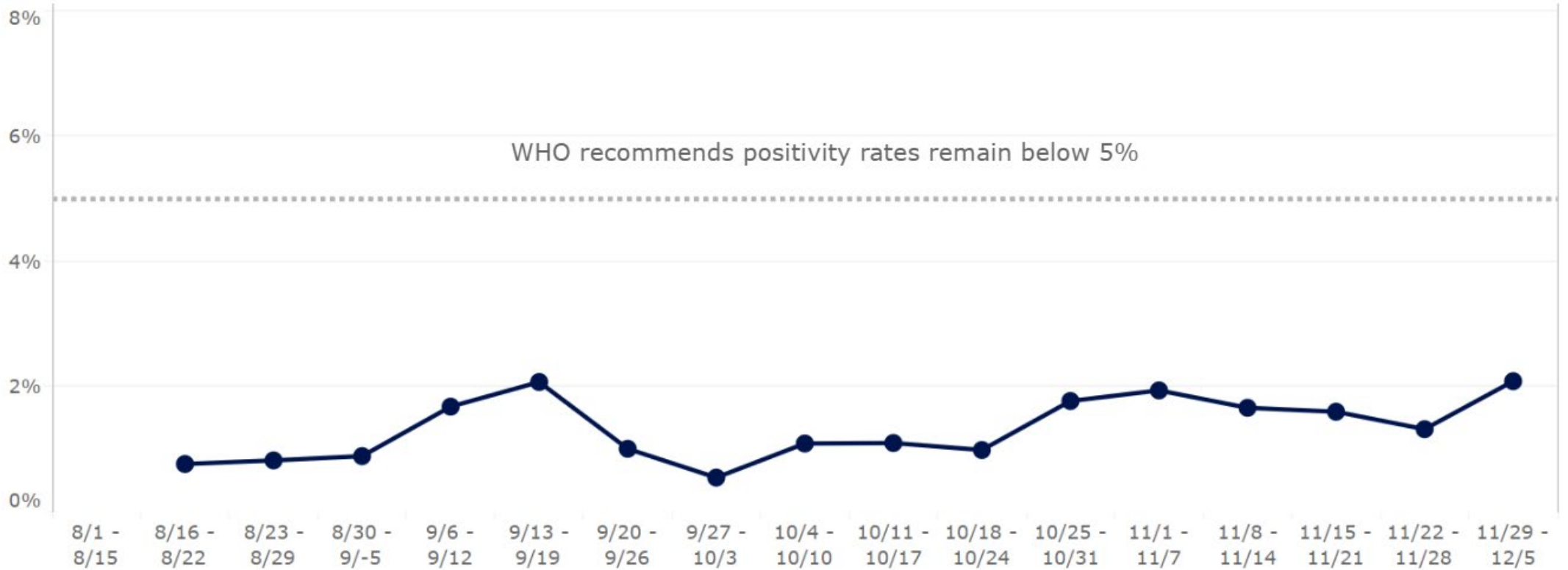
COVID-19 Dashboard

Choose a Population

Total

Positivity Rate (2-week rolling average)

Total



Spring Testing Criteria

When the spring semester begins, saliva-based screening will be required for these groups:

- Undergraduates living on campus or off campus in the Philadelphia area must be tested twice per week on preassigned days.
- Graduate students who come to campus must be tested once per week. Clinical students whose clinical rotations take them away from campus are not required to be tested.
- Faculty, staff, and postdocs who live in College Houses must be tested twice per week, at least two days apart.

Spring Testing Criteria: Faculty, Staff, Postdocs

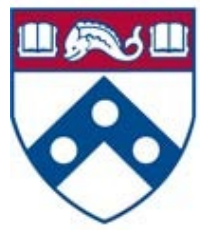
To offer important protection for the Penn community, screening testing will be required for faculty, staff, and postdocs who meet one or more of the following conditions:

- On campus for four or more hours each week interacting with other community members;
- Activities on campus involve teaching;
- Regularly in an aggregate setting of ten or more people in a single shared space on campus.

Spring Semester Testing

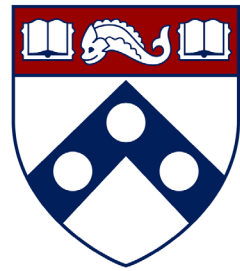
*Mark Dingfield, PhD, Associate Provost
for Finance and Planning*

A True Collaboration



Penn Medicine

+



Penn
UNIVERSITY of PENNSYLVANIA

=



Penn *Cares*

TEST • TRACE • ISOLATE

Spring Testing: Saliva-Based Screening

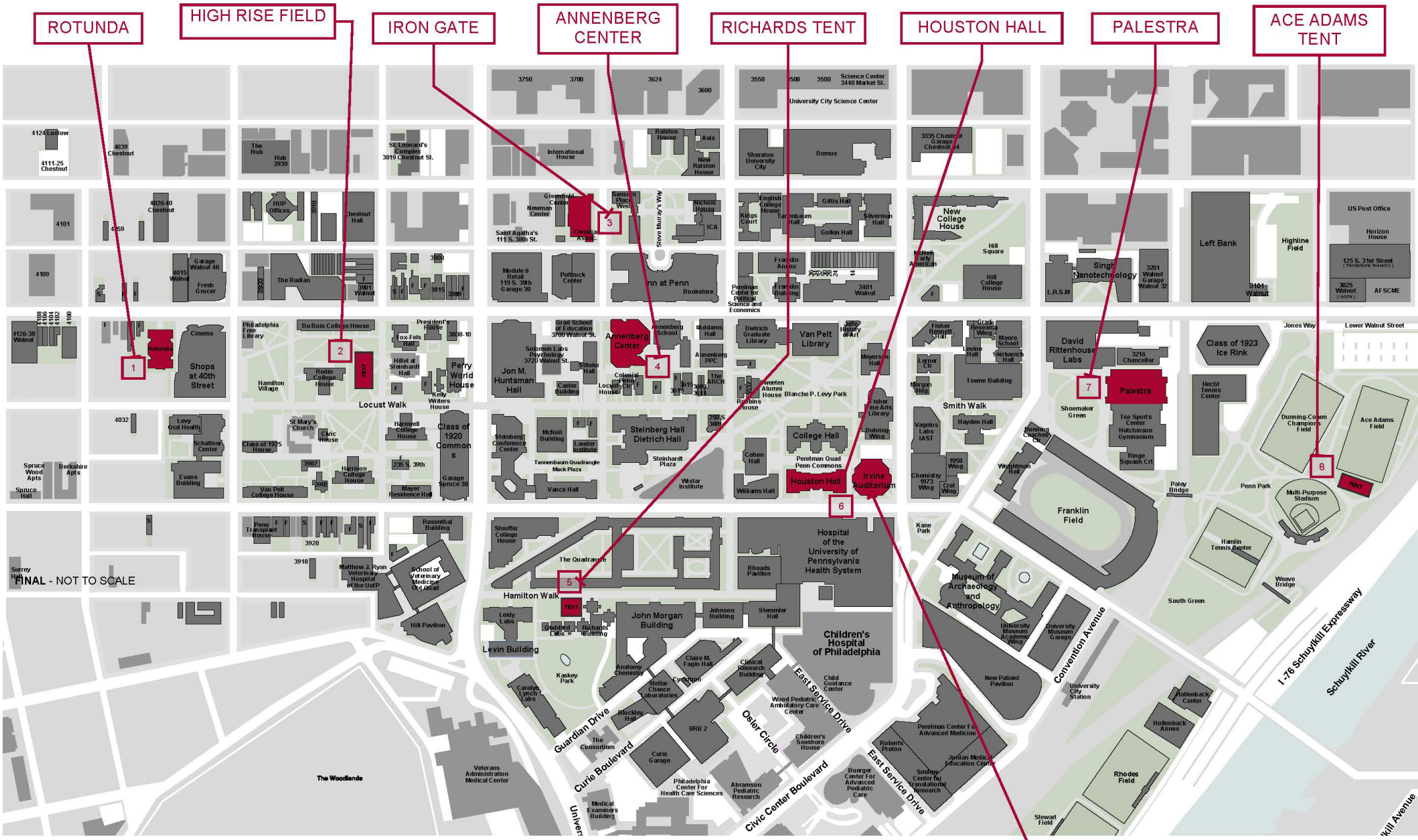
- Saliva-based testing allows us to dramatically increase our screening testing capacity for the Spring semester.
- This FDA-approved, saliva-based assay will be processed using automation in new labs in Stemmler Hall and eventually at Penn Medicine Rittenhouse.
- Through our partnership with Penn Medicine, we are prepared to offer up to 40,000 screening tests per week beginning in January.
- Testing for symptomatic individuals identified through PennOpen Pass will continue to use nasal swab test.

Spring Testing: Planning Principles

- Make testing accessible, accurate, and safe.
- Follow public health guidance and best practices from other institutions.
- Where possible, leverage technology to manage scale.
- Be clear and consistent but prepare to adapt.
- Draw upon the knowledge and skills in the university community.

Spring Testing: Locations

- Locations across campus are undergoing historic transformations to serve as easy-access screening sites starting in January. Additionally, one site is dedicated to testing for those who have symptoms or have had an exposure to COVID-19.
- These locations include:
 1. Rotunda
 2. Tent, High Rise Field
 3. Iron Gate Theater
 4. Annenberg Center for the Performing Arts
 5. Tent, Richards Plaza
 6. Houston Hall
 7. Palestra Concourse
 8. Tent, Ace Adams South Field
 9. *Irvine Auditorium (symptomatic and exposure testing)*



ROTUNDA

HIGH RISE FIELD

IRON GATE

ANNENBERG CENTER

RICHARDS TENT

HOUSTON HALL

PALESTRA

ACE ADAMS TENT

1

2

3

4

5

6

7

8

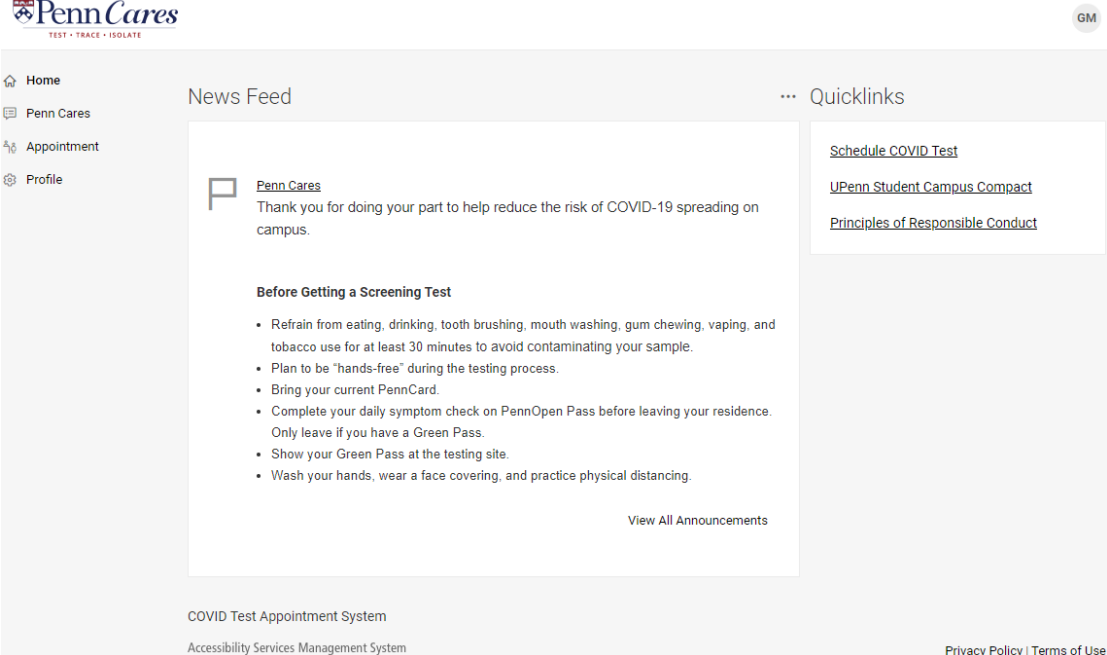
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FINAL - NOT TO SCALE

IRVINE
(POP red pass tests)

Spring Testing: Scheduling

- We are introducing a new web-based scheduling application where you will also be asked to give your consent for the new saliva-based test.
- Beginning January 4, 2021, screening testing will be by appointment for those who meet screening test criteria. You can schedule multiple tests at one time.
- If you meet criteria for screening testing, you will be enrolled when you schedule your first test.
- Appointments will be booked at 15-minute intervals.
- Walk-up testing at High Rise Field and Ace Adams tents will be available to those who are not enrolled in screening testing.




The screenshot displays the Penn Cares website interface. At the top left is the Penn Cares logo with the tagline "TEST • TRACE • ISOLATE". A navigation menu on the left includes links for Home, Penn Cares, Appointment, and Profile. The main content area is titled "News Feed" and features a post from Penn Cares with a large "P" icon. The post text reads: "Thank you for doing your part to help reduce the risk of COVID-19 spreading on campus." Below the text is a section titled "Before Getting a Screening Test" with a bulleted list of instructions: "Refrain from eating, drinking, tooth brushing, mouth washing, gum chewing, vaping, and tobacco use for at least 30 minutes to avoid contaminating your sample.", "Plan to be 'hands-free' during the testing process.", "Bring your current PennCard.", "Complete your daily symptom check on PennOpen Pass before leaving your residence. Only leave if you have a Green Pass.", "Show your Green Pass at the testing site.", and "Wash your hands, wear a face covering, and practice physical distancing." A "View All Announcements" link is positioned at the bottom right of the post. To the right of the news feed is a "Quicklinks" section containing three links: "Schedule COVID Test", "UPenn Student Campus Compact", and "Principles of Responsible Conduct". At the bottom of the page, there are links for "COVID Test Appointment System", "Accessibility Services Management System", and "Privacy Policy | Terms of Use". A "GM" icon is visible in the top right corner.

Saliva Testing Process

COVID-19 TESTING AT THE UNIVERSITY OF PENNSYLVANIA



SCHEDULE

covidsheduling.upenn.edu 



PREPARE

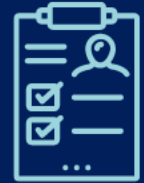
Don't eat, drink, brush teeth, use mouthwash, chew gum, vape or use tobacco **for at least 30 minutes before your test.**

Arrive "hands free" with your PennCard, Green PennOpen Pass, mask and stay physically-distant.




DROOL

You'll receive instructions on how to provide your saliva sample.



CHECK RESULTS

covidresults.upenn.edu 

VISIT CORONAVIRUS.UPENN.EDU FOR MORE INFORMATION ABOUT SALIVA TESTING.

Spring Testing: Timeline

December 7

Saliva
screening
transition

**December 23-
January 2**

Nasal swab
testing at
Irvine only

January 4-8

Spring Testing
ramp-up
**(4 test sites
operational)**

January 10

Move-in for
College Houses
begins

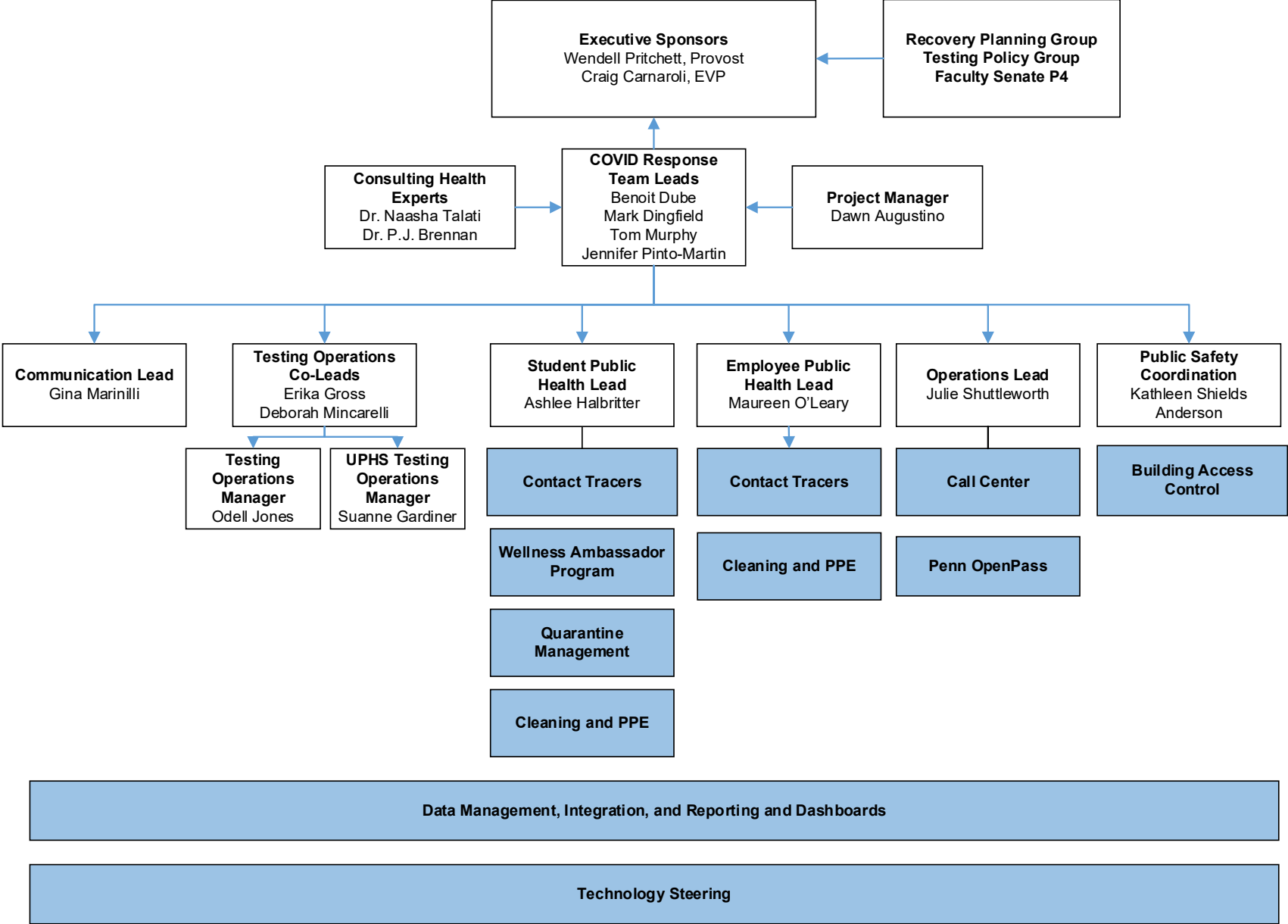
January 11

All testing
locations
operational

January 18

Compliance
monitoring
begins for all

COVID Response Team



Testing Compliance: Faculty, Staff and Postdocs

*Jennifer Pinto-Martin, PhD, MPH, Viola MacInnes Professor,
School of Nursing and Perelman School of Medicine*

*Jeffrey Rowland, Executive Director,
Division of Human Resources*



Compliance: PennOpen Pass

- All Faculty, staff and postdocs are asked to complete a daily symptom check using PennOpen Pass, whether they plan to come to campus or not.
- These data are important for monitoring COVID symptoms in our community and compliance is strongly encouraged.
- This is also the fastest route to testing for those who are exhibiting symptoms or who have had an exposure, so there is a direct benefit to compliance.

PennOpen | Pass



Compliance: Testing Requirements

To offer important protection for the Penn community, screening testing will be required for faculty, staff, and postdocs who meet one or more of the following conditions:

- On campus for four or more hours each week interacting with other community members;
- Activities on campus involve teaching;
- Regularly in an aggregate setting of ten or more people in a single shared space on campus.



Compliance: Guidelines for Faculty & Postdocs

- Faculty and postdocs who meet the testing criteria and do not comply with enrollment or refuse to get tested will not be permitted on campus.
- The PennOpen Pass system will generate a red pass for anyone who misses their required tests for a particular week.
- A copy of that list will be sent to the appropriate school/center designee for follow-up.

PennOpen | Pass



Compliance: Guidelines for Staff

- Staff who meet the testing criteria must self-identify.
- If a staff member tests positive, they will have to stay home (and cannot otherwise work remotely). They will be paid up to 10 working days of their regular pay in a 14-day period.
- Those identified as meeting the criteria must enroll by January 18, 2021. Failure to enroll will restrict access to the campus and may result in disciplinary action up to and including termination.



Compliance: Guidelines for Staff (continued)

- Those who enroll in the testing program but fail to participate may be subject to discipline up to and including termination.
- The PennOpen Pass system will generate a red pass for anyone who misses their required tests for a particular week. A copy of that list will be sent to the appropriate School/Center designee for appropriate follow up.
- Requests for reasonable accommodations should be made to OAA/EOP.



Panel Discussion

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