

COVID-19 Scientific Advisory Board Legislature Presentation May 21, 2020

- President UMaine & UMM Joan Ferrini-Mundy, Ph.D., Chair
- Vaccines/Antivirals - Melissa Maginnis, Ph.D., UMaine
- Diagnostic Testing - Kristy Townsend, Ph.D., UMaine
- Serology Testing/Immunity - Rob Wheeler, Ph.D., UMaine
- Epidemiology and Contact Tracing - Sara Huston, Ph.D., USM
- Transmission in the Environment/Surfaces - Caitlin Howell, Ph.D., UMaine

COVID-19 Vaccines and Therapeutic Development



Vaccines

140

Vaccines in development

4

Leading candidates in clinical development

	Clinical Trial Status	Manufacturing	Company Guidance for Availability
<p>1 ChAdOx1 nCov-19 (Viral Vector)</p> <p><small>THE JENNER INSTITUTE</small> AstraZeneca</p>	<ul style="list-style-type: none"> Phase 1 - complete Phase 2 - March Phase 3 - May/summer (US) 	Partnered with AstraZeneca for global development and distribution BARDA (\$1b) funding to support	400 million doses starting in October, and capacity secured for 1 billion doses 2020-21
<p>2 mRNA-1273 (RNA Vaccine)</p> <p>moderna</p>	<ul style="list-style-type: none"> Phase 1 - complete Phase 2 - approved May 6 Phase 3 - July 	Partnered with Lonza, 10-year agreement BARDA (\$483m) funding to support	Partnership with Lonza enables worldwide vaccine distribution of 1 billion doses/year.
<p>3 INO-4800 (DNA Vaccine)</p> <p>inovia</p>	<ul style="list-style-type: none"> Phase 1 - April Phase 2 - summer Phase 3 - fall 	Partnered with Richter-Helm Biologics	Indicates end of year availability
<p>4 BNT162 program (RNA Vaccine)</p> <p>Pfizer BIOVECTA</p>	<ul style="list-style-type: none"> Phase 1 - April Phase 2 - April Phase 3 - TBD 	Partnered with Pfizer	Emergency use or accelerated approval starting in the fall



Antivirals

219

Drugs in development

2

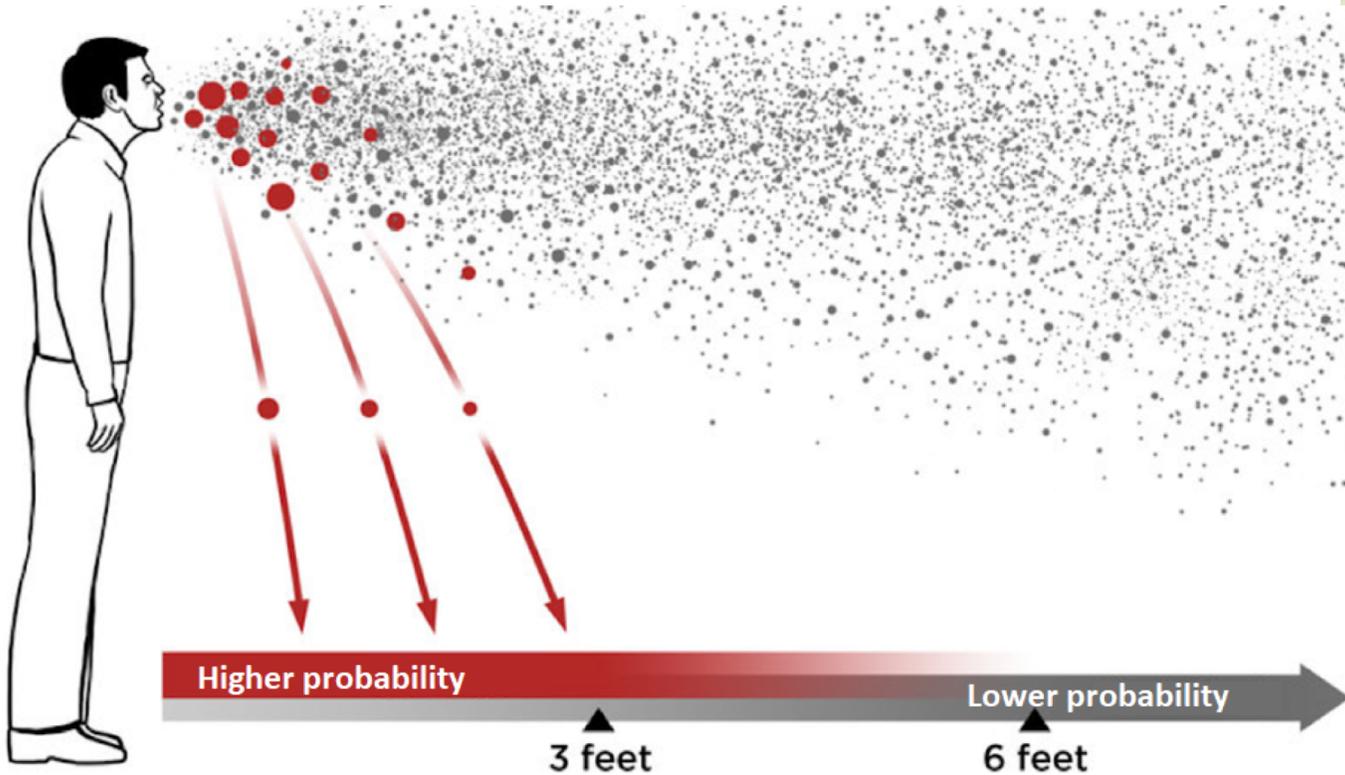
Leading candidates

	Clinical Trial Status	Manufacturing	Distribution
<p>1 Remdesivir (Nucleotide Inhibitor)</p> <p>GILEAD</p>	<ul style="list-style-type: none"> Phase 1-3 - ongoing (5 trials) May 1: FDA issued emergency use authorization for patients with severe disease 	Building global consortium of manufacturers Aim to treat >1 million patients by the end of 2020	Providing 1.5 million free doses to patients
<p>2 Convalescent plasma (anti-CoV Antibodies)</p>	<ul style="list-style-type: none"> Clinical trials Expanded access Emergency IND approval 	Hospital based FDA-registered donations	Relies on donations from recovered patients

BARDA = Biomedical Advanced Research and Development Authority; IND - Investigational New Drug

Primary Transmission Route: Aerosolized Droplets Containing Virus

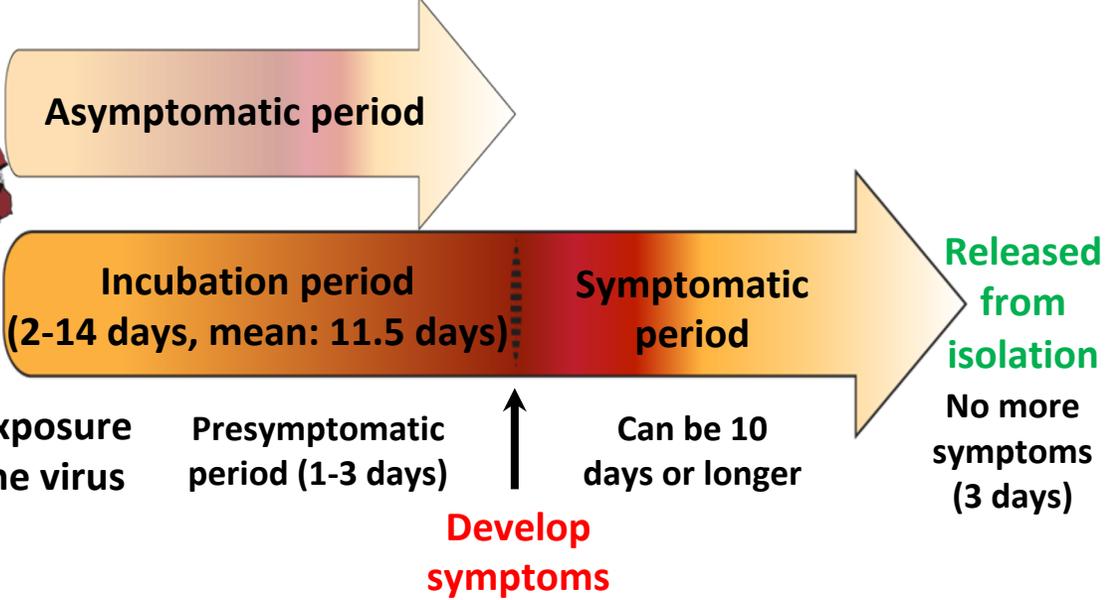
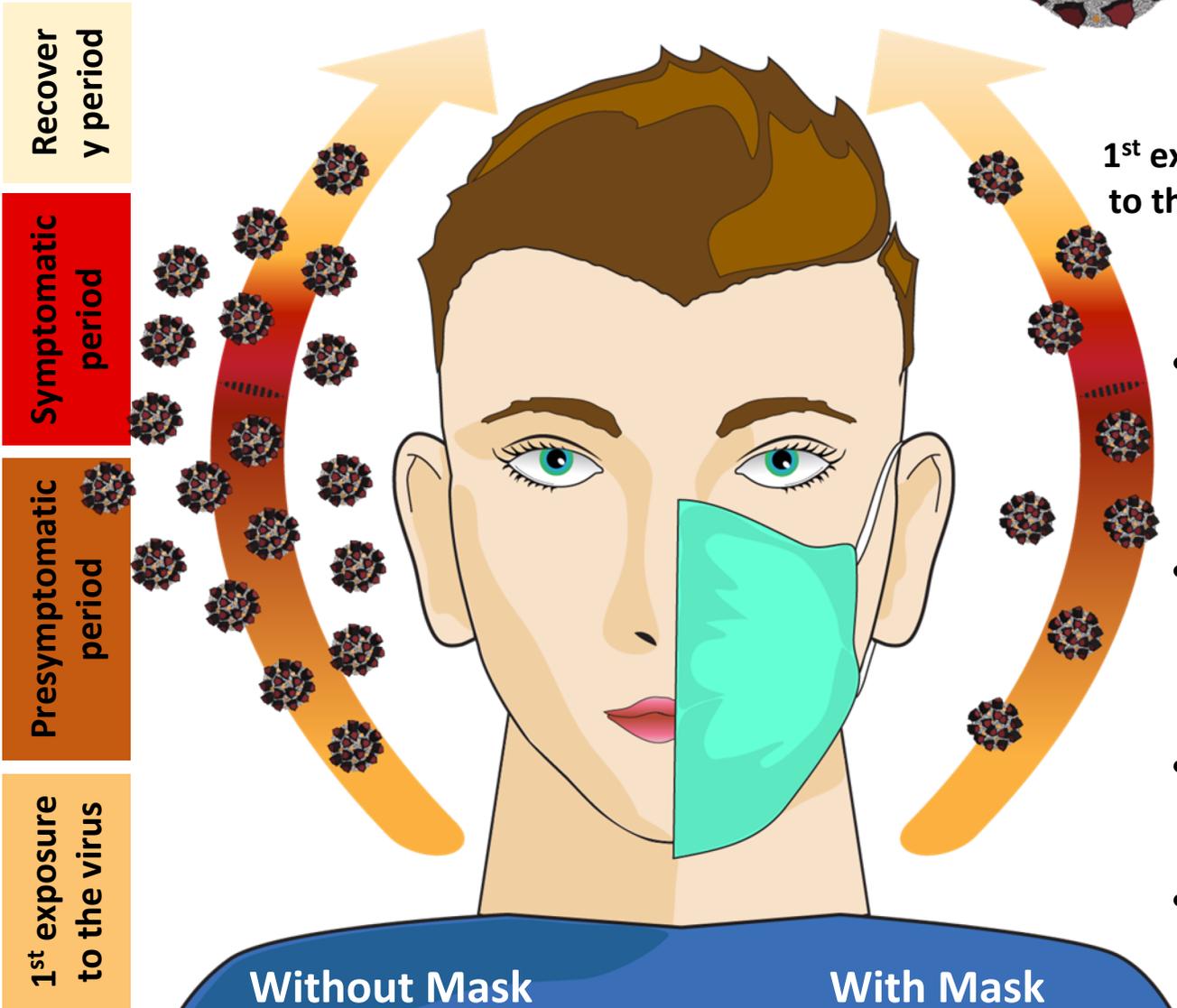
Coughing, Sneezing, and *Speaking*



- Virus can remain stable for up to **3 hours in air**, up to **3 days on surfaces**
- **25-80%** infected individuals from non-healthcare settings **show no symptoms**
- Highest transmissibility likely occurs 2-3 days before symptoms show
- **Increased population density increases probability of presence of virus. Thus, physical distancing and social distancing are key.**
- Transmission appears to be increased with activities that require **heavy or deep breathing** (exercise/singing).

However: Barriers, masks, and other engineered solutions slow the spread if used correctly with high compliance and in conjunction with distancing.

COVID-19 risk: Total virus exposure
 = # of virus particles x time



- Risk of transmission likely the highest **before** the onset of symptoms
 (**Asymptomatic/presymptomatic period**)
- **# of virus particles:** The more people in an area, the higher the chance of virus being present, and in greater amounts
- **Time:** The longer people remain together, the higher the chance of
- Properly fitted cloth masks reduce the number of virus particles entering shared air

Current National Guidance on COVID-19 Management*

Test



Trace



Isolate



Rapid, high-throughput diagnostic testing for the entire community



Contact tracing of COVID-19+ (contacts within <6ft for >30 min are quarantined)



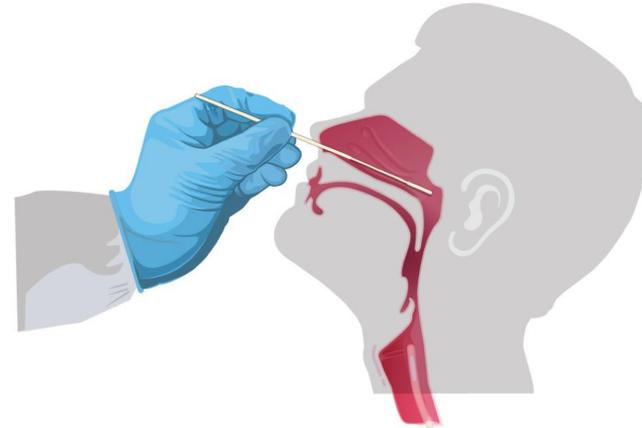
Isolation of COVID-19+ patients in infirmaries until healthy to return

14-day Quarantine: keeps individuals from transmitting disease during the known period of incubation (2-14 days, 5 days median) for SARS-CoV-2¹

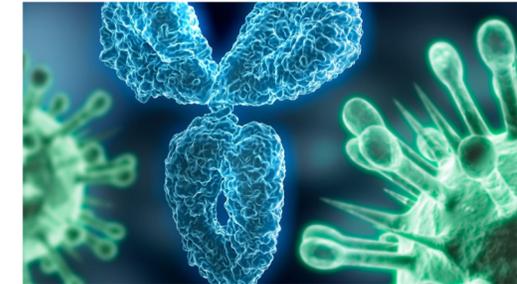
* Based on procedures that have been successful in “flattening the curve” around the globe

Testing for SARS-CoV-2 Infection: An important part of the arsenal to prevent spread of COVID-19

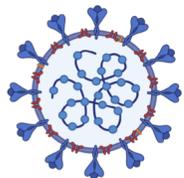
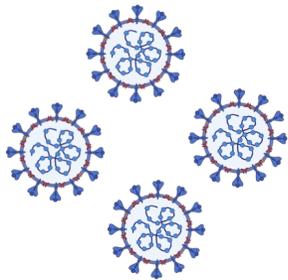
Period of positive diagnostic test
(measures viral RNA by PCR or similar methods)



Period of antibody detection by
serology tests



SARS-CoV-2
Infection



Latency
period

Incubation Period:

- viral replication, shedding (contagious)
- Pre-symptomatic

- Active cases are detected, starting about 1wk before symptoms²
- Workflow is well-validated, good sensitivity and specificity
- Can be cost-effective (high-throughput costs more, may have more false results)
- Positive tests are isolated until recovery
- After about 3wks since symptomatic, lose PCR detection (below threshold for limit of detection)²

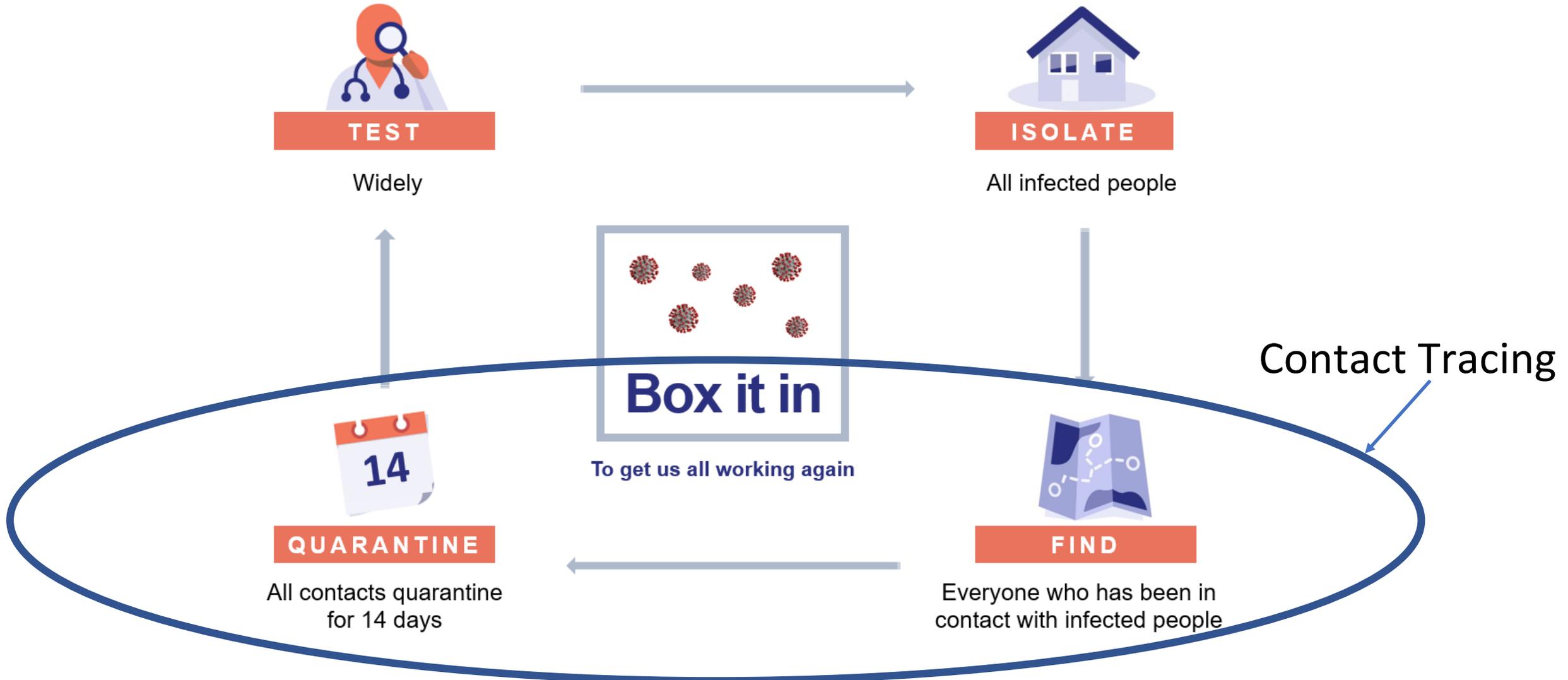
- Detects antibodies from previous infection (IgM & IgG detectable from 2-23d after symptomatic¹; highest around wk 3²)
- Recent data indicate nearly 100% of cases develop antibodies (within 19d of symptom onset)¹
- Antibody+ patients could donate convalescent serum for treatment of active cases
- Unclear if antibody presence indicates immunity (research ongoing)

Variable days depending on disease progression, complications

RECOVERY

Timeline since initial infection

Preventing Spread: Isolate Cases, Quarantine Contacts

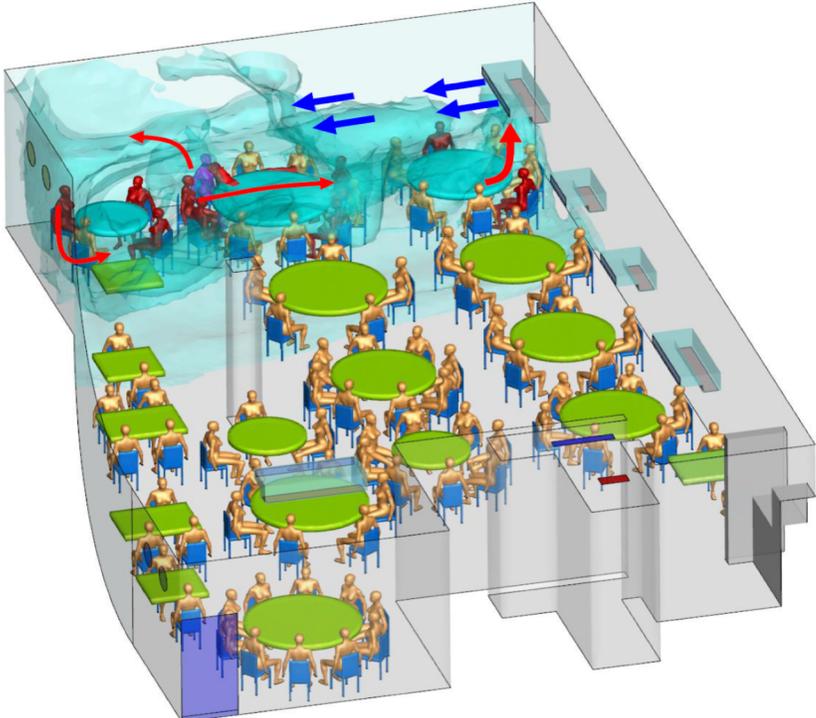


Source: A Coordinated, National Approach to Scaling Public Health Capacity for Contact Tracing and Disease Investigation, Association of State & Territorial Health Officers; and Resolve to Save Lives

Transmission, Mitigation, and Safety in the Built Environment

Caitlin Howell, PhD Assistant Professor of Biomedical Engineering

Movement of virus-containing droplets in the environment



• Li et al. 2020 medRxiv

- **Speaking** can generate aerosols¹
- **Masks** are effective when used correctly and **compliance is high**^{2,3}
- **Good ventilation** is critical; recirculation contributes to spread⁴

Role of surfaces in person-to-person transfer of virus



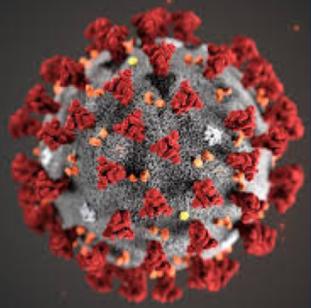
Dietz et al. 2020 mSystems 5: e00245-20

- Virus can land on surfaces and be **re-aerosolized**⁴
- Virus traces found on shoes as well as handles, chairs, etc.⁴
- **Regular disinfection** is effective⁴

Other potential routes of infection and opportunities for detection



- Infectious virus found recently found in feces⁵, viral traces in **toilet areas**⁴
- **Wastewater monitoring** can assist in early identification of outbreaks⁶



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