

**Biosecurity:  
A Multi-Dimensional Challenge of  
Escalating Complexity and Urgency**

**Dr. George Poste**

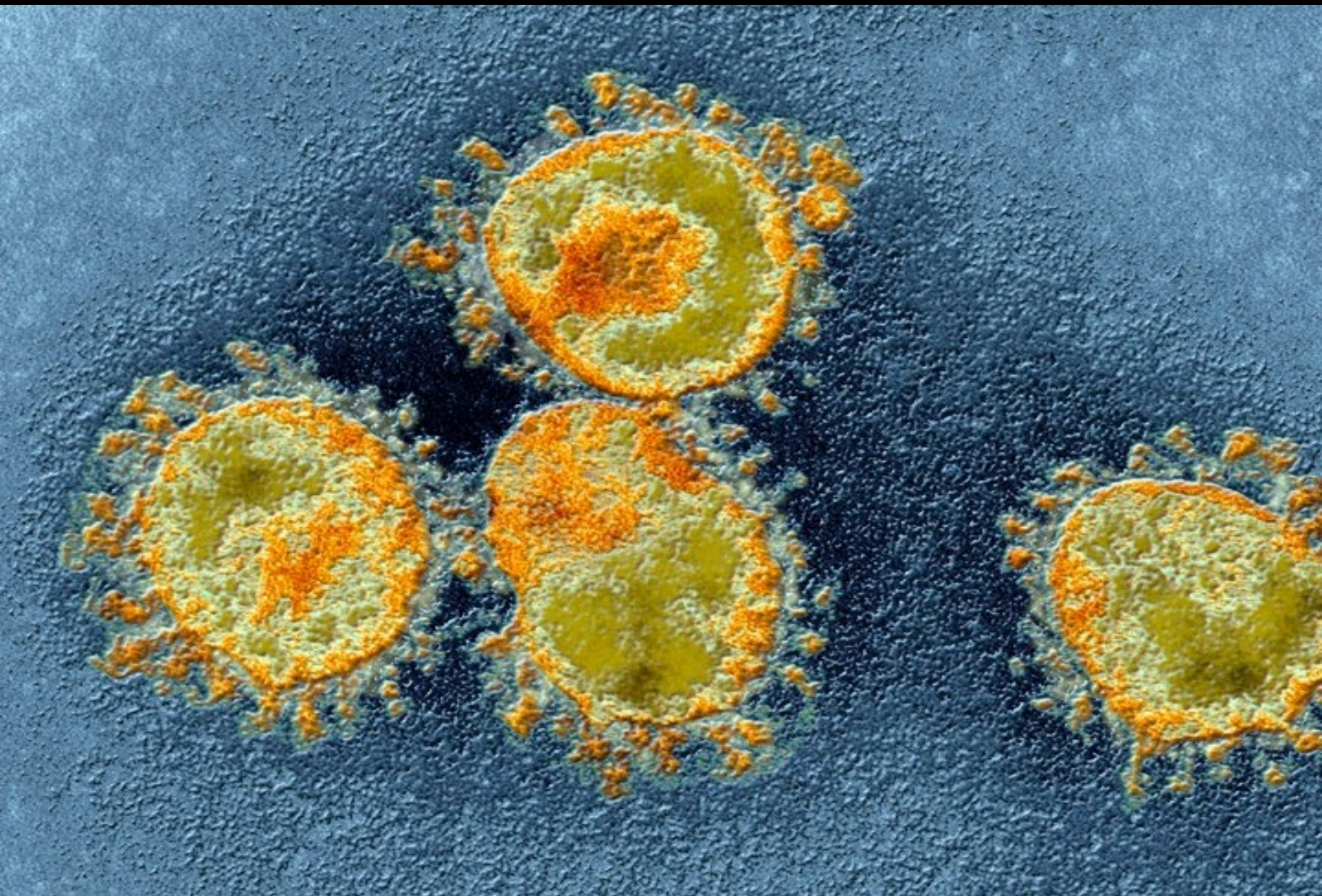
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**Pressing Threats I**  
**New and Emerging Diseases and Patterns**



# A World Transformed By SARS-CoV-2



# **SARS-CoV-2: Future Trajectories and Implications**

- **timing of development of sufficient 'herd immunity' to dramatically curtail pandemic spread**
- **aggressive track and trace campaigns to control new 'hot spots' once reasonable levels of control achieved**
- **longer-term health effects in COVID-19 survivors**
- **indirect health effects created by SDoH, stress, mental illness and delayed care**
- **economic dislocation, recovery and new work patterns**
- **lingering socio-cultural and educational disruption**
- **trust in government and scientific expertise**

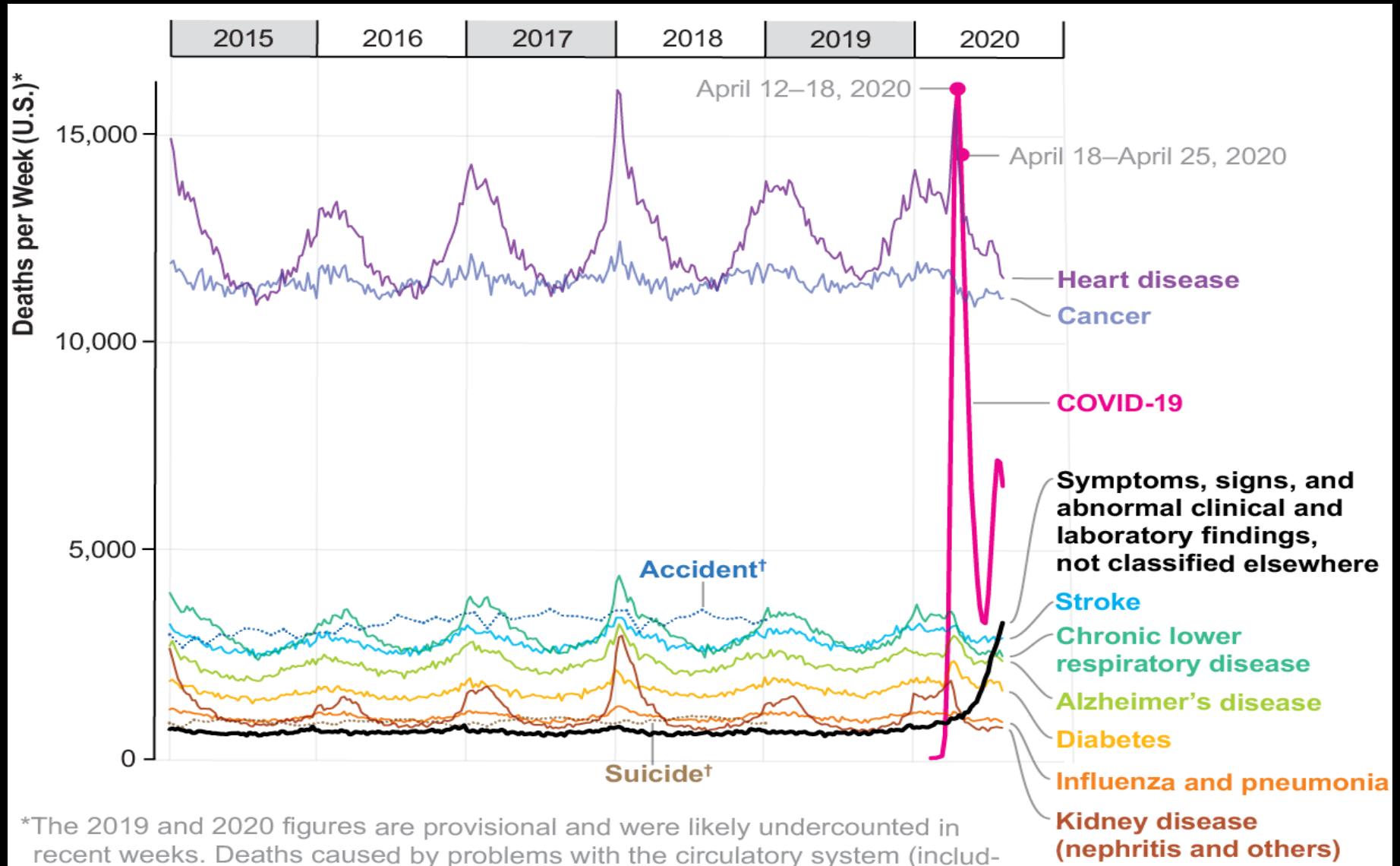


# SARS-CoV-2: US Healthcare System Under Siege



# Top 10 Causes of US Mortality

## COVID-19 Outpaces Stroke, Alzheimer's and Diabetes



## **Chronic Health Effects in Recovered COVID-19 Patients**

- **estimated 1 in 5 patients**
- **graded severity of recovery: weeks to months to ?**
- **respiratory, cardiac, renal effects**
- **impaired cognition**

## Estimated Economic and Clinical Cost of the COVID-19 Pandemic

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category	cost (billions) US\$
lost GDP	7592
health loss	
premature death	4375
long-term health impairment	2572
mental health impairment	1581
total	16,121
% of annual GDP	90

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From: D.M. Cutler and L.H. Summers JAMA (2020) 324, 1495 (October)

# **Estimated Economic and Clinical Cost of COVID-19 Pandemic**

**JAMA (2020) 324, 1495**

- **4X lost output in 1929 Great Recession (inflation adjusted)**
- **2X cost of wars conducted by US since 9/11**
- **est. 2.5 million life years lost (average life span 81 yr.)**



THE

REOPENING

# **Test, Test, Test and Trace, Trace, Trace!**

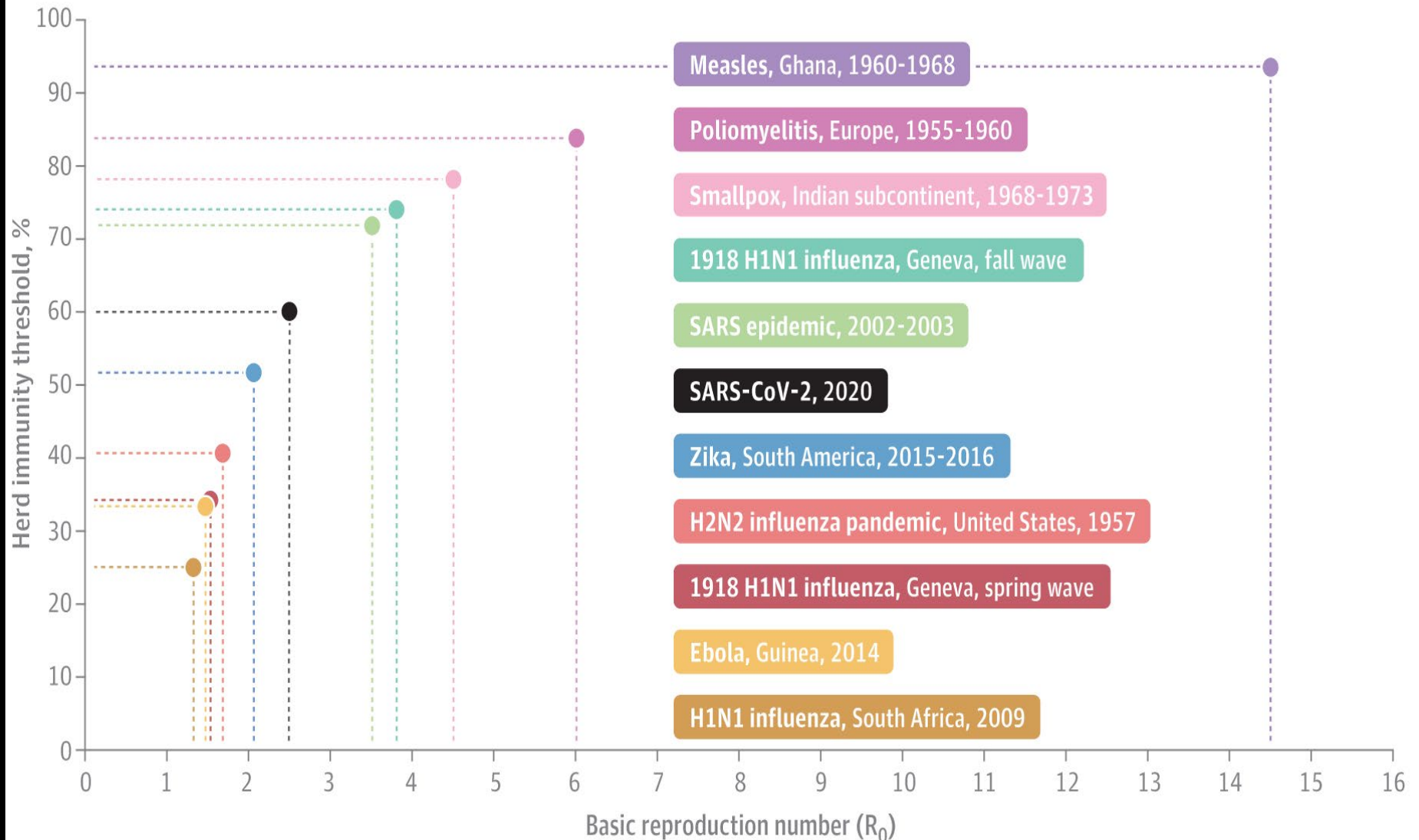
- **the critical ‘tandem’: without BOTH the system is blind**
  - **true prevalence (MDx) and level of herd immunity (serological)**
  - **control of super-spreader events and suppression of new hot spots**

## **“Immunity”**

# **The Trillion Dollar Word in the Control of SARS-CoV-2**

- **immune responses vary substantially between individuals**
- **asymptomatic infections induce weaker immune response**
- **timing of waning immunity not yet defined**
- **what is the frequency of reinfection?**
- **does prior infection with other circulating coronavirus promote cross-reactive immunity and reduced symptoms?**
- **short-lived duration of immunity (40 weeks) to the four less virulent coronaviruses (OC43, HKU1, 229E and NL63) and reinfection common**

# Herd Immunity Thresholds by Disease





# The Quest for Herd Immunity

- **should we let the virus rip?**

*or*

- **wait for vaccines and conduct an extensive immunization campaign?**

*plus*

- **protect the most vulnerable populations until robust herd immunity is achieved?**

# Therapeutics and Vaccines: Critical Dependence on Private Sector Innovation and Investment



# Operation Warp Speed and Quest for a COVID-19 Vaccine



- **\$10 billion campaign launched May 2020**
  - **300 million doses for US population**
- **complex allocation and distribution logistics**

# Global COVID-19 Vaccine Approval Allocation and Distribution



- EUA versus full approval
- 50% efficacy standard
- single or double dose
- new cold chain needs for mRNA vaccines (-80°C)
- safety monitoring

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**CONSENSUS STUDY REPORT**

FRAMEWORK FOR  
**EQUITABLE**  
ALLOCATION OF  
**COVID-19**  
**VACCINE**

- immunization priorities



# Global COVID-19 Vaccine Approval Allocation and Distribution



- distribution logistics by states
- immunization logistics
- 2009 H1N1 138 million doses

*Walgreens*



**McKESSON**

# Vaccines: Individual Rights Versus Public Good



# Global COVID-19 Allocation and Distribution

- vaccine “nationalism”
- US/EU government large investment in private sector
  - bidding war and over-subscribed purchase orders
- triage priorities?
  - first responders, healthcare, elderly and other vulnerable groups
  - adults (25 yrs +)
  - children
- ethical issues for “fair distribution”
  - international distribution
  - WHO/COVAX/GAVI: proportional to population and scaling from 3 to 20%
  - Coalition for Epidemic Preparedness Innovations (CEPI)

## **COVID-19 Vaccination: Risk Perception and Relative Risk**

- **projected scale of first cycle of US SARS-CoV-2 vaccination**
  - 25 million people
- **separation of true vaccine-related adverse events (AEs) from background/baseline mortality/morbidity statistics**
- **first two days**
  - 2,300 strokes
  - 7,000 heart attacks
- **first week**
  - 9,000 pneumonia cases and 900 deaths
- **no media filter and new feeding frenzy for lawyers (1-800-bad-vacc)**
- **1976 H1N1 influenza (swine flu)**
  - Guillain-Barre disease and CDC halted vaccination
- **H5N1**
  - narcolepsy



# **A Critique of the US Response to COVID-19**

**Consistent Inconsistency**

**Politics + Science = Politics**

## "130,000 – 210,000 **AVOIDABLE** COVID-19 DEATHS – AND COUNTING – IN THE U.S."

By Irwin Redlener, MD; Jeffrey D. Sachs, PhD; Sean Hansen, MPA; Nathaniel Hupert, MD, MPH

October 21, 2020



**National Center for  
Disaster Preparedness**

EARTH INSTITUTE | COLUMBIA UNIVERSITY

[ncdp.columbia.edu](https://ncdp.columbia.edu)

## **A Report Card on US Response to COVID-19**

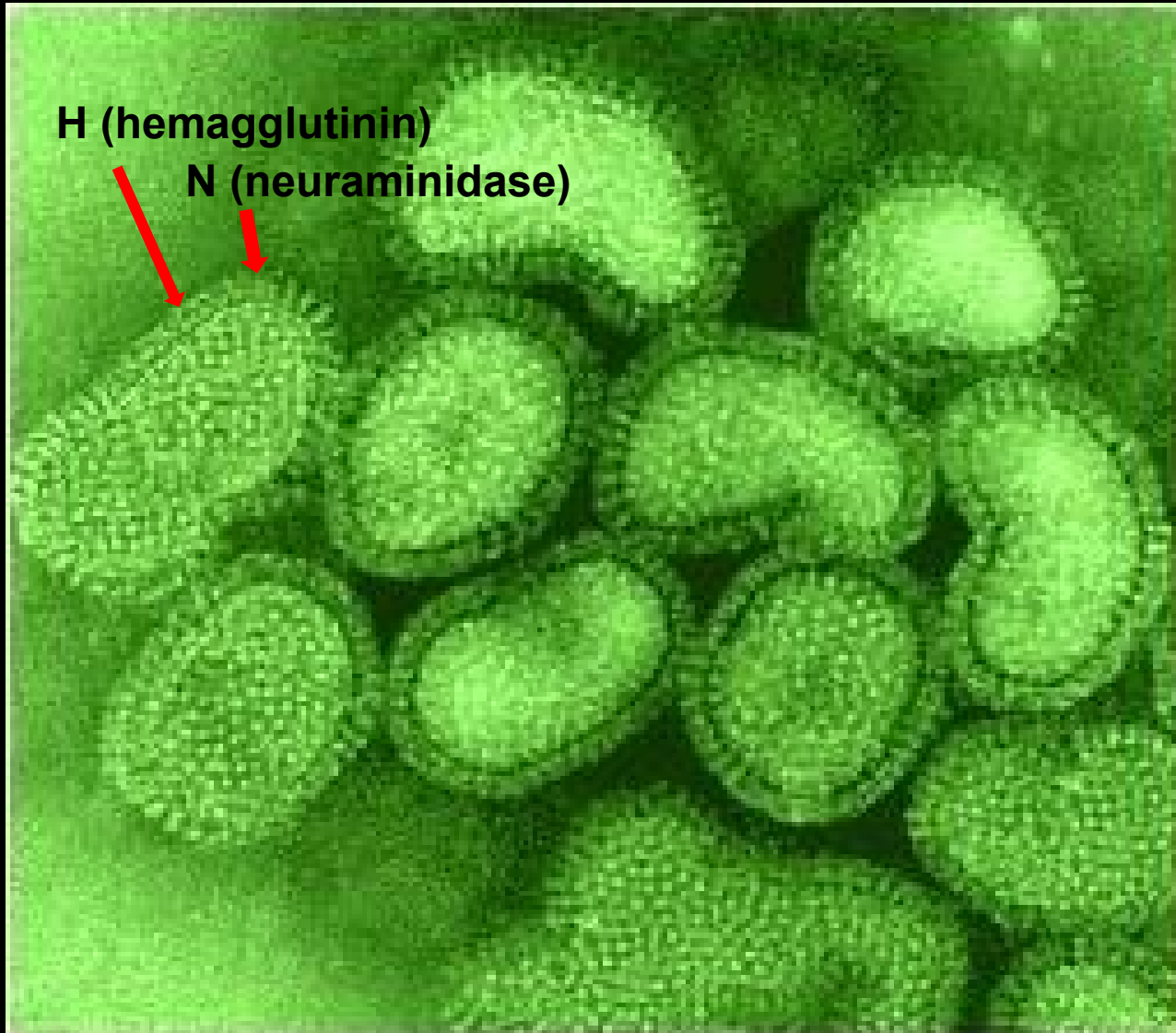
<b>Function</b>	<b>Grade</b>
<b>biosurveillance</b>	<b>D</b>
<b>rapid mobilization of detection/track/contact</b>	<b>F</b>
<b>supply chain for PPE/support resources</b>	<b>D</b>
<b>national coordination plan</b>	<b>F</b>
<b>fact-based communication and consistent messaging</b>	<b>F</b>
<b>politicization and social tensions</b>	<b>F</b>
<b>trust in government</b>	<b>D</b>
<b>accountability</b>	<b>F</b>

# A Report Card on US Response to COVID-19

Function	Grade
biosurveillance	D
rapid mobilization of	F
<b>Operation Warp Speed “A”: This grade assumes that one or more vaccines work</b>	
national coordination plan	F
fact-based communication and consistent messaging	F
politicization and social tensions	F
trust in government	D
accountability	F



# Pandemic Influenza: Still a High Probability Risk



## Historical Major Influenza Infections

Year	Strain	# US Deaths
1917-19	H1N1	est. 675,000
1957-58	H2N2	est. 116,000
1968	H3N2	est. 100,000
2009	H1N1 pdm 2009	12,500 (60 million infections, 240,000 hospitalizations)

# **‘One Health’ Biosurveillance: The Need to Rebuild the Front Line in Biopreparedness**



- **range and physical contact**
- **environmental factors**

- **demographics**
- **cultural, political and economic factors**
- **health system capacity to detect/respond**

**Fast Track Action Committee Report:  
Recommendations on the Select Agent  
Regulations Based on Broad  
Stakeholder Engagement**

**October 2015**

**National Science and Technology Council  
Committee on Homeland and National Security  
Subcommittee on Biological Defense Research and  
Development  
Fast Track Action Committee on the Select Agents  
Regulations**

# Addressing Antibiotic Resistance

A REPORT FROM THE JOINT APLU | AAVMC TASK FORCE  
ON ANTIBIOTIC RESISTANCE IN PRODUCTION AGRICULTURE



## National Quality Partners Playbook™:

ANTIBIOTIC STEWARDSHIP IN  
POST-ACUTE AND LONG-TERM CARE

## ANTIBACTERIAL AGENTS IN CLINICAL DEVELOPMENT

An analysis of the antibacterial clinical development pipeline,  
including tuberculosis



development dialogue paper  
no.26 | december 2018

### Antimicrobial resistance and sustainable development: A planetary threat but a financing orphan

Planet Earth faces the very real threat of having to survive and thrive in a 'post-antibiotic' era in which there are few, if any, antibiotics which effectively and affordably cure infections. A world without antibiotics would necessitate radical changes in health care and farming. Despite the severity of this threat, many low- and middle-income countries struggle to identify resources for even basic activities related to antimicrobial resistance (AMR). In this context, the Dag Hammarskjöld Foundation and ReAct - Action on Antibiotic Resistance hosted a meeting to discuss how AMR could become more visible and how more funds to tackle AMR could be mobilised.



## WHO GUIDELINES ON USE OF MEDICALLY IMPORTANT ANTIMICROBIALS IN FOOD-PRODUCING ANIMALS





## Who Pays for Preparedness?



## The Obligate Role of Private-Public Partnerships in Biosecurity Policy

PROCEEDINGS OF A WORKSHOP

Engaging the  
**Private-Sector Health  
Care System** in Building  
Capacity to Respond to  
Threats to the **Public's  
Health and National  
Security**

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# **Society's Love: Hate Relationship With the Biopharmaceutical Industry: Taking Innovation for Granted**

- **estimated two-decade lifetime expansion in lifespan from 1950 onwards**
  - heart disease/diabetes
  - infectious diseases (Rx and vaccines)
- **among the most technologically sophisticated and highest R&D investment of any industry**
  - \$1.5 to 2 billion per Rx/10-15 years R&D
  - 600-800million per VacX/5-25 years R&D



# Market Failure

- **lack of incentives for private sector to undertake high risk/high cost R&D absent guaranteed markets and ROI**
  - neglected diseases of the developing world
  - antibiotic resistance (global)
  - MCMs for biowarfare select agents
  - emerging infectious diseases
- **outsourcing of critical supply chains (China, India)**
  - generic drugs (80% of US prescriptions)
  - active ingredients for key drug classes (antibiotics)
  - PPE
  - devices (ventilators)



**PREPARE FOR  
TOMORROW'S  
THREAT TODAY**