COVID-19 vaccination

FOR SAGE DECISION ON 5th JANUARY 2021

Progress update and for decision

Recommendation on the first mRNA vaccine
BNT162b2
1) **Values framework** on principles and objectives and target populations – **DONE 14th September 2020**

2) **Roadmap for prioritizing** target populations under different epidemiological and supply scenarios – **DONE 5-7 October 2020**

3) **Vaccination recommendations** once products have been licensed (or authorized under emergency use) – **NOW**
   
   = iterative, product specific and may be significantly impacted by regulatory regime, EUL vs. full licensure
Outline of the 5 Jan 2021 SAGE session on Covid-19 vaccines

Introduction, session objective setting, update on regulatory decisions and overview of Working Group deliverables. H. NOHYNEK SAGE 15 min

Vaccine safety and efficacy data emerging from Pfizer-BioNTech mRNA COVID-19 vaccine clinical trials (phase 1-3 trial results). Risk management plans and other implementation considerations COMPANY PRESENTATION 30 min

Safety monitoring. S. PAL, WHO 10 min

Questions 30 min

BioBreak for 10 min

Assessment of Evidence (SAGE working group) 30 min

Presentation of draft recommendations. H. NOHYNEK, SAGE 20 min

Discussion 1h
Introduction to the session 1

Update on vaccine pipeline, vaccine registration status, vaccine introduction status, population prioritization roadmap, observed virus variants.
COVID-19 vaccines development landscape
Situation as of 4 January 2020, total 291 candidate vaccines of which 68 in clinical trials, 4 licensed by stringent regulatory authorities

https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
Route and dosing of covid-19 vaccine candidates

4. - Dosage, schedule and route of administration of candidates in clinical phase

<table>
<thead>
<tr>
<th>Dosage &amp; schedule</th>
<th>Candidate vaccines (no. and %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose</td>
<td>10</td>
</tr>
<tr>
<td>Day 0</td>
<td>10</td>
</tr>
<tr>
<td>2 doses</td>
<td>37</td>
</tr>
<tr>
<td>Day 0 + 14</td>
<td>5</td>
</tr>
<tr>
<td>Day 0 + 21</td>
<td>14</td>
</tr>
<tr>
<td>Day 0 + 28</td>
<td>18</td>
</tr>
<tr>
<td>3 doses</td>
<td>1</td>
</tr>
<tr>
<td>Day 0 + 28 + 56</td>
<td>1</td>
</tr>
<tr>
<td>TBD / No Data (ND)</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>Injectable</td>
</tr>
<tr>
<td>SC, Sub cutaneous</td>
</tr>
<tr>
<td>ID, Intra dermal</td>
</tr>
<tr>
<td>IM, Intra muscular</td>
</tr>
<tr>
<td>TBD / No Data (ND)</td>
</tr>
</tbody>
</table>

- Day 0: 17 %
- Day 0 + 28: 30 %
- Day 0 + 28 + 56: 2 %
- Day 0 + 14: 8 %
- TBD / No Data (ND): 23 %
Where are the covid-19 vaccine trials taking place?
# Regulatory timeline of key phase III vaccine candidates

Estimated approval dates (includes restricted, emergency and conditional authorizations)

<table>
<thead>
<tr>
<th>Vx candidates</th>
<th>FDA</th>
<th>EMA</th>
<th>MHRA</th>
<th>WHO EUL/PQ</th>
<th>Other NRA's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Biontech</td>
<td>11 Dec. 20</td>
<td>18 Dec. 20</td>
<td>2 Dec. 20</td>
<td>End of Dec. 2020</td>
<td>Several</td>
</tr>
<tr>
<td>Moderna</td>
<td>18 Dec 20</td>
<td>7 Jan 21</td>
<td>No info</td>
<td>Jan. 2021</td>
<td>Several</td>
</tr>
<tr>
<td>AstraZeneca / Oxford</td>
<td>April 21</td>
<td>Feb. 21</td>
<td>30 Dec 20</td>
<td>Between March and June 21</td>
<td>India (SII product)</td>
</tr>
<tr>
<td>Sinopharm / WIBP</td>
<td>No FDA approval</td>
<td>No EMA approval</td>
<td>No info</td>
<td>End February 21 earliest</td>
<td>No information</td>
</tr>
<tr>
<td>Sinopharm / BIBD</td>
<td>No info</td>
<td>No info</td>
<td>No info</td>
<td>No approach to PQ</td>
<td>No information</td>
</tr>
<tr>
<td>Sinopharm / CanSinoBIO</td>
<td>No info</td>
<td>No info</td>
<td>No info</td>
<td>To be confirmed</td>
<td>No information</td>
</tr>
<tr>
<td>Gamaleya Institute of Epidemiology and Microbiology</td>
<td>No info</td>
<td>No info</td>
<td>No info</td>
<td>End February 21 earliest</td>
<td>China, UAE</td>
</tr>
<tr>
<td>Janssen Infectious Diseases &amp; Vaccines</td>
<td>No info</td>
<td>No info</td>
<td>No info</td>
<td>March 21</td>
<td>No information</td>
</tr>
<tr>
<td>No info</td>
<td>No info</td>
<td>No info</td>
<td>To be confirmed</td>
<td>June 21</td>
<td></td>
</tr>
</tbody>
</table>

1. Wuhan Institute of Biological Products Co Ltd
2. Beijing Institute of Biological Products Co-Ltd
COVID-19 vaccination doses administered per 100 people, Jan 4, 2021

Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

Source: Official data collated by Our World in Data. Dates refer to when the data was reported.  
OurWorldInData.org/covid-vaccinations • CC BY
COVID-19 vaccination doses administered per 100 people, Jan 4, 2021

Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

<table>
<thead>
<tr>
<th>Country</th>
<th>Dose administered per 100 people</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Israel</td>
<td>14.14</td>
<td>Jan 3, 2021</td>
</tr>
<tr>
<td>Bahrain</td>
<td>3.57</td>
<td>Jan 3, 2021</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1.39</td>
<td>Dec 27, 2020</td>
</tr>
<tr>
<td>United States</td>
<td>1.28</td>
<td>Jan 2, 2021</td>
</tr>
<tr>
<td>Denmark</td>
<td>0.81</td>
<td>Jan 3, 2021</td>
</tr>
<tr>
<td>Russia</td>
<td>0.55</td>
<td>Jan 2, 2021</td>
</tr>
<tr>
<td>Germany</td>
<td>0.32</td>
<td>Jan 3, 2021</td>
</tr>
<tr>
<td>Canada</td>
<td>0.31</td>
<td>Jan 3, 2021</td>
</tr>
<tr>
<td>China</td>
<td>0.31</td>
<td>Dec 31, 2020</td>
</tr>
<tr>
<td>Italy</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Croatia</td>
<td>0.19</td>
<td>Dec 30, 2020</td>
</tr>
<tr>
<td>Spain</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>World</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>0.07</td>
<td>Dec 31, 2020</td>
</tr>
<tr>
<td>Mexico</td>
<td>0.02</td>
<td>Dec 30, 2020</td>
</tr>
<tr>
<td>France</td>
<td>0</td>
<td>Jan 1, 2021</td>
</tr>
</tbody>
</table>

Source: Official data collated by Our World in Data. Dates refer to when the data was reported. OurWorldInData.org/covid-vaccinations • CC BY
# COVAX Facility Portfolio – Expected supply timelines

<table>
<thead>
<tr>
<th>Vaccine candidates</th>
<th>Q1 2021</th>
<th>Q2 2021</th>
<th>Q3 2021</th>
<th>Q4 2021</th>
<th>Q1 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td></td>
<td></td>
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<tr>
<td>Novavax</td>
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<tr>
<td>Sanofi</td>
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<tr>
<td>Candidate 1</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Candidate 2</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Other Candidates</td>
<td></td>
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</tbody>
</table>

- **Expected regulatory & WHO PQ timeframe**
- **Expected supply timeframe**

HIGHLY PRELIMINARY - AS OF JAN 4
Country readiness and delivery – technical resources

Guidance and Tools
• VIRAT 2.0 and CRD Country Readiness Core Indicator Dashboard
• Operational Guidance on National Vaccine Deployment Plans
• Vaccine introduction costing tool
• Field guide to misinformation management
• Country level monitoring guidance
• Detailed supply & logistics guide
• WHO’s Maintaining essential health services: operational guidance for the COVID-19 context (June 1 update)

Trainings
• Training packages for health workers and national stakeholders
• Designed with end-users in mind (modular virtual and in-person training)
• Leverage existing e-learning platforms: Agora.unicef.org and openwho.org
Guidance on Developing a National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines

- Published on Nov. 16th on the WHO website [here](https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1)

- Built upon existing documents incl. recommendations from the WHO Strategic Advisory Group of Experts (SAGE)

- Includes a suggested template for development of the NDVP

- Will be updated as new information becomes available

Summary of SARS-CoV-2 virus mutations

- Variants identified in UK and South Africa highlight the importance of sequencing of SARS-CoV-2 and sharing of sequence data internationally.

- As all viruses mutate, sequencing will identify a number of mutations; some more common than others. Many mutations have no impact on the virus itself; some may be detrimental to the virus; few may result in an advantage to the virus.

- In order to determine their impact on transmission or vaccines, experiments need to be done with live virus in advanced laboratories. This takes time from weeks to several months; ongoing in UK and South Africa. Also vaccine manufacturers are working on understanding the potential impact on VE.

- WHO and partners are working with a group of international scientists, including the WHO Virus Evolution Working Group, from all over the world to coordinate such research efforts and assess the risk of select mutations on transmission, diagnostics and vaccines. For the moment there is no evidence that monoclonal antibodies or vaccines will not work on the variant strain in the UK.
The outputs from the SAGE COVID-19 working group so far

- Compendium of Critical Questions
- Values Framework
- Prioritization Roadmap
- Vaccine-specific recommendations based on Evidence Framework
- Modeling
- Additional considerations (e.g. current epidemiology)
- Background paper with COVID-19 generic considerations
- Background paper with vaccine-specific considerations
- Interim recommendations for use (product/platform specific)
- Evidence to Recommendations & grading tables
Links to documentation

www.who.int/publications/m/item/critical-evidence-questions-for-covid-19-vaccines-policy-making


www.who.int/immunization/sage/meetings/2020/october/SAGE_eYB_Oct2020final.pdf?ua=1
Acknowledgements

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Peter Figueroa
Adam Finn
Gagandeep Kang
David Kaslow
Ziad Memish
Saad B. Omer
Helen Rees
Christopher Morgan

WHO Secretariat
Annelies Wilder-Smith
Joachim Hombach
Melanie Marti

SAGE Chair
Alejandro Cravioto
Backups
WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020

Executive Summary

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisors at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. This document has been endorsed by the Strategic Advisory Group of Experts on Immunization (SAGE).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing groups for vaccination within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccines or vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, and economic and social impact of the pandemic. Hence, the final vaccination strategy will be defined by the characteristics of vaccine products as they become available.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. The first stage of this process was the identification of populations and sub-populations which would be appropriate target groups for prioritization under the various values-based objectives in the Framework (Table 2), before data on Phase 3 vaccine performance are not yet available. Specific priority group recommendations for specific vaccines will be made as vaccine products become authorized for use; initial vaccine specific policy recommendations are expected in the final quarter of 2020 or early 2021, depending on timing of and findings from phase 3 vaccine trials.

The Framework also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

Roadmap towards prioritization of target populations:

To support country planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability in different epidemiologic settings.

Key assumptions:

- Vaccines are licensed and meet all minimum criteria of WHO TPP;
- Vaccines have at least minimal level efficacy in older age groups; idem for other subpopulations;
- NPI continue to be used;
- Vaccine effect on transmission less relevant for early scenarios, but information becomes available at some point;
- No account has been taken of seroprevalence and the possible degree of population protection already established.

<table>
<thead>
<tr>
<th>Vaccine Effect</th>
<th>Community Transmission</th>
<th>Cluster of Cases/Sporadic Transmission</th>
<th>No Cases, Risk of Importation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Limited Supply (1-10%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited Supply (11-20%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate Supply (21-50%)</td>
<td></td>
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</tbody>
</table>

Contextualized and targeted public health strategies.
## Vaccine policy - Priority groups for COVID-19 vaccination

**Stage I: very limited**
(for 1-10% national population)
- Health workers at high to very high risk of acquiring and transmitting infection

**Stage II: limited**
(for 11-20% national population)
- Older adults (not covered in Stage Ib)
- Individuals with co-morbidities or health status determined to be at significantly higher risk of severe disease or death
- Socio-demographic groups at significantly higher risk of severe disease or death
- Health workers engaged in immunization delivery
- High-priority teachers and school staff

**Stage III: moderate**
(for 21-50% national population)
- Remaining teachers and school staff
- Other essential workers outside health and education
- Pregnant women
- Health workers at low to moderate risk of acquiring and transmitting infection
- Personnel needed for vaccine production and other high-risk laboratory staff
- Social/employment groups at elevated risk of acquiring and transmitting infection (unfortunately unable to maintain physically distance)

*Endorsed by SAGE, published on 19 October 2020*