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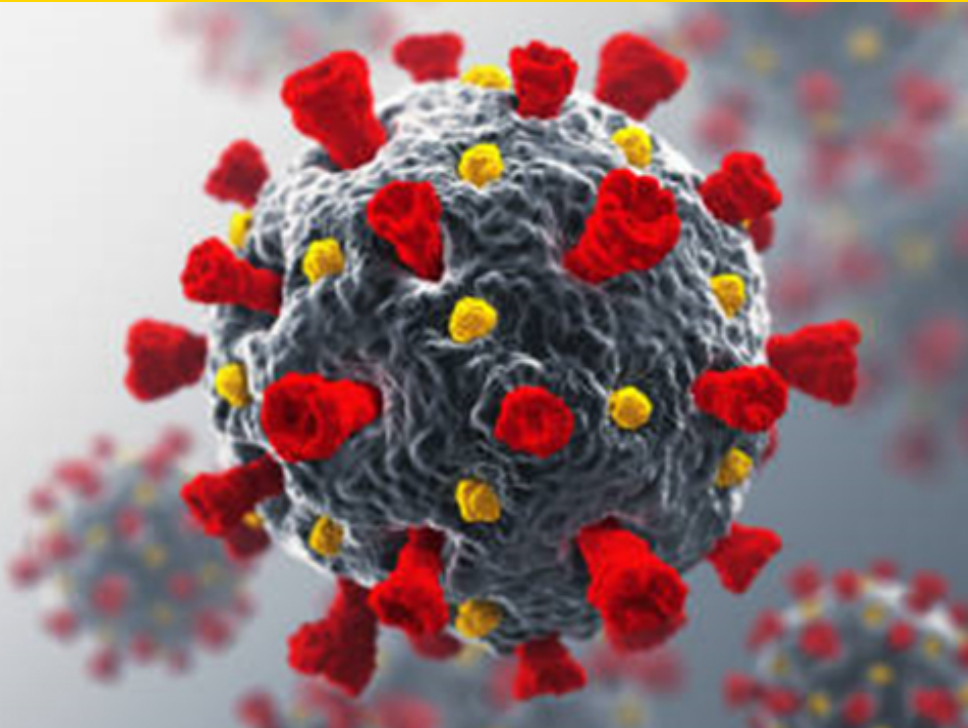
CORONAVIRUS Vaccines Update



Kathleen Neuzil, MD, MPH

November 10, 2020

UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR VACCINE DEVELOPMENT
AND GLOBAL HEALTH

Outline

- **The Complexity of Vaccine Development**
- **Vaccines for SARS-CoV-2**
  - U.S. approach
  - International considerations

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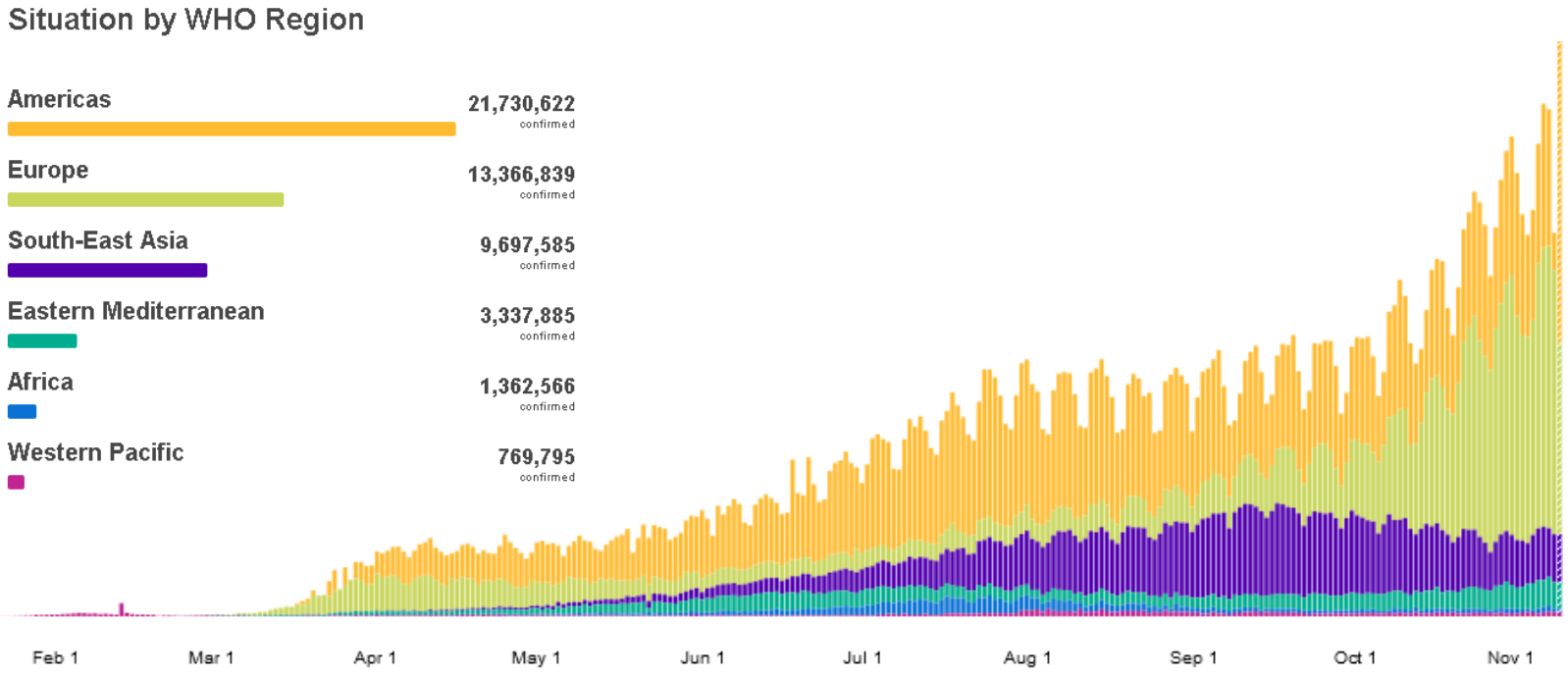
COVID Cases, Globally, November 9, 2020
50 million+ cases and 1.2 million+ deaths



https:covid19.who.int

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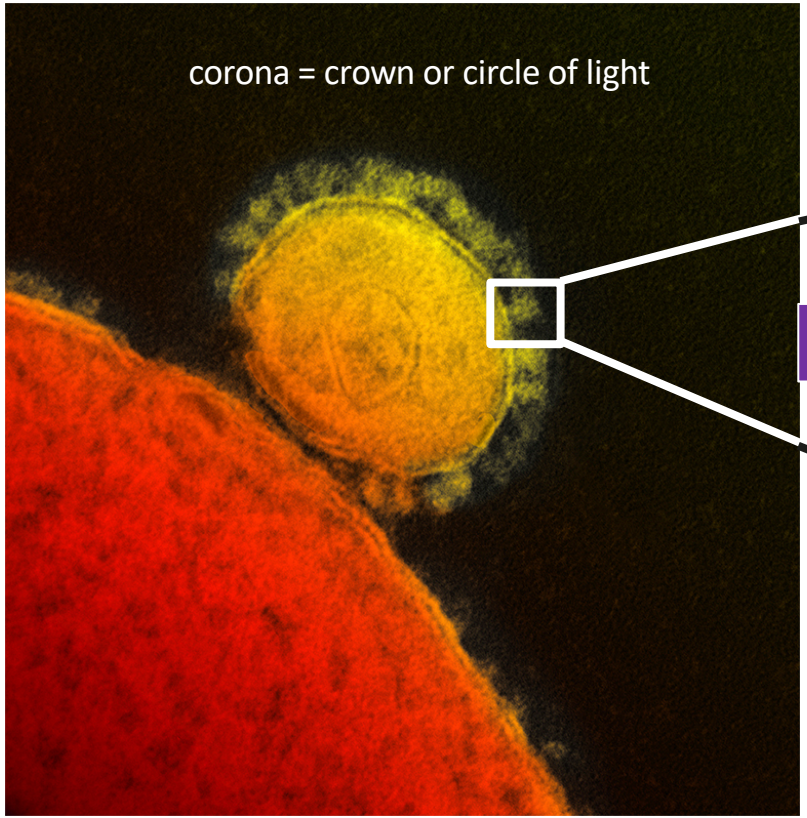
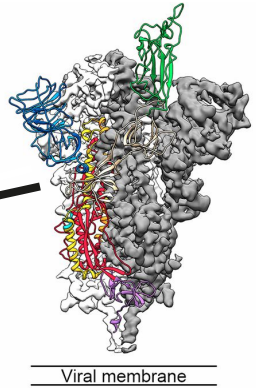
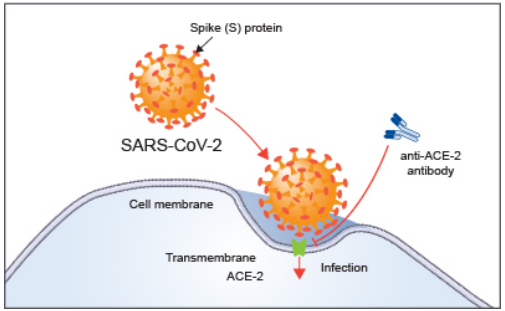
SARS-CoV-2 Spike Protein: Viral Entry



Spike Protein





Wrapp D, Wang N, Corbett KS, Goldsmith JA, Hsieh CL, Abiona O, Graham BS, McLellan JS. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science. 2020 Feb 19:eabb2507. doi: 10.1126/science.abb2507.

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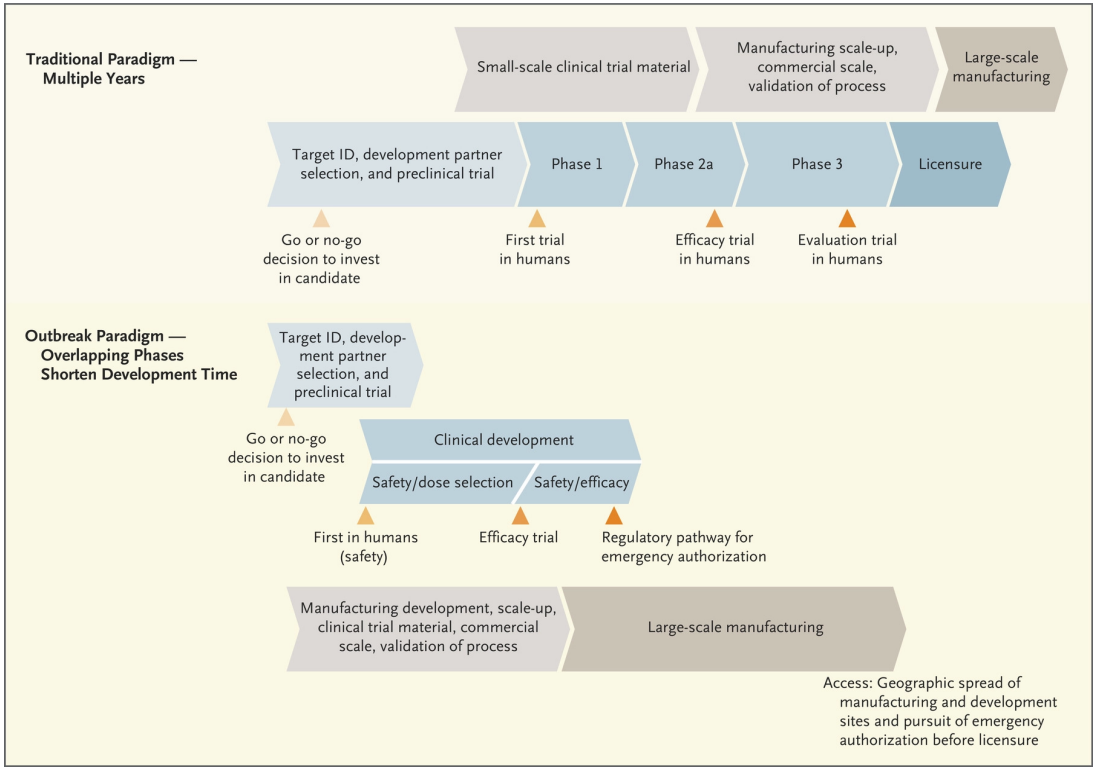
Vaccine Development:
A Lengthy, Risky and Expensive Process



15-20 years

12-18 months

Science
Resources
Assume success

N Engl J Med 2020; 382:1969-1973 **DOI: 10.1056/NEJMp2005630**

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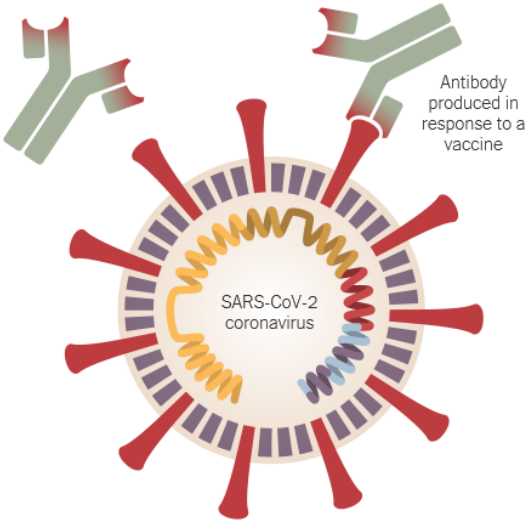

Coronavirus Vaccine Tracker

By Jonathan Corum, Sui-Lee Wee and Carl Zimmer Updated November 9, 2020

WORLD COUNTRIES | U.S.A. STATES COLLEGES

PHASE 1	PHASE 2	PHASE 3	LIMITED	APPROVED
38	14	11	6	0
Vaccines testing safety and dosage	Vaccines in expanded safety trials	Vaccines in large-scale efficacy tests	Vaccines approved for early or limited use	Vaccines approved for full use

https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

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Vaccine Platforms and Attributes

	Single Dose	Licensed Platform	Speed	Scale
DNA	No	No	Fast	Medium
RNA	No	No	Fast	Low to medium
Nonreplicating vector	Maybe	No	Medium	High
Replicating viral vector	Maybe	Yes	Medium	High
Protein-based	No	Yes	Medium	High
Inactivated	No	Yes	Medium	Medium to high
Live attenuated	Yes	Yes	Slow	High

Partially adapted from: N Engl J Med 2020; 382:1969-1973 DOI: 10.1056/NEJMp2005630

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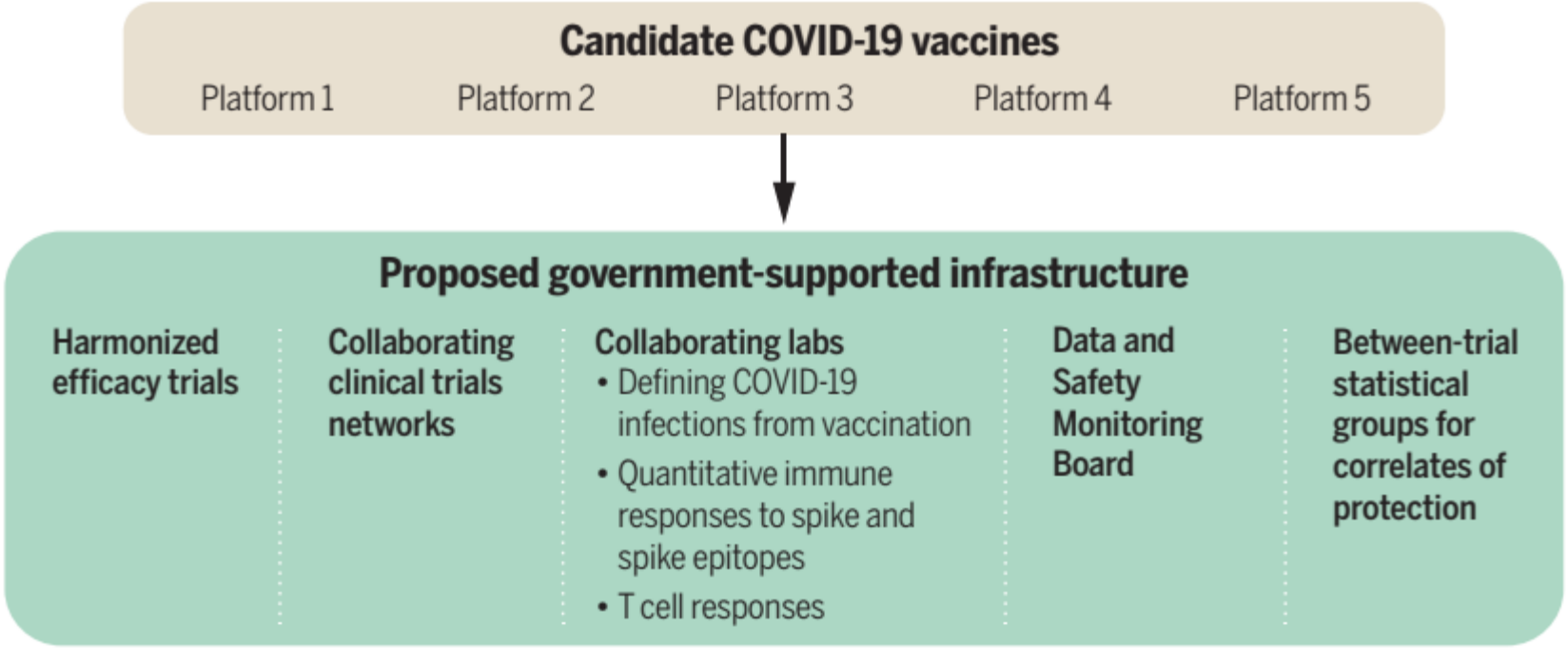
The ACTIV Model for SARS-CoV-2 Vaccine Development



http://science.sciencemag.org/ on June 1, 2020

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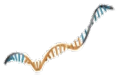
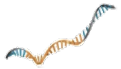
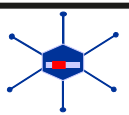
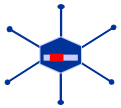
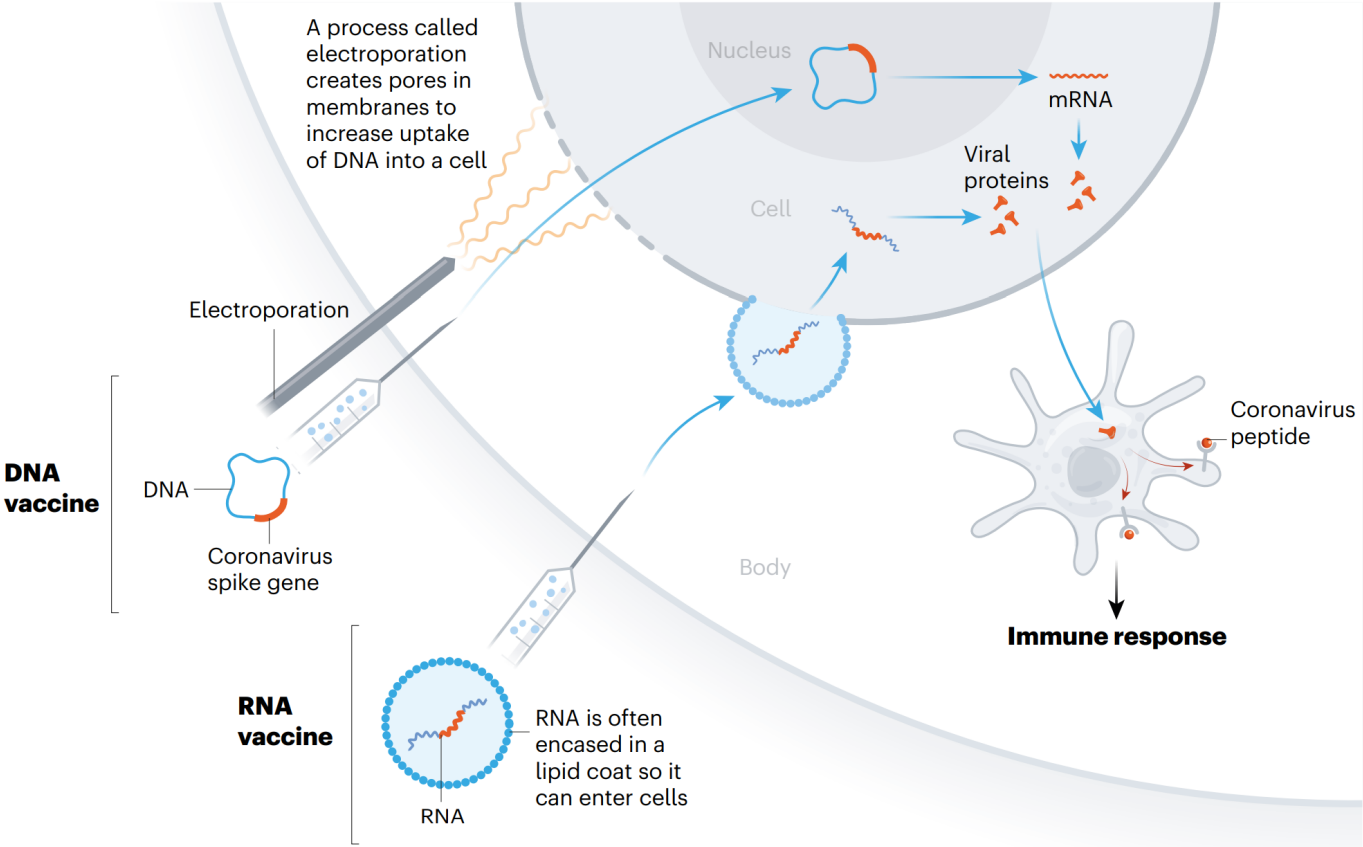
COVID-19 Vaccines in Operation Warp Speed Development

moderna	mRNA	
BIONTECH Pfizer	mRNA	
AstraZeneca	Adenovirus Vector	
janssen	Adenovirus Vector	
NOVAVAX Creating Tomorrow's Vaccines Today	Recombinant Protein+adjuvant	
gsk SANOFI	Recombinant Protein+adjuvant	

NUCLEIC-ACID VACCINES

At least 20 teams are aiming to use genetic instructions (in the form of DNA or RNA) for a coronavirus protein that prompts an immune response. The nucleic acid is inserted into human cells, which then churn out copies of the virus protein; most of these vaccines encode the virus's spike protein.

RNA- and DNA-based vaccines are safe and easy to develop: to produce them involves making genetic material only, not the virus. But they are unproven: no licensed vaccines use this technology.



Nature. vol 580, 30 April 2020

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

An mRNA Vaccine against SARS-CoV-2 — Preliminary Report

L.A. Jackson, E.J. Anderson, N.G. Rouphael, P.C. Roberts, M. Makhene, R.N. Coler, M.P. McCullough, J.D. Chappell, M.R. Denison, L.J. Stevens, A.J. Pruijssers, A. McDermott, B. Flach, N.A. Doria-Rose, K.S. Corbett, K.M. Morabito, S. O'Dell, S.D. Schmidt, P.A. Swanson II, M. Padilla, J.R. Mascola, K.M. Neuzil, H. Bennett, W. Sun, E. Peters, M. Makowski, J. Albert, K. Cross, W. Buchanan, R. Pikaart-Tautges, J.E. Ledgerwood, B.S. Graham, and J.H. Beigel, for the mRNA-1273 Study Group*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults

E.J. Anderson, N.G. Rouphael, A.T. Widge, L.A. Jackson, P.C. Roberts, M. Makhene, J.D. Chappell, M.R. Denison, L.J. Stevens, A.J. Pruijssers, A.B. McDermott, B. Flach, B.C. Lin, N.A. Doria-Rose, S. O'Dell, S.D. Schmidt, K.S. Corbett, P.A. Swanson II, M. Padilla, K.M. Neuzil, H. Bennett, B. Leav, M. Makowski, J. Albert, K. Cross, V.V. Edara, K. Floyd, M.S. Suthar, D.R. Martinez, R. Baric, W. Buchanan, C.J. Luke, V.K. Phadke, C.A. Rostad, J.E. Ledgerwood, B.S. Graham, and J.H. Beigel, for the mRNA-1273 Study Group*

Article

Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults

https://doi.org/10.1038/s41586-020-2639-4
Received: 29 June 2020
Accepted: 4 August 2020
Published online: 12 August 2020
Check for updates

Mark J. Mulligan[1,17], Kirsten E. Lyke[2,17], Nicholas Kitchin[3,17], Judith Absalon[4,5], Alejandra Gurtman[6], Stephen Lockhart[6], Kathleen Neuzil[7], Vanessa Raabe[1,2], Ruth Bailey[6], Kena A. Swanson[8], Ping Li[8], Kenneth Koury[8], Warren Kalina[8], David Cooper[8], Camila Fontes-Garfias[8], Pei-Yong Shi[9], Özlem Türeci[10], Kristin R. Tompkins[8], Edward E. Walsh[11,12], Robert Frenck[13], Ann R. Falsey[11,12], Philip R. Dormitzer[8], William C. Gruber[8], Uğur Şahin[10] & Kathrin U. Jansen[8]

In March 2020, the World Health Organization (WHO) declared coronavirus disease

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates

Edward E. Walsh, M.D., Robert W. Frenck, Jr., M.D., Ann R. Falsey, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., Kathleen Neuzil, M.D., Mark J. Mulligan, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Ping Li, Ph.D., Kenneth Koury, Ph.D., Warren Kalina, Ph.D., David Cooper, Ph.D., Camila Fontes-Garfias, B.Sc., Pei-Yong Shi, Ph.D., Özlem Türeci, M.D., Kristin R. Tompkins, B.Sc., Kirsten E. Lyke, M.D., Vanessa Raabe, M.D., Philip R. Dormitzer, M.D., Kathrin U. Jansen, Ph.D., Uğur Şahin, M.D., and William C. Gruber, M.D.

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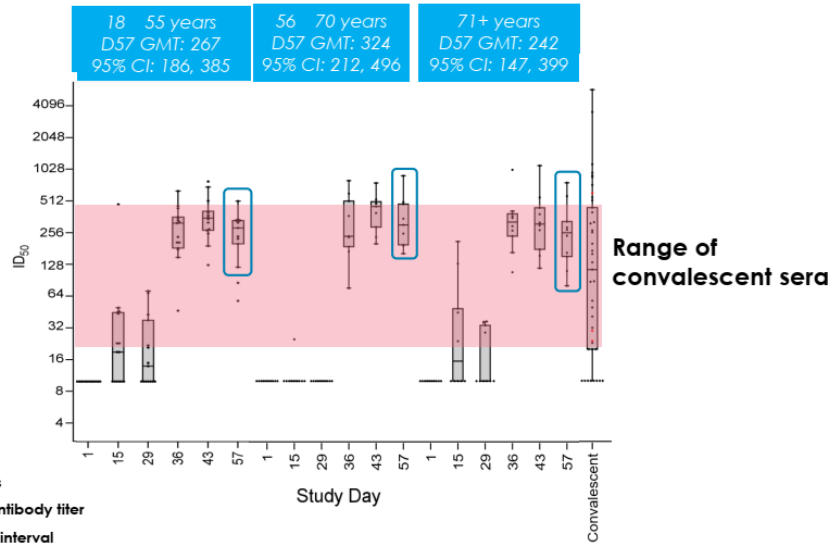
SARS-CoV-2 Immune Responses Comparable Across Age Strata, Moderna mRNA vaccine

- Binding Antibody Responses After Dose 1
- Neutralizing Antibody Responses After Dose 2
- Reactogenic vaccines, particularly after second dose

Pseudovirus neutralization assay titers (ID50)- 100 µg at Day 1 and Day 29



D57: one month post-dos
GMT: geometric mean antibody titer
95% CI: 95% confidence interval
PD2= Post-dose 2
Vaccination administered at Day 1 and Day 29

https://www.cdc.gov/vaccines/acip/meetings/index.html

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CVD was first to vaccinate as part of Pfizer mRNA Phase 1 trial: May 4, 2020

The Washington Post

Pharmaceutical giant Pfizer begins testing coronavirus vaccine in people

WALL STREET JOURNAL

Coronavirus Vaccine Enters Human Testing in U.S.

THE BALTIMORE SUN

University of Maryland injects coronavirus vaccine in first volunteers, aiming for approvals in fall

Medical staff at the University of Maryland School of Medicine has begun injecting the first few people with a potential vaccine for the coronavirus as part of an accelerated international effort to have a vaccine ready to begin use in some people as early as this fall.

REUTERS

Pfizer, BioNTech set to begin U.S. coronavirus vaccine trial

Carl O'Donnell, Michael Erman

(Reuters) - Pfizer Inc and BioNTech SE said on Tuesday they have begun delivering doses of their experimental coronavirus vaccines for initial human testing in the United States.

Pfizer announces early results, November 9, 2020

Coronavirus Latest news U.S. map World map FAQ Vaccine tracker Coronavirus Living Extraordinary People

Health

Pfizer's coronavirus vaccine is more than 90 percent effective in first analysis, company reports

Pfizer's Early Data Shows Vaccine Is More Than 90% Effective

Pfizer announced positive early results from its coronavirus vaccine trial, cementing the lead in a frenzied global race that has unfolded at record-breaking speed.

CNN health Food Fitness Wellness Parenting Vital Signs • LIVE TV Edition

START TODAY HERE

Tropical Storm Eta, Biden's big plans, Covid-19, Trump questions election, best mullet style

Pfizer says early analysis shows its Covid-19 vaccine is 90% effective

By Nadia Kounang, CNN

Updated 9:49 AM ET, Mon November 9, 2020

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Pfizer vaccine: What do we know?

- 43,500 participants enrolled
- Nearly 39,000 have received second dose.
- 150 clinical trial sites in 6 countries, including 39 U.S. states
- 2 doses 21 days apart
- Primary endpoint: Efficacy of vaccine against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination
- 94 cases occurring 7 days after second dose
- Study on-going for required follow-up
- Important results!
  - Excellent efficacy, likely against mild disease
  - Proof of principle for vaccine targeting Spike protein

PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines)
Protocol C4591001

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

Study Sponsor:	BioNTech
Study Conducted By:	Pfizer
Study Intervention Number:	PF-07302048
Study Intervention Name:	RNA-Based COVID-19 Vaccines
US IND Number:	19736
EudraCT Number:	2020-002641-42
Protocol Number:	C4591001
Phase:	1/2/3

Short Title: A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

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Overall Phase 3 Plans Based on FDA Guidance

- Multiple Efficacy Trials Planned
- FDA: Minimum Efficacy 50%; Lower Bound CI 30%
- Sample Size: 30,000
- CDC Definition of COVID Disease With More Serious Outcomes as Secondary
- Close Follow-up of COVID Positives
- Enrollment of Those at High Risk for Disease- older Age Groups, Chronic Conditions, Minorities
- Multiple Blood Draws During Course of Trial for Correlates of Protection Analyses

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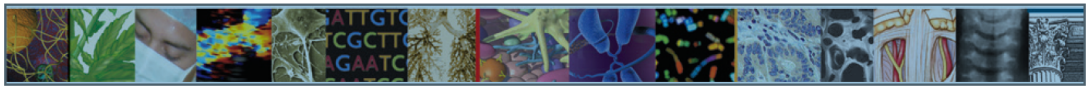


The NEW ENGLAND JOURNAL of MEDICINE

Perspective

NOVEMBER 5, 2020

Emergency Use Authorization of Covid Vaccines — Safety and Efficacy Follow-up Considerations

Philip R. Krause, M.D., and Marion F. Gruber, Ph.D.

- EUA allows use of unapproved medical products to diagnose, treat or prevent serious or life-threatening diseases in response to a declare public healthy emergency for which there are no adequate, approved and available alternatives.
- Known and potential benefits of a product must outweigh known and potential risks
- Median follow-up duration of at least 2 months after completion of full vaccination regimen (meaning that at least half of vaccine recipients in clinical trials have at least 2 months of follow-up)

VIRAL-VECTOR VACCINES

Around 25 groups say they are working on viral-vector vaccines. A virus such as measles or adenovirus is genetically engineered so that it can produce coronavirus proteins in the body. These viruses are weakened so they cannot cause disease. There are two types: those that can still replicate within cells and those that cannot because key genes have been disabled.

Replicating viral vector (such as weakened measles)

The newly approved Ebola vaccine is an example of a viral-vector vaccine that replicates within cells. Such vaccines tend to be safe and provoke a strong immune response. Existing immunity to the vector could blunt the vaccine's effectiveness, however.

Non-replicating viral vector (such as adenovirus)

No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.

PROTEIN-BASED VACCINES

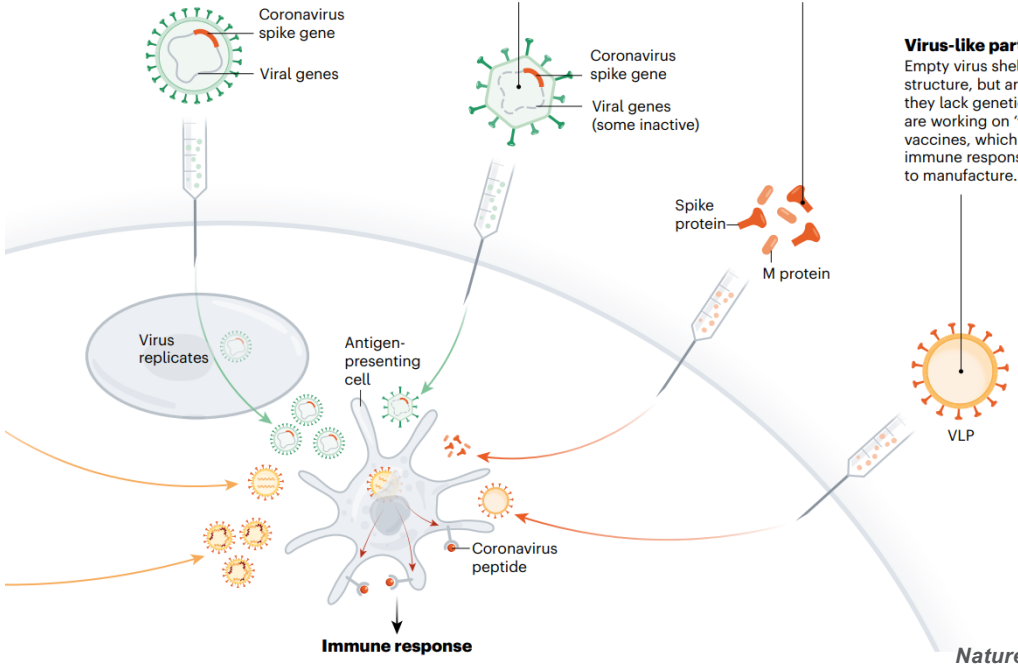
Many researchers want to inject coronavirus proteins directly into the body. Fragments of proteins or protein shells that mimic the coronavirus's outer coat can also be used.

Protein subunits

Twenty-eight teams are working on vaccines with viral protein subunits — most of them are focusing on the virus's spike protein or a key part of it called the receptor binding domain. Similar vaccines against the SARS virus protected monkeys against infection but haven't been tested in people. To work, these vaccines might require adjuvants — immune-stimulating molecules delivered alongside the vaccine — as well as multiple doses.

Virus-like particles

Empty virus shells mimic the coronavirus structure, but aren't infectious because they lack genetic material. Five teams are working on 'virus-like particle' (VLP) vaccines, which can trigger a strong immune response, but can be difficult to manufacture.



Nature. vol 580, 30 April 2020

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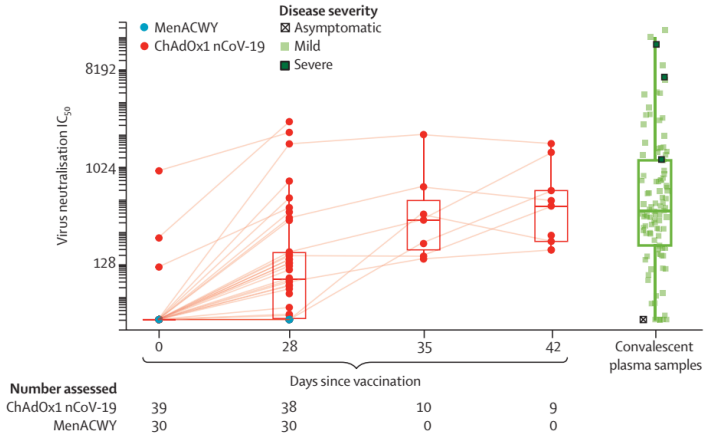
Adenovirus Vector Vaccines

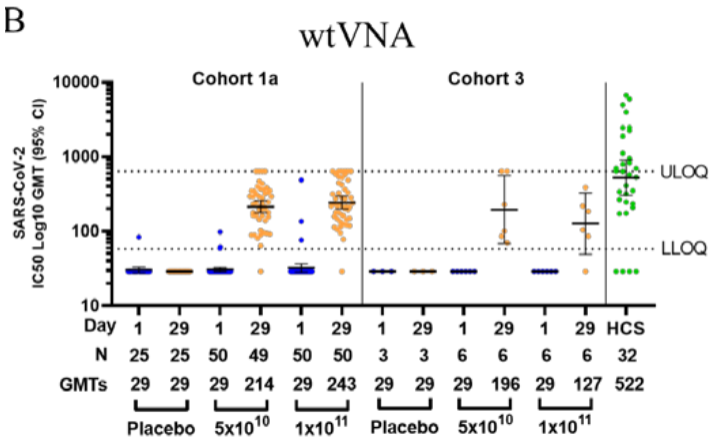
Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial

Pedro M Folegatti, Katie J Ewer*, Parvinder K Aley, Brian Angus, Stephan Becker, Sandra Belij-Rammerstorfer, Duncan Bellamy, Sagida Bibi, Mustapha Bittaye, Elizabeth A Clutterbuck, Christina Dold, Saul N Faust, Adam Finn, Amy L Flaxman, Bassam Hallis, Paul Heath, Daniel Jenkin, Rajeka Lazarus, Rebecca Makinson, Angela M Minassian, Katrina M Pollock, Maheshi Ramasamy, Hannah Robinson, Matthew Snape, Richard Tarrant, Merryn Voysey, Catherine Green*, Alexander D Douglas*, Adrian V S Hill*, Teresa Lambe*, Sarah C Gilbert*, Andrew J Pollard*, on behalf of the Oxford COVID Vaccine Trial Group†*



Safety and immunogenicity of the Ad26.COV2.S COVID-19 vaccine candidate: interim results of a phase 1/2a, double-blind, randomized, placebo-controlled trial

Jerald Sadoff[1§], MD; Mathieu Le Gars[1§], PhD; Georgi Shukarev[1], MD; Dirk Heerwegh[2], PhD;



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Novavax Recombinant Spike Nanoparticle Vaccine

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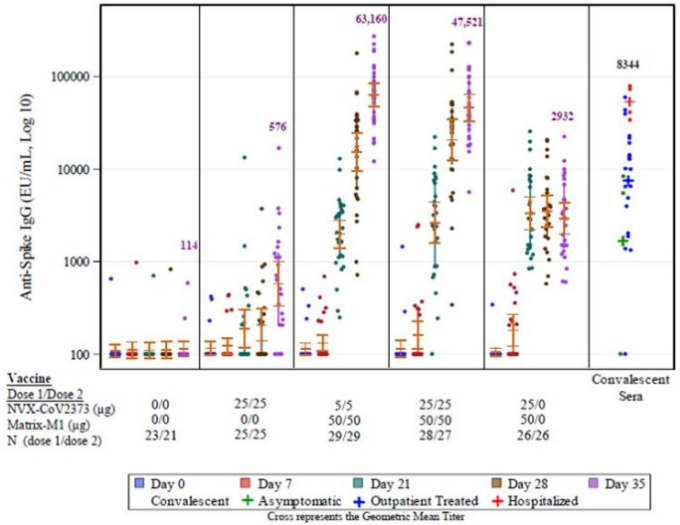
Please review the Supplemental Files folder to review documents not compiled in the PDF.

First-in-Human Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine



- 131 healthy young adults
- 5 or 15 mcg +/- Matrix-M1
- 2 doses 21 days apart
- Well-tolerated; reactogenicity increased after dose 2
- Two dose 5 mcg Matrix-M1 induced highest antibody responses and exceeded mean responses in convalescent sera
- Th1 phenotype

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EXCLUSIVE

AstraZeneca Covid-19 vaccine study put on hold due to suspected adverse reaction in participant in the U.K.

By REBECCA ROBBINS @rebeccadrobbins, ADAM FEUERSTEIN @adamfeuerstein, *and* HELEN BRANSWELL @HelenBranswell / SEPTEMBER 8, 2020

Reprints

KIRSTY WIGGLESWORTH/AP

https://www.statnews.com/2020/09/08/astrazeneca-covid-19-vaccine-study-put-on-hold-due-to-suspected-adverse-reaction-in-participant-in-the-u-k/

HEALTH

As AstraZeneca's Covid-19 vaccine trial remains on hold in U.S., participants waiting on a second dose are in limbo

By REBECCA ROBBINS @rebeccadrobbins / OCTOBER 6, 2020

Reprints

A participant in AstraZeneca and Oxford's Covid-19 vaccine trial in Brazil receives a shot. While other holds globally have been lifted, the U.S. trial remains halted.

NELSON ALMEIDA/AFP VIA GETTY IMAGES

https://www.statnews.com/2020/10/06/astrazeneca-covid19-second-dose-trial-vaccine/

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What does a clinical hold mean?

AstraZeneca's Trial Is on Hold. It's a Sign that the Science Is Working.

COMMENTARY Norman Baylor Sept. 21, 2020 5:00 pm ET

- A **clinical hold** is an order issued by FDA to the sponsor of an IND application to delay a proposed **clinical** investigation or to suspend an ongoing investigation.
- All or some of the investigations conducted under an IND application may be placed on **clinical hold**.
- The reason for a clinical hold is concern for the safety of clinical trial participants.
- An independent review is required to determine whether the event is the result of a vaccine candidate or just a random unrelated illness.

https://www.barrons.com/articles/astrazenecas-trial-on-hold-sign-science-is-working-fda-51600721992

Safety Assessments

- **New Disease**
  - Poorly understood immunity
  - Rare complications and long-term sequalae not well-elucidated
  - Differentiating vaccine-enhanced illness?
- **Accelerated Development of Vaccines with New Vaccine Platforms**
- **Vaccinations Occurring in a Short Time-frame with Relatively Short Follow-up Before Efficacy Signal May Be Reached**

Science PERSPECTIVES

Cite as: B. S. Graham *et al.*, *Science* 10.1126/science.abb8923 (2020).

Rapid COVID-19 vaccine development

By **Barney S. Graham**

Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA. Email: bgraham@mail.nih.gov

Finding the fastest pathway to vaccine availability includes the avoidance of safety pitfalls

Potential risks associated with vaccine development for COVID-19

Antibodies that bind virus without neutralizing infectivity can cause disease through increased viral replication or formation of immune complexes that deposit in tissue and activate complement pathways associated with inflammation. T helper 2 cell (T_H2)–biased responses have also been associated with ineffective vaccines that lead to enhanced disease after subsequent infection. Antibody-dependent enhancement (ADE) of viral replication has occurred in viruses with innate macrophage tropism. Virus-antibody immune complexes and T_H2-biased responses can both occur in vaccine-associated enhanced respiratory disease (VAERD).

	Antibody-mediated		T cell–mediated
	ADE	**VAERD**	**VAERD**
Mechanism	Fc-mediated increase in viral entry	Immune complex formation and complement deposition	T_H2-biased immune response
Effectors	Macrophage activation and inflammatory cytokines	Complement activation and inflammatory cytokines	Allergic inflammation and T_H2 cytokines
Mitigation	Conformationally correct antigens and high-quality neutralizing antibody		T_H1-biasing immunization and $CD8^+$ T cells

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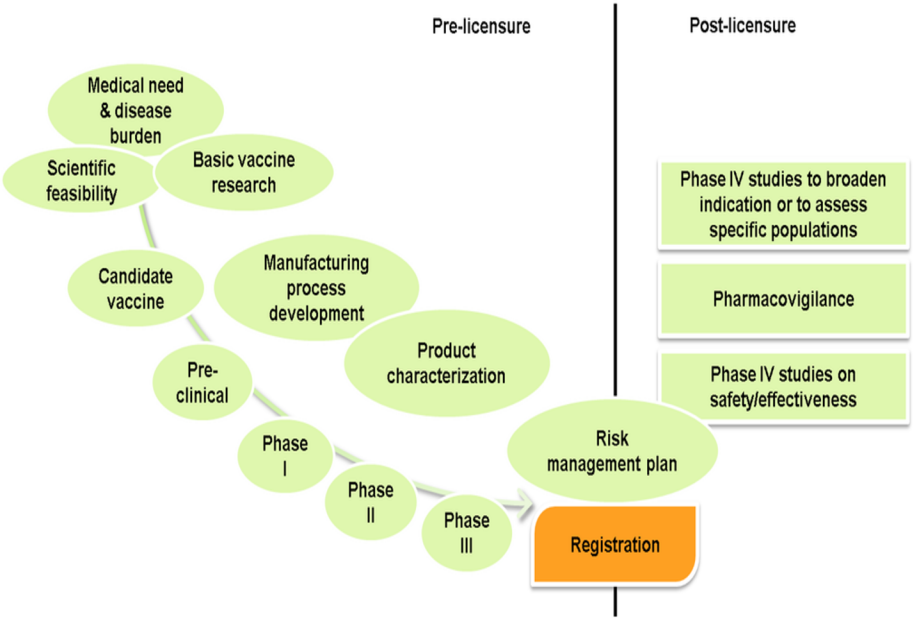
Vaccine Confidence and Communication

- **Strong Science is a Necessary Starting Point**
- **Trust in the Process is Paramount**



http://www.mdpi.com/2076-393X/1/3/204/htm

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Special Populations: Children and Pregnant Women

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
September 16, 2020

Characteristics and Maternal and Birth Outcomes of Hospitalized Pregnant Women with Laboratory-Confirmed COVID-19 — COVID-NET, 13 States, March 1–August 22, 2020

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
September 16, 2020

SARS-CoV-2 Infection Among Hospitalized Pregnant Women: Reasons for Admission and Pregnancy Characteristics — Eight U.S. Health Care Centers, March 1–May 30, 2020

Lakshmi Panagiotakopoulos, MD[1]; Tanya R. Myers, PhD[1]; Julianne Gee, MPH[1]; Heather S. Lipkind, MD[2]; Elyse O. Kharbanda, MD[3]; Denison S. Ryan, MPH[4]; Joshua T.B. Williams, MD[5,6]; Allison L. Naleway, PhD[7]; Nicola P. Klein, MD, PhD[8]; Simon J. Hambidge, MD, PhD[5,6]; Steven J. Jacobsen, MD, PhD[4]; Jason M. Glanz, PhD[9]; Lisa A. Jackson, MD[10]; Tom T. Shimabukuro, MD[1]; Eric S. Weintraub, MPH[1]

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
September 15, 2020

SARS-CoV-2–Associated Deaths Among Persons Aged <21 Years — United States, February 12–July 31, 2020

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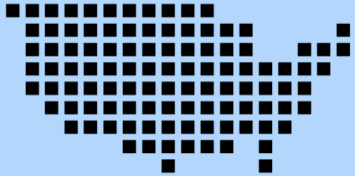
COVID-19 vaccine prioritization: Work Group considerations: Kathleen Dooling, MD MPH

Identifying groups for allocation of initial doses COVID-19 vaccine:

critical for program planning

Strengthen vaccine distribution networks to reach target groups



Develop state and local microplans for vaccine implementation

Create communications strategies to promote vaccination in target groups

Plan evaluations to rapidly monitor vaccine safety, effectiveness, and coverage

Engage partners and stakeholders

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-08-Dooling.pdf

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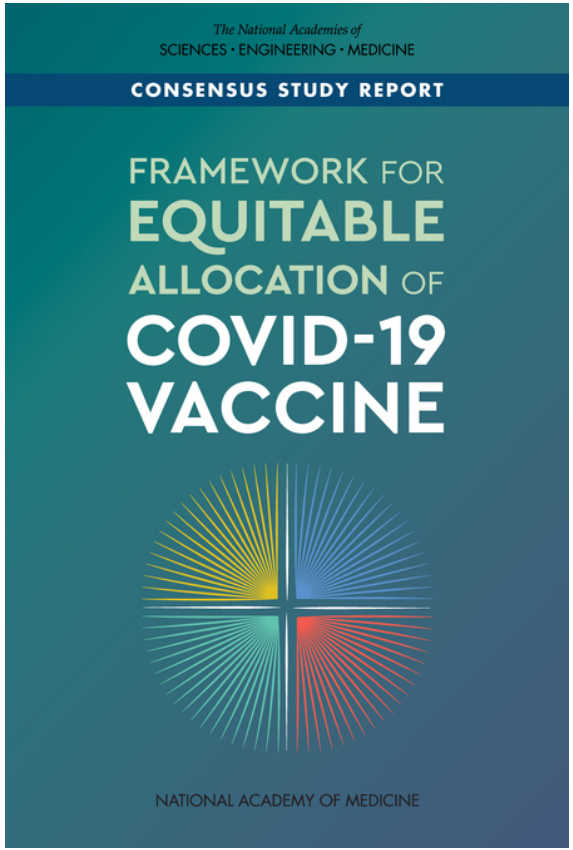
Report by the National Academies



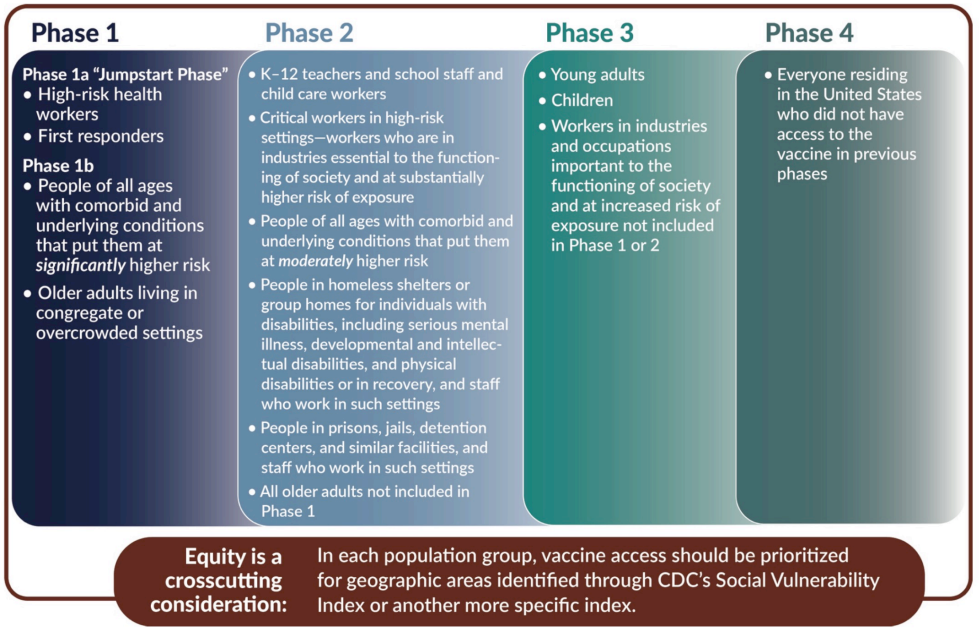


FIGURE S-2 A phased approach to vaccine allocation for COVID-19.

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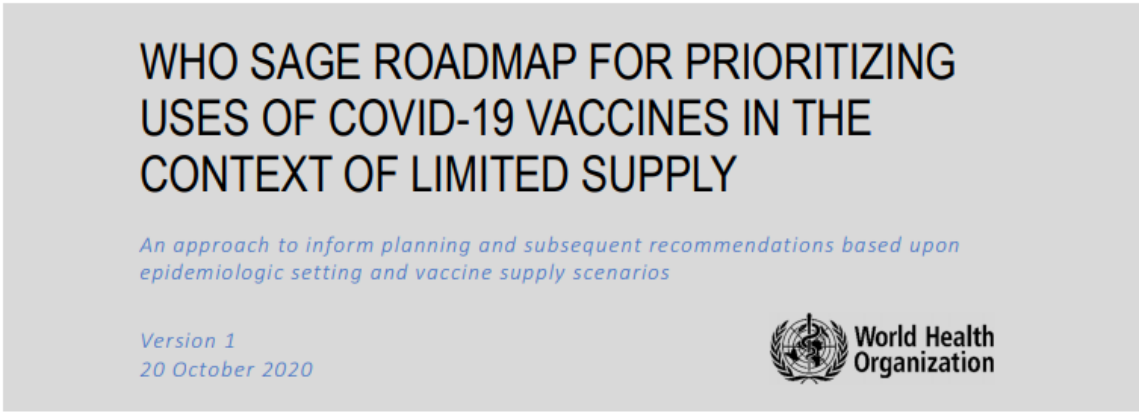

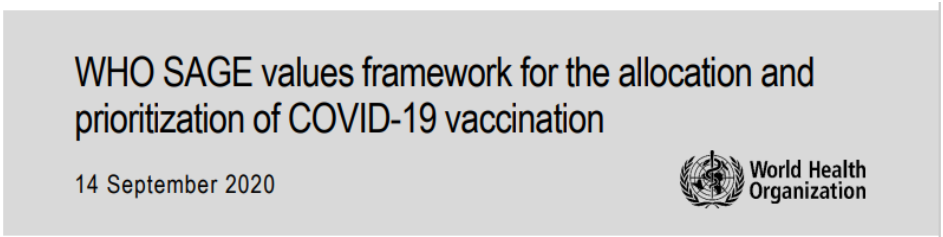

https://www.who.int/immunization/sage/covid-19_documents/en/

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ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

24 April 2020

COMMITMENT and CALL TO ACTION

Our Vision and Mission

Grounded in a vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, we, an initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders, are launching a landmark, global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.

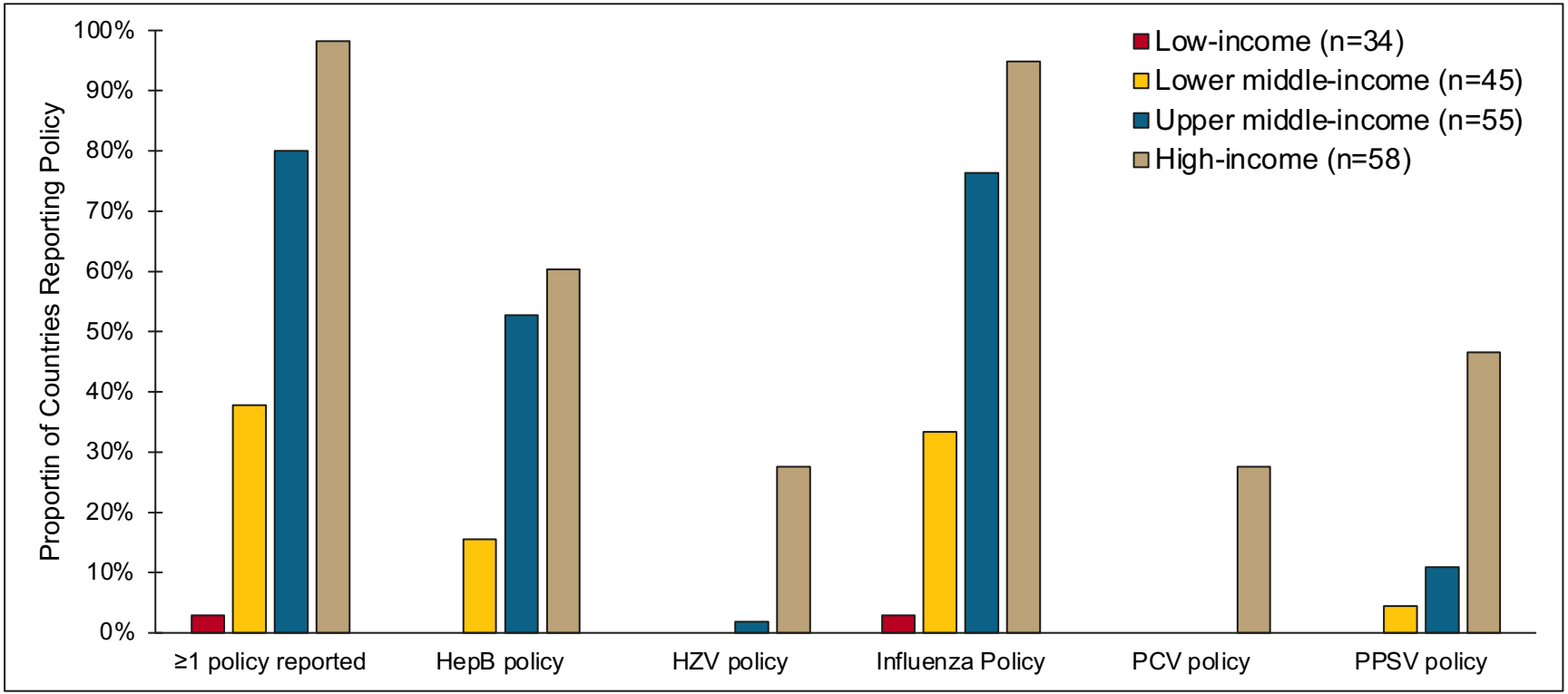
Our Mission is not only accelerated development and availability of new COVID-19 tools – it is to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.

Our Commitment

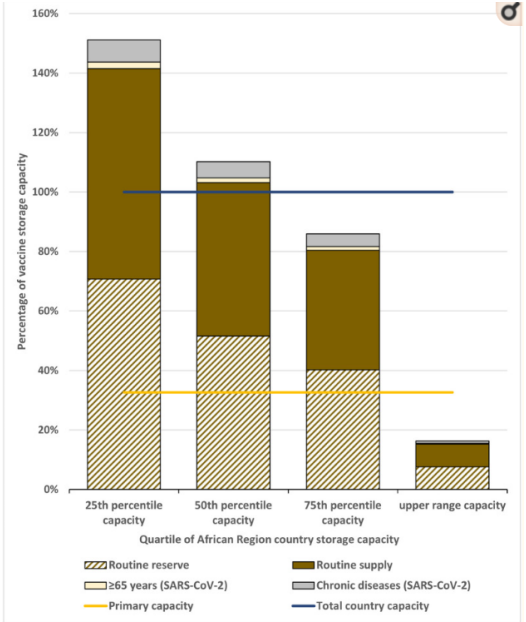
1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.

Bill & Melinda Gates foundation
dcvmn Developing Countries Vaccine Manufacturers Network
The Global Fund
IGBA International Generic and Biosimilar Medicines Association
wellcome
CEPI
Gavi The Vaccine Alliance
IFPMA International Federation of Pharmaceutical Manufacturers & Associations
Unitaid Innovation in Global Health
World Health Organization

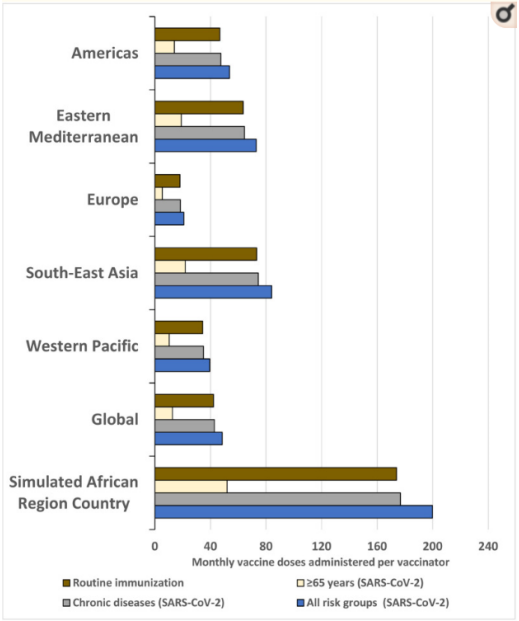
Reported Adult Immunization Programs by World Bank Income Category in 2018



Capacity to Deliver COVID-19 Vaccines



Maximum national level monthly routine and SARS-CoV-2 vaccine volumes as a proportion of total country capacity, by quartile of African Region country storage capacity



Monthly routine and SARS-CoV-2 campaign vaccine doses per vaccinator, by WHO Region estimated nurse density

Ortiz et al. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430629/

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Summary

- **Safe and Effective Vaccines that are Accessible, Affordable and Globally Available are Needed for COVID-19**
- **Robust Pipeline of Promising Candidates in Clinical Development**
  - We need multiple wins
  - Many challenges – New disease, poorly understood immunity, uncertain trajectory of outbreak
- **Safety Systems and Processes in Place**
  - Vaccine safety will be meticulously assessed
  - Adverse events after immunization (AEFI) will occur
- **Studies are Large and May Reach Efficacy Targets Early**
  - Need to plan now for priority groups in supply-constrained situation
  - Need to plan for distribution and uptake

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Thank You

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