University of Nebraska Medical Center

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Hearing on Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust

Witness appearing before the

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Subcommittee on Oversight and Investigations

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TALKING POINTS

Introduction

- Good afternoon, Rep. Diana DeGette, Chair of the Subcommittee, ranking member Brett Guthrie, and members of the subcommittee.
- I'm Ali S. Khan, a physician, former Assistant Surgeon General at the Centers for Disease Control and Prevention responsible for national preparedness, and currently dean of the College of Public Health at the University of Nebraska Medical Center.
- I am pleased to be here today to offer testimony to examine the future safety, efficacy, and accessibility of COVID-19 vaccines and the challenges with trust.

Problem Statement – General

- We are currently witnessing the greatest public health failure in our nation's history.
- A sluggish and shortsighted government response combined with a disregard for scientific expertise has undermined public health and allowed a novel coronavirus to gain a foothold in the U.S.

Solution – General

- I am here to discuss my prior experience with preparedness planning and to reinforce that we must heed the lessons learned from prior vaccination campaigns like 2009 H1N1p
- However, with ~750 preventable deaths occurring each day in the U.S., we cannot wait for a vaccine to contain this outbreak.
- We can take evidence-based steps to drive down the number of new cases and deaths today with the public health tools we already have available.

Problem Statement – Vaccine Timeline

- While the preliminary data is hopeful, the prediction of an election day COVID19 vaccine has raised numerous concerns in the vaccine scientific and development community as well as in our communities.
- I would like to remind members of the subcommittee that we have been waiting 30 years for an HIV vaccine and we still do not have effective vaccines for dengue, RSV, noroviruses, and numerous other viral diseases.
- Please note that going back to my earlier comment of we cannot wait of a vaccine to use public health measures to contain this disease, if the FDA finally mandates 2 months of post-vaccine monitoring in Phase 3 trials before approval, that will equate to at least more 30K additional deaths.

Problem Statement – Trust

- In line with getting the messaging right, public acceptance of a COVID-19 vaccine is not a given.
- Trust of the vaccine will be as important if not more so than the safety and efficacy which are much easier to manage.
- A recent study and poll from the Associated Press-NORC Center for Public Affairs Research suggest that a 1/4 to a 1/2 of the U.S. population would not be willing to receive it.[1]
- Some people may legitimately fear that if a vaccine is developed too quickly and corners were cut, there won't be time to adequately test it.
- If you recall, in 1976, a failed political campaign to mass-vaccinate the public against a strain of the **swine flu** virus negatively influenced the public's perception of the flu vaccine in this country.
    - 45 million were vaccinated in 10 weeks.
    - However, there was no swine outbreak and, instead, the vaccine resulted in over **450 people developing the paralyzing Guillain-Barré syndrome at a rate above baseline of ~1 per 100,000.**
    - Political expediency and self-interest of government health bureaucracy were attributed to this fiasco although it reflected the precautionary principle.
- Again, in 1998, the FDA approved a new recombinant **Lyme vaccine**, LYMErix™, which reduced new infections in vaccinated adults by nearly 80%.
    - Just 3 years later, the manufacturer voluntarily withdrew its product from the market amidst negative media coverage, the public's fear of the side-effects, and declining sales.

Problem Statement – 2009 H1N1p experience

- In 2009, **H1N1p influenza** uncovered communication, operational and policy challenges across the federal government with regard to the distribution of vaccines.
    - Similar to COVID-19, H1N1p was novel, with the majority of the U.S. population lacking immunity to the virus, and an understanding of its virulence was unknown.
    - The H1N1 vaccine was initially available in the United States in October 2009, almost four months after the World Health Organization's (WHO) pandemic declaration but did not become more broadly available until late December 2009.
    - By the time a vaccine was available, the peak of H1N1 had passed, and many individuals were no longer as interested in getting vaccinated.

[1] The Associated Press-NORC Center for Public Affairs Research. Expectations for a COVID-19 Vaccine

- "By the end of 2009, approximately 61 million persons had been vaccinated. By January 29, 2010, approximately 124 million doses had been distributed."[2] By May 31, 2010, an estimated 90 doses had been administered or 27% of the population above 6 months of age.
- Vaccine distribution was delegated to state and local jurisdictions, which were provided flexibility in deciding the best methods for distribution.
- The distributor (McKesson) required a 100-dose minimum order and many states were forced to break down and repackage the vaccine to efficiently serve smaller vaccination sites, such as nursing homes, rural doctors' offices, and schools.[3]
- State leaders had poorly well-defined, initial target groups for vaccination with unexplained variations between entities.

- Accurate communication for the H1N1 vaccine and response was a challenge.
  - The credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials.
  - Vaccine administration plans varied across the nation which required time clarifying information to ensure local accuracy.
  - The availability of multiple vaccine formulations with varying contraindications for various priority groups complicated vaccine administration plans even further, which in turn had to be shared with the public.

Problem Statement – Challenges of Vaccine Distribution

- While the Federal Distribution Strategy outlines that each state will develop its own COVID-19 immunization program, the guidance leaves open many issues critical to successful vaccine distribution.
  - Transportation and storage – Different types of vaccines need different transportation and storage conditions. One of the biggest distribution challenges is temperature control.
    - The two vaccines that seem most likely to be ready first are from Pfizer and Moderna.
    - These vaccines are stored at different temperatures (Moderna -20 degrees, Pfizer -94 degrees) and require different kinds of preparation by the health care provider.
    - According to The IQVIA Institute for Human Data Science, the biopharma industry loses 35 billion dollars each year due to temperature-control failures across their supply chains.

[2] Interim Results: Influenza A (H1N1) 2009 Monovalent Vaccination Coverage --- United States, October--December 2009. MMWR, January 22, 2010 / 59(02);44-48. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5902a4.htm
[3] Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning GAO-11-632: Published: Jun 27, 2011. https://www.gao.gov/assets/330/320176.pdf

        - State Health Departments may be required to allocate half of their allotted vaccine which may pose storage challenges.
        - State Health Departments may need to beak down 975 – dose shipments of the Pfizer vaccine for smaller jurisdictions.
    - Tracking – product security and traceability is critical when managing temperature sensitive vaccines on a global scale.
        - CDC is already rethinking an untested vaccine registration system [Vaccine Administration Management System (VAMS)] and potentially relying on state immunization registries. However, linkages will be essential.
        - The CDC will require vaccinators to provide dose-level accounting and reporting for vaccinations, so we know where every dose of COVID-19 vaccine is at any point in time.
        - Although the sophistication of our tracking systems have improved dramatically in the past decade many states will still face major challenges meeting the necessary tracking and reporting expectations.
        - We have a limited window of just months to fully assess and implement a tracking solution.

Problem Statement – Equity

- COVID-19 Amplifies exiting racial health disparities.
- Non-white, socioeconomically disadvantaged, and non–English-speaking populations shoulder disproportionate COVID-19 burdens.
- As of April 15, 2020, case data from CDC show that in COVID-19 cases where race was specified, Blacks, who comprise 13 percent of the total U.S. population (U.S. Census Bureau, 2018), make up 30 percent of COVID-19 cases; Latinos, who make up 18 percent of the population (U.S. Census Bureau, 2018), account for 17 percent of COVID-19 cases.[4]
- However, a survey of the U.S. adult population in May 2020 found that Black Americans reported lower influenza vaccine uptake and lower COVID-19 vaccine acceptance than all other racial groups.[5]
- Despite outreach efforts to minimize disparities for the 2009-H1N1p Influenza vaccine uptake and free vaccine, a difference persisted between Blacks and Whites (13.8% vs 20.4%); Whites and Hispanics had similar 2009-H1N1 vaccination rates.[6]

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[4] Double Jeopardy: COVID-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S. SAMHSA; 2020. https://www.samhsa.gov/sites/default/files/covid19-behavioral-health-disparities-black-latino-communities.pdf

[5] Malik, A.; McFadden, S.; Elharake, J.; Omer, S. Determinants of COVID-19 vaccine acceptance in the US. The Lancet; 2020. https://doi.org/10.1016/j.eclinm.2020.100495

[6] Uscher-Pines, L., Maurer, J., & Harris, K. M. (2011). Racial and ethnic disparities in uptake and location of vaccination for 2009-H1N1 and seasonal influenza. *American journal of public health*, *101*(7), 1252–1255. https://doi.org/10.2105/AJPH.2011.300133

- Vaccination coverage is significantly lower among non-Hispanic blacks, Hispanics, and non-Hispanic Asians compared with non-Hispanic whites adults for 6 vaccines, with only a few exceptions.[7]

Solution – Leverage Our Existing Distribution Infrastructure

- When the time comes, we can leverage our nation's existing vaccine distribution infrastructure to ensure efficient, effective, and equitable access to COVID-19 vaccines.
    - CDC has worked for decades with state, local and tribal health departments to develop plans for vaccine distribution and administration.
    - Each state can leverage this past preparedness work and refine their plans to ensure public health systems are prepared with trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a COVID vaccine program.
- Thanks to congressional support, state preparedness efforts for **anthrax and smallpox attacks** provides an additional framework that we can leverage for effective COVID vaccine distribution.
    - The mass prophylaxis protocols for anthrax and smallpox provide models of government-led vaccination targeted at rapidly protecting large segments of the population.
    - States have planned to receive countermeasures directly and then dispensed to the public, either directly to Points of Dispensing (PODs) or through intermediate receiving, staging, and storage (RSS) centers, which may be operated by state, county, or local agencies.
    - PODs can be administered by both public and private sector agencies and may provide useful models for the distribution of the COVID vaccine.
    - This includes for outbreaks of measles, mumps, and meningitis
- The **Vaccines for Children (VFC) program** can be and has been leveraged to provide federally purchased vaccines to children; adults who are uninsured or underinsured; and fully insured individuals during public health emergencies.
- During H1N1, we leveraged this infrastructure and partnerships between federal officials and their state and local counterparts to increase vaccine uptake.
    - Pandemic vaccine shipments finally hit their stride in December, reaching the 100 million-dose milestone by the middle of the month.
    - Sebelius, at a December 17 2009, press briefing, told reporters that partnerships between federal officials and their state and local counterparts would yield long-term

[7] Lu, P. J., O'Halloran, A., Williams, W. W., Lindley, M. C., Farrall, S., & Bridges, C. B. (2015). Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S. *American journal of preventive medicine*, *49*(6 Suppl 4), S412–S425. https://doi.org/10.1016/j.amepre.2015.03.005

benefits. "One of the key lessons we learned is you can't mount a public health response only from the beltway," she said.[8]

- States set up immunization clinics in nontraditional venues such as shopping malls, airports, subway stations, and sporting events.
- Also, 40 states used school-based vaccinations to some degree and the CDC reported that three of the four states that had the highest vaccine uptake were among those with school-based vaccine clinics.

- Additionally, the 2019 measles outbreak driven by 1) pockets of low vaccination coverage and variable vaccine acceptance; 2) relatively high population density and closed social nature of the affected community; and 3) repeated importations of measles cases among unvaccinated persons traveling internationally and returning to or visiting the affected communities. [9]
  - Robust responses in New York city and New York state leveraged multiple partners for their vaccination efforts, including administration of approximately 60,000 MMR vaccine doses in the affected communities; locally tailored communication campaigns; partnerships with religious leaders, local physicians, health centers, and advocacy groups; and use of local public health statutory authorities.
  - These combined efforts ended transmission before the 12-month elimination deadline.

Solution – Trust

- Getting trust and safety issues wrong with a COVID-19 vaccine could both jeopardize containment of COVID-19 and set the United States back for years or even decades when it comes to public acceptance of vaccines.
- To ensure the public adopts evidence-based prevention steps and to increase vaccine uptake, we must avoid the use of predictions in our messaging.
- Lessons learned from H1N1 and Measles reinforce that we need to under promise and over deliver and ensure we meet complex demands with rapidly evolving, fact-based messaging.
- Embrace clear, consistent, and fact-based messaging
- We also need to make sure we include appropriately targeted messaging to reach diverse populations, such as those disproportionately affected.

[8] Schnirring, L. H1N1 Lessons Learned: Vaccination campaign weathered rough road, paid dividends. CIDRAP; 2010. https://www.cidrap.umn.edu/news-perspective/2010/04/h1n1-lessons-learned-vaccination-campaign-weathered-rough-road-paid

[9] Patel, M., Lee, A. D., Clemmons, N. S., Redd, S. B., Poser, S., Blog, D., Zucker, J. R., Leung, J., Link-Gelles, R., Pham, H., Arciuolo, R. J., Rausch-Phung, E., Bankamp, B., Rota, P. A., Weinbaum, C. M., & Gastañaduy, P. A. (2019). National Update on Measles Cases and Outbreaks - United States, January 1-October 1, 2019. *MMWR. Morbidity and mortality weekly report*, *68*(40), 893–896. https://doi.org/10.15585/mmwr.mm6840e2

Solution – Efficient and Equitable Vaccine Distribution

- We cannot wait 3 months for distribution to pharmacies after the first orders like we did with the H1N1 vaccine.
- Couple free vaccine with reimbursed costs of administration.
- And since 660 million doses will not be immediately available, we must follow the National Academy of Medicine's four-phased approach[10] guided by evidence and criteria for equitable distribution.

Solution – Unified Planning and Priorities

- Drive informed and evidence-based development and execution of vaccine distribution plans.
- Planning efforts cannot be undertaken by a single individual, healthcare system, city, or state.
- We are currently seeing the siloed development of plans for hospitals, corporations, cities, and states all with different priorities and rationales, some of them in contradiction of the other, which will impact the success of our response.
- Instead, development of a locally tailored plan needs to include collaboration, expertise, and input from many partners within the community to be effective to include well documented priority groups and phases.

Solution – Data for Action

- We will need to scale up, test, assess upgrades, and ensure data linkages for:
    - HHS's Vaccine Tracking System (VTrckS)
    - Vaccine Administration Management System (VAMS)
    - Vaccine Adverse Event Reporting System
    - State Immunization Registries
- Supplement surveillance and administrative data with survey data

[10] Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine. NAP; 2020. https://www.nap.edu/read/25914/chapter/4#56

Conclusion

- Lives—and a normal way of life—are at stake.
- Right now, while we wait for the vaccine, we have the ability to implement an evidence-based playbook that will reduce the number of cases and deaths. This will require unified local, state, and federal leadership that is evidence based and uses metrics to:
    - Create a comprehensive testing, solitary isolation, and contract tracing program
    - Reinforce community engagement prevention practices like wearing a mask, handwashing, physical distancing, and avoiding crowds, and
    - Continue our exemplary efforts in reducing deaths of those who do get infected.
- Clear, Consistent, and Fact-Based Messaging can start today in conjunction with equitable vaccine distribution planning to ensure trust in an eventual safe and effective vaccine(s).
- With unified leadership at the federal level, the implementation of evidence-based practices, and funding, the federal government can heed the lessons from previous pandemics and other nations to conquer this pandemic and set the stage for a healthier future.

Thank you, Rep. DeGette and members. I will try to answer any questions you might have.