

Learning at the Bedside to Inform Clinical Research in Outbreaks

Translating Anecdote to Evidence

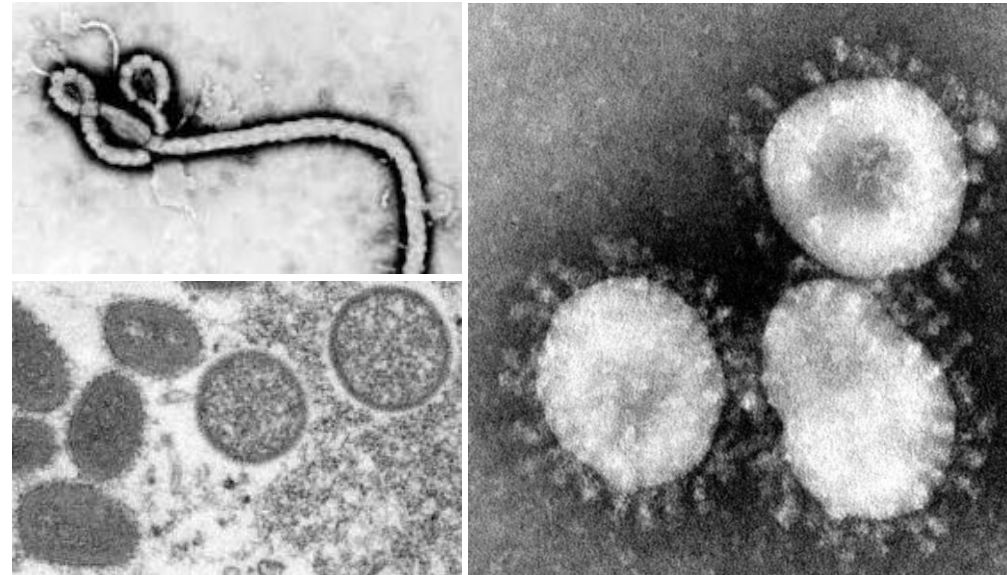
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Key Messages

- Clinical information needed for clinical trials and outbreak response is routinely collected at the bedside but RARELY shared
- We won't be prepared for tomorrow if we don't do the work TODAY
 - Pandemic preparedness must be integrated into daily clinical care
 - Streamline regulatory processes
 - Leverage existing data platforms to tell us WHO is infected and WHAT happens
 - Learn the rules of the disease (pathogen/immune response kinetics)
- Pandemics are global problems – data, like diagnostics, vaccines, and therapeutics must be shared rapidly and widely

Patients tell us what we need to know...

China CDC Weekly

WHO, WHAT, WHEN

Vital Surveillances

The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) — China, 2020

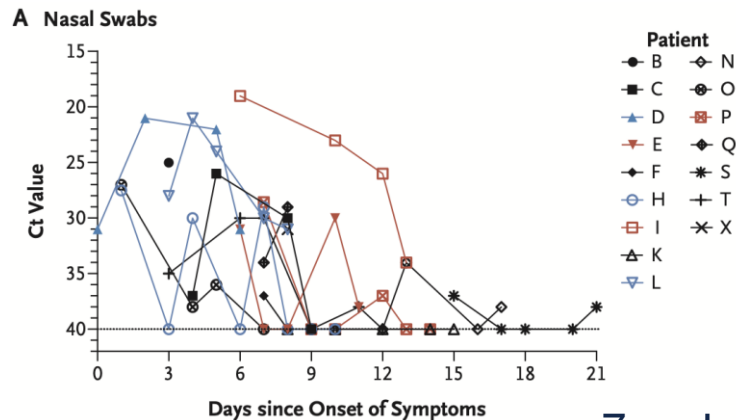
The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team

LONG-HAULERS ARE REDEFINING COVID-19

Without understanding the lingering illness that some patients experience, we can't understand the pandemic.

The NEW ENGLAND JOURNAL of MEDICINE

SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients



Zou, L NEJM 2020



This is an official
CDC HEALTH ADVISORY

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COVID-19 Rebound After Paxlovid Treatment

What are the Barriers to Transforming this Information into Action?



Systems

Staff

Stuff

Clinical presentation



Case definition

Demographics



RF for severe disease/death

Natural history



Clinical complications

Clinical excess of lab samples →

kinetics/pathogen-specific endpoints

Ebola Epidemic Timeline

*The NEW ENGLAND
JOURNAL of MEDICINE*

ESTABLISHED IN 1812

OCTOBER 16, 2014

VOL. 371 NO. 16

Ebola Virus Disease in West Africa — The First 9 Months
of the Epidemic and Forward Projections

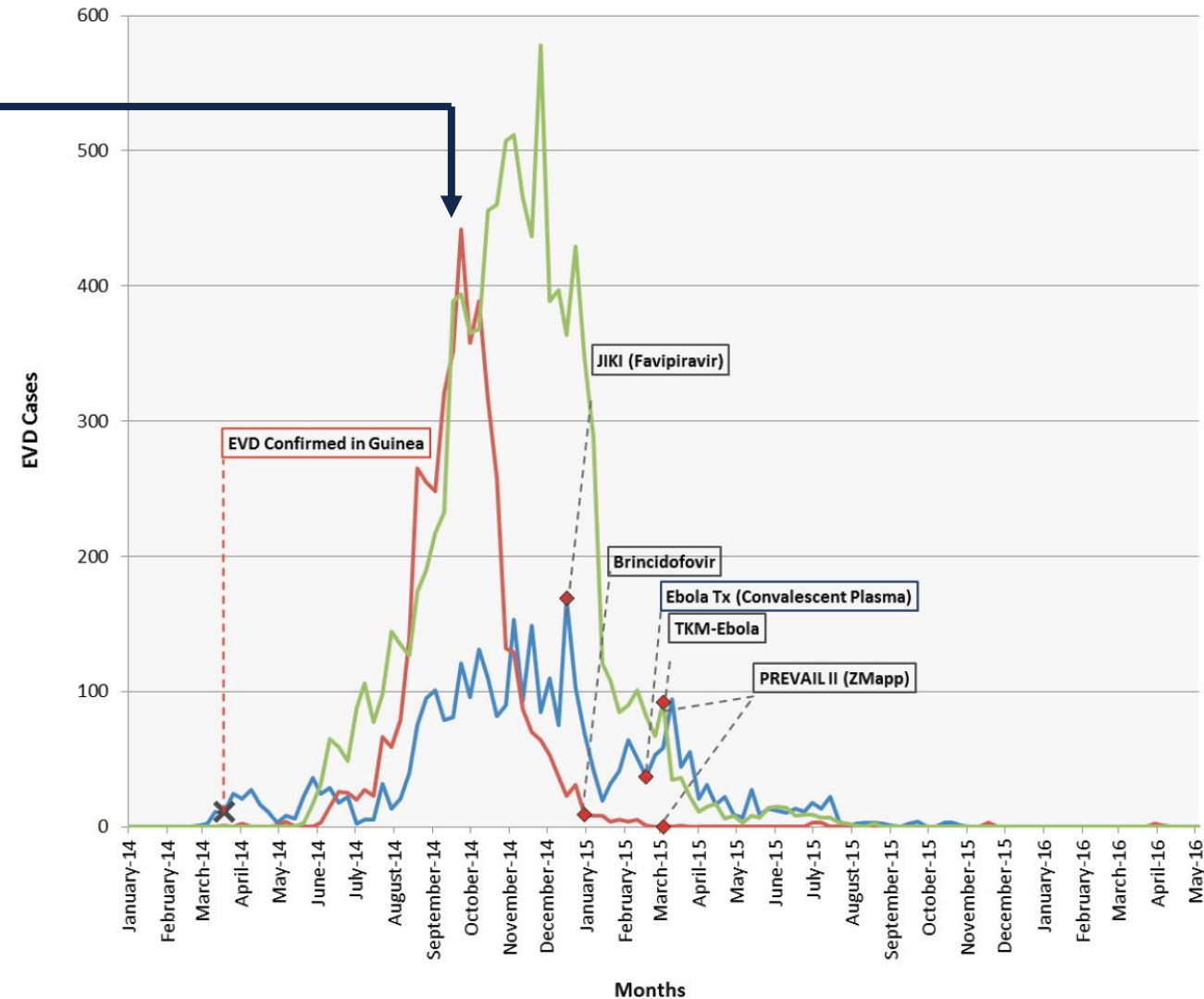
WHO Ebola Response Team*

INTEGRATING CLINICAL RESEARCH
INTO EPIDEMIC RESPONSE

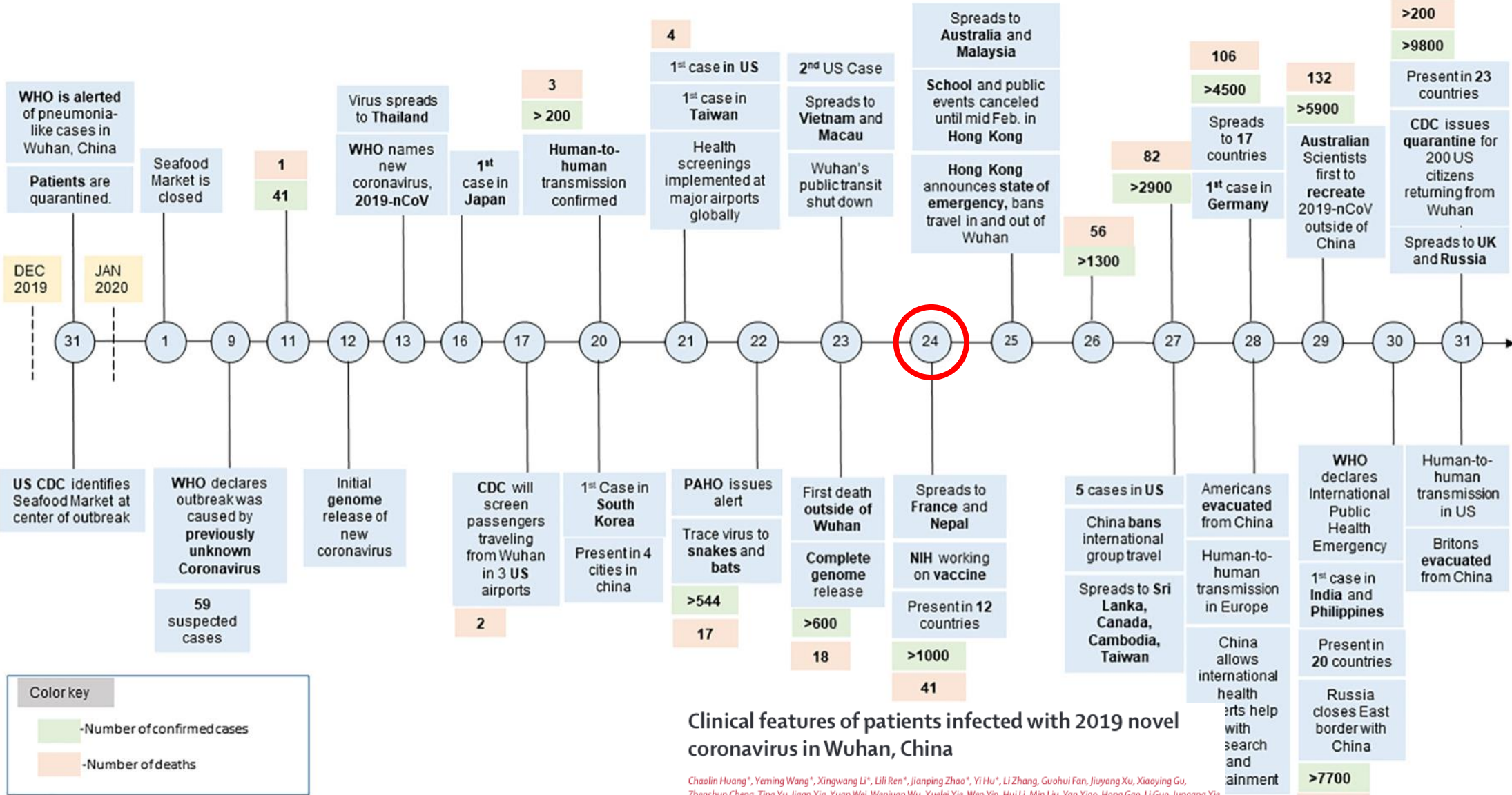
THE EBOLA EXPERIENCE

6 Major Capacity Challenges

1. Lack of clinical experience with Ebola
2. Poor surveillance/laboratory capacity
3. Deficiency of healthcare infrastructure and HCWs
4. Limited research experience
5. Under supported ethics review boards
6. Delays in legal/bureaucratic steps



COVID Timeline



Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China

Chaolin Huang*, Yeming Wang*, Xingwang Li*, Lili Ren*, Jianping Zhao*, Yi Hu*, Li Zhang, Guohui Fan, Jiuyang Xu, Xiaoying Gu, Zhenshun Cheng, Ting Yu, Jiaan Xia, Yuan Wei, Wenjuan Wu, Xuelei Xie, Wen Yin, Hui Li, Min Liu, Yan Xiao, Hong Gao, Li Guo, Jiongang Xie, Guangfa Wang, Rongmeng Jiang, Zhancheng Gao, Qi Jin, Jianwei Wang†, Bin Cao†

Feb 17

China
CDC
Report

Strategies to Accelerate Understanding of Clinical Course of Disease

Problem 1: Sustainable health systems including research capacity

- Diagnostics, Data collection systems, and better supportive care
- Leverage existing clinical databases to provide high level information (Who, What)
- Smaller more granular studies of pathogen kinetics and immune responses (When)

Problem 2: Regulatory pathways

- Memoranda of understanding
- Facilitate rapid ethics review in a public health emergency
- Provide resources to support local data collection/analysis/sharing (public health agencies)

Problem 3: Data sharing - ACCESS

- Public health dashboards (UKHSA, WHO, CDC)
- Pre-print/GISAID

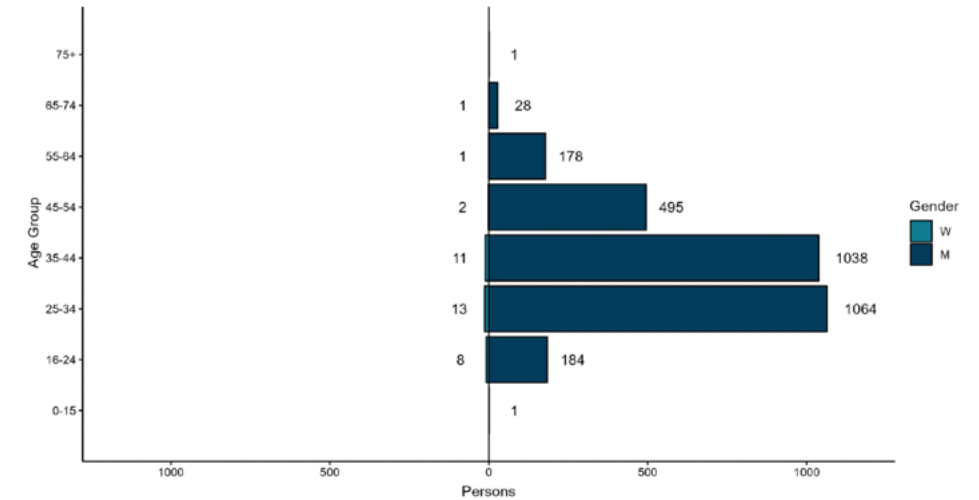
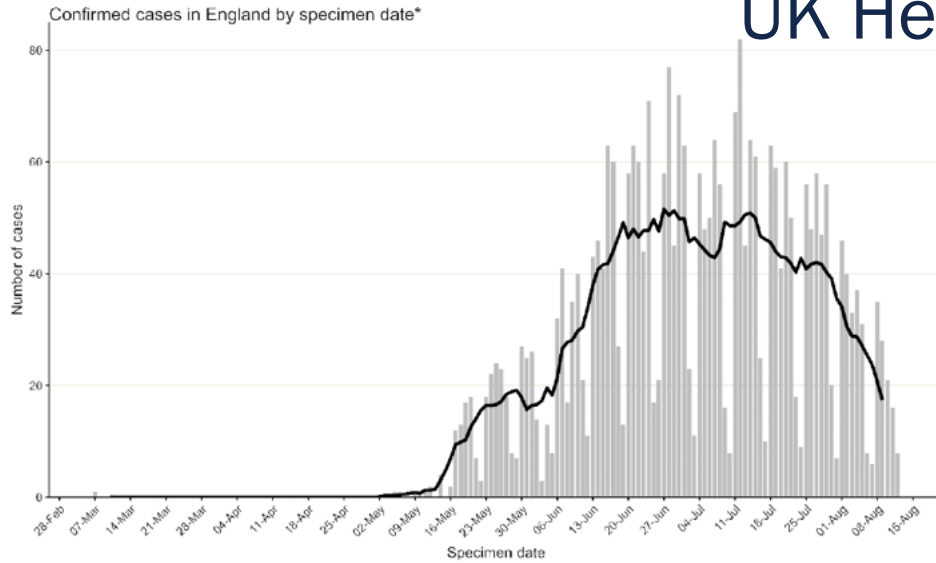
Problem 4: We have to create systems that allow us to learn what we don't know

- Learn the WHO, WHAT, WHEN + rules of the virus
- “Outbreak response must evolve from crisis response to integrated cycles of preparation, response and recovery*”

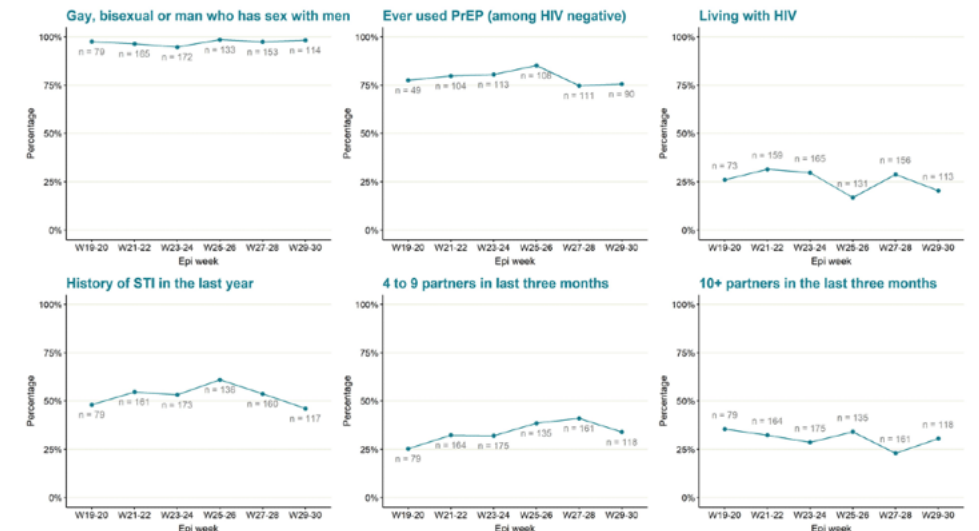
*Bedford, J et al. Nature 2019

Coordination – Gov't/Academic Partnership

UK Health Security Agency



Metric	Count	Denominator (excluding cases with missing responses)	Percentage (%)
Gay, bisexual, or men who have sex with men	857	886	96.7%
History of STI in the last year	481	899	53.5%
4 to 9 sexual partners in the last 3 months	312	904	34.5%
10+ sexual partners in last 3 months	267	904	29.5%
Living with HIV	228	867	26.3%
Ever used PrEP (among HIV negative)	490	624	78.5%



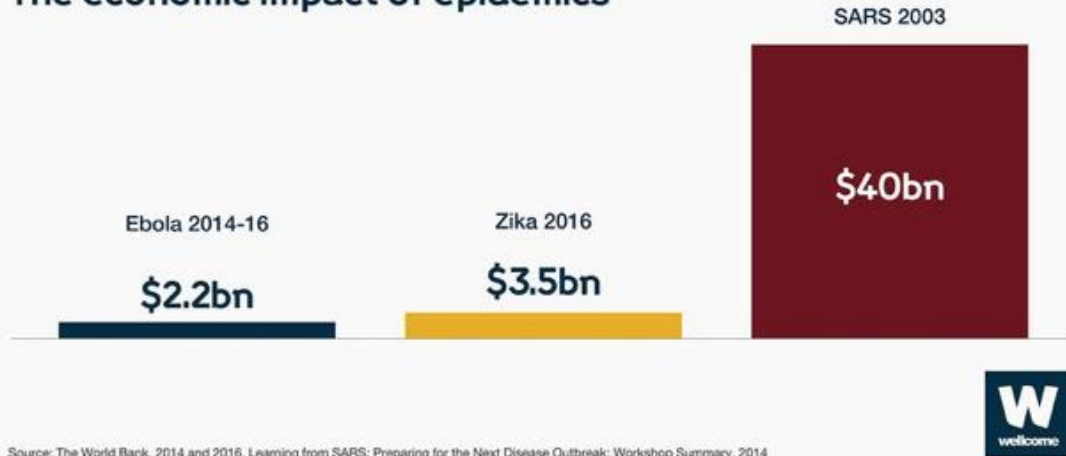
What are We Willing to Spend?

Systems

Staff

Stuff

The economic impact of epidemics



The COVID-19 Pandemic and the \$16 Trillion Virus

David M. Cutler, PhD¹; Lawrence H. Summers, PhD²

» [Author Affiliations](#) | [Article Information](#)

JAMA. 2020;324(15):1495-1496. doi:10.1001/jama.2020.19759

<https://wellcome.org/news/cost-of-not-preparing-for-infectious-diseases>

Thank You

- To the many patients who teach us how to respond better

UNC

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- Victor Garcia
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- Diana Stanley

WHO

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- Nikki Shindo

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- Many others

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- Many Others



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AND INFECTIOUS DISEASES