

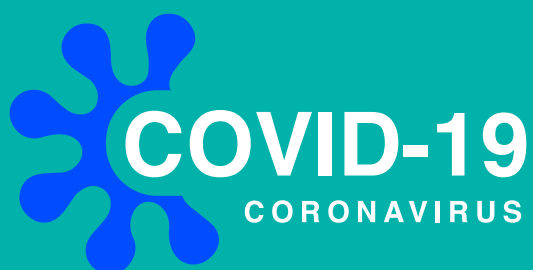


**World
Physiotherapy**

World Physiotherapy response to COVID-19

Briefing paper 8

COVID-19 VACCINES AND IMMUNISATION



May 2021

COVID-19 vaccines and immunisation

Briefing paper

World Physiotherapy briefing papers

World Physiotherapy briefing papers inform our member organisations and others about key issues that affect the physiotherapy profession.

World Physiotherapy is producing a series of papers in response to COVID-19.

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➤ Introduction

Globally, from the beginning of the outbreak to the beginning of May 2021, there have been more than 3.2 million COVID-19 related deaths and more than 155 million COVID-19 related cases. ¹ World Physiotherapy has another briefing paper providing an [overview of COVID-19](#). ²

Efficacious safe vaccines have the potential to control the COVID-19 pandemic if there is sufficient production capacity and if they are distributed fairly and equitably. Successful immunisation programmes need to ensure effective community engagement, building local vaccine acceptability and confidence, and overcoming cultural, socioeconomic, and political barriers that lead to mistrust and hinder uptake of vaccines. ³

Key messages

➤ Vaccines for disease prevention



- research has demonstrated that COVID-19 vaccines are safe and effective in preventing the COVID-19 disease and reducing the chance of serious illness if an immunised person contracts COVID-19
- COVID-19 vaccination is a crucial tool to manage and eliminate the COVID-19 disease

➤ Immunisation strategy



- to contain and control the COVID-19 pandemic, a collaborative global effort is required to ensure all countries have rapid, fair and equitable access to safe, effective vaccines
- populations at higher risk of COVID-19 infection should be identified for priority vaccination (eg physiotherapists, other health workers, older people or those with underlying health conditions)
- with pressure to vaccinate entire populations, physiotherapists are being utilised as vaccinators where approved as within their scope of practice limitations and the vaccinator education requirements of the specific jurisdictions
- immunisation strategies, including non-traditional and even novel ones, will be essential to reach priority populations equitably
- effective immunisation strategies require a comprehensive communication plan to run in tandem with the continuous promotion of prevention measures

➤ Immunisation and vaccination overview

The World Health Organization (WHO) describes vaccination as a simple, safe, and effective way of protecting people against harmful diseases before they come into contact with them. It uses the body's natural defences to build resistance to specific infections and makes the immune system stronger.

Vaccines train the immune system to create antibodies, just as it does when exposed to a disease. However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, they do not cause the disease or put you at risk of its complications. ⁴

In total, vaccines are estimated to save between two and three million lives every year. WHO's vaccine safety programme is constantly helping monitor vaccines' safety. It works with governments, vaccine manufacturers, scientists, and medical experts to help ensure that vaccines are safe. ⁵

A vaccine is a biological antigenic preparation that stimulates the body's immune system to recognise pathogens without causing the specific illness. All vaccines follow the basic principle of imitating an infection to enable the immune system to develop protective or adaptive immunity. The ideal vaccine is safe, immunogenic, efficacious, long-lasting and stable.

➤ The SARS-CoV-2 virus and vaccine types

SARS-CoV-2 is a ribonucleic (RNA) virus. The spike protein gives the virus its shape and crown-like appearance. This protein is the key to transmitting the virus into human cells via the angiotensin-converting enzyme 2 (ACE2) receptor. The virus replicates inside cells using its RNA. Blocking the virus from entering the cell prevents virus infection.

Most vaccines have been designed to induce an antibody response to the spike protein to prevent the binding to the ACE2 receptor. This prevents the virus from entering the cell and replicating. The production of these neutralising antibodies is the hallmark of an effective vaccine to eliminate COVID-19 infection.

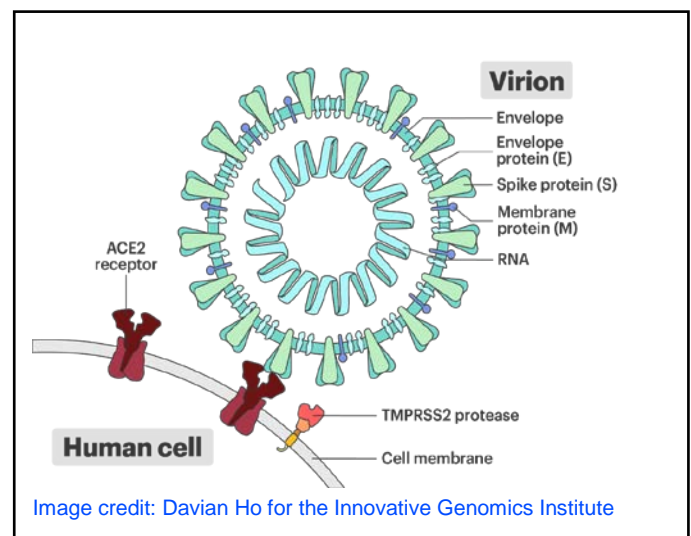
There are several different types of vaccines that have been approved in countries for COVID-19 immunisation. These have specific storage requirements and recommended dosages.

The main types are:

Genetic: these vaccines are the newest approach. They use genetically engineered messenger RNA material to generate a piece of the spike protein to elicit an immune response (eg Comirnaty, Moderna).

Viral vector: these vaccines use a safe adenovirus, a type of the common cold, as a platform to carry the genetic instructions to generate the spike protein. After attaching to cells, they inject DNA to cause the spike protein production and the accompanying immune response (eg COVID-19 Vaccine AstraZeneca, COVID-19 Vaccine Janssen, Sputnik V).

Figure 1 The SARS-CoV-2-virus



Protein-based: protein vaccines utilise harmless fragments of the coronavirus spike protein, which the immune system finds to stimulate a positive response (eg NVX-CoV2373 Novavax).

Inactivated: these use a form of the virus that has been inactivated or weakened to generate an immune response and not the actual disease safely. They take longer to make as the coronavirus has to be first grown, then chemically or heat inactivated, then made into a vaccine (eg CoronaVac, BBIBP-CorV).

For an overview of how different types of vaccines work see the [images](#) from the Royal Pharmaceutical Society (UK). ⁶

➤ Approved vaccines

In February 2021, there were seven different vaccines approved for use worldwide. There were also 200 additional vaccines in development, with more than 60 in the clinical development stage. On April 30 2021, there were 14 vaccines approved by at least one country, 111 vaccine candidates and 326 trials in process. ⁷ Existing manufacturers have indicated they can modify their existing vaccine to respond to mutations. ⁸

WHO approves novel health products during public emergencies for its emergency use listing (EUL). The approval process ensures medicines, vaccines, and diagnostics have fulfilled specific criteria of safety, efficacy and quality, so that these products may be readily available in the case of an emergency. ⁹ The Pfizer, AstraZeneca, Johnson & Johnson and Moderna vaccines were listed between December 2020 and March 2021.

On May 7 2021, WHO approved the Sinopharm COVID-19 vaccine for emergency use. ¹⁰ This is the first vaccine from a non-Western country to receive the WHO endorsement. It has already been given to millions of people in China and other countries. The Sinopharm vaccine can be stored in a standard refrigerator, making it highly suitable for low-resource settings. WHO's assessment of China's Sinovac vaccine is also awaited.

The vaccines in table 1 have been approved or authorised by many different countries (May 2021). ¹¹

Table 1 Approved or authorised vaccines

Name	Vaccine type	Primary developers	Efficacy ¹²	Country of origin	Dose
Comirnaty	mRNA	Pfizer/BioNTech	95%	Multinational	Two
COVID-19 Vaccine AstraZeneca; also known as Vaxzervria and Covishield	Viral vector	AstraZeneca/Oxford	62%-90% Depending on dosage	UK	Two
COVID-19 Vaccine Janssen	Viral vector	Janssen Vaccines	72% in US 66% in Latin America 57% in South Africa	The Netherlands, US	One

Name	Vaccine type	Primary developers	Efficacy ¹²	Country of origin	Dose
Sputnik V	Viral vector	Gamaleya Research Institute	91.4%	Russia	Two
CoronaVac	Inactivated vaccine	Sinovac	50.8%	China	Two
Moderna COVID-19 Vaccine	mRNA	Moderna	94.5%	US	Two
BBIBP-CorV	Inactivated vaccine	Sinopharm; Beijing institute of Biological Products	79.3%	China	Two
EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology	Unknown	Russia	Two
Covaxin	Inactivated vaccine	Bharat Biotech, ICMR	Unknown	India	Two
Potential vaccines					
NVX-CoV2373	Nano particle	Novavax	89.3%	US	Two
VIR-7831	Plant-based adjuvant	Medicago	Unknown	Canada	Two
CVnCoV	mRNA	Curevac	Unknown	Germany	Two
ZyCoV-D	DNA plasmid	Zydus Cadila	Unknown	India	Three

New variants and vaccines: Viral variants are normal and inevitable. The current vaccines are still effective against the new variants though their efficacy has decreased. Pfizer and Oxford-AstraZeneca are reported to be developing modifications that target the new variants. ¹³

Storage: There is a range of storage requirements for the COVID-19 vaccines. The requirements reflect the environment that is necessary to ensure the stability of the vaccine. This significantly impacts the vaccine cost and ease of distribution. At the extreme of the range is the Comirnaty vaccine that needs storage at -70°C, whereas the AstraZeneca is stable in a refrigerator for at least six months.

➤ Safety

There are multiple ways to produce a vaccine. These all have to undergo rigorous testing to ensure they meet the country specific regulatory requirements for safety and efficacy.

The vaccine clinical trial process consists of three phases:

1. This tests the vaccine safety and immunogenicity on low-risk individuals (10-100 participants).
2. This tests the safety, potential side effects, immune response and potential dosage of the vaccine (100-1,000 participants).
3. The clinical efficacy of the disease prevention is tested in conjunction with more safety data with more heterogeneous populations over an extended time (1,000- 10,000 or more participants).

In conjunction with ongoing monitoring, the clinical trial process ensures the vaccines are continually being assessed to confirm they remain safe and effective for those who receive them.

Side effects: The COVID-19 vaccine side effects are mild and can include a low-grade fever, pain or redness at the injection site, fatigue, headache, muscle aches, and diarrhoea. These usually resolve within a few days. More severe or long-lasting side effects are extremely rare. ¹⁴

There has been some concern over reports of unusual blood clots following the first dose of the AstraZeneca and Janssen COVID-19 vaccines. In the United Kingdom, with over 20 million vaccinated with AstraZeneca, the blood clot cases equate to one per 250,000 people vaccinated (0.0004%) and one death in a million. ¹⁵ Both WHO and the International Society on Thrombosis and Hemostasis have concluded that the benefits of administering these two vaccines outweigh the risks.

^{16, 17}

The safety guidance includes assessment for defined populations.

Pregnant women: COVID-19 vaccination is recommended in pregnancy due to the benefits outweighing the increased risks associated with contracting COVID-19. Although the data is limited, it is reassuring, leading to the regulatory bodies in the United Kingdom, European Union and the United States recommending vaccination in pregnancy. ¹⁸

Breastfeeding mothers: It has been recommended that lactating women can be safely included in COVID-19 vaccination programmes. ¹⁹

Children: In May 2021, children were not being vaccinated for COVID-19 as they develop only mild effects from contracting the infection and their role in virus transmission is minimal. ²⁰ There is also minimal research covering the effectiveness and safety of any of the COVID-19 vaccines for use with children.

➤ Vaccine equity

'No one is safe unless everyone is safe' is often quoted regarding vaccination and particularly COVID-19. ²¹

COVID-19 Vaccine Global Access ([COVAX](#)) was formed in March 2020 following a call from G20 leaders. It is one of three pillars of the Access to COVID-19 Tools (ACT) Accelerator, launched in April 2020 by WHO, the European Commission, France and the Bill and Melinda Gates Foundation. The COVAX pillar is co-managed by three partner agencies: Gavi, the Vaccine Alliance (Gavi), the Coalition for Epidemic Preparedness Innovations and WHO. They work with manufacturers in high and low income countries to develop, manufacture and deliver COVID-19 vaccines globally to countries in all resource settings. ²²

COVAX works to ensure that all countries have rapid, fair and equitable access to safe, effective vaccines to facilitate a timely end to the pandemic's acute phase. To achieve this, COVAX needs to ensure it has manufactured quality vaccines in sufficient quantities required to end the crisis. The

WHO's EUL is a prerequisite for COVAX facility vaccine supply. The EUL listing allows countries to expedite their regulatory approval to import and administer COVID-19 vaccines.

The initial goal of COVAX was to fairly distribute 2 billion doses of COVID-19 vaccines across 200 countries by the end of 2021. Gavi estimated this was enough doses to protect the high-risk and vulnerable people, including healthcare workers.²² The United Nations International Children's Emergency Fund (UNICEF) has been working on the behalf of COVAX to procure and deliver vaccines. In February 2021, the countries Ghana and Cote d'Ivoire were the first to receive vaccines from COVAX.²³

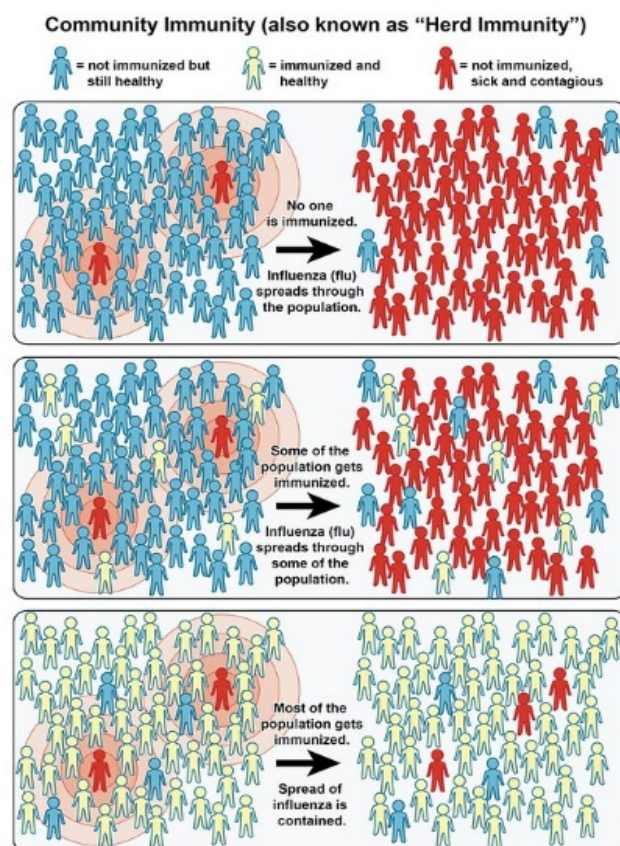
#VaccinEquity is a call to action issued by WHO in January 2021 to encourage all countries to work together to overcome the pandemic, inequalities inherent to global health challenges and drive global recovery.²⁴ The [#VaccinEquity Declaration](#) states that vaccine equity for all health workers must be accelerated to protect these vulnerable workers at the forefront of the pandemic response, most of whom are women. WHO reported that after 100 days over half a billion COVID-19 vaccines had been administered worldwide, over 38 million COVAX doses had been sent to over 100 countries, tens of thousands of individuals, and nearly 1,500 organisations had signed the #VaccinEquity Declaration. World Physiotherapy is a signatory to the #VaccinEquity Declaration.

➤ Herd immunity

Herd immunity is a concept that when sufficient people in the population have immunity to infection through immunisation or previous infection, the whole population, including those unvaccinated, are protected from the disease.²⁵ The current estimates for COVID-19 suggest that to achieve herd immunity, 60-80% of the population needs to be immunised.²⁶

The crucial aspect of herd immunity is that if a person becomes infected, there are not enough susceptible hosts to maintain transmission. This 60-80% threshold will be a challenge for many reasons. Although several COVID-19 vaccines are highly effective at preventing symptomatic disease, it is not known if an asymptomatic infected individual could spread the virus. It is also not known how long an individual's immunity lasts from either a COVID-19 infection or vaccination and whether an annual immunisation will be required. This would create an additional financial burden on countries. Finally, any new variants could complicate the herd immunity equation.

Figure 2 Herd immunity [source: NIAID]



➤ **Mandatory vaccination?**

Most countries have legislation that protects an individual's fundamental right of personal autonomy. This is the specific right to bodily integrity, and with this, the right to refuse medical treatment. Forcing a person to be vaccinated would be a violation of this right. Counter to the individual's right is a government's duty to safeguard citizens' lives and protecting them against life-threatening diseases. It is a difficult balance between the rights of that state for the greater good versus those of the individual.

Public informed consent is vital for a successful vaccination programme. This allows a competent person to be informed and able to balance the pros and cons of vaccination and then voluntarily consent. The success of a voluntary vaccination programme would be universal access backed by a comprehensive education campaign.

Various airlines worldwide will not let travellers fly unless they have proof of a valid negative COVID-19 test. Some universities also require a negative COVID-19 test and a signed declaration that the faculty or student is well for entry to the facility. These organisations and other workplaces could enforce mandatory vaccination in the future when vaccination programmes are more widespread.

Frontline health care professionals (HCPs) and border workers are now being vaccinated globally. The right of these workers to refuse vaccination is the subject of much debate.²⁷ Prioritising HCPs has been generally accepted due to their right to a safe workplace and protection from occupational infection. Worldwide HCPs are in high demand, which increases the necessity to keep these workers safe.

Ethically, HCPs also have the right to autonomy and the ability to refuse vaccination. The core ethical principle of beneficence - to benefit or help patients - is coupled with non-maleficence - to do no harm. Vaccination to ensure HCPs' immunity from COVID-19 and other occupational risks such as hepatitis B, measles, mumps, rubella, diphtheria and pertussis, is key to protecting the vulnerable populations, they serve, including the elderly, patients with comorbidities and those that are immunocompromised.²⁸ It has been suggested that although mandating COVID-19 vaccination of HCPs could maximise vaccine uptake, it might undermine the trust between HCPs and their institutions.²⁷

Although some jurisdictions will not permit termination of the job as a result of a vaccine refusal, they may allow the person to be redeployed to low-risk areas.

➤ **Vaccine hesitancy**

Vaccine hesitancy is characterised by uncertainty and ambivalence about vaccination. This legitimate viewpoint underscores the failure or lack of effective public messaging.²⁹ The vaccine-hesitant have concerns about the vaccine's safety, efficacy, and necessity. The unprecedented speed in developing COVID-19 vaccines has increased the most common vaccine concern about side effects and the long-term health effects. These concerns are heightened by miscommunication and mistrust. Ethnic minorities (within a UK context) have lower levels of vaccination related to lower levels of trust in the government or health care system.²⁶

A large number of studies in different countries and regions have reported COVID-19 acceptance rates below 60%. This seriously affects the ability to gain control of the pandemic.³⁰ Trust building by education is key to decreasing hesitancy. Physiotherapists, alongside other HCPs, are credible sources of information that should be utilised to educate and gain public trust, particularly the vulnerable. Vaccination information needs to be targeted, culturally competent and accessible in

multiple languages. Engaging champions, community groups with cultural, religious, and political leaders would also help reduce hesitancy. Media communication needs to be timely and clear through trusted channels reinforcing the safety and effectiveness of the current COVID-19 vaccines.

Vaccine hesitancy can also exist among HCPs. The Center for Disease Control (USA) has developed a [COVID-19 Vaccination Communication Toolkit](#) to promote vaccine confidence among healthcare providers.

➤ Immunisation strategies

The limited initial supply of vaccines has necessitated countries to ethically prioritise who receives the first doses to achieve the greatest impact in protecting individuals and minimising community transmission.³¹ Most countries COVID-19 immunisation strategies have centred on protecting the most vulnerable to severe illness and disease, maintaining health care capacity and minimising transmission.³² These considerations have resulted in some countries, including the UK, vaccinating more individuals with the first dose of available vaccines and delaying the second to enable more of the population to have some COVID immunity. This policy was updated in May 2021 in response to the spread of the Indian variant of the disease.

Novel immunisation strategies have centred on access to vaccination. An increased supply of COVID-19 vaccines in some countries, coupled with pressure to vaccinate entire populations, has required a more significant number of HCPs to administer it. In some country's physiotherapists are being utilised as vaccinators. This is subject to the specific jurisdiction's legislative and scope of practice limitations, and the vaccinator education requirements. In the United Kingdom, registered health professionals, and suitably trained non-registered health workers, can administer the vaccine under clinical supervision.

To further improve access, some countries have now set up vaccination centres in highly accessible areas including, shopping malls, large workplaces and drive-through facilities. In May 2021, in New York, USA, baseball fans were offered free tickets if they received a COVID-19 vaccination at the stadium. This strategy was aimed to counter COVID-19 complacency and the low vaccination uptake.

Effective immunisation strategies require a comprehensive communication plan to run in tandem with the continuous promotion of prevention measures.

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