LAST UPDATE: 06 October 2020

CORONAVIRUS
UPDATE

37

What we know about COVID-19 vaccine development

THE LATEST ON THE COVID-19 GLOBAL SITUATION & VACCINE DEVELOPMENT







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Current global situation

As of 04 October 2020; (10H CEST)

- > 34 million cases
- 5 countries with highest cumulative number of cases
 - United States of America
 - India
 - Brazil
 - Russian Federation
 - **Colombia**

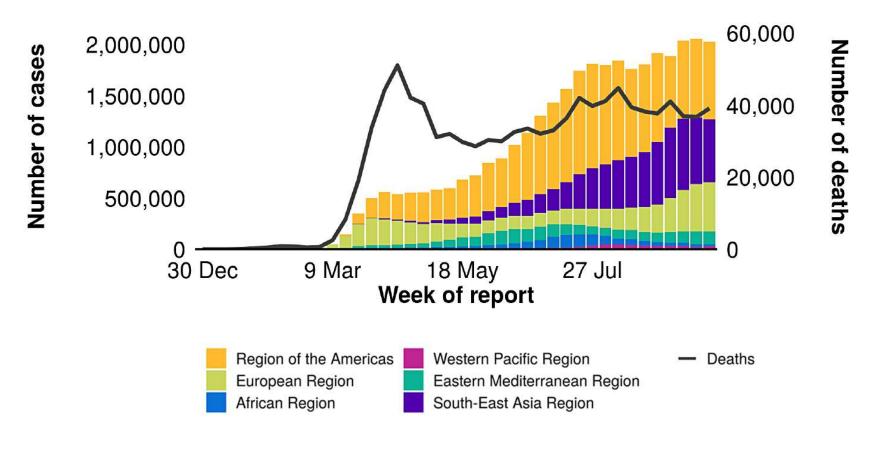
> 1 million deaths

(exceeded 30 September 2020)

- 5 countries with highest cumulative number of deaths
 - United States of America
 - Srazil
 - India
 - Mexico
 - The United Kingdom

Current global situation

(Cases reported to WHO as of 04 October 2020, 10:00 CEST)



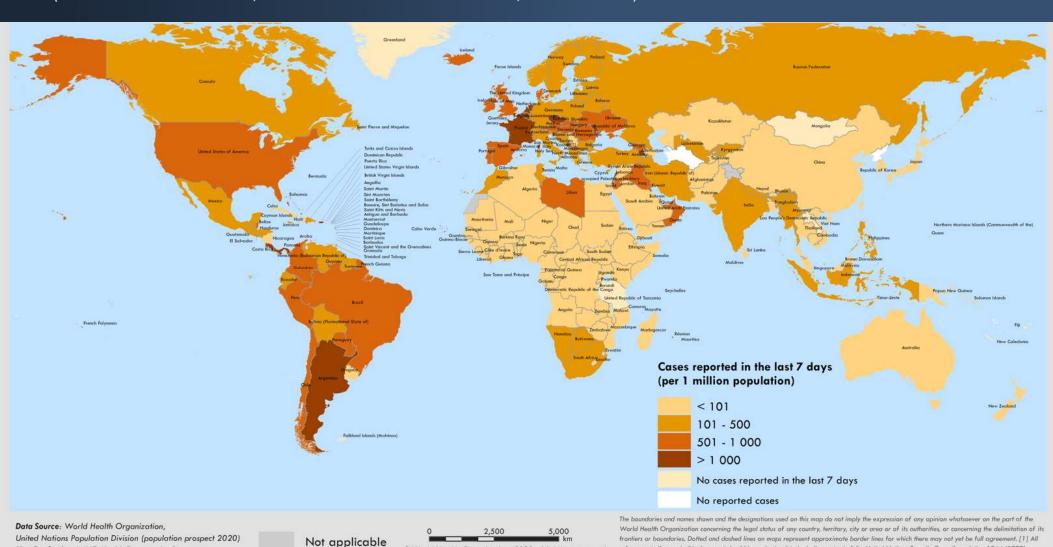
^{*} Cases depicted by bars; deaths depicted by line

COVID-19 cases reported in the last 7 days

Per million population

Map Production: WHO Health Emergencies Programme

(FROM 28 SEPTEMBER 2020, 10:00AM CEST to 04 OCTOBER 2020, 10:00 AM CEST)



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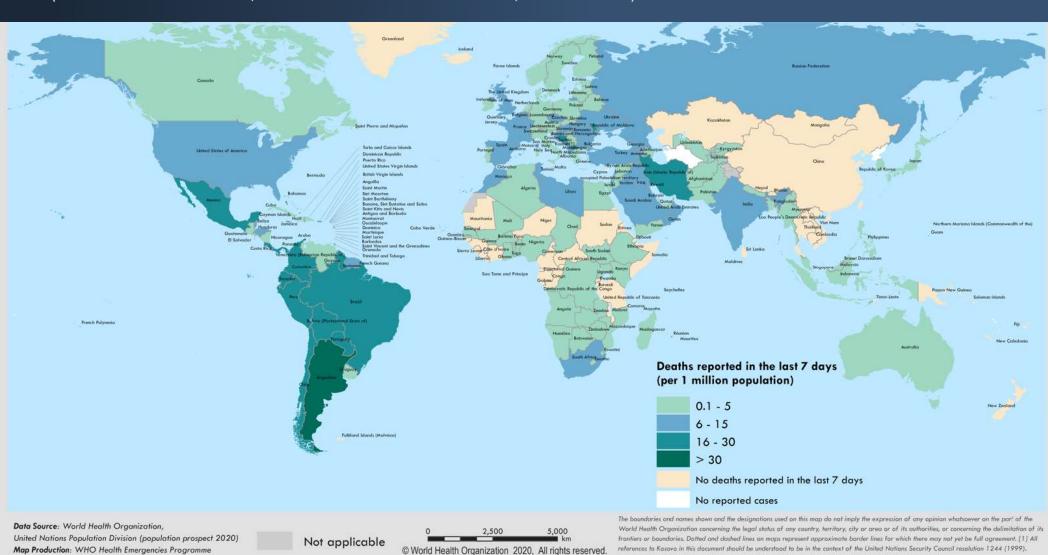
references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Number of cases of Serbia and Kosova (UNSCR 1244, 1999) have been aggregated for visualization purpose:

COVID-19 deaths reported in the last 7 days

Per million population

(FROM 28 SEPTEMBER 2020, 10:00AM CEST to 04 OCTOBER 2020, 10:00 AM CEST)



Number of cases of Serbia and Kosovo (UNSCR 1244, 1999) have been aggregated for visualization purposes.

Why we use vaccines

- Vaccines can prevent infectious diseases. Examples of vaccine-preventable diseases are: measles, polio, hepatitis B, influenza and many others.
- When most people in a community are vaccinated against a disease, the ability of the pathogen to spread is limited. This is called 'herd' or 'indirect' or 'population' immunity.
- When many people have immunity, this also indirectly protects people who cannot be vaccinated, such as very young babies and those who have compromised immune systems.



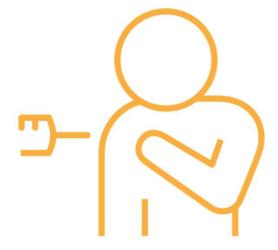
How vaccines work

- Vaccines greatly reduce the risk of infection by training the immune system to recognize and fight pathogens such as viruses or bacteria
- Vaccines safely deliver an immunogen which is a specific type of antigen that elicits an immune response, to train the immune system to recognize the pathogen when it is encountered naturally.



How vaccines are delivered

- A vaccine can be administered through different routes, for example injection in the muscle or under the skin or via the oral route.
- Vaccines sometimes require more than one dose to:
 - build complete immunity
 - give a 'booster' dose when immunity wears off
 - immunize people against viruses causing disease that may be different from season to season, for example, the yearly flu vaccine



Immunogens used to develop viral vaccines

 Vaccines are being developed with different technologies — some well-known and others completely new for human vaccines, such as peptide and nucleic acid technologies

| IMMUNOGEN | HOW IT WORKS | ADVANTAGE | DISADVANTAGE | EXAMPLE of vaccines |
|---|---|--|---|--|
| Attenuated live virus | Live virus but doesn't cause disease | Induces same response as natural infection | Not recommended for pregnant women and immunocompromised persons | Measles, rubella, mumps, yellow fever, smallpox (vaccinia) |
| Whole inactivated virus | Inactivated dead virus | Induces strong antibody response | Requires large quantities of virus | Influenza, rabies hepatitis A |
| Protein subunit | A protein derived from a pathogen | May have fewer side effects than whole virus (redness, swelling at injection site) | May be poorly immunogenic; complex process | Influenza |
| Recombinant | Host cell is used to express an antigen | No need to produce the whole virus | May be poorly immunogenic; High cost | Hepatitis B |
| Peptides | Synthetic produced fragment of an antigen | Rapid development | Poorly immunogenic; High cost | COVID-19 vaccines in development |
| Replicating or non- replicating viral vector | Viral pathogen expressed on a safe virus that doesn't cause disease | Rapid development | Prior exposure to vector virus (eg. adenovirus) may reduce immunogenicity | Ebola |
| Nucleic acid | DNA or RNA coding for a viral protein | Strong cellular immunity; rapid development | Relatively low antibody response | COVID-19 vaccines in development |



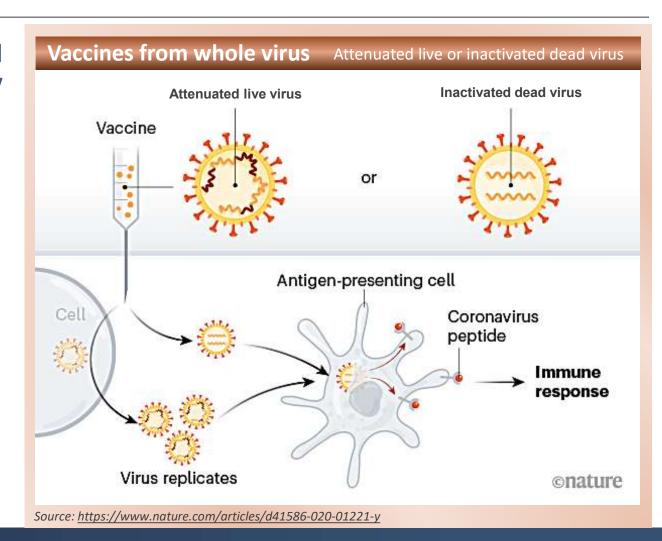


Virus vaccines

 Virus is selected, modified (weakened) or completely inactivated so that it will not cause disease

Note:

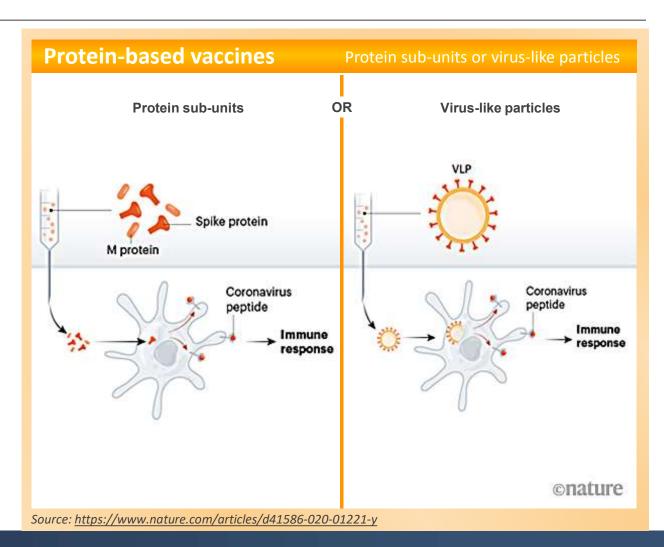
This illustration shows injectable vaccines. Some vaccines in this category are administered orally





Protein-based vaccines

- A protein is extracted from the virus (alive or inactivated), purified, and injected as a vaccine
- For coronavirus, this is most commonly the spike protein
- Virus-like particles work in the same way



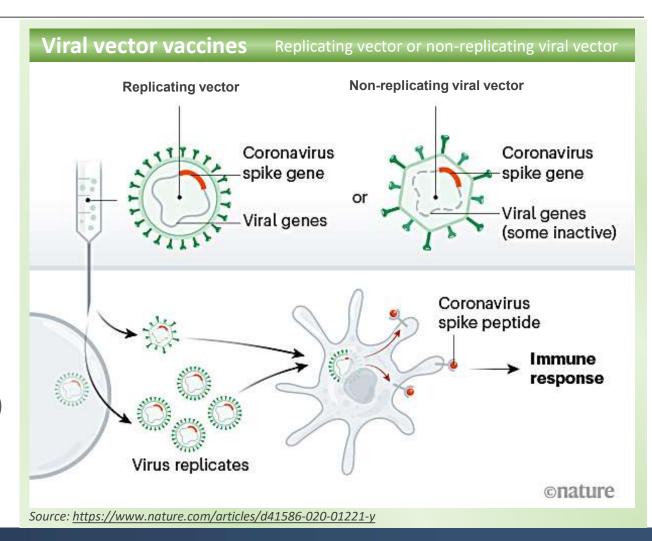






Viral vector vaccines

- The gene for a pathogen protein is inserted into a different virus that can infect someone without causing disease
- The safe virus serves as a 'platform' or 'vector' to deliver the protein that triggers an immune response
- The safe virus is then injected as a vaccine
- Some replicate (reproduce) in the body and some do not





EPI·WiN

Nucleic acid vaccines

- Instead of a virus, a protein antigen, or a virus expressing the protein, nucleic acid coding for the antigen is injected
- DNA plasmid: enters nucleus, translated to mRNA for expression of protein
- Or mRNA can be injected. More direct (no translation required) but less stable than DNA
- This is new technology no other vaccines for human use have used this

Nucleic acid vaccines DNA vaccine or RNA vaccine **DNA** vaccine RNA vaccine Electroporation Coronavirus spike gene RNA is often encased in a lipid coat so it can enter cells DNA RNA Coronavirus spike peptide Immune response Viral proteins Nucleus mRNA onature

Source: https://www.nature.com/articles/d41586-020-01221-y

Steps in vaccine development

Actions taken to ensure a new vaccine is safe and works well

Pre-clinical studies

Vaccine is tested in animal studies for efficacy and safety, including challenge studies

Phase I clinical trial

Small groups of healthy adult volunteers receive the vaccine to test for safety

Phase II clinical trial

Vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended

Phase III clinical trial

Vaccine is given to thousands of people and tested for efficacy and safety

Phase IV post marketing surveillance

Ongoing studies after the vaccine is approved and licensed, to monitor adverse events and to study long-term effects of the vaccine in the population

Human challenge studies

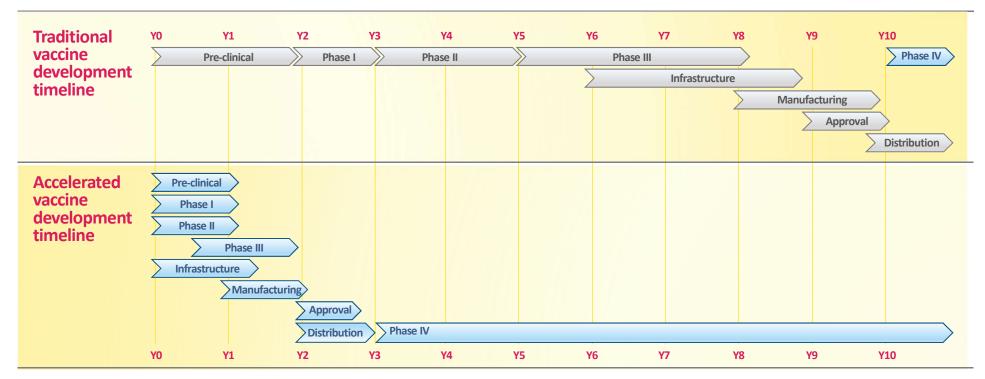
Studies in which a vaccine is given followed by the pathogen against which the vaccine is designed to protect. Such trials are uncommon in people as they present considerable ethical challenges

Why there are so many COVID-19 vaccines in development

- There are many different COVID-19 vaccines in development because it is not yet known which ones will be effective and safe
- Based on experience, roughly 7% of vaccines in preclinical studies succeed. Candidates that reach clinical trials have about a 20% chance of succeeding.
- Different vaccine types may be needed for different population groups
- For example, some vaccines may work in older persons and some may not, as the immune system weakens with older age



COVID-19 vaccine accelerated development



- Normal vaccine development performs each step in sequence
- To accelerate COVID-19 vaccine development, steps are done in parallel
- All usual safety and efficacy monitoring mechanisms remain in place; such as adverse event surveillance, safety data monitoring & long-term follow-up
- Phase IV post-marketing surveillance for side effects is critical and essential





COVID-19 vaccine candidates in Phase III trials

- As of 02 October 2020 there are 42 COVID-19 candidate vaccines in clinical evaluation of which 10 in Phase III trials
- There are another 151 candidate vaccines in preclinical evaluation
- Phase III trials usually require 30,000 or more participants
- All top candidate vaccines are for intra-muscular injection
- Most are designed for a two-dose schedule (exceptions with a * in table are single dose)

| 10 CANIDATE VACCINES IN PHASE III CLINICAL EVALUATION | VACCINE PLATFORM | LOCATION OF PHASE III STUDIES |
|--|-------------------|--|
| Sinovac | Inactivated virus | Brazil |
| Wuhan Institute of Biological Products / Sinopharm | Inactivated virus | United Arab Emirates |
| Beijing Institute of Biological Products / Sinopharm | Inactivated virus | China |
| University of Oxford / AstraZeneca | Viral vector * | United States of America |
| CanSino Biological Inc. / Beijing Institute of Biotechnology | Viral vector * | Pakistan |
| Gamaleya Research Institute | Viral vector | Russia |
| Janssen Pharmaceutical Companies | Viral vector | USA, Brazil, Colombia, Peru, Mexico, Philippines, South Africa |
| Novavax | Protein subunit | The United Kingdom |
| Moderna / NIAID | RNA | USA |
| BioNTech / Fosun Pharma / Pfizer | RNA | USA, Argentina, Brazil |

https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

* Single dose schedule







WHO COVID-19 Solidarity vaccine trial

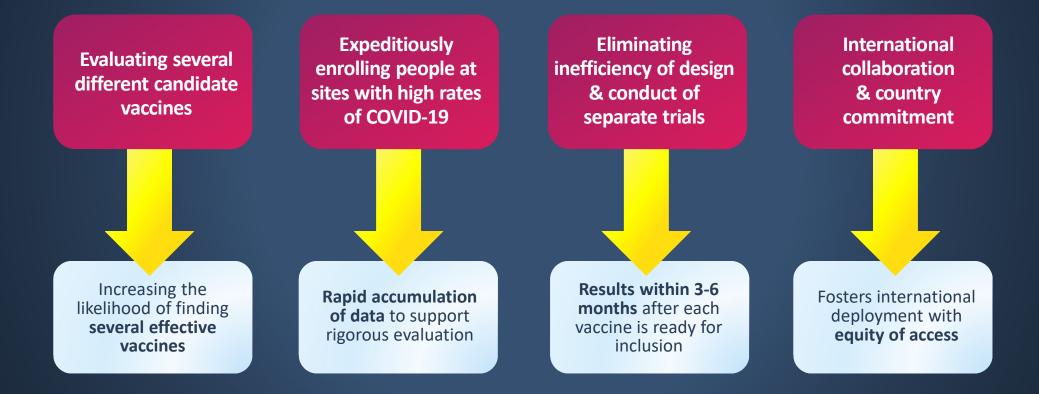
- On 28 May 2020, WHO announced the launch of a coordinated international, concurrent randomized controlled Phase III trial of different vaccine candidates.
- A trial in several sites at once will help speed evaluation and ensure that vaccines will have been tested in different populations.
- The trial aims to enroll more than 280,000 participants from at least 470 different sites in 34 countries.
- Local involvement will help to identify trial sites with high COVID-19 transmission and ensure community engagement.

https://www.who.int/publications/i/item/an-international-randomised-trial-of-candidate-vaccines-against-covid-19

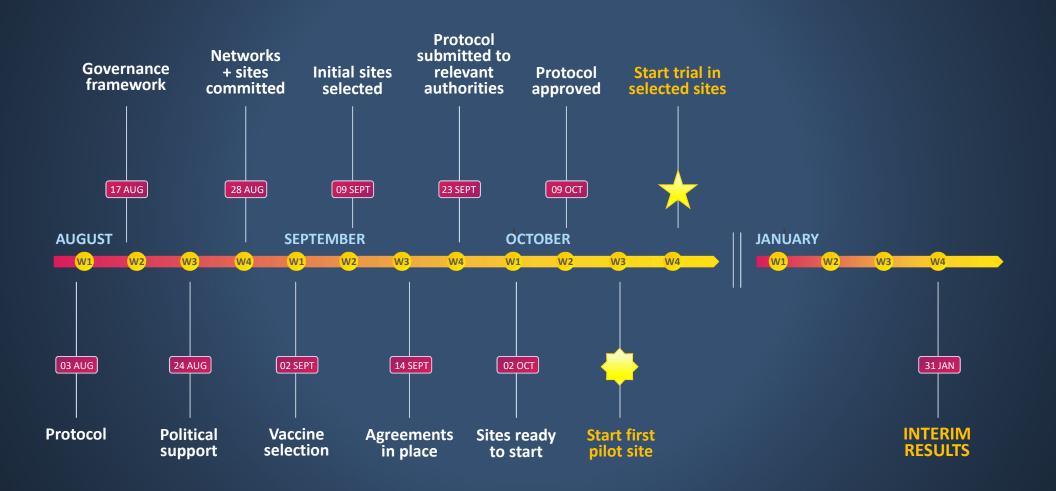


WHO Solidarity vaccine trial

Achieving rapid progress towards global objectives



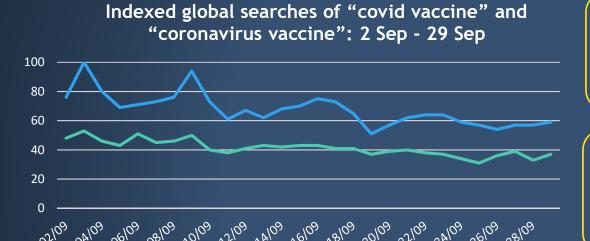
WHO Solidarity vaccine trial milestones



Monitoring social media on vaccine development

Most discussed topics surrounding COVID-19 vaccines development on social media

(24 SEPTEMBER to 30 SEPTEMBER 2020)



News: the Johnson & Johnson COVID-19 vaccine trial showed it was well tolerated and that a "strong immune response" was produced in almost all 800 participants.

Response: Concern that vaccine development in the US has been politicised and may lead to a vaccine being rushed was seen across many top posts.

INTERNET SEARCHES

In the past week, searches for "johnson and johnson covid vaccine" rose by 250%

"Covid vaccine" was most likely to be searched in Brunei, Ireland and Ethiopia. Meanwhile, "coronavirus vaccine" saw the highest volume of searches in Ireland, Trinidad & Tobago and Nepal.

Working together to deliver vaccine to all countries

- The Access to COVID-19 Tools (ACT) <u>Accelerator</u> was launched in April 2020 to speed up development and delivery to countries of diagnostics, treatments and vaccines. It includes a health systems connector to support delivery of these resources to countries. Watch the video here!
- WHO developed a **framework** for equitable and affordable access to safe and effective vaccines.
- The COVAX Facility is an umbrella mechanism through which demand and resources are pooled to support procurement of, and equitable access to, COVID-19 vaccines.
- The ACT Accelerator aims to deliver two billion vaccine doses for global needs by the end of 2021.
- Vaccine allocation will be driven by public health needs for priority groups, which may represent about 20% of the population, in the first year.
- Countries will be asked to develop vaccination plans following advice from <u>SAGE</u>.
- WHO recommends **front-line personnel** (such as health workers) **and seniors** be the first priority to receive vaccine.
- Coordinated by GAVI, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO.



Resources on COVID-19 vaccine development

WHO Target Product Profile for COVID-19 vaccine

This Target Product Profile (TPP) describes the preferred and minimally acceptable profiles for human vaccines for long term protection of persons at high ongoing risk of COVID-19, such as health workers, and for reactive use in outbreak settings with rapid onset of immunity.

Vaccine landscape

Landscape documents prepared by the WHO for information purposes concerning the 2019-2020 global development of new COVID-19 vaccines.

Solidarity Vaccine Trial

This large, international, randomized controlled clinical trial is designed to enable an expeditious, agile and concurrent evaluation of the benefits and risks of multiple candidate preventive vaccines against COVID-19 at international sites with sufficient COVID-19 attack rates.

Access to COVID Tools (ACT) Accelerator

The vaccines pillar of the ACT Accelerator, convened is speeding up the search for an effective vaccine for all countries.

- Covax facility (WHO) Covax explained (GAVI) COVAX (CEPI)
- CEPI, Gavi and WHO launched COVAX to ensure equitable access to COVID-19 vaccines and end the acute phase of the pandemic by the end of 2021.

WHO Guidance on ethics of vaccine allocation

This policy brief answers a number of questions about the ethics of setting priorities for the allocation of resources during times of scarcity. Such decisions may include access to hospitals, ventilators, vaccines and medicines.



How to protect ourselves & others

9 important COVID-19 prevention measures



Stay home and self-isolate if you feel unwell, even with mild symptoms



Clean hands frequently with

with alcohol-based hand rub



Cover your nose and mouth with a disposable tissue or flexed elbow when you cough or sneeze



Avoid touching your eyes, nose and mouth



Maintain a minimum physical distance of at least 1 metre from others



O6 Stay away from crowds and avoid poorly ventilated indoor spaces



Use a fabric mask where physical distancing of at least 1 metre is not possible



Use a medical / surgical mask if you may be at higher risk (age, medical conditions)



Regularly clean & disinfect frequently touched surfaces

WHO guidance on COVID-19

VIDEO RESOURCES

Masks



Medical and fabric masks: who wears what when?



How to wear a fabric mask safely



How to wear a fabric mask



How to wear a medical mask

Transmission



How to break the chains of transmission

Protecting ourselves



How to protect yourself against COVID-19



Seven steps to prevent the spread of the virus

Call for applicants: 1st WHO training in infodemic management

Online training over 4 weeks

3 – 27 November 2020

DEADLINE FOR SUBMISSION:

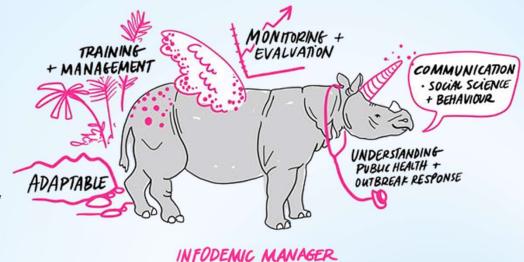
18 October 2020, 18:00 CET

WHO is developing activities to support country preparedness and to mitigate the current COVID-19 pandemic. There is an urgent need to address the infodemic along with the COVID-19 pandemic, as most countries are battling both.

Applications are open to freelance consultants, national health authority staff and United Nations staff who meet the selection criteria to constitute a cohort of trained infodemic managers to support response in countries.

The primary objective of the training is to build the skills of health authority personnel in infodemic management.

Find out more about the training and specific eligibility criteria.



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