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

Dr. George Poste
Chief Scientist, Complex Adaptive Systems Initiative
and Regents Professor of Health Innovation
Arizona State University george.poste@asu.edu  www.casi.asu.edu

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

Symptoms, signs, and abnormal clinical and laboratory findings, not classified elsewhere
- Stroke
- Chronic lower respiratory disease
- Alzheimer’s disease
- Diabetes
- Influenza and pneumonia
- Kidney disease (nephritis and others)

*The 2019 and 2020 figures are provisional and were likely undercounted in recent weeks. Deaths caused by problems with the circulatory system (including heart disease and stroke) are included in the total death toll but are not broken out as a cause of death.

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

<table>
<thead>
<tr>
<th>category</th>
<th>cost (billions) US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>lost GDP</td>
<td>7592</td>
</tr>
<tr>
<td>health loss</td>
<td></td>
</tr>
<tr>
<td>premature death</td>
<td>4375</td>
</tr>
<tr>
<td>long-term health impairment</td>
<td>2572</td>
</tr>
<tr>
<td>mental health impairment</td>
<td>1581</td>
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<tr>
<td>total</td>
<td>16,121</td>
</tr>
<tr>
<td>% of annual GDP</td>
<td>90</td>
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</table>

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.)
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
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

“Immunity”
The Trillion Dollar Word in the Control of SARS-CoV-2
Herd Immunity Thresholds by Disease

S.B. Omer et. al. JAMA Online 10/19/20
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

- immunization priorities
Global COVID-19 Vaccine Approval
Allocation and Distribution

- distribution logistics by states
- immunization logistics
- 2009 H1N1 138 million doses
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 Hansee, MPA; Nathaniel Hupert, MD, MPH

October 21, 2020
## A Report Card on US Response to COVID-19

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<tr>
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<td>D</td>
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**Operation Warp Speed “A”:**
This grade assumes that one or more vaccines work
Pandemic Influenza: Still a High Probability Risk

H (hemagglutinin)
N (neuraminidase)
# Historical Major Influenza Infections

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<tr>
<th>Year</th>
<th>Strain</th>
<th># US Deaths</th>
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<tr>
<td>1917-19</td>
<td>H1N1</td>
<td>est. 675,000</td>
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<tr>
<td>1957-58</td>
<td>H2N2</td>
<td>est. 116,000</td>
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<tr>
<td>1968</td>
<td>H3N2</td>
<td>est. 100,000</td>
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<tr>
<td>2009</td>
<td>H1N1 pdm 2009</td>
<td>12,500 (60 million infections, 240,000 hospitalizations)</td>
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‘One Health’ Biosurveillance: The Need to Rebuild the Front Line in Biopreparedness

Natural reservoirs and ecological niches of emerging viruses

- range and physical contact
- environmental factors

Susceptible human host

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

Who Pays for Preparedness?

The Obligate Role of Private-Public Partnerships in Biosecurity Policy

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

The National Academies of Sciences, Engineering, and Medicine
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
  - 600-800 million 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)