

BACK-TO-WORK FORUM



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Webinar Procedures



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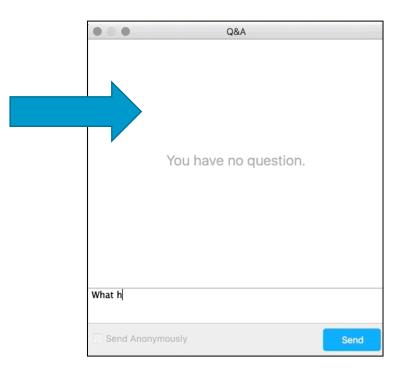
Please submit all questions using the "Q&A" dialog box



Email Diane Engel at dengel@nebgh.org with any issues during this webinar



The recording and a PDF of the slides will be shared









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COVID-19 Return to Work Forum: Testing and Treatment

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May 14th 2020





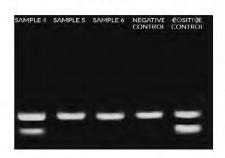
COVID-19 Testing: Overview

There are two main types of COVID-19 tests: 1) Diagnostic tests that identify those who are actively infected and 2) Antibody tests that identify those who have been recently infected

Diagnostic Tests

- Identifies those who are actively infected
- Nasal, throat, or saliva samples

1. Polymerase Chain Reaction (PCR) Tests



- "Gold Standard"
- Analyzed on-site or at lab
- Widespread availability

2. Rapid Antigen Tests



- Less reliable
- Rapid; Analyzed on-site
- Only 1 test with EUA

Antibody Tests

- Identifies those who have been recently infected
- Blood samples

1. Enzyme-linked Immunosorbent Assay (ELISA)



- Yes/no result + quantity
- Results read by machine
- More reliable

2. Lateral Flow Assay (LFA)



- Yes/no result only
- Difficult to read results
- Less reliable



COVID-19 Testing: State of Play

On May 4th, the FDA required all diagnostic and antibody tests to have approval under emergency use authorization (EUA). These tests are becoming more widely available in the US through a variety of "providers"

Diagnostic Tests

Antibody Tests

PRODUCTS

81

with approval under FDA EUA1

12

with approval under FDA EUA1

AVAILABILITY

Providers

(

Direct to Consumer



Pharmacies



Big Box Retailers



COVID-19 Testing: Comparison of Antibody Tests

Only 12 antibody tests, including one from Mount Sinai, have received FDA authorization. However, sensitivity and specificity can vary widely even among these tests as illustrated below

<u> </u>	Mount Sinai	Abbott	Others		
Result Type	Yes/No + Quantity	Yes/No	Yes/No		
Antibodies Detected	lgG	lgG	IgM and/or IgG and IgA		
Specificity	100.0%	99.6%	94.4% - 100.0%		
Sensitivity*	92.5% - 94.0%	100.0%	83.3% - 100.0%		

Tests with the highest specificity will enable employers to accurately identify individuals with antibodies



^{*}Source: US Food & Drug Administration, In Vitro COVID-19 Diagnostics EUAs, Test Kits and Commercial Labs Table. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance



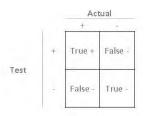
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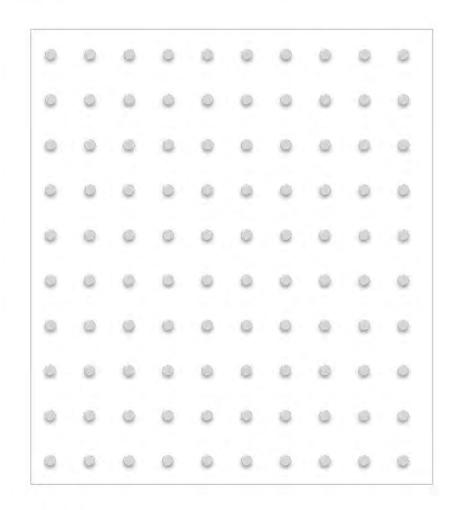
^{*}Source for Mount Sinai includes US FDA and sensitivity reported by Dr. Anya Wajnberg in a press release. Link at https://www.advisory.com/daily-briefing/2020/05/12/covid-family

COVID-19 Testing: Antibody Test Accuracy

Using a reliable antibody test is critical to accurately identifying individuals with antibodies

Assume a population of 10,000 individuals





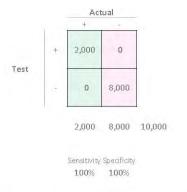
100 Individuals

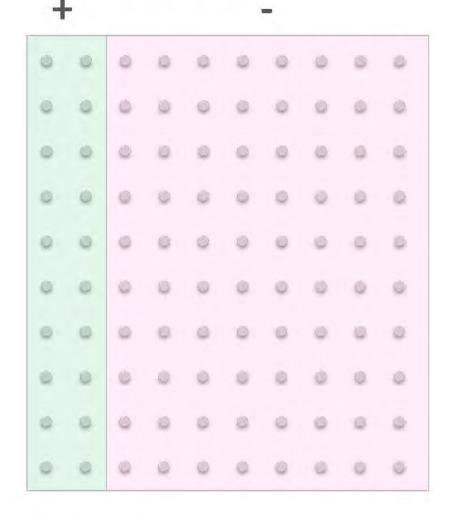


COVID-19 Testing: True Prevalence

In this example, using a "perfect" antibody test would result in 2,000 individuals testing positive

- Now assume the following:
 - o True antibody prevalence: 20%
 - o Perfect test with 100% specificity and sensitivity
- Then 2,000 individuals would test positive





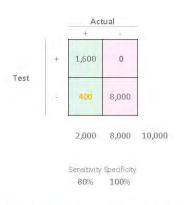


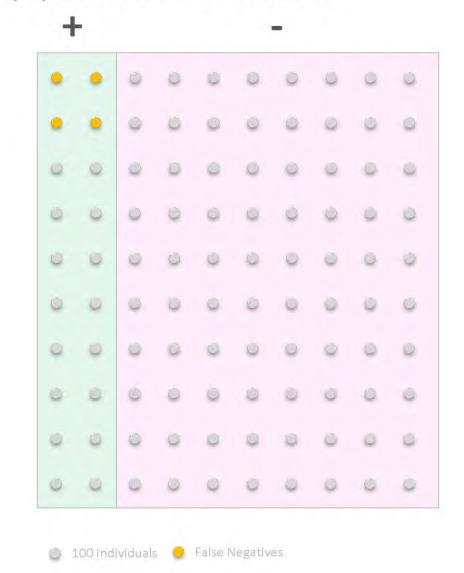


COVID-19 Testing: False Negatives

However, using a test with 80% sensitivity would only capture 1,600 of those 2,000 individuals

- Now assume test sensitivity is 80%
- Then 400 who should test positive will test negative
 - Minimal safety risk; can re-test these individuals

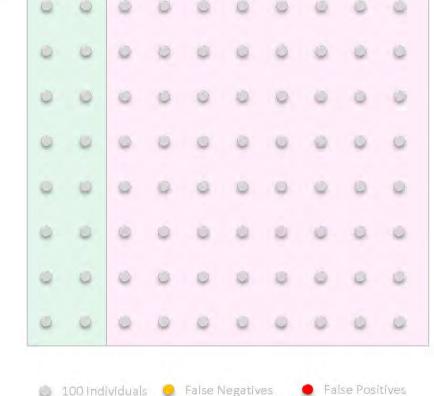


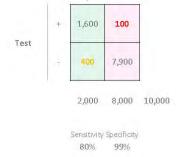


COVID-19 Testing: False Positives

Of greater concern is using a test with lower specificity. Even a test with 99% specificity would result in 100 individuals without antibodies testing positive

- Now assume test specificity is 99%
- Then 100 who should test negative will test positive
 - Higher safety risk; these 100 could believe they are protected, but get infected and transmit the disease





Actual



COVID-19 Testing: Role in Return to Work

Testing could play an integral role in a return-to-work plan but will not guarantee 100% safety. Testing should be paired with other risk mitigation strategies such as symptom monitoring and contact tracing.

Return-to-Work Toolkit













COVID-19 Treatments and Vaccines: Overview

There are many treatments in the pipeline for COVID-19. The treatments being investigated can be grouped into several categories, each targeting slightly different elements of this infectious disease.



Repurposed Drugs



Antibodies



Vaccines

DESCRIPTION

- Use existing antivirals and medications to treat COVID-19
- Leverage specific antibodies that can neutralize the virus
- Provide protection against future infection

EXAMPLES

- Remdesivir
- Hydroxychloroquine / Azithromycin
- IL-6 Inhibitors e.g. Tocilizumab
- Anticoagulants

- Convalescent plasma
- COVI-SHIELD

- Oxford vaccine
- Pfizer / BioNTech vaccine

TIMING

- · Ongoing clinical trials
- 1 drug already with FDA EUA
- Ongoing trials and studies
- Q3 Q4 2020

- Ongoing clinical trials
- 12 18 months



COVID-19 Treatments: Remdesivir and Convalescent Plasma

Two treatments have been discussed frequently: 1. Remdesivir, which has received an FDA EUA, and 2. Convalescent Plasma, which uses the antibodies in recovered patients to treat infected patients.

	Remdesivir	Convalescent Plasma Antibodies					
Treatment Category	Repurposed Drug						
Definition	Anti-viral drug used to treat Ebola	Antibodies against SARS-CoV-2 contained within the blood					
How it Works	Nucleotide analog that inhibits production of viral RNA	Transfuse plasma from patients who have developed antibodies to infected patients to offer passive immunity					
FDA EUA	Yes; authorized on 5/1/2020	No; FDA-approved clinical trial only					
	31% faster time to recovery (11 days vs. 15 days) ¹	Previously used for 1918 Flu, H1N1, SARS, MERS, Ebola					
Key Results	 No statistically significant difference in reduction in mortality (11.6% vs. 8.0%)¹ 	 > 6,000 patients have been treated with convalescent plasma in the US; > 350 at Mount Sinai 					
	 Ongoing trial to evaluate safety and efficacy of 5-day and 10-day dosing regimens 	 Results to be published, but a Mount Sinai study found that 99.5% of COVID-19 positive donors had antibodies² 					



Thational Institute of Allergy and Infectious Disease, April 2919, 2020 https://www.niaid.nih.gov/news-events/nih-dinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19
Wainberg et al. "Himoral Immune response and prolonged PCR positivity in a cohort of 1343 SARS-CoV-2 patients in the New York City region," medRXiv, May 59, 2020, https://www.medrxiv.org/content/10.1101/2020.04.30.20085613v1



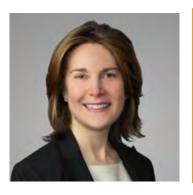
Return to Work Considerations

Epstein Becker Green

May 14, 2020

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Employment Law Considerations

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Laws and Guidance

Federal Guidelines – Guidelines for Opening Up America Again

- Regional Gating Criteria
 - Symptoms, Cases, Hospitals
- Preparedness
- Phased Guidelines
 - Three phases, consider:
 - Individuals
 - Employers
 - Specific Types of Employers
- Also, OSHA, CDC, EEOC Guidance



Review applicable **State/Industry Plans**Be mindful of:

- Industry Rules
- Regional Specifications (e.g., NYC v. Upstate)
- Even where states permit opening, counties and cities espousing "stay at home" recommendations (e.g., Houston, Texas Stay-Home, Work-Safe Order in light of Texas Re-openings)



Considerations Before Employees Arrive

Training for all employees and managers on:

- New safety and capacity rules
- New company policies/procedures

Will returning to work be voluntary? If so, how to determine who will come

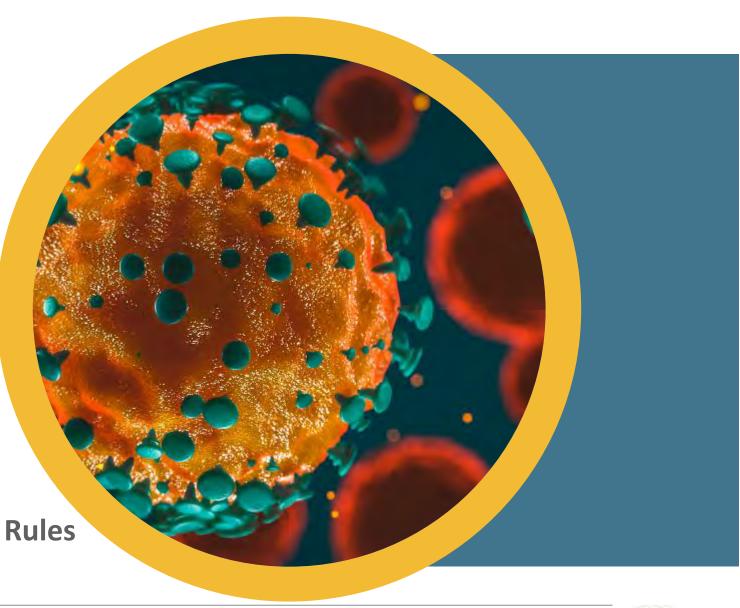
- Questionnaires
- Assess job duties

Changes to the office/facility, including logistical considerations

- Physical space changes
- Process changes
- Create Team to coordinate efforts (HR, Legal, IT, Office Services, Security)

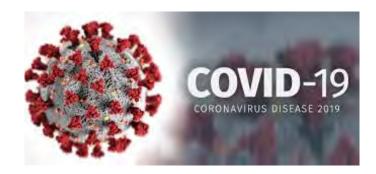
Prerequisites for Entering the Workplace

- Testing
 - Temperatures
 - COVID-19
 - Antibody
- Questionnaires (Red/Green Light)
 - Temperature
 - Symptoms
 - Diagnosis (employee and household)
 - Close contact
 - Travel
- Voluntariness; Following Company Rules
- Waiver?



Reasonable Accommodation of "Vulnerable Employees"

- EEOC's Updated Guidance
 - Are underlying conditions and bases for compromised immune systems disabilities?
 - Precluding "vulnerable" employees from entering the workplace permissible?
 - Age not a disability, but a basis for accommodation?
 - What about "vulnerable" household/family members accommodations required?
 - If no "vulnerability," accommodation required?
 - Elevated requirements under state and local law?
 - If no legal obligation, should employers accommodate?
 - Be consistent
 - Consider unemployment insurance eligibility implications
 - Texas eligible if age concerns, "vulnerable" factors not addressed
 - What will other states do?



Other Liability Concerns



Discrimination/harassment claims: in connection with reductions in force, selection for furlough, return from furlough, reasonable accommodation, national origin harassment, disability discrimination and failure to accommodate



Wage and hour concerns: compensation for temperature testing; change in exempt status due to pay reductions; call-in pay concerns; overtime uncertainty with remote working; reimbursement of equipment during remote working periods (different state rules)



NLRA concerns: protected, concerted activity; are we creating a breeding ground for unions?



FFCRA, FMLA, other leave requirements: sick time, expanded FMLA leave under FFCRA; NYS sick time law; existing sick time rules (some states have modified how they work; retaliation claims



OSHA concerns: is your workplace safe; reporting requirements; negligence standards and creating a workplace free of "recognized hazards"

Remote Working Considerations

Managing Remote Workers in Response to COVID-19



- Create/Revise Remote Working Policies
- Can all job duties be performed remotely?
 - If not, burden will be on employer to prove
 - Undue hardship analysis
 - Be consistent
 - If not, can we separate "in-office" responsibilities, and
 - Have employee come in one day a week to perform same
 - Redistribute job duties so that "in-office" duties are no longer part of the employee's job

Cyber and Other Tech Considerations

Cybersecurity

Prepare risk assessment and cybersecurity plans for remote workforce

Consider requiring multifactor authentication

Enhance "BYOD" security/policies

Assess risks associated with cloud-based computing

Plan for threats/security incidents

Encryption of devices

Privacy and Data Security Concerns

Ensure that
maintaining certain
health-related
information does not
violate international (if
applicable) and
domestic data
security/privacy laws

Employee Monitoring Concerns

If you are considering spyware/surveillance/key stroke logging, consider possible claims under the Stored Communications Act, state or local social media password protection laws, and other consumer protection laws like the CA Consumer Protection Act

Biometrics Laws

If considering the capturing of biometric data, be mindful of various state biometric laws, in particular, those in IL, WA, and TX.

Consent and/or prior notice may be required





Benefits Considerations

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Testing: Temperatures, COVID-19, Antibodies and Other Health Screening

- Are these programs being provided under a group health plan, wellness program or EAP?
 - Subject to ERISA group health plan requirements or HIPAA excepted benefit
 - Co-pays, waivers, medical expenses
 - There is an exception to the Americans with Disabilities Act for wellness programs
 - Voluntary nature of participation for plans and programs



Revamping Group Health Plans for Telemedicine / Telemental Health

- Will the CARES Act and related federal/state expansion of telehealth services be extended
- Legislation on provider payments for telehealth services versus in-patient services
- How will changes impact plan design?
- Will telemental services satisfy parity requirements?
- Receipt of protected health information in an employment context



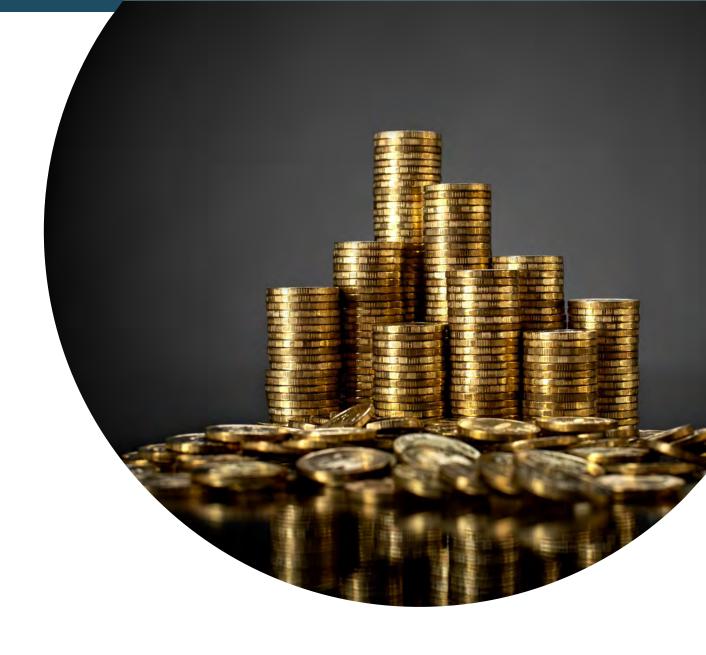
Benefits Considerations as Employees Return to Work

- Plan eligibility, service credit and vesting
- Were employees on furlough or temporary layoff or leave of absence?
- What do the plan provisions provide?
- Are there any limitations to eligibility for benefit plans, such as waiting periods?
- How is service credited for the period the employee was not working?



Benefits Considerations as Employees Return to Work (continued)

- Retirement plan contributions and compensation
- Incentive compensation plans and programs/bonuses
 - Performance targets
 - Extraordinary event adjustments
 - Management discretion
 - Equity compensation valuations
- Employment agreements
 - Change in duties and location
 - Visa issues and mobility



Benefits Considerations as Employees Return to Work (continued)

- Health continuation coverage during leaves of absences
- Severance program repayments
- Reimbursement programs
 - Flexible spending account elections and
 - qualified expenses (over the counter medications and products)
 - Dependent care reimbursement account elections
- Commuting expenses
 - How will employees get to work?
 - Can employers subsidize transportation?
 - Commuter reimbursement accounts what are qualified expenses?



Epstein Becker Green Coronavirus Resource Center

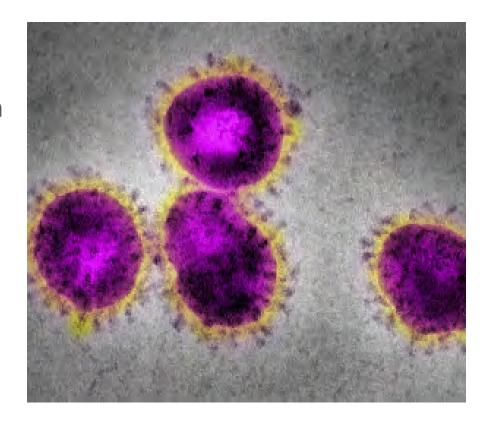
Epstein Becker Green Coronavirus News and Updates

Employers throughout all industries, and particularly those within health care, are now grappling with how to deal with the various implications of the coronavirus (COVID-19) on their businesses and workforce.

Please see below for our latest news, <u>subscribe for email</u> <u>notifications</u>, and revisit for updates.

Health Care & Life Sciences

Workforce Management



https://www.ebglaw.com/coronavirus-resource-center/

Questions?



SAFE RETURN TO WORK



White House / CDC Criteria for Reopening

SYMPTOMS

Downward trajectory of influenzalike illnesses (ILI) reported within a 14-day period

AND

Downward trajectory of COVID-like syndromic cases reported within a 14-day period

CASES

Downward trajectory of documented cases within a 14-day period

OR

Downward trajectory of positive tests as a percent of total tests within a 14-day period (flat or increasing volume of tests)

HOSPITALS

Treat all patients without crises care

AND

Robust testing program in place for at-risk healthcare workers, including emerging antibody testing

States Planning to Reopen

Alaska	States Planning to reopen									Maine	States Failing to Meet Criteria Ma							Maine			
					Wis.				Vt.	N.H.											N.H.
Wash.	Idaho	Mont.	N.D.	Minn.	III.	Mich.		N.Y.	Mass.			Idaho			Minn.						
Ore.	Nev.	Wyo.	S.D.	lowa	Ind.	Ohio	Pa.	N.J.	Conn.	R.I.			Wyo.	S.D.	lowa	Ind.	Ohio		N.J.		R.I.
Calif.	Utah	Colo.	Neb.	Mo.	Ку.	W.Va.	Va.	Md.	Del.			Utah	Colo.	Neb.	Mo.	Ку.	W.Va.	Va.			
	Ariz.	N.M.	Kan.	Ark.	Tenn.	N.C.	S.C.	Г				Ariz.	N.M.	Kan.	Ark.	Tenn.	N.C.	S.C.			
			Okla.	La.	Miss.	Ala.	Ga.							Okla.	La.	Miss.	Ala.	Ga.			
Hawaii			Texas					Fla.						Texas					Fla.		

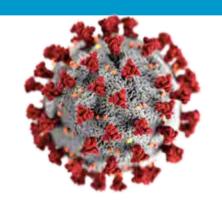


Organizational Considerations

- ✓ State/Government Approval
- ✓ Availability of personal protective equipment (masks)
- ✓ Availability of hand sanitizer, disinfectants etc...
- ✓ Ability to social distance within the workplace
- ✓ Ability to safely get to and from work
- ✓ Organizational dashboard

Case Trend	New Cases	Infectivity	Testing	Contact Tracing	PPE & Sanitizer	Social Distancing	Immunity	Employee Cases
Case trend over time	Number of new cases per million	R ₀ <1 or <0.5	Testing per positive or Testing per capita	Effectiveness of community contact tracing	PPE & cleaning supplies availability	Can be achieved +/- alternative controls	Community or employee antibody testing	Number of employee cases





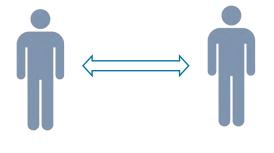
How People Act is Critical







Cough etiquette



Social Distancing









Wear a mask

Not sharing

Safe commuting

Increased Cleaning



Screens and Separation

- Plexiglass screens to separate workers where social distancing not possible
- Separating workstations
- Markers to prompt social distancing

















Density and Isolation



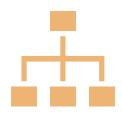
Continue work from home if possible



Shifts:

Reduce density of population
Staggered start times
Non-peak commuting

4-10 cycle – 4 days at work – 10 days off or WFH



Have cells or pods – separating key groups of workers



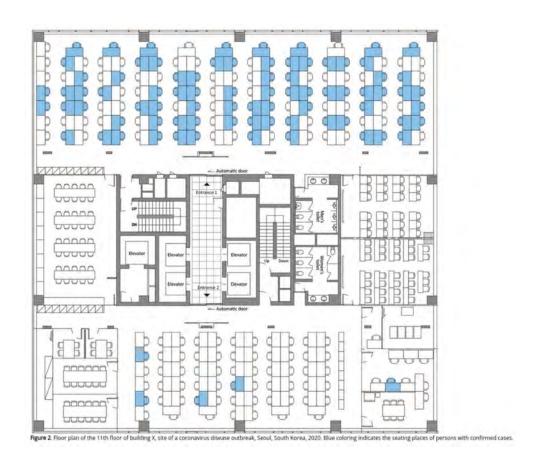
Limit in person meetings

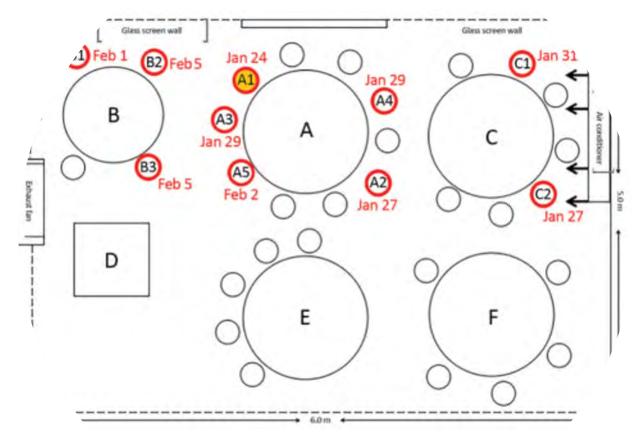


Manage common spaces — canteens, change rooms, coffee stations



Space, Time and Airflow







Access

- Symptom & TemperatureScreening
 - Limited effectiveness false negatives, asymptomatic carriers....
 - Reminder to stay at home if sick
 - Provides a level of reassurance
- Visitors, Contractors and the public:
 - Restricting access for nonessential visitors and the public
 - Controlled area for deliveries

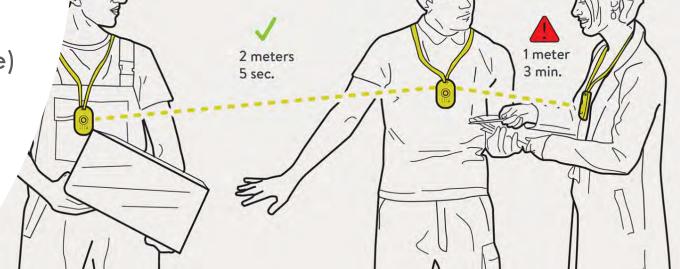




Technology

- Social distancing wearables
 - Buzz/vibrate when get within 6 feet
- Contact Tracing Public Health:
 - Google-Apple based Apps
- Workplace contact tracing:
 - Wearables or an app
 - Identify close contacts (Space and time)
 - Track all employees and can rapidly identify potential close contacts







Immunity Passports

- Concept that identifying who is immune so they can return to work or work in certain areas
- Challenges:
 - False positive and false negative tests
 - Low predictive positive rate when prevalence low
 - Potential to discriminate
 - May encourage risky behaviors
 - May encourage corrupt service providers





Strong Leadership

- Genuinely has employee's health as a priority
- Clear and regular communication
- Visible and accessible
- Affirms with action









Have a question? Use the Q&A box!

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Upcoming NEBGH webinars:

- May 18: NEBGH Medical Director's Weekly Monday COVID-19 Update
- May 19: Diabetes, Lower-Wage Workers and COVID-19
- July 9: Prevention Strategies and Population Health