AFC COVID-19 GRAND ROUNDS
THANK YOU FOR JOINING THIS WEBINAR!
Maintaining Vaccine Confidence in Midst of Madness – and Despite the Politics

Mitchell Warren, Executive Director
26 October 2020
AIDS Foundation of Chicago Grand Rounds
Some Questions to Consider

1. Is one vaccine enough?
2. How is vaccine development going so fast?
3. But is it safe?
4. When might we really have a vaccine?
5. Can I trust the process?
6. If we build it, will they come?
7. Will the first one be the best one?
8. Who should get the vaccine? And who decides?
9. Is a vaccine is sufficient to end the pandemic?
AVAC’s involvement in the COVID response

AVAC synthesizes complex information to develop and implement smart, actionable and adaptable agendas for biomedical prevention and product introduction, which are crucial for a meaningful and measurable impact on the COVID response.

Learn more at: https://www.avac.org/covid

Inform key audiences, including advocates, the media, and policymakers on intersections between COVID and HIV, including the impact of COVID on HIV research, to strengthen our advocacy

Engage with key audiences, including CSOs, policymakers, funders, and developers to ensure ethical and informed conduct of COVID research – including the co-convening of the COVID Advocates Advisory Board

Advocate to demand equity and access to prevention and treatment tools for both COVID and HIV AND ensure that hard-won gains in the HIV/AIDS field are not lost
How Fast? Too Fast?

How Fast? Too Fast?

Speed is important…
but not at the expense of ethics,
safety, robust engagement,
equitable access, and scientific
rigor including independent peer
and regulatory review.

Leveraging HIV Vaccine for COVID-19
Who’s Who?

**US Effort**

*Operation Warp Speed (OWS):* USG body responsible for strategic approach, coordination and resource allocation

*ACTIV:* NIH established public-private partnership for coordinating COVID-19 response

*COVPN:* NIH funded networks being utilized for COVID-19 Phase 3 trial design and execution

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**Global Effort**

**ACT-A:** Global collaboration to accelerate development, production and equitable access to new diagnostics, therapeutics and vaccines

- **Vaccines:** COVAX Facility (GAVI, CEPI, WHO)
- **Diagnostics:** FIND, Global Fund
- **Treatment:** Unitaid, Wellcome Trust
- **Health Systems Strengthening:** World Bank, Global Fund

**CEPI:** Global partnership to accelerate development of vaccines against emerging infectious diseases and enable equitable access

**GAVI:** Global vaccine alliance with goal of creating equal access to new and underused vaccines

**CONCVACT:** Africa Centres for Disease Control and Prevention Consortium for COVID-19 Vaccine Clinical Trials
## COVID Vaccine Pipeline

<table>
<thead>
<tr>
<th>Sanofi*</th>
<th>J&amp;J*</th>
<th>Pfizer</th>
<th>Moderna*</th>
<th>AZ/Oxford*</th>
<th>Novavax</th>
<th>Inovio</th>
<th>Merck</th>
<th>Clover Bio-pharm</th>
<th>U. of Queensland</th>
<th>CureVac</th>
<th>U of Hong Kong</th>
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<td>China</td>
<td>Australia</td>
<td>Germany</td>
<td>China</td>
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<td>mRNA</td>
<td>mRNA</td>
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<td>Protein</td>
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<td>Ph3</td>
<td>Ph 2/3</td>
<td>Ph 3</td>
<td>Ph 3</td>
<td>Ph 2</td>
<td>Ph1</td>
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<td>Ph1</td>
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<td>CEPI 750M</td>
<td>EU 923M</td>
<td>CEPI 388M</td>
<td>US 17.3M</td>
<td>EU 5M</td>
<td>US 38M</td>
<td>CEPI 620K</td>
<td>CEPI 10.6M</td>
<td>CEPI 8.3M</td>
<td>CEPI 421M</td>
<td>COVAX Portfolio</td>
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<td>CEPI 8.3M</td>
<td>CEPI 421M</td>
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*Overlapping USG and COVAC investments

**USG Funding**  
*Operation Warp Speed Finalist*  

**COVAX Portfolio**
The Race to Efficacy Data

Experts estimate that in each trial, ~150 infections will be required to demonstrate 60% efficacy with statistical significance. Speed of enrollment and rate of infection will determine when efficacy data will be available.

<table>
<thead>
<tr>
<th>Company</th>
<th>Enrollment Period</th>
<th>Start Date</th>
<th>Countries</th>
<th>Follow-Up Period</th>
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<tbody>
<tr>
<td>Oxford/AZ - 2B</td>
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<tr>
<td>Oxford/AZ - 2B</td>
<td>2K, Brazil</td>
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<tr>
<td>Pfizer - 3</td>
<td>44K, US, Brazil, Germany, Argentina</td>
<td>started 27 July 2020</td>
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<tr>
<td>Moderna - 3</td>
<td>30K, US</td>
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<td>Novavax - 2B</td>
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<td>Novavax - 3</td>
<td>9K, UK</td>
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<tr>
<td>Oxford/AZ - 3</td>
<td>30K, US</td>
<td>started 1 Sept 2020</td>
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<tr>
<td>J &amp; J - 3</td>
<td>60K, US, SA, Argentina, Brazil, Chile, Colombia, Mexico, Peru, Ukraine</td>
<td>started 23 Sep 2020</td>
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<tr>
<td>INOVIO – 2B</td>
<td>Planned</td>
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<tr>
<td>CureVac- 2b/3</td>
<td>Planned 30K</td>
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<tr>
<td>Novavax - 3</td>
<td>Planned 30K, US+</td>
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<tr>
<td>Sanofi - 3</td>
<td>Planned 40K US+</td>
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Bold color is proposed enrollment period; shaded color is estimated follow-up period.
For every 100 doses of vaccines pre-purchased, 84 have been reserved by high income countries.

3.82 Billion doses reserved
Key Messages

• No vaccine should be approved for use until safety and efficacy have been proven in populations at significant risk of COVID-19

• US FDA review should involve the Vaccines and Related Biologics Product Approval Committee (VRBPAC) to allow unbiased, external experts to evaluate safety and efficacy

• When results are announced, comprehensive data-sets should be made publicly available for peer review. Publication via press release or political podiums is not scientifically rigorous, promotes mistrust and fuels public concerns around the politicization of science
What Can We Do?

- Promote the GPP Principles in research
- Insist on high-quality community engagement
- Ensure that affected communities lead
- Resist the politicization of science
- Help to rebuild public faith in vaccines, science, research
- Advocate for a comprehensive, integrated, sustained response – prevention, treatment and research

Sound familiar?
Some Questions to Consider

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Key Resources

- *Science, Not Politics, Must Lead to COVID Vaccine Approvals*
- *Go As Fast As You Can – But Always Follow the Science*
- COVID Vaccine Overview/Cheat Sheet on Platforms and Products
- *Advocates Guide to the risks, benefits, and potential opportunities and complications of expedited COVID vaccine research*
- *Regulatory Approval Primer for Vaccine Advocates*
- *New York Times Coronavirus Vaccine Tracker*
- COVID-19 Pipeline
- COVID Mythbusters
- COVID Resources
- More resources at [https://www.avac.org/covid](https://www.avac.org/covid)