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Safety and Effectiveness of the COVID-19 vaccines

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I declare no conflict of interest .

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Introduction

- A new virus emerged in Wuhan, China during December 2019
- This virus, which causes respiratory disease, was identified as being part of the Coronavirus family and it rapidly spread to many other countries around the world
- As of now estimated 200 million people infected, and 4 million died .
- Common symptoms of COVID-19 include a high temperature, a continuous dry cough and loss or change to sense of smell and taste
- About 80% of infected people have no or mild symptoms; 1 in every 6 people who gets COVID-19 becomes seriously ill
- Older people and those with underlying medical problems are more likely to develop serious illness or die from COVID-19
- Measures to contain the virus have included the introduction of social distancing measures, travel restrictions, closure of public spaces and the wearing of face coverings
- despite these measures, the number of positive cases and deaths continue to increase on a daily basis COMPOUNDED BY THE MUTATION AND THE VARIANTS OF CONCERN



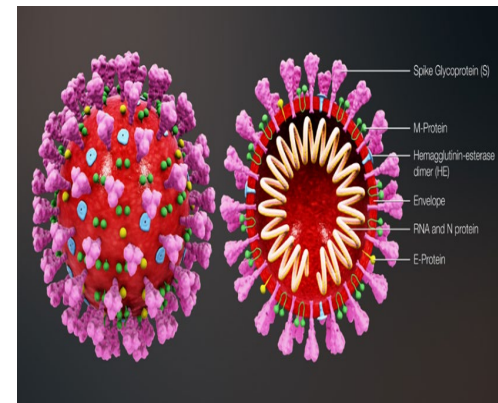
Key messages

- The ongoing global COVID-19 pandemic continues to cause millions of infections and over a million deaths across the world (200/4)
- A vaccine to prevent COVID-19 is the most effective way to control the pandemic
- scientists across the world have worked to develop vaccines which have then been rigorously tested for safety and efficacy
- it is crucial that the COVID-19 vaccine is safely and effectively delivered to as many of those eligible as possible
- those with a role in delivering the COVID-19 vaccine programme need to be knowledgeable, confident and competent in order to promote confidence in the vaccination programme and deliver the vaccine safely
- A continuous changing variant/ advancement in science/and clinical spectrum , makes it important to vigorously be upto-date



Coronavirus structure

- the key parts of the coronavirus are the RNA and the spike proteins
- the RNA is surrounded by an **envelope** which has different roles in the life cycle of the virus. These may include the assembly of new virus and helping new virus to leave the infected cell
- the **spike proteins** (S) are anchored into the viral **envelope** and form a crown like appearance, like the solar corona, hence the name coronavirus. The spike proteins attach to the target cell and allow the virus to enter it
- the **RNA** is inside the envelope and acts as a template so that once it is inside the host cell, the coronavirus can replicate itself and be released into the body
- the Spike protein and the RNA have been used to develop and make different vaccines to protect against SARs-CoV-2



April 2021

The different types of COVID-19 vaccines

Vaccines will play a major role in **ending the COVID-19 pandemic**.
COVID-19 vaccines have already been proven **highly effective** at preventing severe illness, hospitalisation and death.

Approach

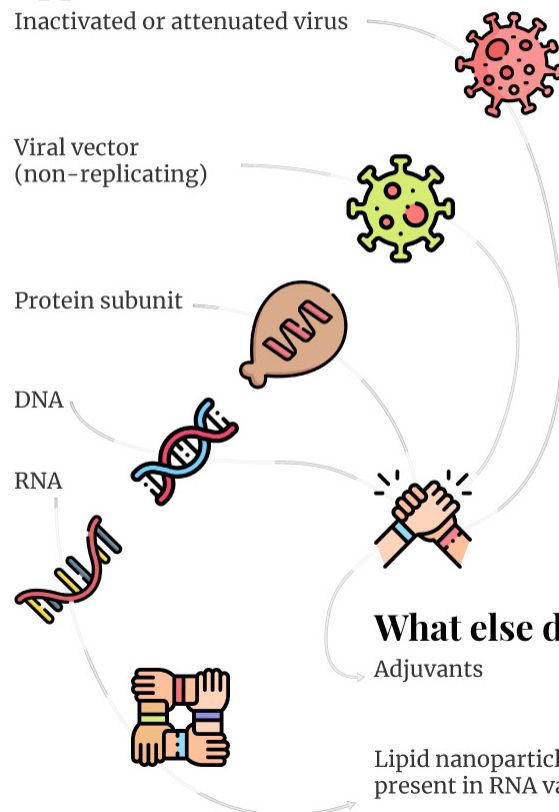
Inactivated or attenuated virus

Viral vector
(non-replicating)

Protein subunit

DNA

RNA



How does it work?

Uses a form of the **virus** that has been **inactivated** or **weakened** so it doesn't cause disease, but still generates an immune response

Uses a virus that has been **genetically engineered** so that it can't cause disease but produces coronavirus proteins to safely generate an immune response

Uses harmless fragments of proteins that **mimic** the COVID-19 virus to safely generate an immune response

Synthetic **DNA fragment** (plasmid) that encodes a COVID-19 antigen

Typically the **RNA segment** of the viral genome that codes for the virus spike protein (or other antigenic region) is prepared in a suspension of lipid nanoparticles

What else do vaccines contain?

Adjuvants

Lipid nanoparticles (NLPs), present in RNA vaccines only

SARS-CoV-19 vaccines *

Sinopharm,
Sinovac

Gamaleya Research Inst. (Sputnik V),
AstraZeneca and Univ. Oxford,
CanSino Biological Inc.,
Johnson & Johnson

EpiVacCorona,
Novavax

Inovio

Pfizer/BioNTech,
Moderna,
Curevac

Similar vaccines

Cholera, Polio, MMR,
Yellow fever,
TBC

Ebola

Seasonal influenza,
Hepatitis B,
Tetanus

None (new tech)

None (new tech)

Why are they there?

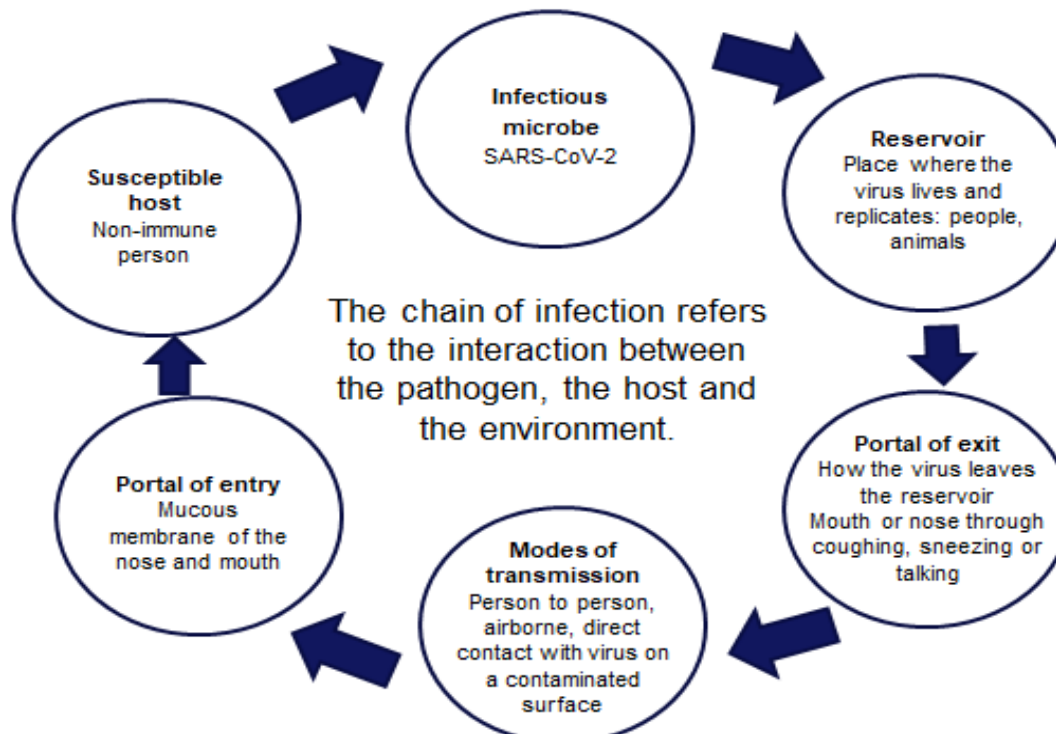
To **enhance** the **immune response** and reduce the dose of antigen needed, e.g. by stimulating the body to produce more antibodies or a longer-lasting immune response

Encapsulate and **protect** the RNA and help it enter the body's cells where the RNA can start producing the desired protein that will produce the antigenic response

*Mention here is for illustrative purposes only and does not signify endorsement by the InterAcademy Partnership (IAP).

Other vaccines produced using similar processes may be equally or more effective or still under trial. Icons designed by Freepik from Flaticon.com.

COVID-19 Chain of infection



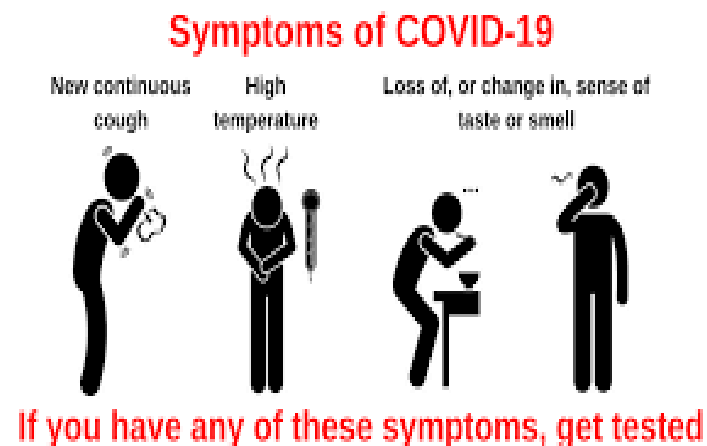
Transmission of COVID-19 infection

- For transmission to occur, the SARS-CoV-2 virus needs to be transported to a susceptible person. To do this, it needs to have:
 - a portal of exit (from the place where it is living and replicating)
 - a mode of transmission (such as coughing or sneezing) and
 - a portal of entry (to the susceptible host)
- COVID-19 spreads primarily from person to person through small droplets from the nose or mouth which are expelled when a person with COVID-19 coughs, sneezes, or speaks.
- These droplets can also survive on objects and surfaces such as tables, doorknobs and handrails.
- People can catch COVID-19 if they breathe in these droplets from a person infected with the virus or
- by touching contaminated objects or surfaces, then touching their eyes, nose or mouth.



COVID-19 Symptoms

- The estimated incubation period is 3 to 6 days but can vary between 1 and 11 days.
- Symptoms may vary by age but the main symptoms of coronavirus are:
 - **a new, continuous cough** – coughing for more than an hour, or 3 or more coughing episodes in 24 hours
 - **a high temperature**
 - **a loss or change to sense of smell or taste**
- Other symptoms reported include:
 - fatigue and lethargy
 - shortness of breath
 - headache
 - sore throat
 - aching muscles
 - diarrhoea and vomiting



COVID-19 symptom progression

- Symptoms may begin gradually and are usually mild.
- the majority of people (around 80%) have asymptomatic to moderate disease and recover without needing hospital treatment
- around 15% may get severe disease including pneumonia
 - older people and those with underlying medical problems such as high blood pressure, heart and lung problems, diabetes, or cancer are more likely to develop serious illness
- around 5% become critically unwell. This may include septic shock and/or multi-organ and respiratory failure
- The infection fatality rate (the proportion of deaths among all infected individuals) is estimated to be
- 0.9% but it varies according to age and sex. It is lower in younger people (0.5% for those 45-64
- years) and higher in those over 75 years of age (11.6%)



The different types of COVID-19 vaccines

Vaccines will play a major role in **ending the COVID-19 pandemic**.
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Complications of Covid-19 disease

- Complications from COVID-19 can be severe and fatal.
- The risk of developing complications increases with age and is greater in those with underlying health conditions.
- The type of complication that can develop may include:
 - venous thromboembolism
 - heart, liver and kidney problems
 - neurological problems
 - coagulation (blood clotting) failure
 - respiratory failure
 - multiple organ failure
 - septic shock



COVID-19 complications in pregnancy

- maternal morbidity is similar to that of other women of reproductive age and the outcome for women infected during pregnancy is usually good
- however, pregnant women with pre-existing comorbidities such as chronic hypertension or diabetes, those with higher maternal age, and high body mass index may experience severe COVID-19 disease
- they may also require intensive care unit admission and invasive ventilation and around 6% of pregnant women may experience a spontaneous pre-term delivery
- neonates born to mothers with COVID-19 have an increased risk of admission to a neonatal unit
- although stillbirths have been reported, perinatal deaths are rare and occur in less than 1% of cases



Symptoms in children and young people

- children comprise only 1 to 2% of cases of COVID-19 worldwide and are more likely to have mild symptoms or asymptomatic infection
- a study of children and young people aged less than 19 years admitted to hospital with laboratory confirmed SARS-CoV-2 reported that the median age of those enrolled in the study was 4.6 years
- other clinical features included age, sex and ethnicity: 35% (225/651) of them were under 12 months old; 56% (367/650) were male; 57% (330/576) were white; 12% (67/576) were South Asian and 10% (56/576) were Black
- of the 651 children and young people in the study, 42% had at least one other medical condition (co-morbidity). These included neurological conditions (11%), haematological, oncological or immunological conditions (8%) and asthma (7%)



Complications from COVID-19 in children and young people

- An extremely rare but severe multisystem inflammatory syndrome (MIS-C) occurring 2 to 4 weeks after the onset of COVID-19 has been identified in children and adolescents
- Cardiac complications were documented in 57% (21/37) of mis-c cases. These were more frequent in post-acute / antibody positive cases (75% 15/20) than in the acute phase 35% (6/17)
- Of the children admitted to hospital, 18% required critical care. This was associated with:
 - Age, particularly for those less than one month old and for those age 10 -14 years
 - black ethnicity and
 - admission to hospital for more than five days before symptom onset
- Other complications from covid-19 in children and young people include fever, cardiac symptoms (myocarditis, heart failure) and gi symptoms (abdominal pain, diarrhoea, vomiting)



COVID-19 vaccine development

- Scientists, industry and other organisations have worked collaboratively across the globe to complete the different phases of vaccine development in parallel, rather than sequentially to make a safe and effective vaccine available as soon as possible
- By knowing the genetic code for the SARS-CoV-2 virus, various methods to create vaccines can be used such as using the code itself (mRNA vaccines) or inserting part of this code into existing viruses (viral vector vaccines)
- By December 2020, over 270 different COVID-19 vaccines were in early development, over 50 of these were being given to people in clinical trials and 11 were being trialled in large phase 3 trials
- Some vaccines have been made using currently used vaccine technology, others have been made using new approaches or methods used during previous emergencies such as the SARS pandemic and west African Ebola



COVID-19 vaccine taskforce

- As the majority of the population are still susceptible (non-immune) to the SARS-CoV-2 virus and the virus spreads easily, it is clear that a safe and effective vaccine is needed to prevent further cases
- A COVID-19 vaccine prepares the immune system so that in the event of an exposure to the virus, it is able to respond and prevent or reduce the severity of infection

In April 2021, The Tanzania Special Committee was nominated by the President to look into the science, effectivity, safety ,procurement and distribution of a SARS-CoV-2 vaccine



Properties of an ideal vaccine

Ideally, a vaccine will:

- Produce the same immune protection which usually follows natural infection but without causing disease
- Generate long lasting immunity so that the person is protected if they are exposed to the antigen several years after vaccination
- Interrupt the spread of infection by preventing carriage of the organism in the vaccinated person
- Vaccines need to be safe and the risk from any side effects should be much lower than the benefit of preventing
- Deaths and serious complications of the disease.
- For the covid-19 vaccines, many of these properties can be confirmed from the clinical vaccine trials.
- Longer term ongoing surveillance of the disease and of those vaccinated will show whether:
- Vaccine protection is long lasting or booster or annual doses are needed
- The vaccine prevents a vaccinated person from carrying and spreading the virus



Stages of vaccine trials

Vaccines are extensively tested through several different phases of trials.

- **Pre-clinical studies** using tissue-culture, cell-culture or animal studies. At this stage, safety and immunogenicity (the ability of the vaccine to produce an immune response) are assessed. If pre-clinical studies are successful, the vaccine then goes through several different phases of vaccine trials in humans
- **Phase i clinical trials** are small-scale trials in healthy adult volunteers (generally 20-100) to assess whether the vaccine is safe in humans and type and extent of immune response it induces
- **Phase ii clinical trials** are larger (several hundred healthy volunteers) and usually carried out in the target age group(s) the vaccine is likely to be used in. They are looking mainly to assess the efficacy of the vaccine against artificial infection and clinical disease. Vaccine safety, side-effects and immune response are also studied
- **Phase iii clinical trials** involve the vaccine being studied on a large scale in many hundreds or thousands of subjects across several sites to evaluate efficacy under natural disease conditions and make sure that there are no unintended side effects not detected in phase ii studies



What are the benefits of getting a COVID-19 vaccine?

- COVID-19 vaccination will help keep you from getting sick from COVID-19.
- All COVID-19 vaccines available in the U.S. have been shown to be very effective.
- The combination of getting vaccinated and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.
- The more people who get vaccinated, the faster we can get back to our normal lives.



Safety

- Before any of the COVID vaccines can be authorised for widespread use in the population, the manufacturers have to demonstrate that they are safe and effective
- Tens of thousands of people across the world have already received covid-19 vaccines in clinical trials
- No serious adverse reactions to the vaccines were seen in the trial participants who received them
- Any reactions reported were similar to those seen following other vaccines such as pain and tenderness at the injection site and fever, headache, muscle aches and fatigue



Effectiveness

- Manufacturers of the COVID-19 vaccines need to show evidence that they will be effective
- They can do this by showing a reduction in virus levels in animal studies where the vaccines were used and that people in the trials have made an antibody response to the vaccine
- Vaccine effectiveness can be calculated by comparing the number of cases of COVID-19 disease in trial participants who received the COVID-19 vaccine with the number of trial participants who received the placebo or alternative (non-covid-19) vaccine
- Those running clinical trials will also look at antibody response:
 - After one dose and two doses
 - At different dosages of the vaccine
 - With different time intervals between vaccine doses
 - In different age groups
- Over time, they will look at
- How long the antibodies last and the effect on antibody levels if a booster dose is given.
- Whether the vaccine only stops people from becoming severely ill or if it also stops them spreading the virus too



Regulatory Affairs

- The United Republic of Tanzania has established two executive agencies under the ministries of health for regulation and control of medicinal products (including vaccines);
- The Tanzania Medicines and Medical Devices Authority (TMDA) for Tanzania Mainland and Zanzibar Food and Drugs Agency (ZFDA) for Zanzibar. TMDA was established under the Tanzania Medicines and Medical Devices Act, Cap 219 and ZFDA under Zanzibar Food, Drug and Cosmetics Act No. 2 of 2006, respectively. The legislations provide a framework for regulation of quality, safety and effectiveness of medicines (including vaccines), medical devices and diagnostics.



THE UNITED REPUBLIC OF TANZANIA



MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY
AND CHILDREN

**NATIONAL DEPLOYMENT AND VACCINATION PLAN (NDVP)
FOR COVID-19 VACCINE**

June 2021



Post authorisation surveillance

- On-going studies of vaccines continue after the vaccine has been authorised for use.
- These studies aim to assess long term efficacy and to detect any rare adverse effects
- Because in real life administration, compared to pre-licensure trials, there will be:
 - Some variability in preparation of the vaccine as vaccines will come from different batches
 - Possible variability in stability and storage, for example the cold chain may not be as rigidly maintained in practice as it was in a clinical trial
 - Use of the vaccines in different groups than in pre-license studies, for example they will be given to people with underlying medical conditions who would not necessarily have been included in a pre-licensure clinical trial



Regulatory approval and licencing

- In our country the TMDA, ZFDA, Government Chemist, Microbiologist, Immunologist and other scientist are involved in the regulatory affairs to ensure the safety of the vaccine.
- NGOs, Embassies and other organizations are allowed to import after permission from the authorities for their staff.
- A detailed guideline of the vaccination program has been made and is being implemented for the same.
- In exceptional situations, the Government will allow emergency suse of the vaccines, example for Hajj after ensuring safety , the process involves the same level of scrutiny as the usual licensing process and this exception is only used when strictly necessary to speed up access to a potentially life-saving intervention .
- The SADC, WHO and other alliances are also involved i n the oversight .



What vaccines are available ?



COVID-19 mRNA vaccine BNT162B2 (Pfizer BioNtech)

- The COVID-19 mRNA vaccine bnt162b2 vaccine is a messenger ribonucleic acid (mRNA) vaccine.
- It contains the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.
- When injected, the mRNA is taken up by the host's cells which translate the genetic information and produce the spike proteins.
- These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.
- As there is no whole or live virus involved, the vaccine cannot cause
- disease. The mRNA naturally degrades after a few days.



AstraZeneca COVID-19 vaccine

- AstraZeneca COVID-19 vaccine is a viral vector vaccine which uses a weakened adenovirus as a carrier to deliver the SARS-CoV-2 antigen.
- The adenovirus has been modified so that it cannot replicate (grow and multiply by making copies of itself) in human cells and therefore cause any disease.
- The genes that encode for the spike protein on the SARS-CoV-2 virus have been inserted into the adenovirus's genetic code to make the vaccine.
- When the vaccine is injected, it enters the host's cells which then manufacture the spike protein.
- This then stimulates the immune system which reacts by producing antibodies and memory cells to the SARS-CoV-2 virus without causing disease.



Vaccine interchangeability

- Data is not yet available on the interchangeability of different COVID-19 vaccines
- Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine
- For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or where the first product received is unknown, it is reasonable to offer a single dose of the locally available product
- This option is preferred if that individual is likely to be at immediate high risk or is considered unlikely to attend again
- As the pfizer-biontech bnt162b2 vaccine and the astrazeneca vaccine are both based on the spike protein of the virus, it is likely that the second dose will help to boost the response to the first dose
- Further doses of vaccine are not required unless additional information becomes available



COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech)

- The vaccine contains BNT162b2 messenger RNA embedded in lipid nanoparticles
- The vaccine does not contain preservative
- No animal products are used in the manufacture of this vaccine
- Product information about the COVID-19 mRNA Vaccine BNT162b2 is available at <https://coronavirus-yellowcard.mhra.gov.uk/productinformation>



Precautions to COVID-19 mRNA Vaccine BNT162b2

- A very small number of individuals have experienced anaphylaxis when vaccinated with the COVID-19 mRNA vaccine bnt162b2 vaccine
- Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to a component (excipient) of the vaccine
- All recipients of this vaccine should be kept for observation and monitored for a minimum of 15 minutes
- Facilities for management of anaphylaxis should be available at all vaccination sites
- Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. A hospital)
- Individuals with non-allergic reactions (vasovagal (fainting) episodes, non-urticarial skin reaction or non-specific symptoms) can receive the second dose of vaccine in any vaccination setting



Contraindications to COVID-19 mRNA Vaccine BNT162b2

- The COVID-19 mRNA vaccine bnt162b2 vaccine should not be given to people who have had a confirmed anaphylactic reaction to the vaccine or any components of the vaccine
- In addition to the highly purified bnt162b2 messenger RNA, the vaccine also contains:
 - ALC-0315 = (4-hydroxybutyl) azanediylbis (hexane-6,1-diyl)bis(2-hexyldecanoate)
 - ALC-0159 = 2-[(polyethylene glycol)-2000]-n,n-ditetradecylacetamide
 - 1,2-distearoyl-sn-glycero-3-phosphocholine
 - Cholesterol
 - Potassium chloride
 - Potassium dihydrogen phosphate
 - Sodium chloride
 - Disodium hydrogen phosphate dihydrate
 - Sucrose
 - Water for injections

Polyethylene glycol (PEG) is an allergen commonly found in medicines and also in household goods and cosmetics. Known allergy to PEG is extremely rare but would contraindicate receipt of this vaccine.

- The AstraZeneca vaccine does not contain PEG and is a suitable alternative.



Adverse reactions following COVID-19 mRNA Vaccine BNT162b2

The following reactions were reported by the vaccine clinical trial participants

Local reactions:

- Over 80% reported pain at the injection site. Redness and swelling was also commonly reported

Systemic reactions

- The most frequently reported systemic reactions (reactions affecting the whole body) were
- Tiredness (> 60%) headache (> 50%)
- Muscle aches (> 30%) chills (> 30%)
- Joint pain (> 20%) raised temperature (pyrexia)(> 10%)
- These symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination.
- Medicines such as paracetamol can be given for pain or fever if required.
- Inform vaccinees these symptoms normally last less than a week but if their symptoms get worse or they are concerned, they should speak to their gp



COVID-19 mRNA Vaccine BNT162b2 presentation

- The vaccine packs contain 195 vials of vaccine (975 doses per pack as each vial contains 5 doses)
- The vaccine is contained in a multidose clear glass vial. The vial has a rubber (bromobutyl) stopper, aluminium seal and a flip-off plastic cap. The stopper does not contain latex
- Each vial contains 0.45 ml of vaccine and should be diluted with 1.8 ml of sodium chloride 0.9% solution for injection (normal saline). Once diluted, each reconstituted vaccine will supply 5 doses of 0.3 ml (30 mcg)
- **Note:** after withdrawing 5 full 0.3ml doses from the vial, it may be possible to withdraw a sixth full dose if the dose-sparing needles and syringes being provided with the vaccine are being used. Care should be taken to ensure a full 0.3 ml dose will be administered to the patient from the same vial. Where a full 0.3 ml dose cannot be extracted, the contents should be discarded
- A separate ampoule containing a minimum of 2ml of normal saline is required for vaccine reconstitution
- Each ampoule of diluent is single use and any remaining diluent must be discarded after 0.3ml has been withdrawn, regardless of the ampoule volume



COVID-19 mRNA Vaccine BNT162b2 dose and schedule

- A single dose is 0.3 ml (30 mcgs)
- Two doses of covid-19 mrna vaccine bnt162b2 are required with a minimum 21-day interval between doses
- Operationally, it is recommended that the second dose of covid-19 vaccine should be routinely scheduled between four and 12 weeks after the first dose
- This will allow more people to benefit from the protection provided from the first dose during the roll out phase
- Longer term protection will then be provided by the second dose



Contraindications to Covid-19 Vaccine AstraZeneca

- The **COVID-19 Vaccine AstraZeneca vaccine** should also not be given to people who have had a confirmed anaphylactic reaction to the vaccine or any components of the vaccine.
- The COVID-19 Vaccine AstraZeneca contains recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

It also contains:

- L-Histidine
- L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- Water for injections

The vaccine does not contain preservative



Adverse reactions following Covid-19 Vaccine AstraZeneca

The following reactions were reported by the vaccine clinical trial participants:

Local reactions

- More than 60% reported tenderness at the injection site with redness, swelling, pain also being reported

Systemic reactions

- The most frequently reported systemic reactions (reactions affecting the whole body) were
Tiredness (> 50%) headache (> 50%)
Muscle aches (> 40%) feeling generally unwell (>40%)
Chills (> 30%) raised temperature (pyrexia)(> 30%)
Joint pain (> 20%) nausea (> 20%)
- These symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination
- Medicines such as paracetamol can be given for post-vaccination pain or fever if required
- Inform vaccinees these symptoms normally last less than a week but if their symptoms get worse or they are concerned, they should speak to their GP



Covid-19 Vaccine AstraZeneca presentation

- COVID-19 vaccine astrazeneca is presented in a multidose vial containing a solution which should be colourless to slightly brown, clear to slightly opaque and free of particles
- The vial has a halobutyl rubber stopper and is sealed with an aluminium overseal. There is no latex in the vial stopper (bung)
- Astrazeneca vaccine will be delivered in packs that contain 10 vials
- Two different presentations of the astrazeneca vaccine are expected to be provided:
 - » 80 dose packs (ten 4 ml vials with 8 doses per vial)
 - » 100 dose packs (ten 5 ml vials with 10 doses per vial)
- The majority of the vaccine will be supplied as the 8 doses per vial presentation but the 10 dose vial may be provided initially
- **Vaccinators must check how many doses the vial they are using contains so that vaccine is not wasted**



Covid-19 Vaccine AstraZeneca dose and schedule

- A single dose is 0.5ml
- Two doses of astrazeneca vaccine are required with a minimum 28-day interval between doses
- Operationally, it is recommended that the second dose of covid-19 vaccine should be routinely scheduled between four and 12 weeks after the first dose
- This will allow more people to benefit from the protection provided from the first dose during the roll out phase
- High levels of protection are evident after the first dose of vaccine
- Longer term protection will then be provided by the second dose



Covid-19 Vaccine AstraZeneca storage and use

- Upon delivery, astrazeneca vaccine should be transferred to a fridge immediately and stored between +2°C and +8°C
- Vials should be kept upright in their box and away from direct sunlight to prevent prolonged light exposure
- Once the vial bung is punctured, the vaccine must be used as soon as possible and within 6 hours of first puncture (during which time it can be stored between +2°C to +25°C)
- As the vaccine does not contain preservative, any unused vaccine must be discarded if not used within this 6 hour time period



Sinovac : BBIBP-CorV

- Key evidence to inform policy recommendations on the use of bbibp-corv
- Clinical development safety summary
- No safety concerns identified from pre-clinical or repro/tox studies
- Clinical safety database: 16,671 participants who received any dose/schedule of bbibp-corv product, of
 - Which 97% received authorized dose/schedule
- Most aes were mild to moderate: most common adverse events were pain at the injection site,
- Headache, and fatigue
- No imbalance in the number of reported serious adverse events, adverse events of special interest
- (Neurological diseases), or grade 3+ adverse event between bbibp-corv and placebo group
- Two serious adverse events assessed to be possibly linked to vaccination (serious nausea and
- Inflammatory demyelination syndrome/acute disseminated encephalomyelitis)
- One death occurred in the phase 3 trial, in the placebo group
- One participant with a diagnosis of thrombus was identified in the phase 3 trial, in the bbibp-corv group
- All acute allergic reactions were grade 1 and 2 in bbibp-corv group (no anaphylaxis) and no difference



Moderna vaccine

- Safety – Special Considerations: PEGylation (or pegylation)
- The vaccine contains four lipids. The lipids encapsulate the mRNA in the form of a lipid nanoparticle to aid cell entry, ensure stability and have an adjuvant effect.
- Two of the lipids are commonly used in approved medicinal products (cholesterol and 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)) and two have not been commonly used in an authorised medicinal product. SM-102 (proprietary to Moderna). 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]
- Anaphylaxis cases reported with the Moderna vaccine.
- The potential role of the PEG in the anaphylactic reactions, and whether IgE or CARPA (complement activation-related pseudoallergy), a non-IgE-mediated pseudoallergy, related to be determined.



Sputnik Light (One dose)

- Offering a 79.4% efficacy and costing less than \$10 per dose, sputnik light solves the challenge of immunizing large groups of people in a shorter time frame, according to kirill dmitriev. Dmitriev is head of the russian direct investment fund, which is responsible for promoting sputnik vaccines abroad.
- The adverse events that people have reported after receiving sputnik light are, so far, similar to those of other covid-19 vaccines. They include:
 - Mild pain at the injection site
 - Fever
 - Headaches
 - Fatigue
 - Muscle aches
- At present, there are no reports of the rare blood-clotting side effects that people have reported in connection with the oxford-astrazeneca and johnson & johnson covid-19 vaccines.



Sputnik Light (Ad26)

- WHO interim inspection did not identify any critical issues , it was related to 4 issues in the filling sites of the vials and none related to production line

Read more at:

http://timesofindia.indiatimes.com/articleshow/83815533.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst



Janssen(J &J)

Date of WHO Emergency Use Listing (EUL) recommendation: 12 March 2021

The COVID-19 Vaccine Janssen (Ad26.COVS-S [recombinant]) is a non-replicating adenoviral vector vaccine against coronavirus disease 2019 (COVID-19). The vector virus contained within the vaccine delivers an instruction to host cells to produce the SARS-CoV-2 antigen called the spike protein, which triggers the production of antibodies. This allows the body to generate an immune response and to retain that information in memory immune cells. Efficacy shown in clinical trials in participants who received a single dose of COVID-19 Vaccine Janssen was 66.9% against symptomatic SARS-CoV-2 infection, 76.7% against severe COVID-19 after 14 days and 85.4% after 28 days, and 93.1% against hospitalizations. The data reviewed at this time support the conclusion that the known and potential benefits of COVID-19 Vaccine Janssen outweigh the known and potential risks.



April 2021

The different types of COVID-19 vaccines

Vaccines will play a major role in **ending the COVID-19 pandemic**.
COVID-19 vaccines have already been proven **highly effective** at preventing severe illness, hospitalisation and death.

Approach

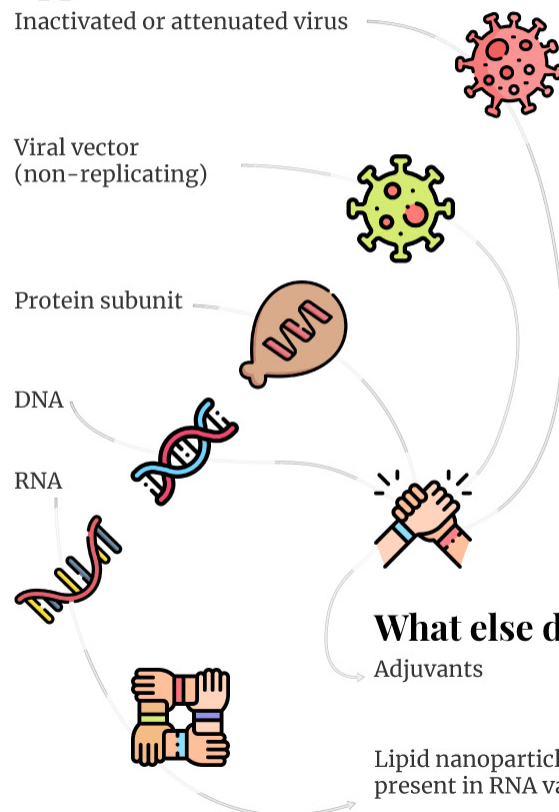
Inactivated or attenuated virus

Viral vector
(non-replicating)

Protein subunit

DNA

RNA



How does it work?

Uses a form of the **virus** that has been **inactivated** or **weakened** so it doesn't cause disease, but still generates an immune response

Uses a virus that has been **genetically engineered** so that it can't cause disease but produces coronavirus proteins to safely generate an immune response

Uses harmless fragments of proteins that **mimic** the COVID-19 virus to safely generate an immune response

Synthetic **DNA fragment** (plasmid) that encodes a COVID-19 antigen

Typically the **RNA segment** of the viral genome that codes for the virus spike protein (or other antigenic region) is prepared in a suspension of lipid nanoparticles

What else do vaccines contain?

Adjuvants

Lipid nanoparticles (NLPs), present in RNA vaccines only

SARS-CoV-19 vaccines *

Sinopharm,
Sinovac

Gamaleya Research Inst. (Sputnik V),
AstraZeneca and Univ. Oxford,
CanSino Biological Inc.,
Johnson & Johnson

EpiVacCorona,
Novavax

Inovio

Pfizer/BioNTech,
Moderna,
Curevac

Similar vaccines

Cholera, Polio, MMR,
Yellow fever,
TBC

Ebola

Seasonal influenza,
Hepatitis B,
Tetanus

None (new tech)

None (new tech)

Why are they there?

To **enhance** the **immune response** and reduce the dose of antigen needed, e.g. by stimulating the body to produce more antibodies or a longer-lasting immune response

Encapsulate and **protect** the RNA and help it enter the body's cells where the RNA can start producing the desired protein that will produce the antigenic response

*Mention here is for illustrative purposes only and does not signify endorsement by the InterAcademy Partnership (IAP).

Other vaccines produced using similar processes may be equally or more effective or still under trial. Icons designed by Freepik from Flaticon.com.

UK variant (B.1.1.7 or 20I/501Y.V1)

B.1.1.7, also known as VOC202012/01 was detected in September, 2020 in the UK. It has 23 mutations compared to the original strain found in Wuhan, China. Eight of these mutations were found to be in the S protein. Its notable mutations are N501Y, 69/70 deletion and P681H. The N501Y mutation appears to allow for the S protein to bind more tightly to the ACE2 receptor .

It is 40-80% more transmissible, the mortality was approximately 55% higher when compared to other variants



South African variant (B.1.351 or 20H/501Y.V2)

The B.1.351 variant, also known as 501Y.V2 was first identified as early as October 2020 in Nelson Mandela Bay in South Africa. It is suggested to have increased transmissibility and most commonly seen in young people without underlying diseases .

- The mutation E484K in this variant mediates the antibody escape is the main reason for the reduced sensitivity to vaccines.



Brazilian variant (P.1 or 20J/501Y.V3)

- P.1 variant also known as B.1.1.28.1 was first detected in North Brazil in the city of Manaus in the Amazonas state in December 2020.
- This variant is 2.2 times higher transmissible that led to a few cases of reinfection who recovered from COVID-19, and almost has a similar rate infection in the younger (18 - 59 years old) and older (> 60 years old) patients .
- Sinovac Biotech has initiated the clinical trials which demonstrated that the CoronoVac vaccine is 50% effective in preventing infection with the P.1 variant in Brazil.



Double mutant variant (B.1.617)

- This variant is first detected in India. As two mutations are seen in the same virus, this variant is called a “double mutant” variant. There was a significant increase in COVID-19 cases in India.
- These variants are at increased risk of transmission and also resistant to vaccination. According to Indian Council of Medical Research Virology Lab, Bharat Biotech’s COVAXIN vaccine has been found to effectively neutralize the infection, and is 78% effective against the double mutant variant .



COVID-19 Vaccine Challenges

A small percentage of the fully immunized population will still get sick to varying degrees from COVID-19 disease. They are known as vaccine breakthrough cases.

Vaccine refusal has been an issue physicians have had to deal with even in pre-pandemic times . There has been growing COVID-19 vaccine hesitancy- the anti-vaxx!! . Equitable vaccine distribution, storage requirements and cost are factors that will have a significant impact in areas across the world.

Targeted about 11 million population initially(which is 20% of the population) of Tanzanians. (Ref : NDVP and Prof. Abel Makubi: The Citizen 23rh July, 2021)



Conclusions

The emerging variants not only result in increased transmissibility, morbidity and mortality but also have the ability to evade detection by diagnostic tests, exhibit decreased susceptibility to treatment including antivirals, monoclonal antibodies and convalescent plasma, possess the ability to cause reinfection in previously recovered and vaccinated individuals. Children and immunocompromised individuals are at increased risk of developing multisystem inflammatory syndrome or long-haul COVID .

The longer the virus propagates the chance of mutations are higher.

Vaccine breakthrough cases are often undercounted and fully vaccinated populations should still practice preventative measures.

Continuation of precautionary measures including masking, hand hygiene, isolation and quarantine along with other public health mitigation strategies, genomic surveillance and vaccination plays an important role in prevention of spread; early identification of variants, prevention of mutations and viral replication, respectively, and still form the cornerstone of the action plan to control the COVID-19 pandemic .



Vasireddy D, Vanaparthi R, Mohan G, Malayala SV,
Atluri P. Review of COVID-19 Variants and COVID-19
Vaccine Efficacy: What the Clinician Should Know?. J
Clin Med Res. 2021;13(6):317-325.
doi:10.14740/jocmr4518



Important Findings : In the context of the Vaccine in Tanzania

- Rapid and massive vaccine rollouts using current SARS-CoV-2 vaccines
- The clinical protection findings of the Johnson & Johnson and Novartis vaccines against the South African variant indicate that even though the protection efficacy of these vaccines is lower than those against previous epidemic strains, they are still higher than or close to the protection level criterion of at least 50% as defined by the World Health Organization (i.e. 57% and 49.4%, respectively) [46,48]. In other words, the vaccines retain a certain level of effectiveness against the variant. *Hence, the urgent rollouts of current vaccines to immunize a large proportion of the population is currently the best option to manage the threat of emerging variants.*



References

1. Johnson & Johnson. Johnson & Johnson announces single-shot Janssen COVID-19 vaccine candidate met primary endpoints in interim analysis of its Phase 3 ENSEMBLE trial 2021 . Available from: <https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial> .
2. Witwatersrand U Oxford Covid-19 vaccine trial results 2021 . Available from: <https://www.wits.ac.za/covid19/covid19-news/latest/oxford-covid-19-vaccine-trial-results.html>
3. Novavax. Novavax COVID-19 vaccine demonstrates 89.3% efficacy in UK Phase 3 trial 2021. Available from: <https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>



N Engl J Med 2021; 385:179-186

Table 2. Key Spike Protein Mutations in Five SARS-CoV-2 Variants.

Variant	Phenotypic Change	Amino Acid Position in Prototype Virus and Proposed Effect of Changing It*						
		$\Delta 69-70$ Increase transmission	K417 Decrease neutralization	L452 Decrease neutralization	E484 Decrease neutralization	N501 Increase transmission	D614 Increase transmission	P681 Increase transmission
B.1.1.7 (or alpha)	Increase transmission	69-70 deleted			K (later change)	Y	G	H
B.1.351 (or beta)	Increase transmission and virulence		N		K	Y	G	
B.1.1.28.1 (or gamma or P.1)	Increase transmission and virulence, decrease neutral- ization		N/T		K	Y	G	
B.1.617.2 (or delta)	Increase transmis- sion, decrease neutralization			R			R	R
B.1.617.1 (or kappa)	Increase transmis- sion, decrease virulence			R	Q		G	R

Single letter codes of amino acid changes at specified positions for the listed variants are shown.



How some of the Covid-19 vaccines compare

Company	Doses	Storage
RNA		
 Pfizer (BioNTech)		 -80 to -60°C (6 months) and 2 to 8°C (for up to 5 days)
 Moderna		 -25 to -15°C (6 months) and 2 to 8°C (for 30 days)
Viral vector		
 Oxford-AstraZeneca		 2 to 8°C (6 months)
 Sputnik V (Gamaleya)		 -18.5°C (liquid form) 2 to 8°C (dry form)
 Johnson & Johnson (Janssen)		 2 to 8°C (3 months)
Inactivated virus		
 CoronaVac (Sinovac)		 2 to 8°C
 Sinopharm		 2 to 8°C
 Covaxin (Bharat Biotech)		 2 to 8°C
Protein-based		
 Novavax		 2 to 8°C

Source: Wellcome Trust, BBC research

BBC





Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant

RESULTS

Effectiveness after one dose of vaccine (BNT162b2 or ChAdOx1 nCoV-19) was notably lower among persons with the delta variant (30.7%; 95% confidence interval [CI], 25.2 to 35.7) than among those with the alpha variant (48.7%; 95% CI, 45.5 to 51.7); the results were similar for both vaccines. With the BNT162b2 vaccine, the effectiveness of two doses was 93.7% (95% CI, 91.6 to 95.3) among persons with the alpha variant and 88.0% (95% CI, 85.3 to 90.1) among those with the delta variant. With the ChAdOx1 nCoV-19 vaccine, the effectiveness of two doses was 74.5% (95% CI, 68.4 to 79.4) among persons with the alpha variant and 67.0% (95% CI, 61.3 to 71.8) among those with the delta variant.

CONCLUSIONS

Only modest differences in vaccine effectiveness were noted with the delta variant as compared with the alpha variant after the receipt of two vaccine doses. Absolute differences in vaccine effectiveness were more marked after the receipt of the first dose. This finding would support efforts to maximize vaccine uptake with two doses among vulnerable populations.

The future.....

To Manufacture our own vaccines (e.g Rwanda). The way we have done many animal vaccines .Initiatives are ongoing .

Vaccine
Manufacturing in
Africa: What It
Takes and Why It
Matters

TOYIN ABIODUN
HAYLEY ANDERSEN
LIYA TEMESELEW MAMO
OB SISAY

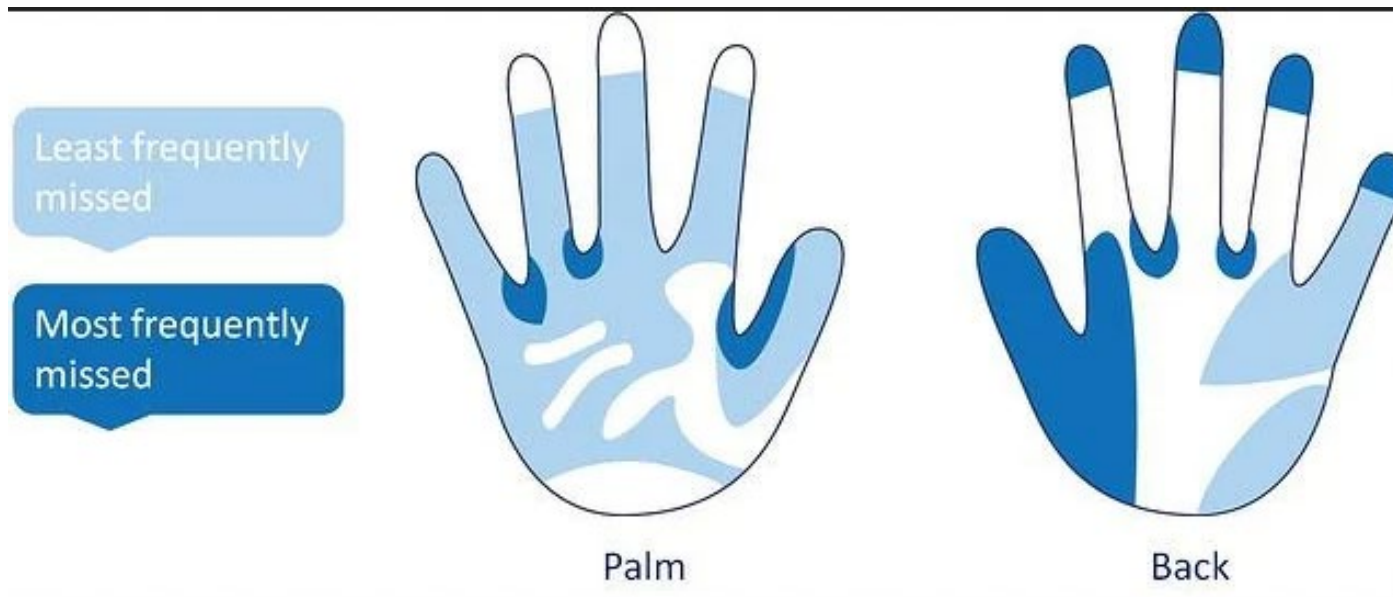


TONY BLAIR
INSTITUTE
FOR GLOBAL
CHANGE



Lastly: How do you wash well?

- These are the parts of the hand we usually forget to wash:



How do you wash well?

Hand washing technique with soap and water



Wet hands
with water



Apply enough soap
to cover all hand
surfaces



Rub hands palm
to palm



Rub back of each hand
with palm of other hand
with fingers interlaced



Rub palm to palm with
fingers interlaced



Rub with back of fingers
to opposing palms with
fingers interlocked



Rub each thumb clasped
in opposite hand using a
rotational movement



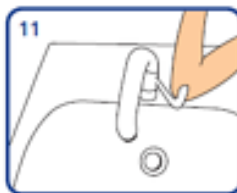
Rub tips of fingers in
opposite palm in a
circular motion



Rub each wrist with
opposite hand



Rinse hands
with water



Use elbow to turn off tap
(if no elbow tap available
use paper towel to turn off tap)



Dry thoroughly with
a single-use towel



Hand washing should
take 40-60 seconds

Issued by  www.debgroup.com



World Health
Organization

Adapted from World Health Organization Guidelines
on Hand Hygiene in Health Care 2009

UKLIT0477/0216

Face Masks slow the spread of COVID-19

Cloth face masks should be worn in public settings where social distancing measures are difficult to maintain, such as in grocery stores, classroom, or especially in areas of significant community-based transmission (daladala).

But wearing one is an act of
ALTRUISM



1. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html>.
2. [https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak).

Thank you for listening !!!