CEPI

CEPI and COVID-19 VACCINES

June 9, 2020

Nicole Lurie, MD, MSPH

Strategic Advisor to the CEO and Incident Manager, COVID response team

CEPI

A world in which epidemics are no longer a threat to humanity

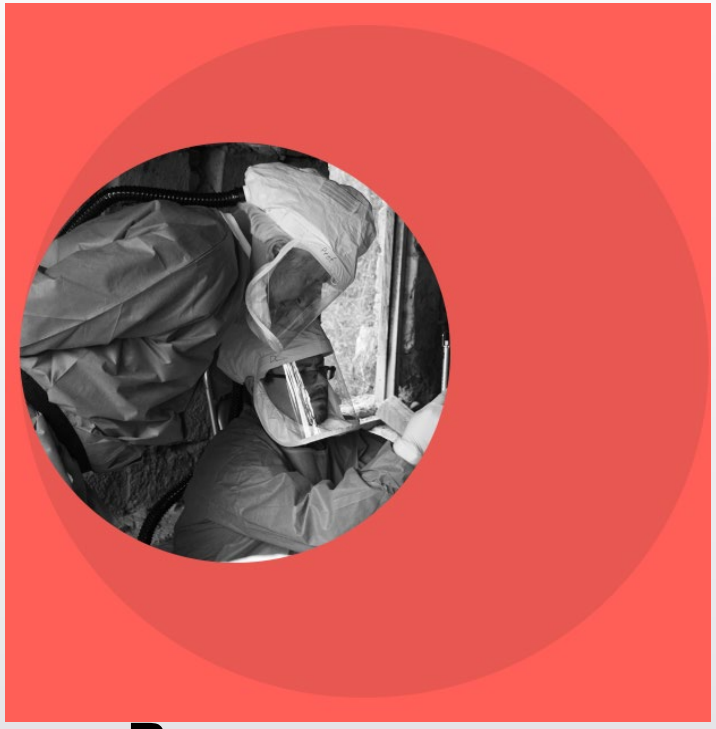
CEPI accelerates development of vaccines against emerging infectious diseases and enables equitable access to these vaccines for affected populations during outbreaks

Image left slide (right-click to replace image)

CEPI Strategic Objectives

Preparedness

Advance access to safe and effective vaccines against emerging infectious diseases



Response

Accelerate the research, development and use of vaccines during outbreaks

Sustainability

Create durable and equitable solutions for outbreak response capacity

3 Column slide

Small images or graphics can be used to highlight key items. These should always be circular

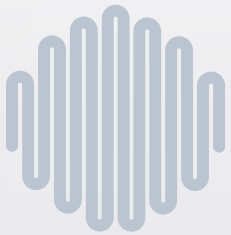
CEPI has multiple investments against its priority pathogens

MERS

5 vaccine candidates

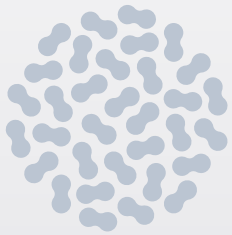
Lassa

6 vaccine candidates



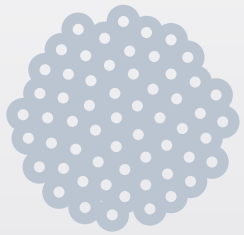
Nipah

4 vaccine candidates



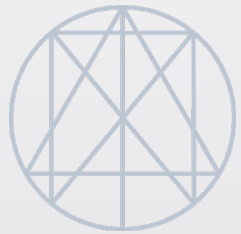
Chikungunya

2 vaccine candidates



Rift Valley fever

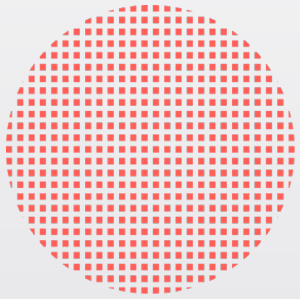
2 vaccine candidates



Disease X

3 platform technologies

COVID-19 portfolio goals



Speed

Developing Covid-19 vaccines at pandemic speed

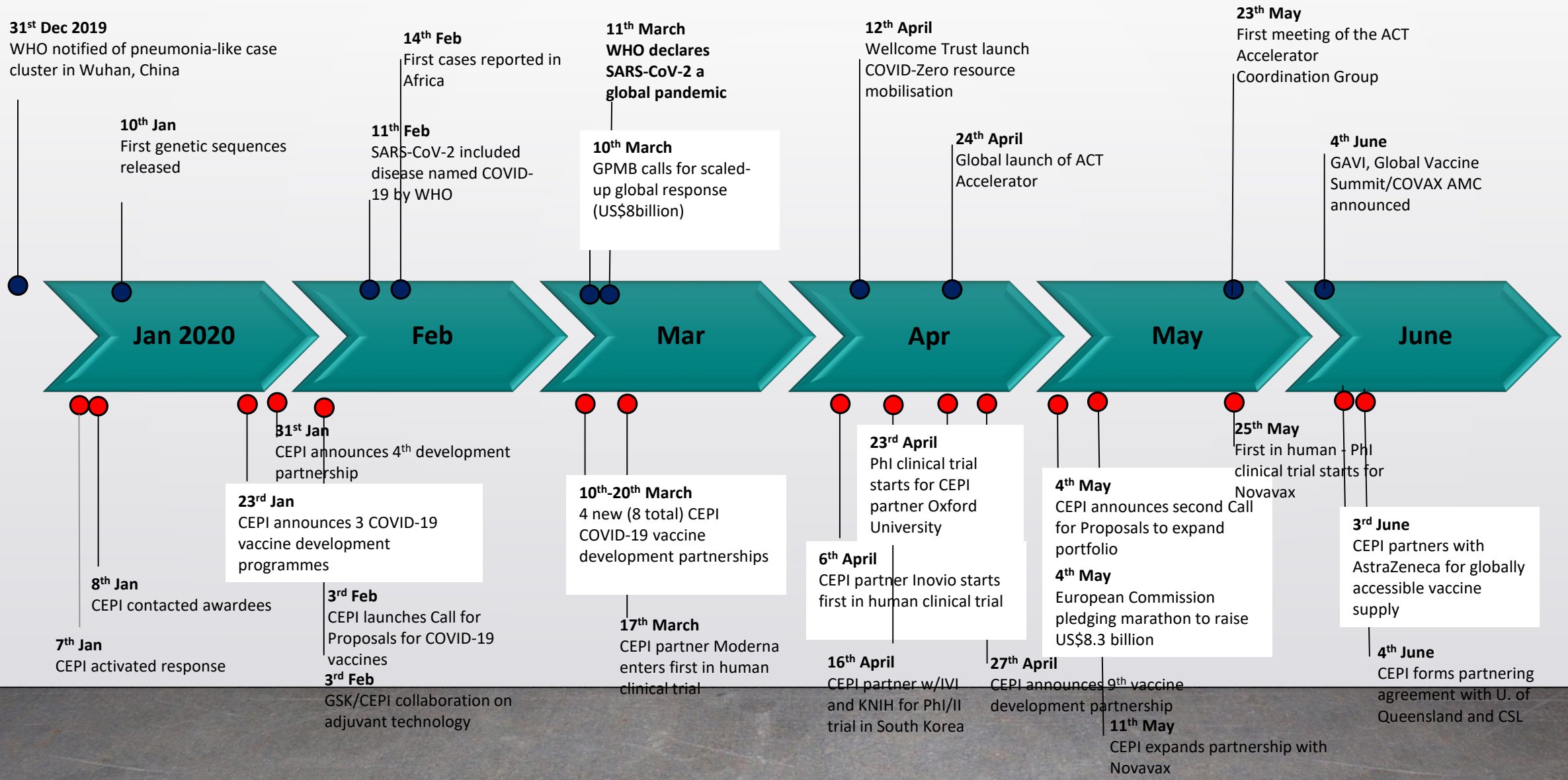
Scale

Scaling up and scaling out vaccine manufacturing capacity

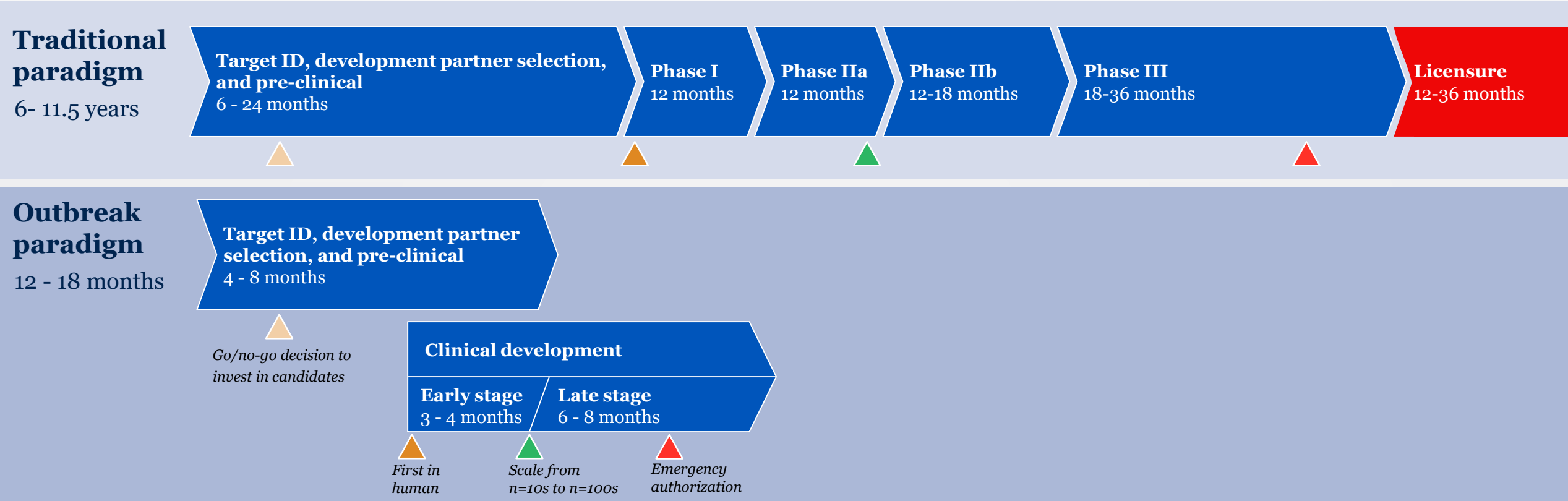
Access

Working with global partners to ensure fair allocation of COVID-19 vaccines

CEPI vaccine development so far….



Only a fundamental paradigm shift provides potential of rapid vaccine development with appropriate safety standards



Major shifts

Speed: Accelerate and advance development stages in parallel with continuous risk-benefit monitoring; quickly raise and deploy funds

Scale: Adaptive versus rigid development process and earlier launch of scale-up

Access: Geographic spread of manufacturing and development sites and pursuit of emergency authorization before licensure

Lurie N, et al. New Engl J Med. 30 March 2020. DOI: 10.1056/NEJMp2005630

CEPI currently supports 9 vaccine candidates, with more to come

COVID-19

	Inovio	University of Queensland / CSL	CureVac	Moderna	Clover BioPharma	Merck / Themis	Novavax	University of Hong Kong	AZ / Univ. Oxford
Location	USA	Australia	Germany	USA	China	India	USA	China	UK
Platform	DNA	Protein	RNA	mRNA	Protein	Viral Vector	Protein	Viral Vector	Viral Vector
Antigen / Adjuvant	Full-length S protein	Full-length S protein / MF59 or AS03 or CPG1018	Full-length S protein	Full-length S protein	Full-length S protein / AS03 or CPG1018	Full-length S protein	Full-length S protein / saponin-based Matrix-M	Receptor Binding Domain / AS03	Full-length S protein
Current phase	Phase 1	Preclinical	Preclinical	Phase I1a	Preclinical	Preclinical	Phase I	Preclinical	Phase I/II
Locations of large scale mfg (DS)	(1) Richter Helm, Germany; (2) Eurogentec, Belgium, (3) Inovio San Diego.	CSL/Seqirus	CureVac (Germany)	(1) Lonza (USA); [*potentially* (2) Lonza (CH); (3) Singapore]	Clover (China)	SII, India	*(1) Emergent (USA)*; (2) SK Bio (KOR); (3) Praha (CZ)	CDMOs (China)	AstraZeneca (UK)

Adjuvants

gsk

DYNAVAX

Seqirus

Paradigm shift in Vx Development (SPEED-ACCESS-SCALE)

In Disease X, fundamental paradigm shifts in vaccine development related to speed, scale, and access are required to ensure development advances as fast as possible while still meeting robust clinical efficacy and safety requirements:

1) Speed is paramount: rapidly accelerate target identification and development of vaccine candidates by using existing and previously validated (where possible) platforms for Disease X vaccines.

2) Parallel versus sequential: launch parallel processes wherever possible to minimize or eliminate whitespace between stages of development (e.g., conduct first in-human clinical trials while in parallel continuing animal studies, ramp-up clinical scale manufacturing while in parallel continuing to advance early stage trials).

3) Adaptive versus rigid development processes: apply integrated and adaptive trial design (e.g., ring vaccination) to replace classical development stages (i.e., Phase I, IIa, IIb/III) with consolidated early-stage development (10s of subjects) and late-stage development (100s of subjects) to accelerate trial timelines.

4) Continuous monitoring and rigorous benefit-risk decision making based on specific scenarios: track real-time epidemic status (e.g., severity of morbidity and mortality rates) to inform benefit-risk decisions at any point in time with pre-established clinical efficacy, safety, and other non-clinical “no go” criteria, as well as accumulation of effectiveness data from every exposed subject.

5) Prioritize rapid and equitable access: pursue emergency authorizations as soon as the benefit-risk profile is sufficiently established for broad scale use (rather than wait for regulation / market authorization).

Challenges ahead

- Resource mobilization, financing and advanced market commitment
- Liability / indemnification
- Balancing fair allocation/equitable access with sovereign country needs
- Safety monitoring and vaccine literacy/confidence
- Delivery / distribution/ last mile

ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

24 April 2020

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

Our Call

We ask the global community and political leaders to support this landmark collaboration, and for donors to provide the necessary resources to accelerate achievement of the objectives of this global collaboration, capitalizing on the opportunity provided by the forthcoming pledging event on 4 May 2020.

Our Commitment

1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.
2. We commit to an unprecedented level of partnership – proactively engaging stakeholders, aligning and coordinating efforts, building on existing collaborations, collectively devising solutions, and grounding our partnership in transparency, and science.
3. We commit to create a strong unified voice to maximize impact, recognizing this is not about singular decision-making authority, but rather collective problem-solving, interconnectedness and inclusivity, where all stakeholders can connect and benefit from the expertise, knowledge and activities of this shared action-oriented platform.
4. We commit to build on past experiences towards achieving this objective, including ensuring that every activity we undertake is executed through the lens of equitable global access, and that the voices of the communities most affected are heard.
5. We commit to be accountable to the world, to communities, and to one another. We are coming together in the spirit of solidarity, and in the service of humanity, to achieve our mission and vision.

Bill & Melinda Gates foundation

dcvmn Developing Countries Vaccine Manufacturers Network

The Global Fund To Fight AIDS, Tuberculosis and Malaria

IGBA International Generic and Biosimilar Medicines Association

wellcome

The World Bank IBRD • IDA | World Bank Group

CEPI

Gavi The Vaccine Alliance

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

Unitaid Innovation in Global Health

World Health Organization

COVAX facility as a global approach

THE COVAX FACILITY

The COVID-19 Global Vaccine Access Facility (Covax Facility) is being developed to address these unprecedented challenges. It will invite global participation to pool demand and resources to support procurement of COVID-19 vaccines. The Facility will be supported by financing instruments to facilitate pooled procurement for all participants. The funding for vaccines for upper middle-income countries (UMICs) and high-income countries (HICs) will be pooled from domestic health funds to secure doses for contributing countries, and the Gavi Covax AMC is being established to support procurement and delivery of vaccines for developing countries.

Just as an insurance policy manages uncertainty, so the uncertainty that is inherent in the current situation – about which vaccine candidates will be effective and safe, and about the course of the pandemic – needs to be managed. The Covax Facility, and the financing for LICs and LMICs provided by the Gavi Covax AMC, which will form part of the Facility, will do this by:

- → **ensuring that funding of vaccines is available for lower-income countries**
- → **pooling resources and sharing risk**
- → **supporting the scale-up of supply**
- → **allocating supply to contain the pandemic**

The Covax Facility is an umbrella mechanism. **Currently being developed in the Vaccine Task Force of the ACT Accelerator, the Covax Facility:**

THE GAVI COVAX AMC

Building upon two decades of experience in accelerating the availability of billions of doses of vaccines, Gavi is launching an investment opportunity: the Gavi Advance Market Commitment for COVID-19 Vaccines (Gavi Covax AMC) – the ODA-supported financing instrument of the Covax Facility.

The Gavi Covax AMC will use official development assistance (ODA) funds from OECD donors to incentivise manufacturers through guarantees to ensure sufficient global capacity is installed before vaccines are licensed. It will then procure vaccines and assist in delivery for LICs and LMICs, including International Development Association (IDA)-eligible small island economies.

Combined, these countries account for almost half of the world's population. Without such an intervention, they may not be able to obtain and use vaccines as part of a global effort to slow and ultimately stop the pandemic.

The Gavi Covax AMC will be the first building block of the Covax Facility and will incentivise investments so that capacity is secured to guarantee access to substantial volumes of safe and efficacious vaccines. It will be supported by additional building blocks to enable self-financed advance commitments towards pooled procurement of doses by HICs and UMICs.

The Gavi Covax AMC will:

The Covax Facility and the Gavi Covax AMC will support each other by:

CEPI

Biotechnology Innovation Organization

Front-runners, Hurdles, and Insider Perspectives: The Race to Develop and Implement a Safe and Effective COVID-19 Vaccine

HHS National Vaccine Advisory Committee (NVAC) Meeting
June 9, 2020

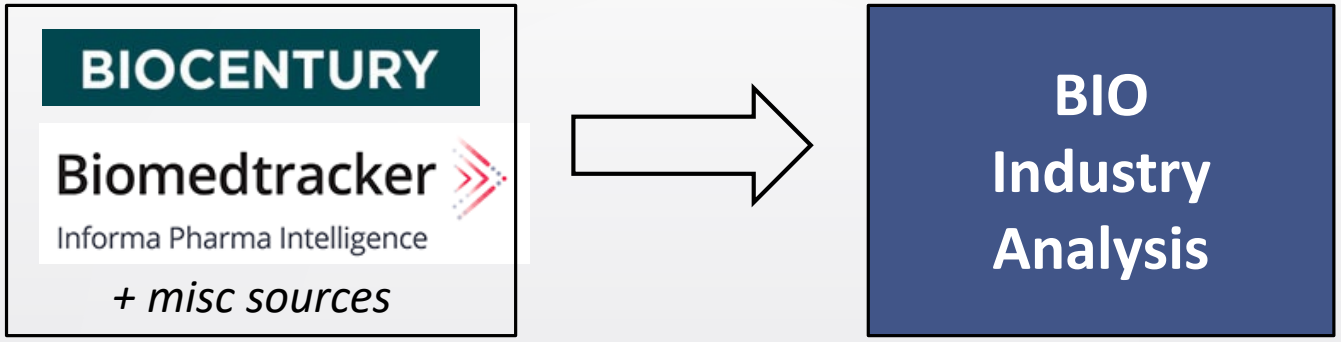
Amy Walker
Senior Manager, Infectious Diseases Policy, BIO

Objectives

- Review current COVID-19 vaccines pipeline and status of R&D
- Overview of challenges to COVID-19 vaccine development


TODAY
US may never get back to 'normal' after coronavirus crisis, Dr. Anthony Fauci says
SHARE THIS –
HEALTH & WELLNESS
US may never get back to 'normal' after coronavirus crisis, Dr. Anthony Fauci says
The White House health adviser said at a press conference that the coronavirus could continue to return and disrupt everyday life until there is a vaccine.

BIO's Approach to COVID-19 Pipeline Analytics



1. **Drug Name**
2. **Phase**
3. **Sponsoring Company**

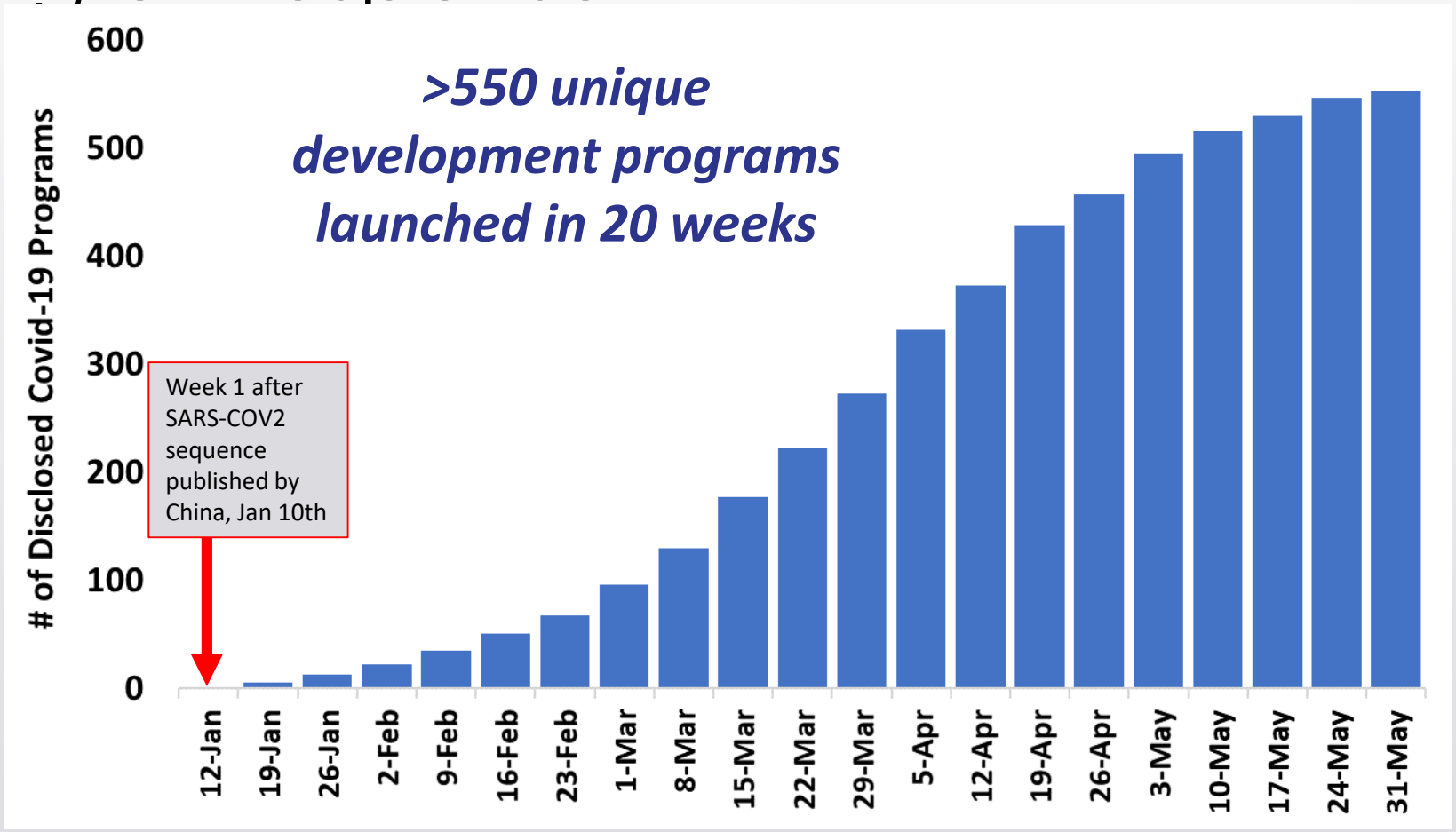
bio.org/covidpipelinetracker

1. **<u>Originating</u> Company**
2. **Pipeline Category (Antiviral, etc.)**
3. **Drug Origin Type (Repurposed, etc.)**
4. **Modality**
5. **Strategy**
6. **Target Family**

Note: BIO **de-duplicates** multiple programs and trials for same drug

Biomedtracker, Biocentury, BIO Industry Analysis (Data as of 6/4/2020)

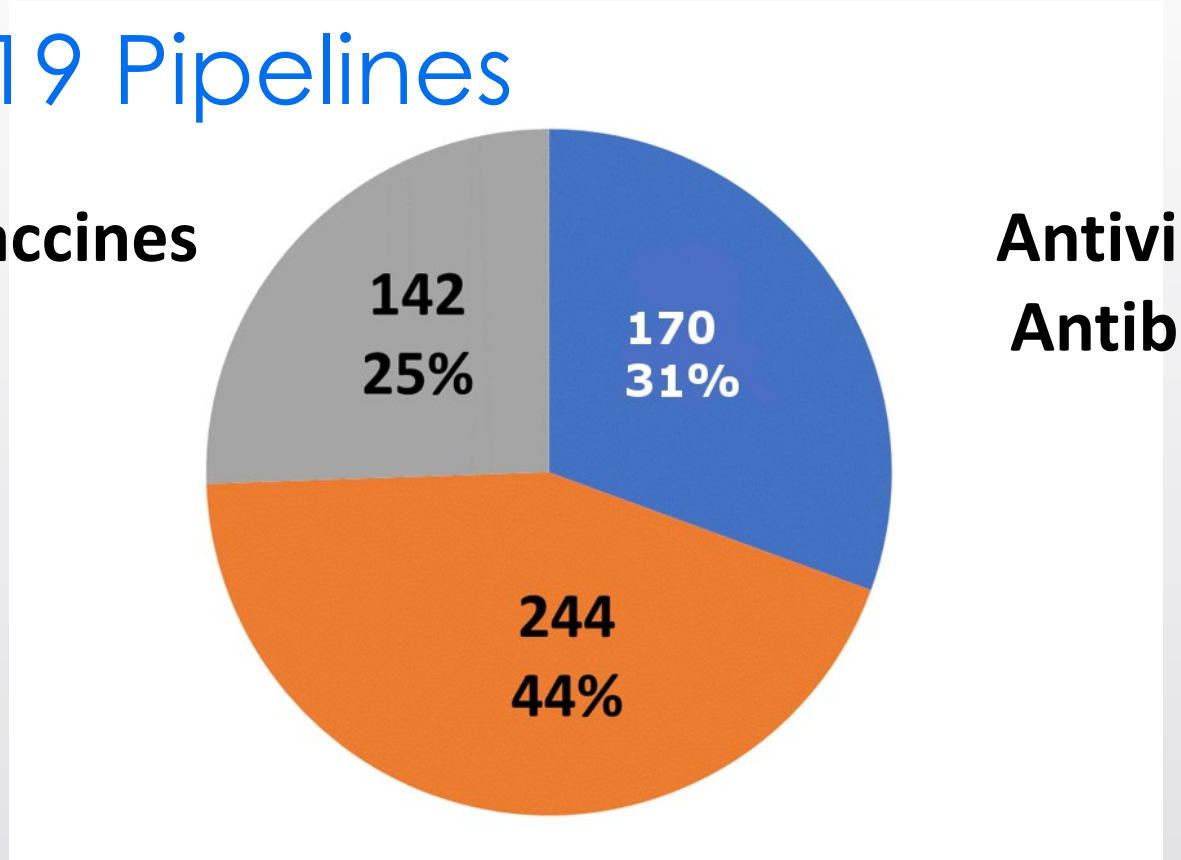
Timing of Response



Week of first press release announcing program

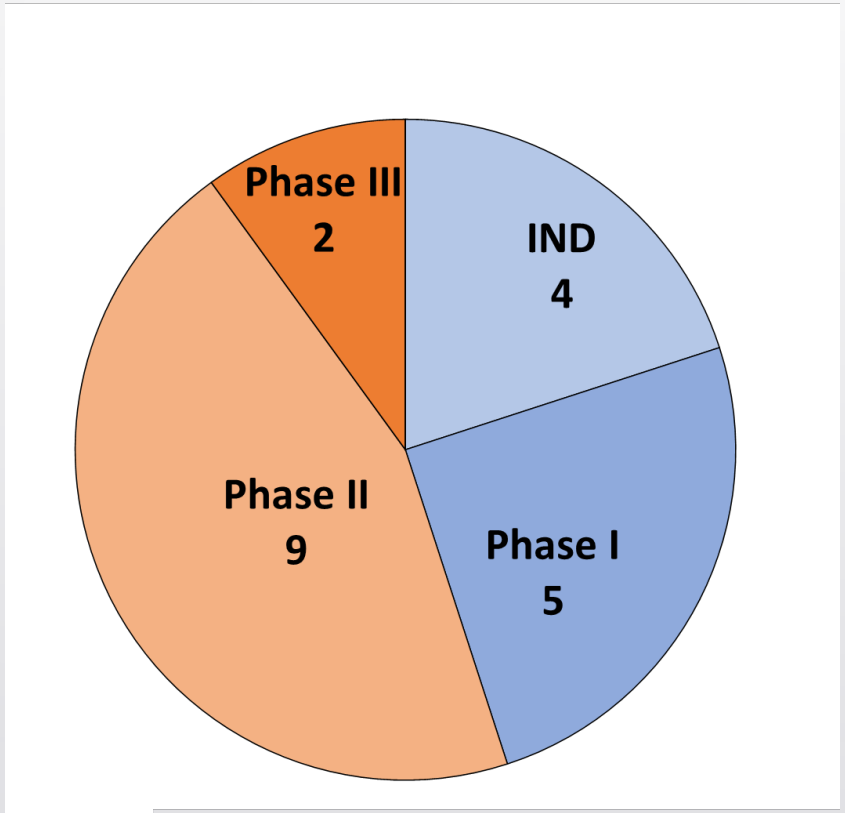
Biomedtracker, Biocentury, BIO Industry Analysis (Data as of 6/4/2020)

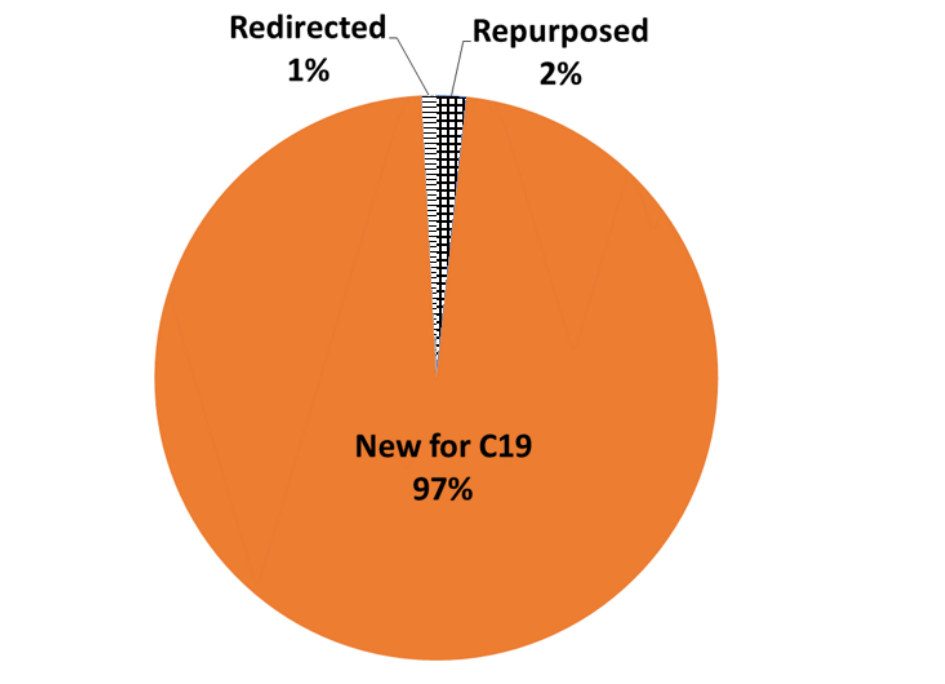
3 COVID-19 Pipelines



Biomedtracker, Biocentury, BIO Industry Analysis (Data as of 6/4/2020)

16 Clinical-Stage COVID-19 Vaccines

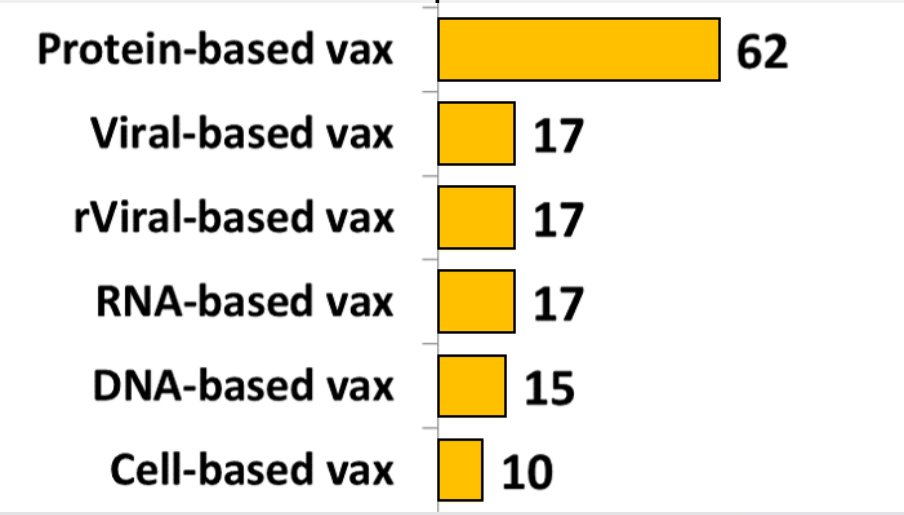




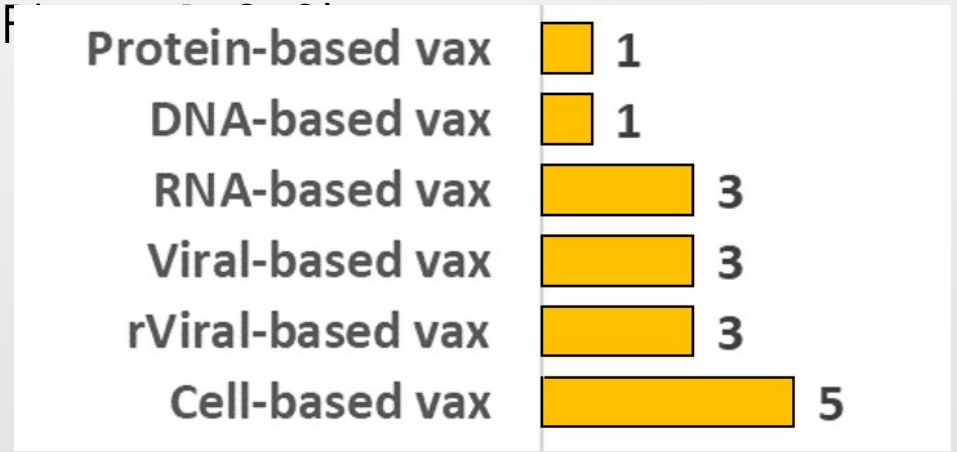
Biomedtracker, Biocentury, BIO Industry Analysis (Data as of 6/4/2020)

Many Technologies Deployed for Many "Shots on Goal"

- Full Vaccine Pipeline



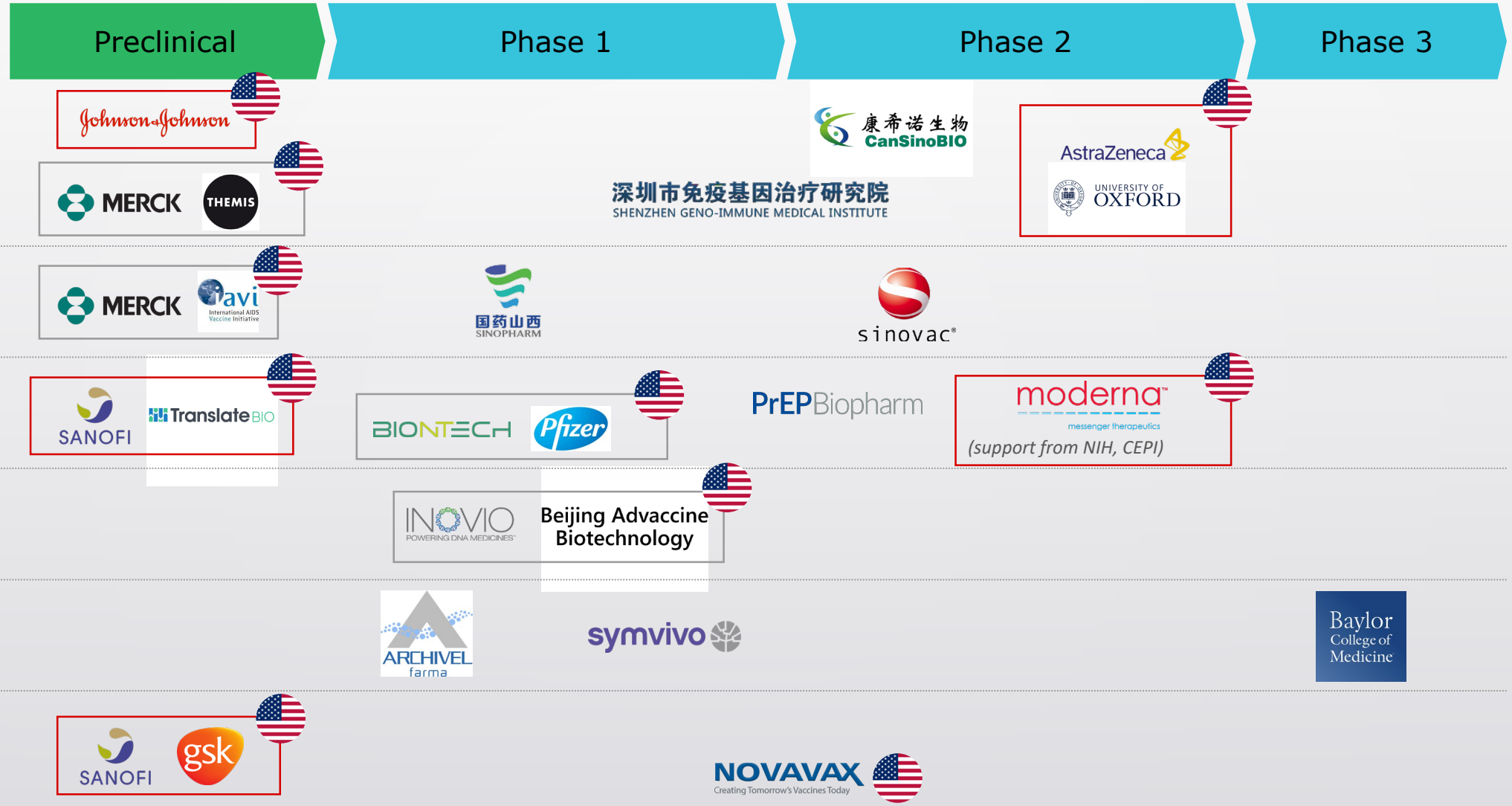
- Clinical Stage Vaccines



Biomedtracker, Biocentury, BIO Industry Analysis (Data as of 6/4/2020)

Clinical Stage Pipeline & Preclinical "Watchlist"

Supported by BARDA
Jointly developed
US focused



Source: Biomedtracker, Biocentury, BIO Industry Analysis
1. PrEP Biopharm vaccine dsRNA, all others mRNA
Oxford, Astrazeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.
Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)

Info as of May 25, not exhaustive

Manufacturing & Scale Up

Manufacturing

Emergent BioSolutions, BARDA reach $628M deal to manufacture COVID-19 vaccine hopefuls

by Kyle Blankenship | Jun 1, 2020 4:00pm

J&J and Catalent ink deal for COVID-19 vaccine manufacturing

Apr 29, 2020

GSK announces intention to produce 1 billion doses of pandemic vaccine adjuvant in 2021 to support multiple COVID-19 vaccine collaborations

Moderna and Lonza Enter Large-Scale Manufacturing Deal for Potential COVID-19 Vaccine

Published: May 01, 2020 | By Mark Terry

HEALTH NEWS JUNE 3, 2020 / 7:22 AM / A DAY AGO

Novavax partners with contract drugmaker for COVID-19 vaccine manufacturing

Manufacturing

AstraZeneca unveils massive $750M deal in effort to produce billions of COVID-19 shots

by Kyle Blankenship | Jun 4, 2020 11:08am

Headlines featured here are a sample of ongoing work, not exhaustive

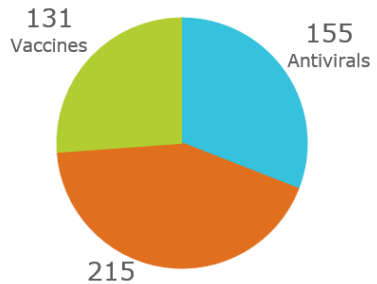
Challenges to COVID-19 Vaccine Development

- Scientific
  - Understanding of disease
  - Understanding of populations most at-risk
  - Shifting epidemiology
- Manufacturing
  - Record time scale-up
  - Fill/finish bottlenecks
  - Ancillary products
  - Not disadvantaging existing routine vaccines
- Public confidence

BIO COVID-19 Pipeline Tracker

COVID-19 Therapeutic Development Tracker

Click on the pie chart to filter the dashboard by therapy type
Hover over the pie to read the therapy definitions



501
Unique Compounds in Development

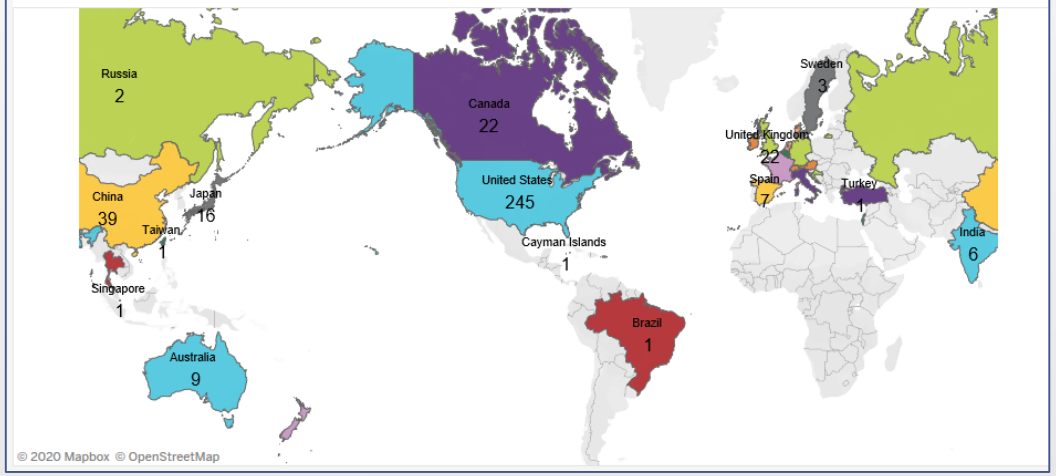
158
Clinical Compounds

343
Preclinical Compounds

Data as of: 5/26/2020 3:48:09 PM

Therapies in Development by Originating Company Headquarters

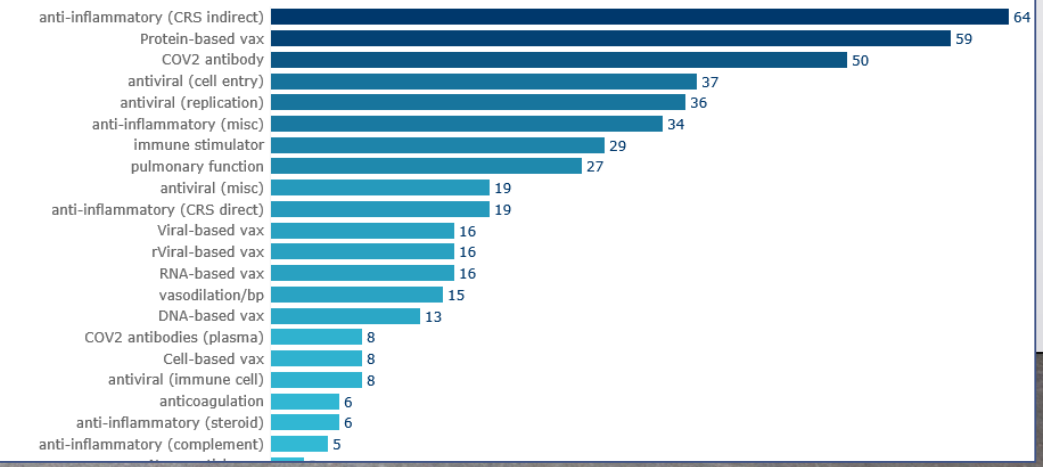
Hover over the map to see details about the companies responsible for COVID-19 therapy development in each country



Most Advanced COVID-19 Antiviral Candidates

Drug	Sponsors, Partners, [Funding]	Phase	Repurposed, Redirected, New	Target family
umifenovir (Arbidol)	Multiple, Ruijin Hospital	Phase IV	Repurposed	neuraminidase
danoprevir + ritonavir	Roche, Ascletis/Roche (Ganovo/Danoprevir), ..	Phase IV	Repurposed	protease
carrimycin	Shenyang Tonglian	Phase IV	Repurposed	macrolide
camostat (Foipan)	University of Aarhus, Heinrich-Heine University	Phase IV	Repurposed	protease
baloxavir marboxil (Xofluza)	The First Hospital Affiliated to Zhejiang Unive..	Phase IV	Repurposed	polymerase
azithromycin	Multiple	Phase IV	Repurposed	macrolide
oseltamivir (Tamiflu)	Multiple, Tongji Hospital, Rajavithi Hospital, U..	Phase III	Repurposed	neuraminidase
nitazoxanide (Alinia)	Romark Laboratories, Lupin, Materno-Perinat..	Phase III	Repurposed	oxidoreductase
favipiravir	.decimal, Inc., Zhejiang Hisun Pharma	Phase III	Repurposed	polymerase
ENU200	Ennaid Therapeutics	Phase III	Repurposed	ACE2/Spike
emtricitabine + tenofovir di..	Plan Nacional sobre el Sida (PNS)	Phase III	Repurposed	reverse transcriptase
ASC09 + ritonavir	J&J, Ascletis Pharma	Phase III	Redirected	protease
Leronlimab	CytoDyn, Inc., Vyera Pharmaceuticals	Phase II/III	Redirected	CCR Family
Hyperimmune plasma	Foundation IRCCS San Matteo Hospital	Phase II/III	New for C19	COV2 epitope
Convalescent Plasma	Multiple	Phase II/III	New for C19	COV2 epitope
Xpovio	Karyopharm Therapeutics	Phase II	Repurposed	exportin
selinexor	Karyopharm	Phase II	Repurposed	exportin
ribavirin (Virazole)	Bausch Health Companies Inc.	Phase II	Repurposed	IMPDH
PP-001	4SC Aq, Panoptes Pharma	Phase II	Redirected	DHODH
piclidenoson	Can-Fite BioPharma, Temple University	Phase II	Redirected	adenosine pathway
merimepodib (Vicromax)	BioSig	Phase II	Redirected	IMPDH
lonafarnib (Sarasar)	Eiger BioPharmaceuticals	Phase II	Redirected	Farnesyl transferase
IMU-838	Immunic, Inc., 4SC AG	Phase II	Redirected	DHODH
galidesivir	BioCryst, [NIH/NIAID]	Phase II	Redirected	polymerase
FW-1022 (niclosamide)	FirstWave	Phase II	Repurposed	NA
FP-025	ForeSee	Phase II	Redirected	protease
Fludase	Ansun BioPharma, Wuhan University	Phase II	Redirected	surface glycans
elsulfavirine (Elpida)	Viriom LLC, Roche, Chinese CDC, Ministry of ..	Phase II	Redirected	reverse transcriptase
bemcentinib	BerGenBio AS, [Department of Health and So..	Phase II	Redirected	kinase inhibition
azvudine	Zhengzhou Granlen PharmaTech	Phase II	Redirected	reverse transcriptase
Aplidin	PharmaMar, S.A., Centro Nacional de Biotecn..	Phase II	Repurposed	translation

Numerous Ways to Target COVID-19: Top Strategies



bio.org/covidpipelinetracker

Amy Walker

Senior Manager, Infectious Diseases Policy, BIO

awalker@bio.org



Development of a Coronavirus Vaccine for Global Access

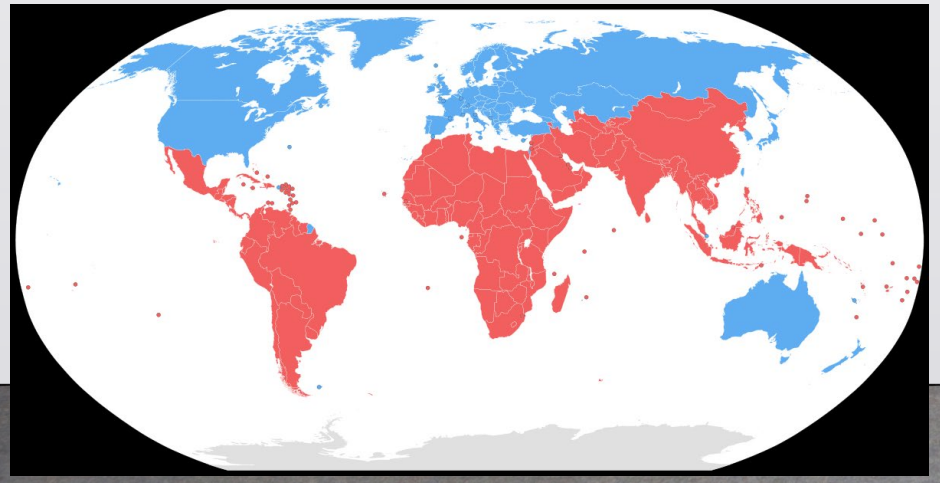
Peter Hotez MD PhD
Professor of Pediatrics and Molecular Virology & Microbiology
Dean, National School of Tropical Medicine
Baylor College of Medicine

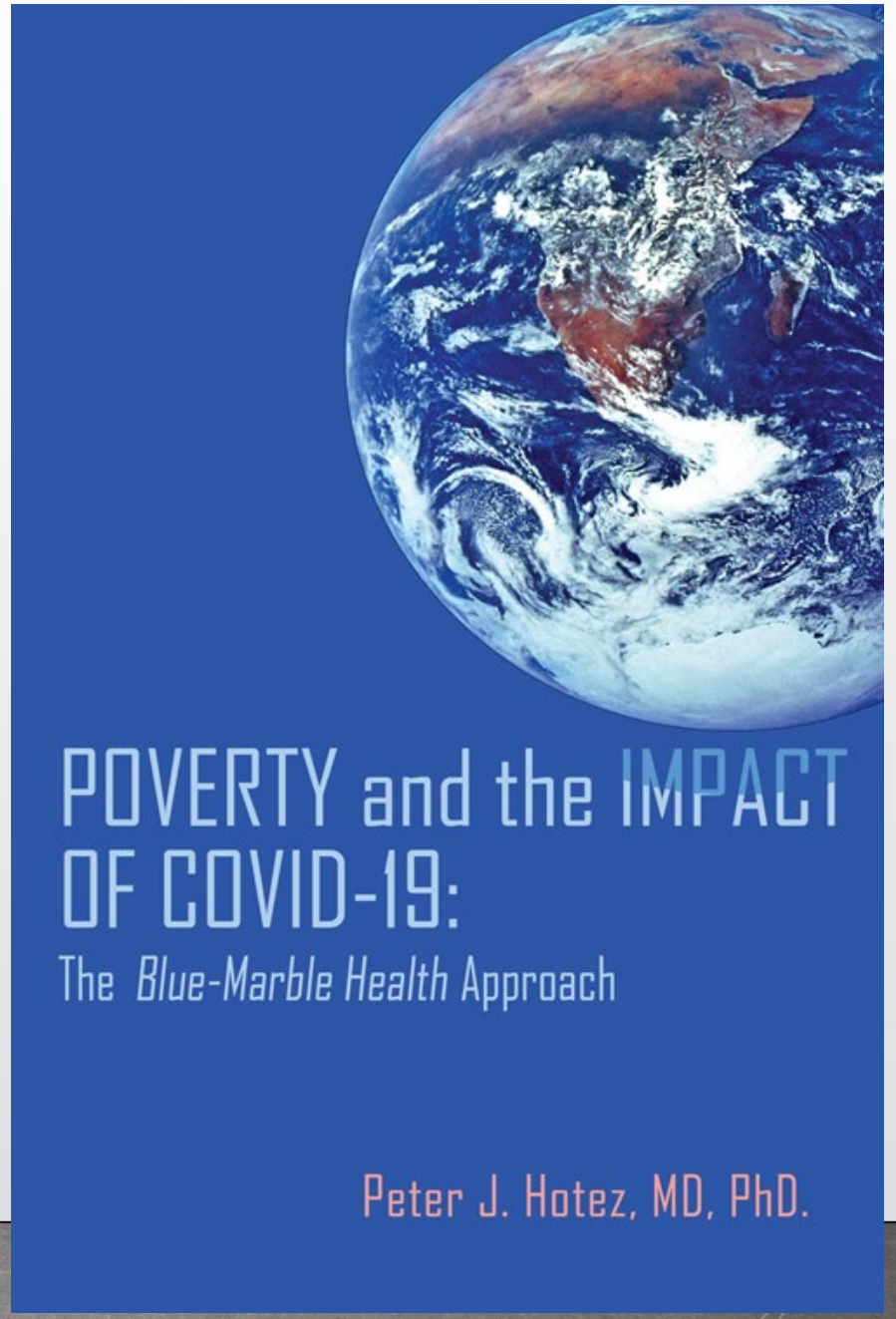
Baylor College of Medicine

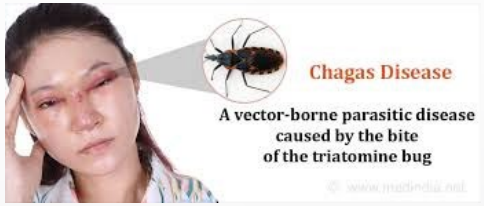
NATIONAL SCHOOL OF TROPICAL MEDICINE

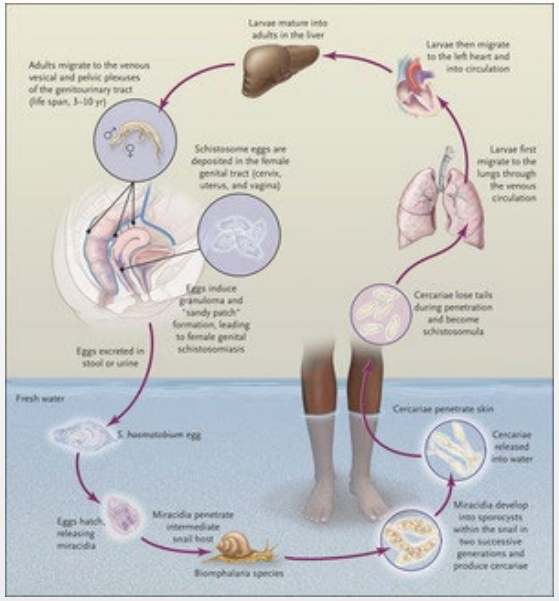
Texas Children's Hospital®

Leading the development and testing of low-cost and effective vaccines against emerging and neglected tropical diseases




POVERTY and the IMPACT OF COVID-19:
The *Blue-Marble Health* Approach
Peter J. Hotez, MD, PhD.



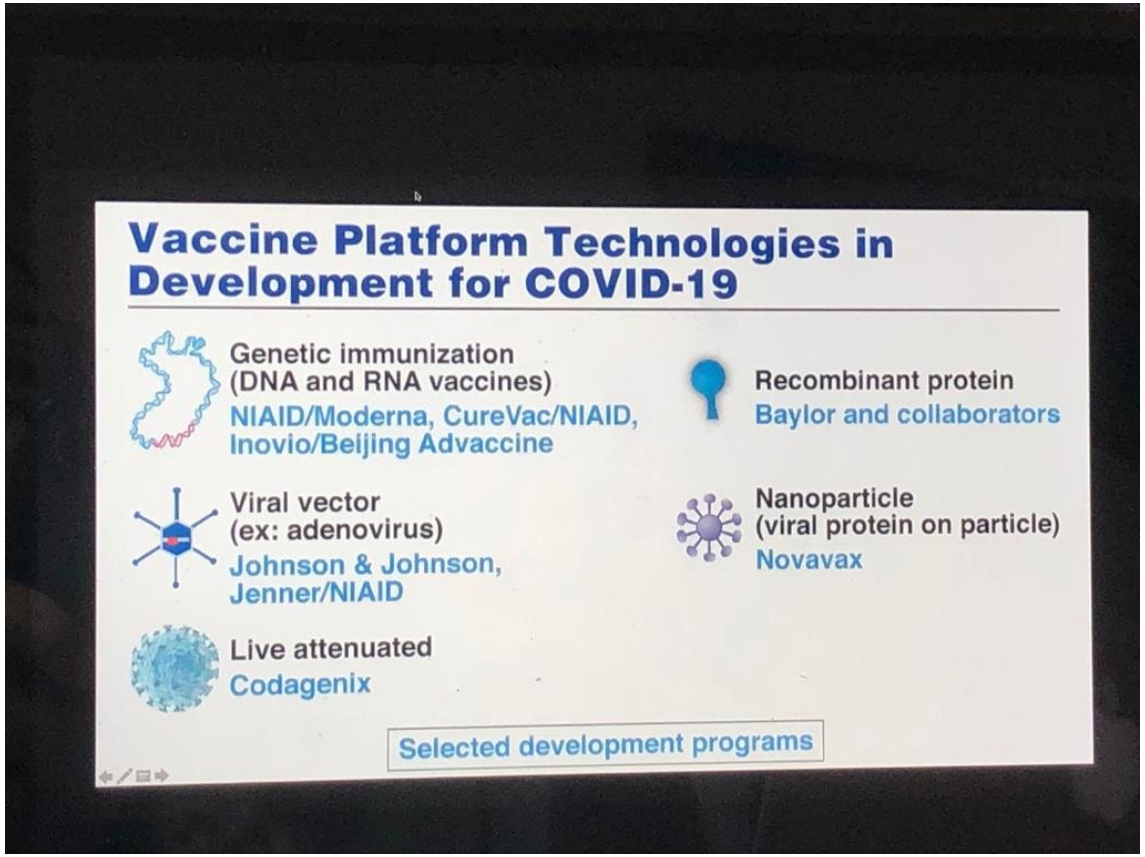


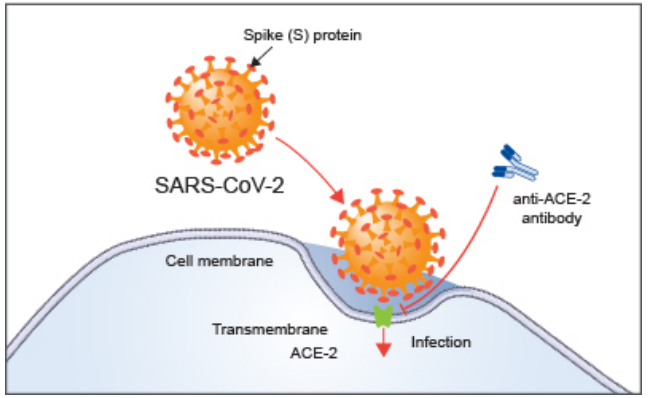
Female Genital Schistosomiasis 40 million Girls and Women

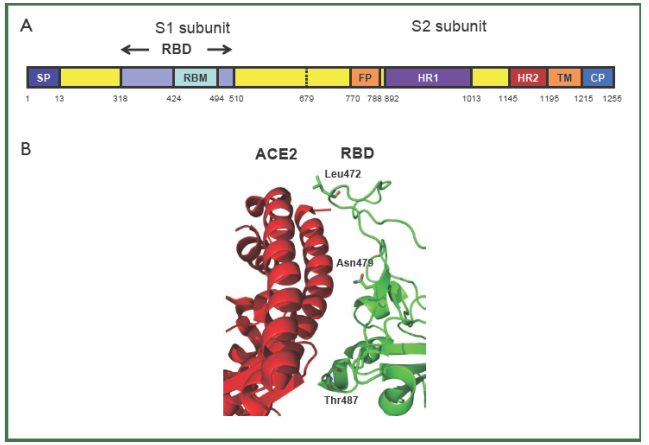
Maria Elena Bottazzi

Leishmaniasis

SARS CoV2-COVID19 Vaccine Approaches







Baylor College of Medicine

Texas Children's Hospital

Coronavirus Vaccine Initiative

Product Development Partnership

Led by Texas Children's Hospital Center for Vaccine Development, Baylor College of Medicine

Partnership launched in 2011 with New York Blood Center (Jiang, S. & Du, L.), University of Texas Medical Branch (Tseng, C-T) & WRAIR

Baylor College of Medicine

Texas Children's Hospital

Grant: R01AI098775

SARS-CoV RBD219-N1 Protein Candidate

Proven Platform: *Pichia pastoris* X-33 Vector: pPICZaA

Insert: SARS-CoV RBD, wild type with N1 deleted, no tags

MCB cGMP Lot # 1970 MFG: WRAIR Jan 12, 2016

PCB cGMP Lot # 1971 MFG: WRAIR Jan 14, 2016

DS cGMP Lot # 2015 MFG: WRAIR July 2016

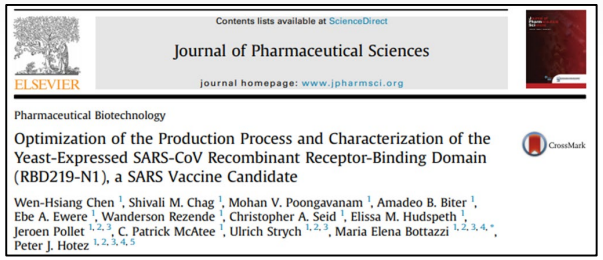
Production Yield: 0.107 g/L DS; **Purification Process Recovery:** ~ 50%

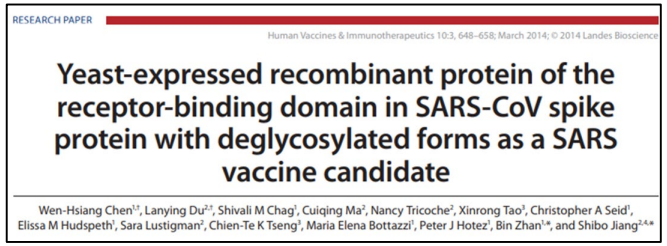
Cost of Goods: Estimated <$10/dose

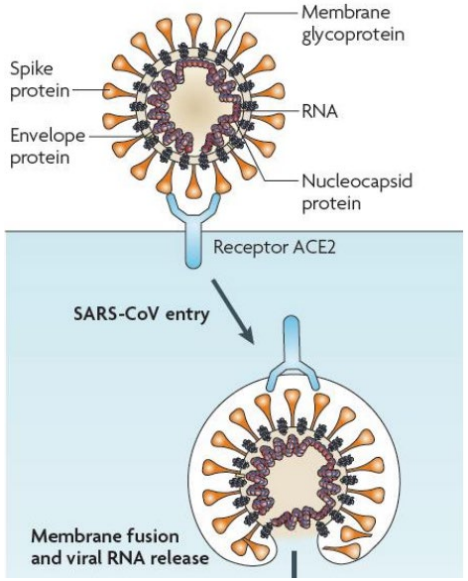
DS concentration: 1.48 mg/mL **Buffer:** 20 mM Tris, 150 mM NaCl, pH 7.5

Stability: at least 36 months, next testing time point at month 48 in July 2020. Stored at frozen (-70ºC to -80º)

Formulation: 100ug with Alhydrogel® in 1.0 mL







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Chen *et al.*, (2017) J. Pharm. Sci. **106**: 8 1961-1970

Chen *et al.*, (2014) Hum Vaccin Immunother **10**: 648-658

Text

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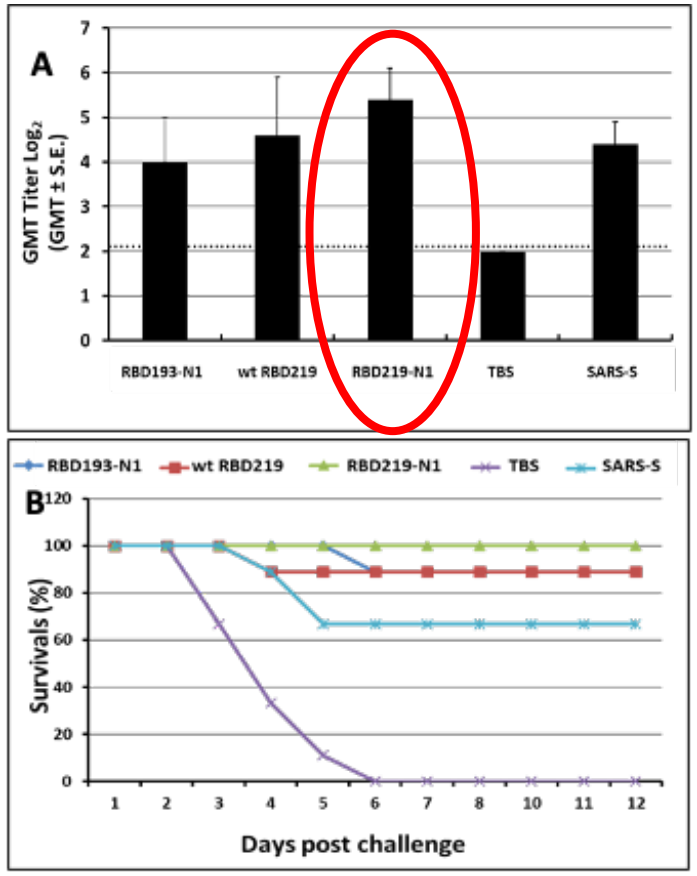
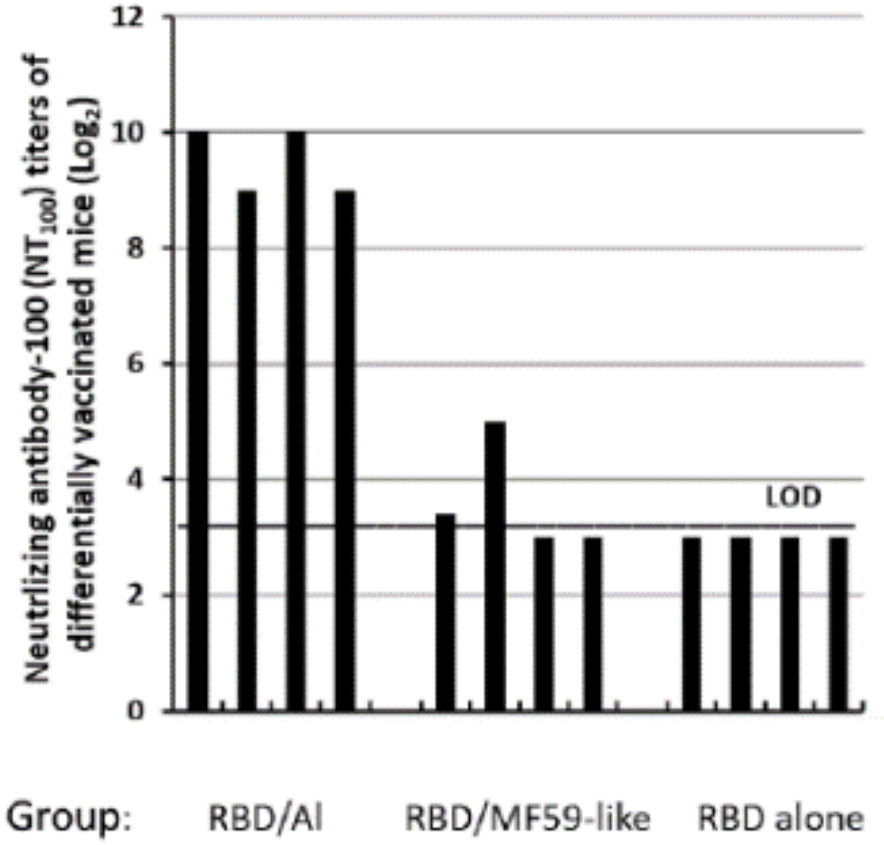
SARS-CoV RBD219-N1 vaccination induces 100% protection against lethal MA-15 SARS-CoV challenge and strong neutralizing antibodies



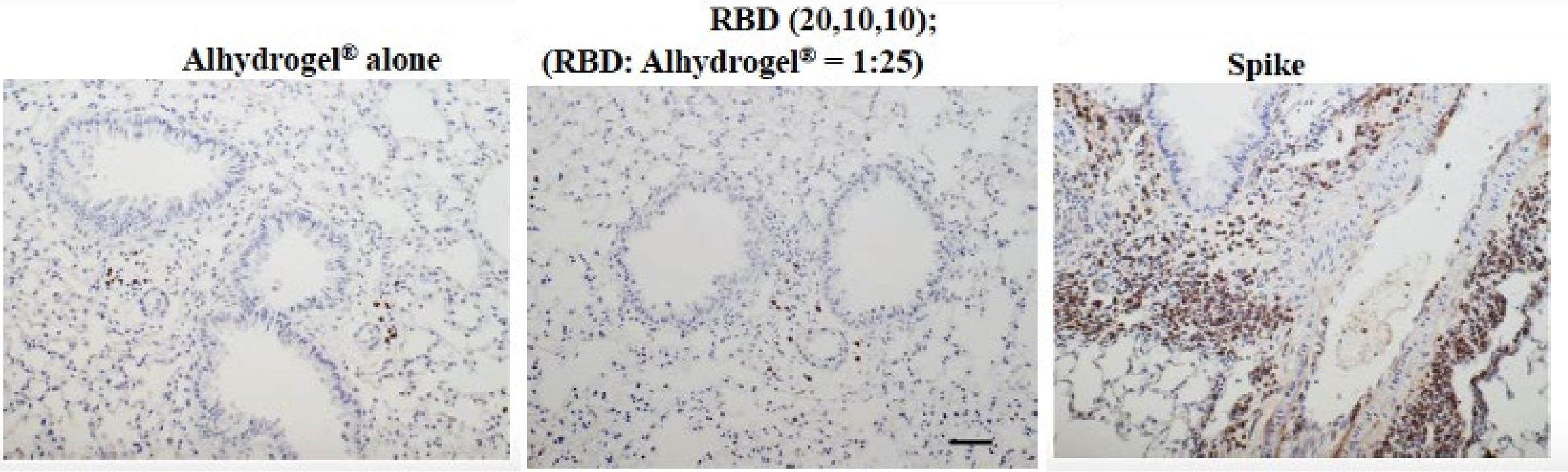
(A) Antibody titers after immunization
(B) Post challenge: survival rates



Comparison of Alhydrogel (Al) and AddaVax (MF-59-like adjuvant).

Submitted to Vaccine

Evidence of Safety for SARS-CoV RBD219-N1 vaccine



Immunohistochemistry for eosinophilic infiltration in mice immunized with Alhydrogel® alone, with SARS-CoV RBD219-N1/Alhyrogel and with SARS-CoV S/Alhydrogel ®. Scale bar = 200 μm.

Baylor College of Medicine | Texas Children's Hospital | utmb Health | Department of Microbiology and Immunology

Submitted to Vacc

Aligning to Achieve Global Access

Partnership between PATH Center for Vaccine Innovation and Access (CVIA) for a 2-stage approach

- An accelerated US-based time schedule for FIH
- Transition to a developing country vaccine manufacturer

A shovel-ready SARS C0V candidate as a heterologous vaccine against COVID-19

- cGMP Formulation, Fill-and-Finish
- Parallel GLP (Rabbit) Toxicology Testing
- All-in Strategy: securing a SARS CoV-2 regulatory strategy with a SARS CoV vaccine candidate
- Proposed Phase 1 randomized, placebo-controlled, observer-blind trial to assess the safety and immunogenicity in healthy adults 18 through 45 years of age.

IDRI TRANSFORMING SCIENCE INTO GLOBAL HEALTH SOLUTIONS

charles river

PATH

David C. Kaslow
VP, Essential Medicines;

and Head CVIA, PATH

Deborah Higgins

Scientific Director & Project Lead, CVIA, PATH

Baylor College of Medicine

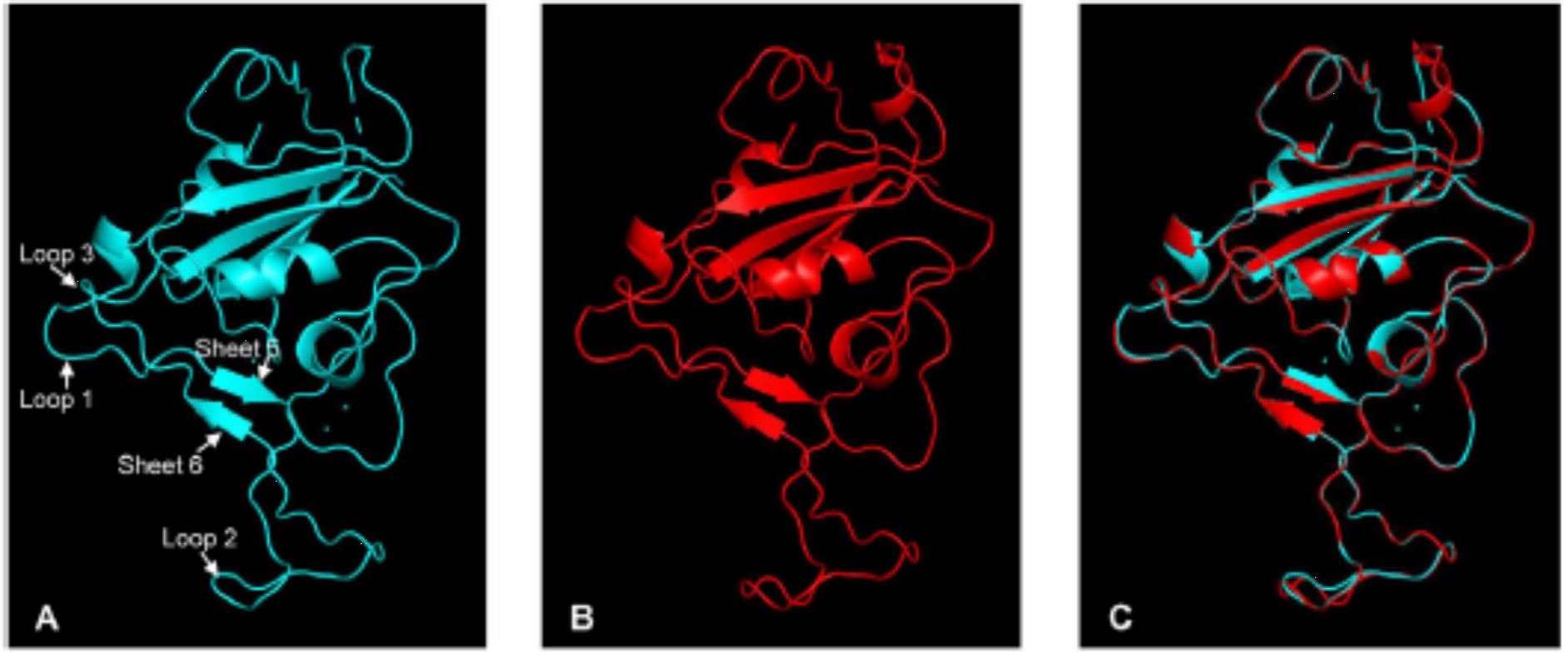
Texas Children's Hospital

Baylor College of Medicine VACCINE & TREATMENT EVALUATION UNIT

BCM Vaccine Research Center

SARS-CoV and COVID-19 spike proteins are structurally very similar

Figure 1. Comparison of the known structure SARS-CoV RBD (A), the deduced molecular model of 2019-nCoV, generated by performing molecular simulation (B), and the two structures superimposed.



SARS-CoV RBD | SARS-CoV-2 RBD | Superimpose

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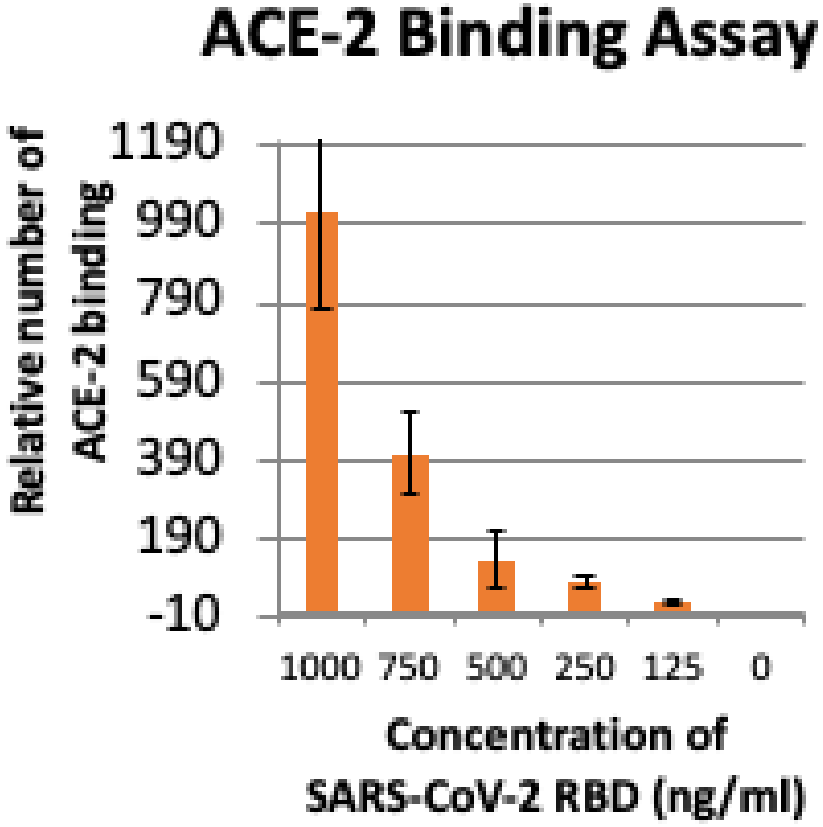
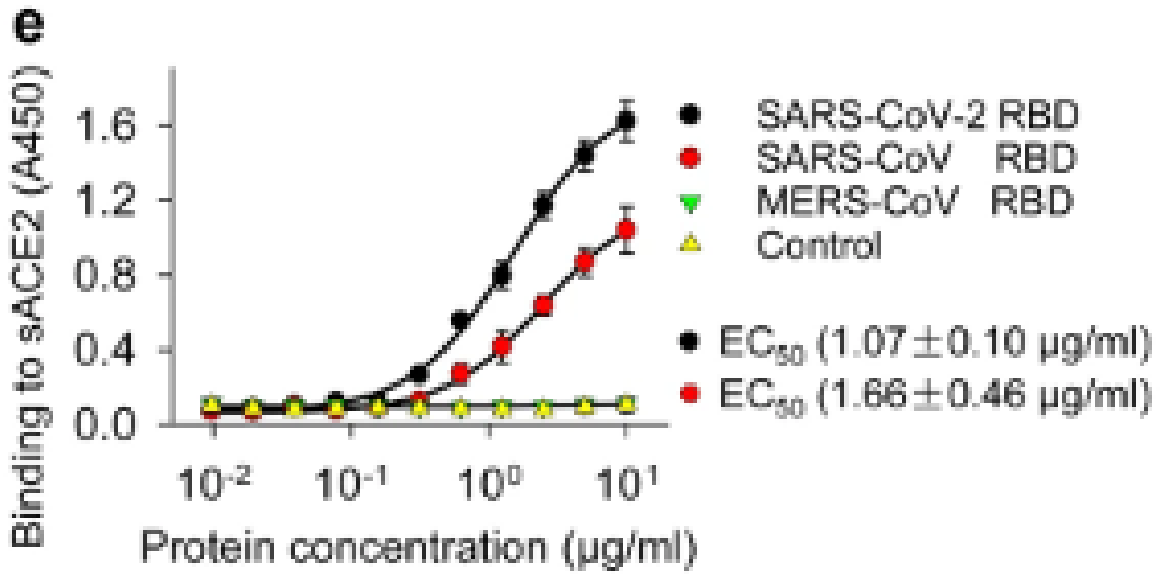
https://www.sciencedirect.com/science/article/pii/S0006291X20303399

Structural alignments of SARS-CoV (6acj) and COVID-19 (6svb). Only central H1 helix back bone atoms used for alignment (RMSD=0.7Å)

Binding of SARS-CoV RBD protein and SARS-CoV-2 RBD to the cell-associated and soluble ACE2 receptor



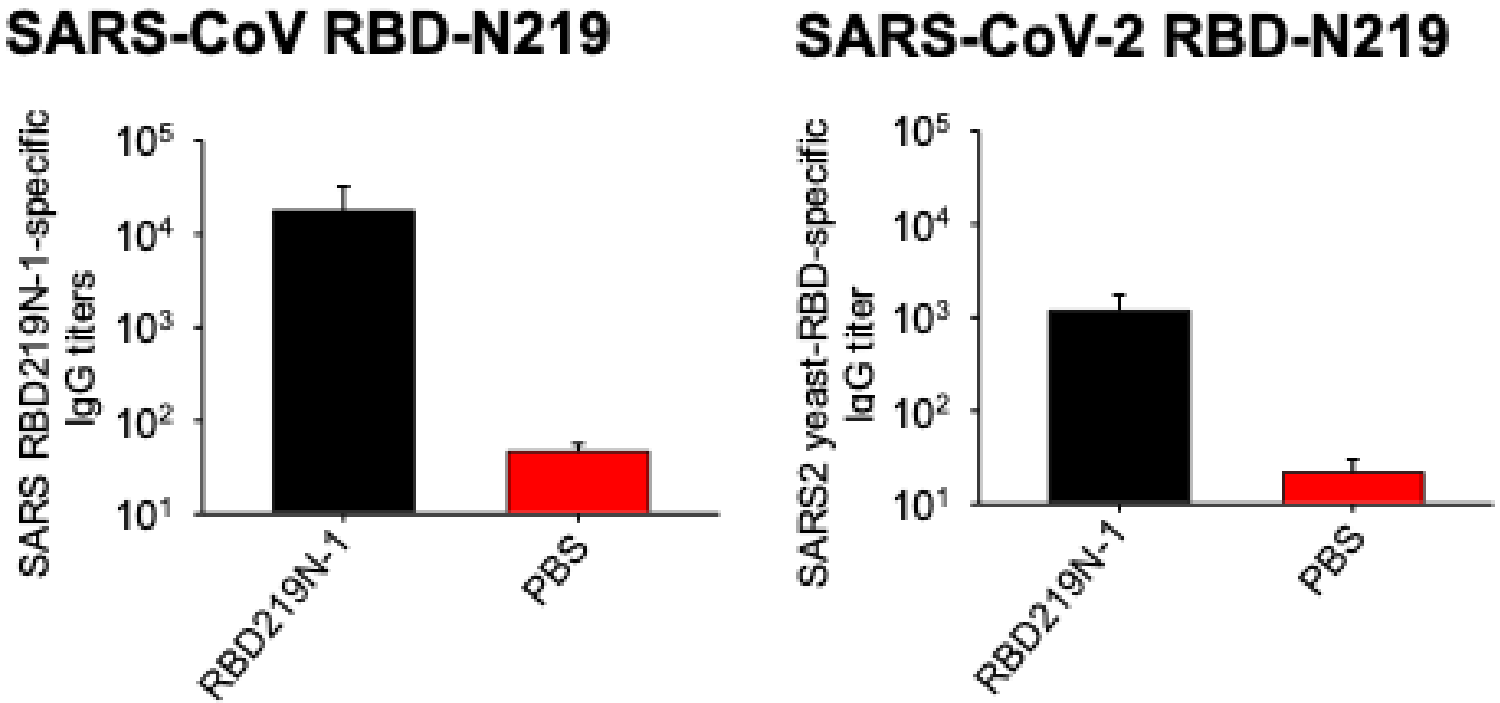


(Tai *et al.*, 2020)

Anti-SARS-CoV-RBD-N219 serum cross-reacts with SARS-CoV-2 RBD and S proteins

Mice immunized w/ SARS-CoV RBD-N-219/Alhydrogel vaccine

1st injectio	2nd injectio	Serum collectio
n	2n	3n
	1	1



Courtesy
Dr. Lanying Du

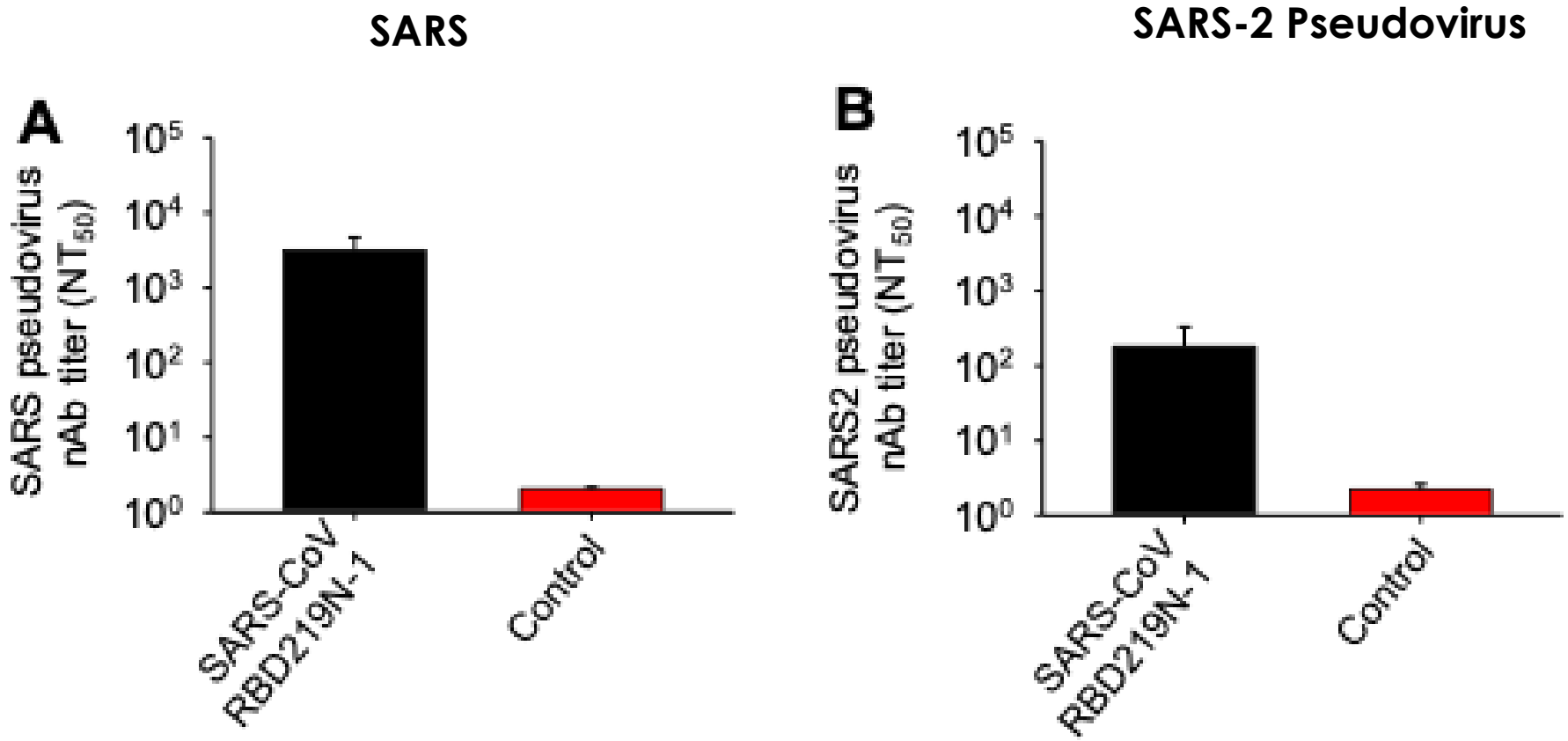
Baylor College of Medicine

Texas Children's Hospital

New York Blood Center

Pooled sera collected from Balb/c mice 10 days after the 2nd subcutaneous immunization with 20 ug SARS-CoV RBD-N219 and 2 mg Alum (Chen et al., 2014).

Mouse sera against SARS-CoV RBD219-N1 vaccine cross-neutralize of SARS-CoV-2 pseudovirus infection



Courtesy
Dr. Lanying Du

Neutralizing antibody (nAb) titer of yeast SARS-CoV RBD219-N1 protein-immunized mouse sera against SARS-CoV (A) and SARS-CoV-2 (B) pseudovirus infection (control: PBS);

Providing additional value towards the COVID-19 vaccine development efforts

A high quality (cGMP) SARS-CoV RBD antigen comparator for:

- Cross-reaction/cross-protection evaluation
- *In vitro* immunoassays and competition assays Cross-neutralization assay
- *In vivo* immunogenicity, safety and efficacy Front run for coronavirus

RBD-based candidate vaccines

- Shovel ready for pre-clinical and clinical studies
- Accelerate and leapfrog fast follow-on SARS-CoV-2RBD-based candidate vaccines (i.e. Sanofi repurposed SARS Vaccine)

An important benchmark for evolution of SARS-CoV-2

- Potentially useful in the event of a mis-matched SARS-CoV-2 vaccine as "drift" accumulates

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COVID19 Meets the Antivaccine Movement

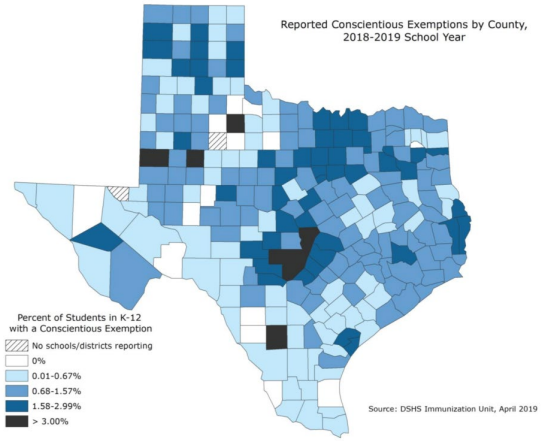
ALL ADULT AMERICANS

Interest in Coronavirus Vaccine

How interested would you be in getting a coronavirus/COVID-19 vaccine, if at all?
How interested would you be in getting your children a coronavirus/COVID-19 vaccine, if at all? (asked of parents)

% Very/Somewhat interested

Figure 1. Percent of Students in Kindergarten through 12th Grade with a Conscientious Exemption on file for at least one vaccine



THANK YOU

Coronavirus Product Development Partnership

Led by Texas Children's Hospital Center for Vaccine Development, Baylor College of Medicine

Partnership with New York Blood Center (Jiang, S. & Du, L.), University of Texas Medical Branch (Tseng, C-T) & WRAIR

New York Blood Center

utmb Health

Working together to work wonders.™

WRAIR Walter Reed Army Institute of Research

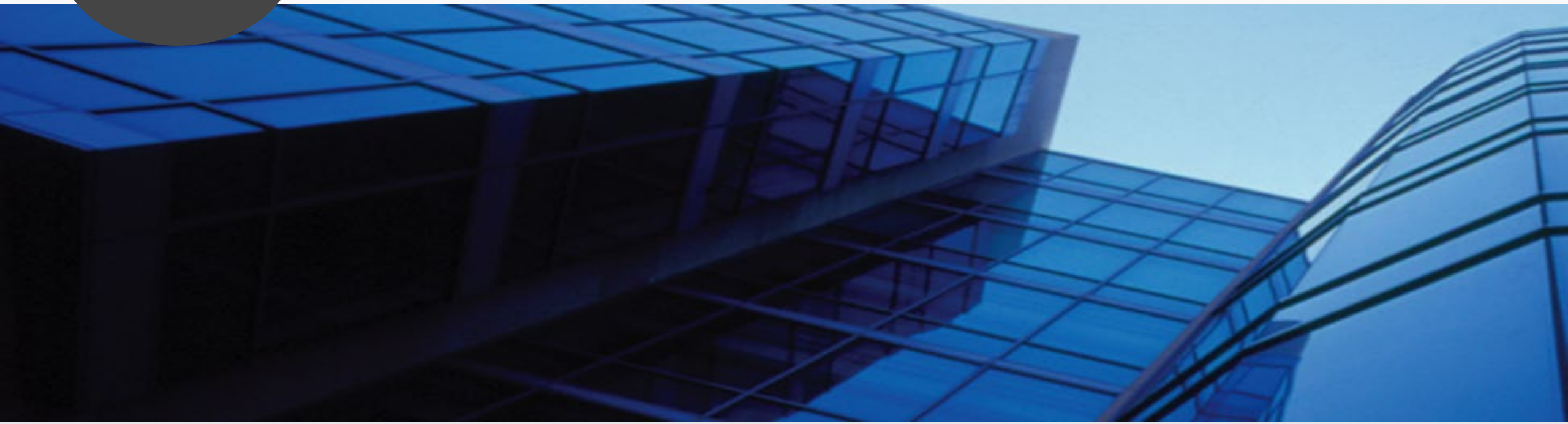
Soldier Health • World Health

NIH National Institute of Allergy and Infectious Diseases

Baylor College of Medicine

NATIONAL SCHOOL OF TROPICAL MEDICINE

Texas Children's Hospital®



Herd Immunity and COVID-19 Vaccines: Five Key Principles

David Dowdy, MD PhD
Dept of Epidemiology, Johns Hopkins Bloomberg School of Public Health
National Vaccine Advisory Committee
June 9, 2020

Herd (Community) Immunity

A situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely.

Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community.

Centers for Disease Control and Prevention, https://www.cdc.gov/vaccines/terms/

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of PUBLIC HEALTH

Principle 1.

As traditionally calculated, the "herd immunity threshold" for SARS-CoV-2 is probably 60-70%.

Standard equation:

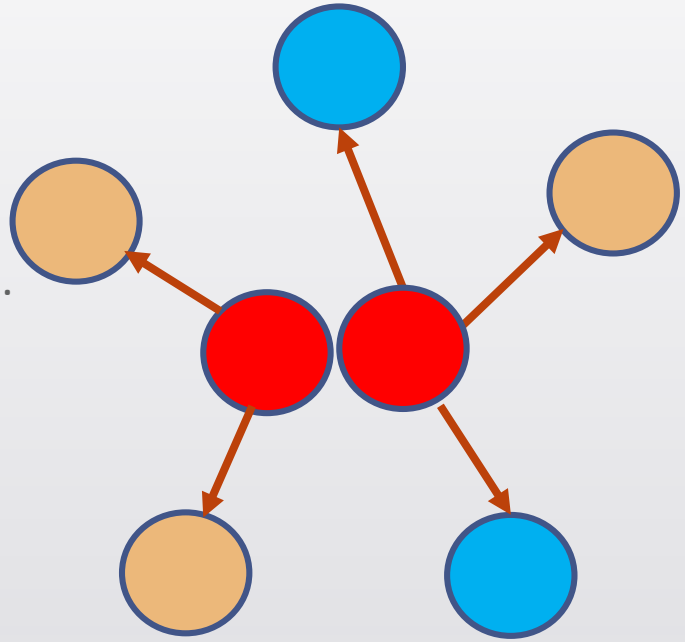
R_0 = Basic reproductive number

(probably ~2.5 for SARS-CoV-2)

Kucharski A et al, Lancet Infect Dis 2020; 20(5):553-558.

Herd immunity threshold = $1 - 1/R_0$

(1 – 1/2.5 = 0.6)



Fully Susceptible Population: 2 index cases → 5 secondary cases

If 60% of Population is Immune: 2 index cases → 2 secondary cases

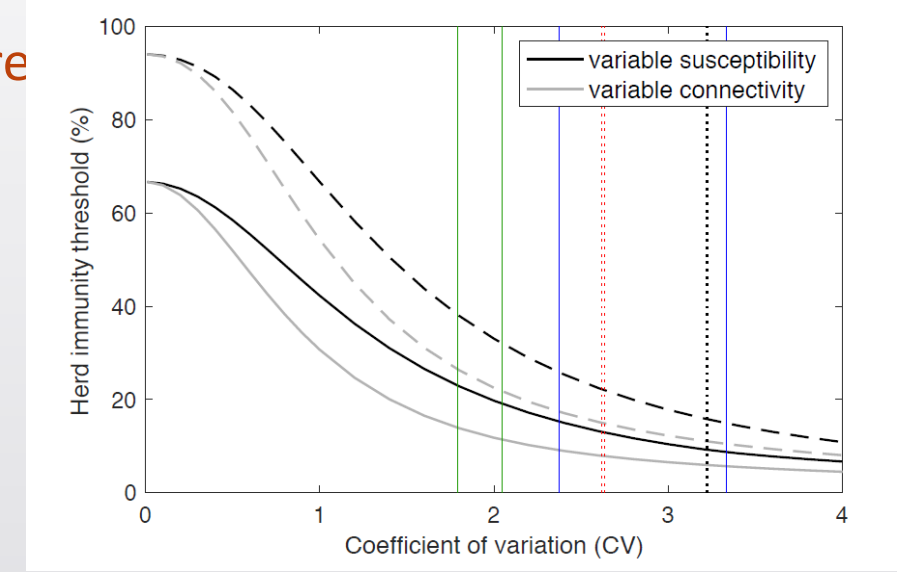
Principle 2.

If susceptibility in the population is non-uniform, the herd immunity threshold is lower.

If the most susceptible individuals are infected first, the remaining population is less at-risk.

Can reflect immunological or sociological differences

One group has suggested the herd immunity threshold for SARS-CoV-2 may therefore be ~30%.



Gomes MGM et al, MedRxiv preprint.

https://www.medrxiv.org/content/medr xiv/early/2020/05/21/2020.04.27.20081 893.full.pdf

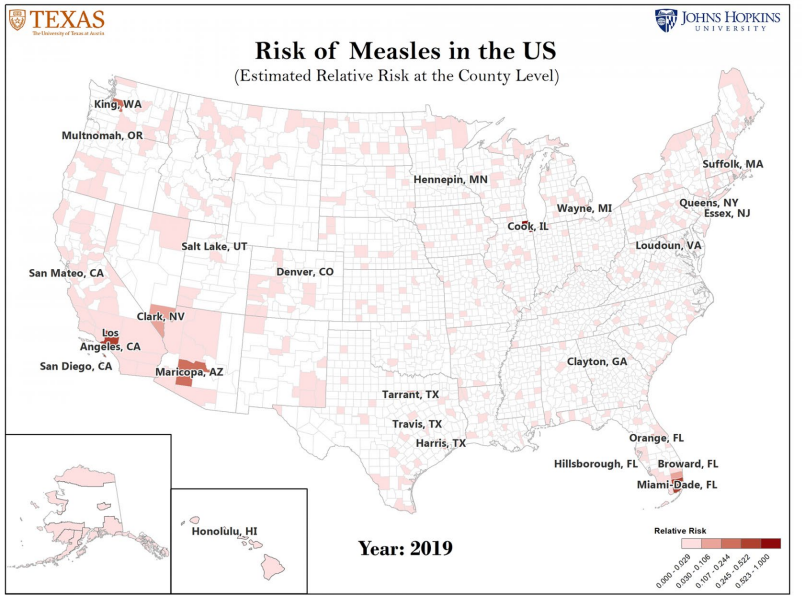
Principle 3.

Even if the herd immunity threshold is met in a population, outbreaks can still occur.

Both natural infection and vaccine uptake will be heterogeneous.

Transmission can still be sustained in populations that are incompletely vaccinated.

Well-known example of measles outbreaks in the USA (91.5% of the US population vaccinated)



Sarkar et al, Lancet Infect Dis 2019; 19(7):684-686.

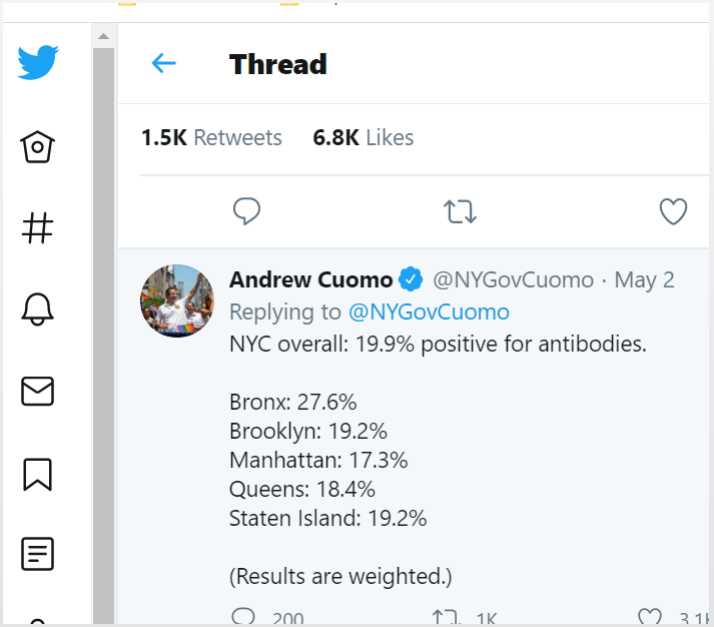
Principle 4.

Herd immunity depends on vaccine efficacy and duration of immunity.

In NYC, 20% tested positive for antibodies in April 2020.

To get to 60% immunity:

- 50% coverage of 100% efficacious, durable vaccine
  - 60% w/ waning natural immunity
- 80% coverage of 70% efficacious, durable vaccine
  - 85% w/ waning natural immunity



Assuming infection-fatality ratio of 0.4%:
- About 8% of the US population immune?
- Increasing by ~1.5% per month?

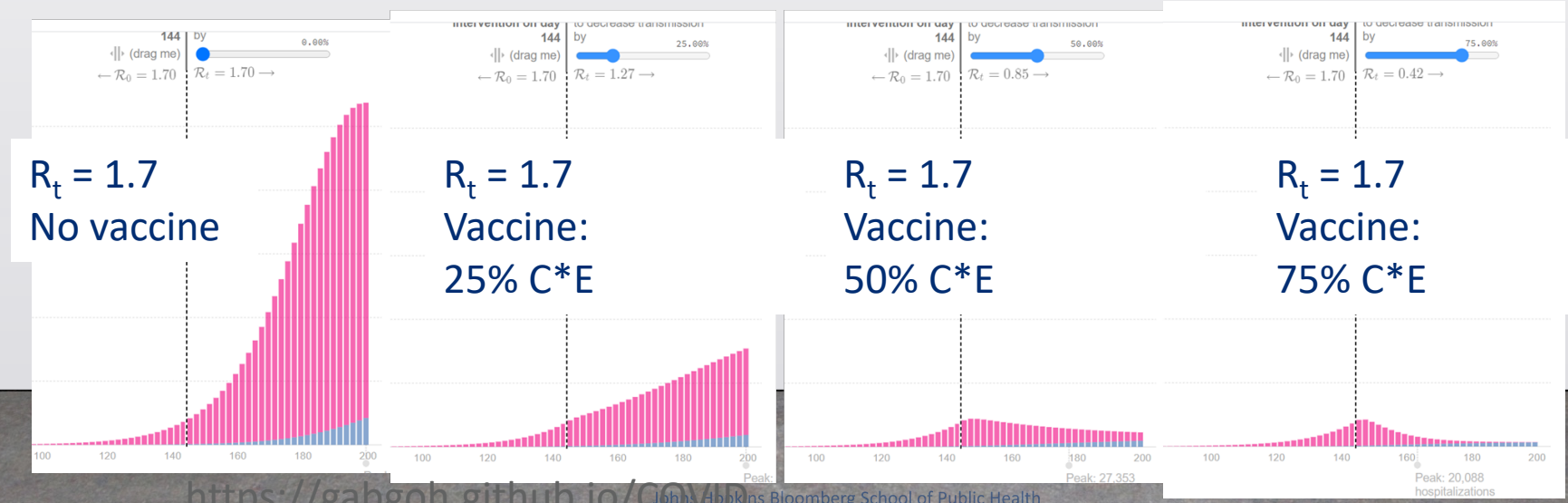
(Streeck et al, MedRxiv preprint. https://doi.org/10.1101/2020.05.04.20090076)

Principle 5.

Herd immunity is a continuum, not a threshold.

The goal of vaccination is not to reach a pre-defined threshold, but to save lives.

Even a vaccine that doesn't achieve a threshold will save lives, and vaccines that far exceed the threshold will save the most.



Summary: Five Principles

- **The “standard” herd immunity threshold is likely 60-70%.**
- **This threshold might be substantially lower (as low as 30%?) if susceptibility is non-uniform.**
- **Outbreaks can still occur if the population as a whole is vaccinated above this threshold.**
- **Achieving herd immunity depends on vaccine efficacy & duration of (natural & vaccine-induced) immunity.**
- **The goal of vaccination should be to optimize coverage * efficacy (and duration), not to meet a specific threshold.**

The Fight Against COVID19- Bedside & Beyond

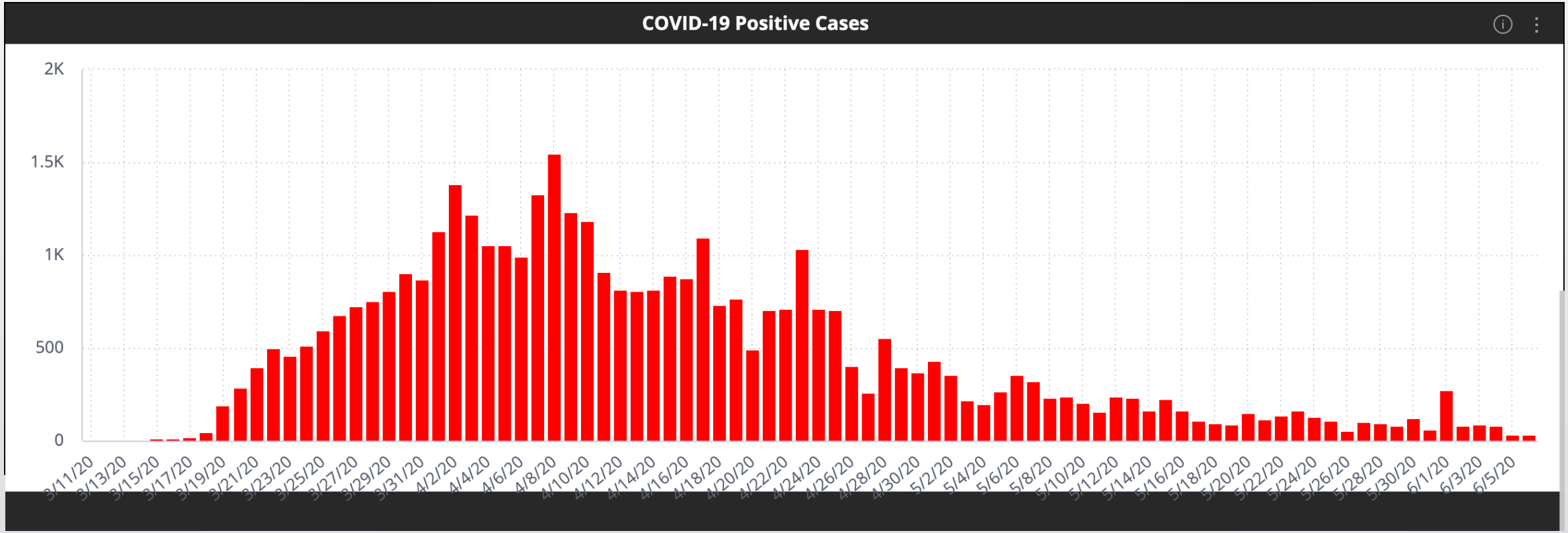
June 9, 20 National Vaccine Advisory Committee

Melody Butler, BSN, RN, CIC

COVID19 – Nursing Perspective

- A Hot Spot Timeline
- Challenges at Bed Side
- Challenges Online
- Lessons and Observations

Suffolk County, NY: COVID-19 Case Timeline



Suffolk County reported the following information related to COVID-19 on June 7, 2020

Testing

216,000 COVID-19 tests have been administered, an addition of 4,582 tests*
18.7 percent of those tested were confirmed positive for COVID-19
128,707 total tested for antibodies

Tested Positive for COVID-19

40,329 total cases
51 new cases

Tested Positive for Antibodies

15,441 individuals not previously tested for COVID-19 have tested positive for antibodies

Hospitalization* as of June 7 at 4:30 p.m.

158 individuals were hospitalized, a decrease of 21
50 patients were in the Intensive Care Unit (ICU), no increase or decrease from 6/7
7 new admissions
26 discharged
5,104 discharged since March 22

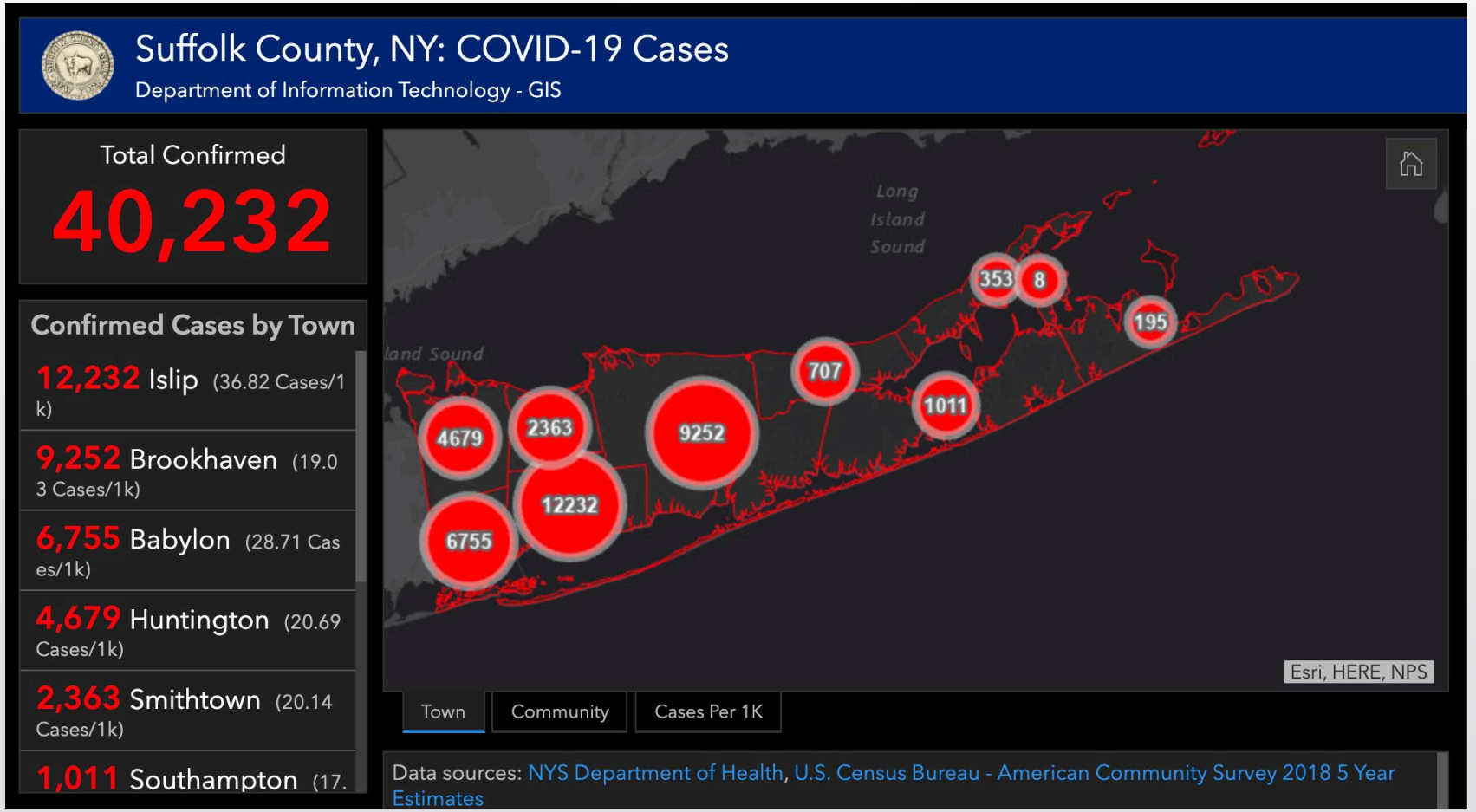
Fatalities

8 new fatality*
1,931 total fatalities

Hospital Beds, as of June 7 at 4:30 p.m.

3015 total hospital beds; 1135 available*
576 ICU beds; 252 available*

Working in a Hotspot



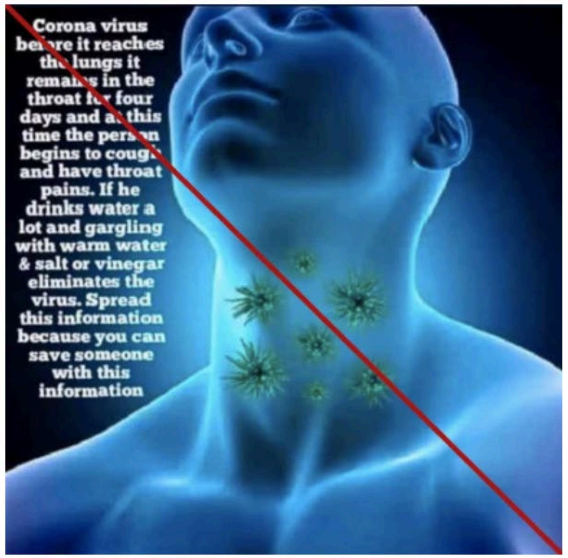
COVID19 At The Bed Side

Supplies
Construction- Environment and rooms
Staffing
Getting better
Use of telehealth

Battling Online COVID 19 Misinformation

Judy Mikovits is a disgraced scientist who claimed a retrovirus caused chronic fatigue syndrome, results later soundly refuted. She went antivaccine for a while but has now been reborn as a COVID-19 grifter.

By Orac May 6, 2020 1,032 Comments



Disinformation shared on social media.
via Twitter

Online Misinformation Long term damage

Battling Online COVID 19 Misinformation

Facebook and the other companies have been much more aggressive about taking down speech by actual Americans that they deem to include dangerous theories about coronavirus. So, for example, you can't — you're not supposed to be able to run an ad that says, buy bleach, bleach will — by drinking bleach, you will kill coronavirus, right? And so they have taken those steps on things that are clearly factually inaccurate.

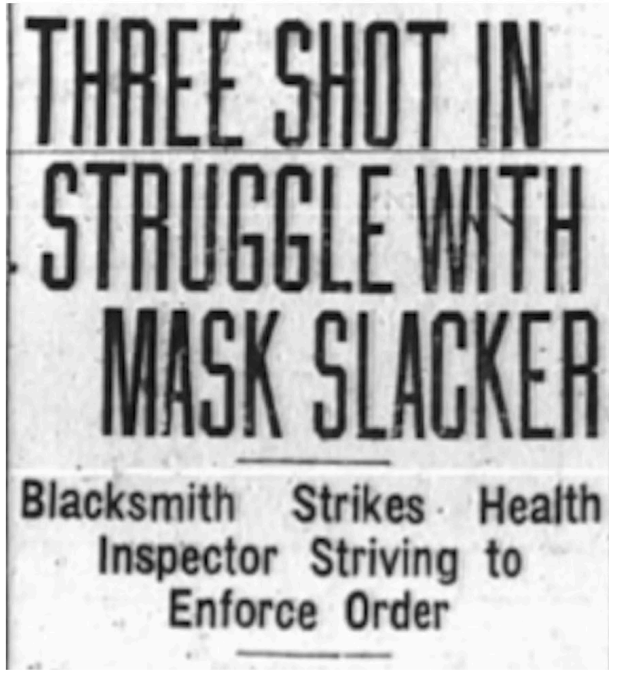
Battling Online COVID 19 Misinformation

- Get Ready for a Vaccine Information War
- Social media platforms already have misinformation about a COVID-19 vaccine, months or years before one even exists

Anti-vaccine demonstrators outside the Centers for Disease Control and Prevention in Atlanta in June. Audra Melton for The New York Times

Flashback to 1918 Spanish flu Pandemic

▲ People wait in line to get flu masks to avoid the spread of Spanish influenza on Montgomery Street in San Francisco in 1918. Photograph: Hamilton Henry Dobbin/California State Library handout/EPA



THREE SHOT IN STRUGGLE WITH MASK SLACKER

Blacksmith Strikes Health Inspector Striving to Enforce Order

A clipping from the San Francisco Chronicle on October 29, 1918. The San Francisco Chronicle

"SANITARY SPARTACANS"

Name of Anti-Mask League in Frisco

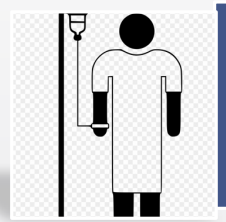
A clipping from a Long Beach newspaper on January 21, 1919. Some referred to San Francisco as "Frisco." The Long Beach Telegram and The Long Beach Daily News

"History doesn't repeat itself, but it often rhymes."

Attributed to Samuel Clemens (Mark Twain)

▲ Protesters rally at the Capitol building in Sacramento on 20 April to demand that Governor Gavin Newsom ease coronavirus restrictions. Photograph: Rich Pedroncelli/Associated Press

Lessons and Observations



Embrace opportunities of incorporating 21st century technologies into patient care and education

Ongoing need for medical surge and intensive care capacity.

Public trust is a government's most valuable asset.

Act quickly and efficiently to educate and debunk misinformation.

Having a system we can trust is critical

Thank You!

Melody Butler, BSN, RN, CIC
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