



COVID-19 Evidence Accelerator Collaborative

Lab Meeting #15

Thursday, July 30, 2020, 3:00-4:00 pm ET

Call Summary

Introduction to Lab Meeting 15

This week's lab meeting took a detour from the Evidence Accelerator's traditionally tech- and data-focused conversations to think about what can be ascertained from previous pandemics to inform our current response, treatments, and understanding of COVID-19. Accelerators were challenged to identify within the theme of "learning from past pandemics," patterns demonstrating the need for transparency and information sharing, the objective evaluation of information, and finding ways to integrate data/information.

Three presentations were given:

1. Presentation on What Past Pandemics Teach Us About COVID-19 (Howard Markel, University of Michigan)
2. Presentation on Learning from the FDA's Role in Past Pandemics (Vanessa Burrows, FDA)
3. Presentation on Learnings from Prior Pandemics (Michael Leavitt, Former US Secretary of Health and Human Services)

Lab Meeting Presentations

What Past Pandemics Teach Us About COVID-19

- Albert Camus's *The Plague* presents a four-act model of epidemics which is generally accurate:
 - Act I: Progressive Revelation
 - As the first few cases appear it is often not apparent that an outbreak has begun or if it is apparent, there is hesitation to believe that an outbreak has begun.
 - This period of progressive revelation allows the microbe to get a "head start" before the world responds.
 - Act II: Managing Randomness
 - Act III: Managing Public Response
 - Act IV: Subsidence and Retrospection
- There are major themes to both epidemics and pandemics:
 - Epidemics are framed and shaped—sometimes advanced, and sometimes hindered—by how a given society understands a particular microbe to infect and spread to others.
 - The economic losses associated with epidemics can have a strong influence on public response.

- There is potential for concealment of an epidemic, delays in reporting one, or the severity being ignored or underestimated by the world at large.
- The movement of people and other living beings and the speed of travel are essential factors in the spread of infectious disease.
- Widespread media coverage of epidemics is hardly new and an essential aspect of any epidemic.
 - Information is now atomized—people can get the source of news that they think best fits their ideology.
- Our fascination with the suddenly appearing microbe that kills relatively few in spectacular fashion often trumps our response to infectious scourges that patiently kill millions every year.
 - COVID began as one of these “spectacular” microbes but has become a microbe that kills many.
 - AIDS continues to kill many people every day but has not been given significant attention in recent years.
- Poverty, and its attendant evils, often fuel the fire of an epidemic.
- Scapegoating or blaming individuals or social groups for the importation of infection.
 - The public health community has decided as a collective to name things in a generic way and not after countries or people to discourage this scapegoating.
- Laws governing migration, individual liberties, and movement to contain the threat (real or perceived) of contagion.
- Internecine rivalries and disputes between local, state, and the federal government.
- Profound amnesia, or the willingness of communities to return to normal without altering behavior based on pandemic learnings, often occurs and is arguably the most dangerous response to a recent epidemic or pandemic.

Learning from FDA’s Role in Past Pandemics

- Four themes emerge from the Food and Drug Administration’s (FDA) past pandemic responses:
 - Maintain integrity of therapeutic marketplace by rooting out fraud.
 - Collaborate and share information with internal/external stakeholders.
 - Evaluate risks and benefits of therapeutics to assess value for specific populations.
 - Leverage regulatory flexibility to develop innovative & expedient solutions.
- FDA action during the “Great Influenza” of 1918
 - In 1918, the FDA (named the US Bureau of Chemistry at that time) was a young agency with limited powers under the 1906 Pure Food and Drugs Act.
 - At this time, there was no requirement that drugs prove safety or efficacy before entry into the marketplace but FDA was tasked with removing drugs from the marketplace which made false claims.
 - For example, the agency was able to successfully remove some products from the market but others, such as a powder for sweeping the floor which claimed to prevent the disease, were not able to be removed.
 - Many companies marketed ineffective products by preying on consumer fears of the influenza.

- Limited enforcement power under the 1906 Pure Food and Drugs Act that were exposed in the effort to root out fraudulent products led to the Agency to forge alliances with the Fair Trade Commission and the Postal Service that enabled the crucial sharing of information.
- FDA action during the 1968 Influenza outbreak
 - By this time, the FDA had been tasked with evaluating the risks/benefits of therapeutics.
 - The efficacy standard of therapeutics for specific indications was established by the 1962 Drug Amendments and was invoked during this pandemic.
 - FDA cautioned the public and industry about potential risks associated with medications (particularly amantadine) that were not approved as a treatment for H3N2 influenza.
- FDA action during the 2009 H1N1 Influenza pandemic
 - FDA leveraged regulatory powers given to it by the 2004 Project Bioshield Act which created Emergency Use Authorization for public health emergencies to issue EUAs to three antiviral drugs: Tamiflu, Relenza, Peramivir.
 - At this time, Tamiflu and Relenza were FDA-approved for other indications, but Peramivir was not yet FDA-approved for any indication.
- Vaccine Development and Safety Monitoring
 - In 1972, the Bureau of Biologics was transferred from the National Institutes of Health (NIH) to FDA, giving FDA authority over vaccines.
 - FDA coordinated with the NIH and industry to ensure the speedy and effective review of vaccine applications in 2009 for the H1N1 influenza virus.
 - Was able to approve four vaccines within only five months of the pandemic.
 - FDA also supported CDC in facilitating the distribution of these vaccines and monitoring vaccine safety, and did so after vaccine approvals during the H1N1 pandemic.

Learning from Prior Pandemics

- Prior to being appointed US Department of Health & Human Services (HHS) Secretary, Michael Leavitt's experience was primarily in the business sector. After four months as Secretary, he had an emergency meeting with the Centers for Disease Control and Prevention (CDC) to discuss a virus with pandemic potential: H5N1 avian influenza.
- This meeting coupled with encouragement from a colleague inspired Leavitt to take up a number of readings about pandemics. Leavitt was impressed by what he read and surprised that somehow the severity of a pandemic had escaped someone in his position and with his experience.
 - According to Leavitt, his story is symbolic of what is happening with the COVID-19 pandemic: many leaders have not been exposed to the problem of pandemics with any degree of seriousness which is having serious ramifications now that COVID-19 has arrived.
- Through his personal experience and extensive learning about pandemics, Leavitt has arrived at "Five lessons of things that should not have surprised us":
 - Anything you say in advance of a pandemic sounds alarmist; anything you do after a pandemic starts will not be enough.

- Over the course of the last 40 years, we have allowed our public health infrastructure to deteriorate and it is now inadequate at a time when we are reliant upon it.
- Our systems of collecting data are inadequate. Our capacity to gather data in an efficient way does not exist.
- We should not have been surprised at all about the finger-pointing that occurred between the states and the Federal government.
 - There are some very clear duties that the Federal government cannot do, simply because of the nature of a pandemic.
 - We need to get the division of labor right, even now in this pandemic.
- Communication is vital.
 - People want to hear from public health professional, not politicians.
- Further, we should not be surprised if the following things occur in the next couple of years:
 - Just finding a vaccine and getting it approved is not the end. There will be manufacturing questions, distribution questions, and many more things to be resolved.
 - We should not be surprised when the public is not prepared for the message that the approval of a vaccine does not resolve all issues.
 - The pandemic will likely affect the next three elections in the United States and the economy will likely need to recover over a much longer period of time.
- We will likely now go into a period of achieving a sustainable risk management where people become better at managing risks once they understand them as they go on with their lives.
 - We need to get information that is accurate, real, and actionable to determine how people can lives in a safe way. This can only come with data and good science.