Progress on COVID-19 candidate vaccines &
country readiness and planning for COVID-19
vaccination

Alba Vilajeliu, MD, MPH, PhD
Comprehensive Family Immunization Unit. Department of Family, Health Promotion and Life
Course. PAHO Regional Office.

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Outline

1. Progress on COVID-19 candidate vaccines
2. Country readiness and planning for COVID-19 vaccination
3. Conclusions
## Landscape COVID-19 Candidate Vaccines

<table>
<thead>
<tr>
<th>Source</th>
<th>Total</th>
<th>Preclinical evaluation</th>
<th>Clinical Evaluation</th>
<th>Regulatory Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="https://www.who.int">World Health Organization</a></td>
<td>182 Candidates (17 Sep 2020)</td>
<td>146</td>
<td>14</td>
<td>13(^a)</td>
</tr>
</tbody>
</table>

- **Clinical trials** plan to:
  - Enroll 280,000 participants
  - 470 clinical trial sites
  - 34 countries participating

- **Timeframe:**
  - For the leading candidates: data to support licensure are expected by the end of 2020 and large-scale manufacturing has already been initiated to enable rapid distribution if approval is obtained.

<table>
<thead>
<tr>
<th>Vaccine developer/manufacturer</th>
<th>Vaccine platform</th>
<th>Name of vaccine candidate</th>
<th>Number of doses and timing</th>
<th>Route of administration</th>
<th>Sample size, age</th>
<th>Location clinical trial</th>
<th>Status</th>
<th>Estimated Primary completion date</th>
<th>Supported by CEPI</th>
<th>Registry number</th>
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</thead>
<tbody>
<tr>
<td>AstraZeneca/Oxford University</td>
<td>Non-replicating</td>
<td>AZD1222</td>
<td>1 dose</td>
<td>IM</td>
<td>2,000, ≥18 - 55 years</td>
<td>UK, Brazil</td>
<td>Recruiting</td>
<td>31/10/2021</td>
<td>x</td>
<td>ISRCTN89951424</td>
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<tr>
<td></td>
<td>viral vector</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2 doses (0, 28 days)</td>
<td>IM</td>
<td>30,000, ≥18 years</td>
<td>US. Other*: South Africa, India, Bangladesh</td>
<td>Recruiting</td>
<td>2/12/2020</td>
<td></td>
<td>NCT04516746</td>
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<td></td>
<td>2 doses (0, 28 days)</td>
<td>IM</td>
<td>100, ≥18 years</td>
<td>Russia</td>
<td>Not yet recruiting</td>
<td>05/05/21</td>
<td></td>
<td>NCT04540393</td>
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<tr>
<td>CanSino Biological Inc./Beijing</td>
<td>Non-replicating</td>
<td>Ad5-nCoV</td>
<td>1 dose</td>
<td>IM</td>
<td>40,000, ≥18 years</td>
<td>Pakistan</td>
<td>Not yet recruiting</td>
<td>30/12/21</td>
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<td>NCT04526990</td>
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<tr>
<td>Institute of Biotechnology</td>
<td>viral vector</td>
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<tr>
<td>Gamaleya Research Institute</td>
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<td>Gam-COVID-Vac</td>
<td>2 doses (0,21 days)</td>
<td>IM</td>
<td>40,000, ≥18 years</td>
<td>Russia. Other*: Kazakhstan, Belarus, Brazil, Mexico.</td>
<td>Recruiting</td>
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<td>Janssen Pharmaceutical Companies</td>
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<td>Ad26.COV2.S1</td>
<td>1 dose</td>
<td>IM</td>
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<td>Brazil, Chile, Colombia, Mexico, Peru, Philippines, South Africa, Ukraine, US</td>
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<td>CoronaVac</td>
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<td>Brazil</td>
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<td>30/09/21</td>
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<td>1,620, ≥18 – 59 years</td>
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<td>Indonesia. Other*: China, Bangladesh, Chile, Indonesia, Turkey.</td>
<td>Recruiting</td>
<td>C/2020</td>
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<td>NCT04456595</td>
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<tr>
<td>Wuhan Institute of Biological</td>
<td>Inactivated</td>
<td>CNBG Wuhan</td>
<td>2 doses (0, 14 days or 0,</td>
<td>IM</td>
<td>15,000, ≥ 18 years</td>
<td>United Arab Emirates. Other*: China, Morocco.</td>
<td>Recruiting</td>
<td>15/07/21</td>
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<tr>
<td>Products/Sinopharm</td>
<td></td>
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<td>21 days)</td>
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<td></td>
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<tr>
<td>Beijing Institute of Biological</td>
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<td>BBIBP - CorV</td>
<td>2 doses (0, 14 days or 0,</td>
<td>IM</td>
<td>15,000, ≥ 18 years</td>
<td>United Arab Emirates.</td>
<td>Recruiting</td>
<td>15/07/21</td>
<td></td>
<td>ChiCTR20000034</td>
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<td></td>
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<td>780</td>
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<tr>
<td>Moderna/NIAID</td>
<td>RNA</td>
<td>mRNA-1273</td>
<td>2 doses (0, 28 days)</td>
<td>IM</td>
<td>30,000, ≥ 18 years</td>
<td>US</td>
<td>Recruiting</td>
<td>27/10/22</td>
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<td>BioNTech/Fosun Pharma/Pfizer</td>
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<td>BNT162b</td>
<td>2 doses (0, 28 days)</td>
<td>IM</td>
<td>29,481, ≥ 18-85 years</td>
<td>Argentina, Brazil, Turkey, US. Other*: Chile, Germany, China.</td>
<td>Recruiting</td>
<td>19/04/21</td>
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</table>

Note: *current/upcoming trials.
Although COVID-19 Vaccine Candidates Have Progressed to Advanced Stages at Exceptional Speed, Many Uncertainties Remain

Which candidate (s) will be successful
Vaccine supply availability
Priority groups for vaccination within countries
Number of doses & schedule
Cold chain requirements
Monodose / multidose presentation
Administration route
Vaccine efficacy
Duration of protection
Coadministration with other existing vaccines
Best vaccine delivery strategies

WHO has released a target product profile for COVID-19 vaccines
1. Progress on COVID-19 candidate vaccines

2. Country readiness and planning for COVID-19 vaccination
   I. Equitable access: COVAX Facility
   II. Allocation framework for COVID-19 vaccines
   III. Immunization policy recommendations
   IV. Planning for implementation
   V. Guidelines and tools

3. Conclusions
Equitable Access: COVAX Facility

- The ACT-Accelerator (ACT-A) (global collaboration) has a Vaccines pillar
- COVAX Facility is a mechanism open to every country, through which they can equitably access COVID-19 as quickly as possible
- COVAX Facility enables countries to share risk of vaccine development and have early access to effective vaccines
- COVAX Facility has the largest and most diverse portfolio of COVID-19 candidate vaccines in the world
  - 9 vaccines in the portfolio, discussions are ongoing with other producers
  - Aiming for 2 billion vaccine doses by the end of 2021
- PAHO Revolving Fund contributed to designing the COVAX Facility and is recognized as a unified bloc (representing 39 countries of the Region) and as a purchase mechanism

Draft for Equitable Allocation Framework for COVID-19 Vaccines

1. Goal
   - Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

2. Priorities
   - Health and social care workers
     - All participant countries receive doses to cover 3% of their population.
       This would be enough to cover all workers involved in health and social care work.
     - All participant countries receive additional doses beyond 3% to total 20% of their population (in tranches).
       This could include the elderly, adults with comorbidities or others depending on locally relevant risk factors
   - Further priority groups
     - Participant countries receive doses to cover more than 20% of their population.
       This would cover additional priority populations.

3. Timing
   - Participant countries receive doses proportionally to their total population
   - If protracted severe supply constraints remain, timing is based on participants’ vulnerability and COVID-19 threat

A buffer will also be set aside for emergency deployment based on immediate needs
Steps Towards COVID-19 Immunization Policy Recommendations

- **Offers guidance:**
  - **globally** on the allocation of COVID-19 vaccines between countries
  - **nationally** on the prioritization of groups for vaccination within the countries while supply is limited

- **6 core principles & 12 objectives**

- **Needs to be complemented with:**
  - Information about specific characteristics of available vaccine or vaccines
  - Benefit risk-assessment of different population groups
  - Amount and pace of vaccine supply
  - Current states of epidemiology, clinical management, and economic and social impact of the pandemic

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**STEP 1**

SAGE will provide guidance on prioritization of target populations (not product specific) under supply constrained situations (October 2020 meeting)

**STEP 2**

SAGE will provide policy recommendations on the use of COVID-19 vaccines once registered (product specific, depending by when results of Phase 3 and regulatory approval obtained)

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**PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases and NITAGs will adapt recommendations to regional and national context**

Some Considerations for Getting Ready for Implementation

- **Planning & Coordination**
  - Develop or update national deployment and vaccination plan
  - Intersectoral approach

- **Immunization policies**
  - Ensure NITAG engagement
  - Leverage surveillance data to identify COVID-19 high-risk populations and inform evidence-based immunization policies

- **Service Delivery**
  - Leverage exiting structures/systems/strategies for vaccination of adults (e.g. influenza vaccination)
  - Consider PPE needs

- **Training & supervision**
  - Consider innovative and e-learning training approaches (social distance measures)

- **Surveillance & M&E**
  - Define sources to estimate denominators for health workers, elderly, and adults with underlying health conditions and potential of vaccination scenarios
  - Strengthen information systems to monitor and report vaccination coverage and to assess vaccine effectiveness

- **Vaccine logistics & cold chain**
  - Assess cold chain capacities and sort out inventory of equipment

- **Safety surveillance**
  - Strengthen AEFI surveillance and participate in regional networks for vaccine safety surveillance

- **Advocacy, mobilization & Comms**
  - Engage communities, local leaders, and civil stakeholders 1) to mobilize community support for and involvement in vaccination campaigns before a vaccine is available and 2) to address misinformation/infodemic
  - Estimate budget needs by component
For More Information / Tools

- **PAHO Guidelines to Plan for COVID-19 Vaccine Introduction**
  - Version 1. 10 July 2020.

- **WHO COVID-19 Vaccine Country Readiness Assessment Tool**
  - Under development

- **PAHO Frequently Asked Questions (FAQ) COVID-19 Candidate Vaccines & Access Mechanisms**

- **Survey tool and guidance. Rapid, simple, flexible behavioral insights on COVID-19**
  - [Link](https://www.paho.org/es/documentos/orientacion-herramienta-para-hacer-encuestas)
Conclusions

• In the context of a pandemic: speed is essential, from vaccine development to reaching the target populations

• Despite the uncertainties, time to start planning and getting ready for COVID-19 vaccine deployment:
  ➔ Developing national deployment and vaccination plans, engaging NITAGs*
  ➔ Engaging relevant stakeholders (intersectoral approach) at all levels*
  ➔ Planning how to leverage existing platforms and systems for adult vaccination (e.g. influenza immunization program)*
  ➔ Given that national immunization programs are the foundation for the introduction of COVID-19 vaccine, strengthening*:
     1) surveillance/information systems
     2) supply and cold chain
     3) vaccine safety surveillance
  ➔ Early community engagement is critical for demand generation*

*Recommendations of PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases, August 2020.
THANK YOU!