FIP vaccination handbook for pharmacists

Procedures, safety aspects, common risk points and frequently asked questions

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International Pharmaceutical Federation

Colophon

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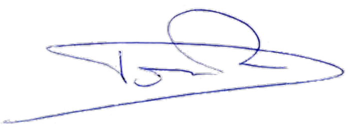
Foreword

According to the World Health Organization (WHO), vaccines save between two and three million lives annually around the world. If coverage were increased for many other diseases that can be effectively prevented through vaccination, a further 1.5 million lives would be saved. Vaccines are safe and effective and they contribute not only to preventing disease, but also to avoiding millions of euros in costs of care, absenteeism and loss of productivity. In fact, the WHO director-general, Dr Tedros Adhanom Ghebreyesus, highlighted the sound economic value of vaccination in a recent statement saying that "prevention is not only better than cure, it's cheaper, and the smartest thing to do". In addition, vaccination is a crucial strategy to fighting antimicrobial resistance by reducing the need for antibiotic use. However, barriers such as misinformation and distrust in vaccines can compromise not only the health of individuals but also public health as a whole. In October 2018, FIP endorsed the WHO Astana Declaration on primary health care (PHC) to deliver universal health coverage (UHC) by 2030. One of the main components of PHC is the provision of a comprehensive range of disease prevention and early screening services, including vaccination. In various parts of the world, pharmacists are the primary access point to PHC, offering advice and supporting the adoption of healthy lifestyles, performing point-of-care tests, referring patients to other healthcare professionals or levels of care, and administering vaccines.

FIP's work on vaccination started over a decade ago and is based on the conviction that improving vaccination coverage and promoting a life-course approach to vaccination are global imperatives to which pharmacists can greatly contribute. Of the 21 FIP Development Goals launched in September 2020, vaccination is linked to 17 goals, which clearly indicates the high priority vaccination holds not only for pharmacy and FIP, but also for global health. In particular, Development Goal 16, focusing on communicable diseases, is overtly linked to the prevention of this group of diseases, in which vaccination plays a prominent role. Recent FIP publications in this area include a members-only advocacy toolkit to support member organisations' advocacy for the implementation of pharmacy-based vaccination, a collection of evidence and guidelines for the development of vaccination services, a survey report on the roles of pharmacy in vaccination, and a regulatory self-evaluation assessment tool for advancing pharmacy services in this area. With adequate training, pharmacists are competent to perform a series of roles that can significantly contribute to improving vaccination coverage, from providing evidence-based advice on vaccines, to administering vaccines and managing vaccination records. Although pharmacists have administered vaccines in several countries for years, this role is still new or even unknown to the profession in many parts of the world. As a role that involves direct contact with patients and the administration of a product by injection, some concerns still exist among pharmacists with regard to the administration procedure, potential errors and the management of anaphylactic reactions.

However, from my experience in my daily community pharmacy practice, the benefit for the population of having the possibility of being vaccinated at their local pharmacy is so clear, especially during these hard times of the pandemic, that it is worth for our profession to make all necessary efforts to advocate to all relevant stakeholders in of our health systems for pharmacists to be granted the authority to vaccinate. We can play a crucial role in motivating and vaccinating people, and therefore contribute to increasing vaccination coverage rates. Joined efforts with other health professionals will be paramount to reach this goal.

With this new publication, FIP aims to support individual pharmacists with understanding how they can contribute to improving vaccination coverage through a range of services, ranging from patient education and advice, to logistical roles and to the administration of vaccines. This handbook provides guidance on the practical implementation of these services and includes guidelines on the procedures, safety aspects, common risk points and frequently asked questions about vaccines and their administration. Naturally, this handbook does not seek to replace the training and certification of the pharmacy workforce for delivering vaccination services, but it may support them in their daily practice and in gaining an overview of these roles and how they may be performed. I trust you may find this handbook useful for your practice and encourage you to continue striving towards offering a better service to our patients and communities.



Dominique Jordan
FIP President

Foreword

Pharmacists play a critical role in healthcare systems around the world. From their acknowledged and significant expertise in the area of medicine and medicines management, through to key roles in preventive care and public health. The trust in the pharmacy workforce by the community, alongside pharmacists' acknowledged skills and knowledge, means pharmacy is a focal point of many health initiatives.

Globally, pharmacists have led many significant initiatives in the community, including key programmes like smoking cessation, needle exchange and opioid substitution. These types of programmes not only reduce the burden of disease for the community itself, but also improve health outcomes and quality of life for individuals.

Globally, the burden of infectious disease on the wider community is still enormous. Vaccines play a critical role as one of the key health interventions in preventive care. This has been no more apparent than during the COVID-19 pandemic. Millions of people world-wide have been infected, hospitalised and have died. Patients with underlying medical conditions, the elderly and adults aged over 40 years have all been at risk. The impact has been felt everywhere. Vaccination for COVID-19 is being rolled out world-wide, across all nations and all health systems. Successful management of the virus will come down to the extent and success of vaccination programmes internationally.

It is not surprising that pharmacists, as key members of the healthcare team with medicines expertise, play a critical role in vaccination and vaccine management. However, while complex vaccines such as the new COVID-19 mRNA type, require specific storage, production and logistical management and handling, these are all core parts of pharmacists' training, and there is more that pharmacy can contribute in global vaccination.

The addition of vaccine administration to the scope of practice of pharmacists started decades ago in some parts of the world. In many countries, pharmacy-based vaccination has provided an opportunity to expand access to immunisation services in the community, and contributes to increased vaccination rates for vaccines like influenza. The visibility of pharmacists and pharmacies as a health epicentre is essential for communities, families and individuals, for vaccination services to be delivered locally where people live and work. Now, in the face of the COVID-19 pandemic, we see that the role of pharmacists in vaccine administration is more important than ever before.

To best achieve the goal of increasing vaccination coverage rates across all ages , we will need both commitment and investment in the training of students, qualified pharmacists (the existing workforce) and the pharmacy support workforce (technicians and assistants) to provide vaccinations . The development of further skills in the administration of not only vaccines but other medicines too, and clinical skills in patient assessment and management, will be key to build the capability and capacity in the profession to contribute to a wider group of emerging healthcare needs.

Another component of progress will be advocating within the pharmacy profession itself, with the wider healthcare team and the health policy and political space to ensure the value provided by the increasing involvement of pharmacists in these key public health and primary care activities is visible and utilised.

Every individual pharmacist can play a role in advocating with patients, the community, health services and political agencies to increase vaccination provision and rates. But where vaccination itself is concerned, pharmacists can play a part in this essential health activity.

Pharmacists — you can!

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1 Introduction

1.1 Why vaccinate?

Getting vaccinated is not only a safe and effective way of protecting oneself from a range of deadly or incapacitating diseases, but also an act of solidarity towards our loved ones and our community. By being vaccinated, we weaken and break chains of disease transmission and contribute to bringing diseases, endemics and pandemics under control. The COVID-19 pandemic has provided a sobering insight into what a world without vaccines would look like, with millions of deaths and people who have fallen ill, millions of jobs lost, millions of people led into poverty and an unprecedented loss of economic prosperity all around the world.

COVID-19 has exposed how vulnerable the world is to new infective agents and disease outbreaks. This pandemic has also taught us how important it is to prepare for future pandemics.

Vaccines are one the most effective public health interventions, second only to clean water.[1] They save millions of lives every year around the world and provide excellent social value and return on investment for health systems. It is a social, ethical and health imperative to improve vaccination coverage rates across all ages, and it is particularly urgent to expand vaccination pathways beyond infancy, to better protect adults and especially older adults and other vulnerable population groups, such as people with underlying conditions and pregnant women. It is particularly important to protect those individuals who are unable to be vaccinated due to health reasons (e.g., people with allergies or who are immunocompromised) or who do not respond to immunisation.[2]

The WHO member states adopted at the end of 2020 the "Immunisation agenda 2030 — A global strategy to leave no one behind". This landmark document builds upon and addresses gaps left by the Global Vaccine Action Plan 2011–2020 and sets an ambitious, overarching global vision and strategy for vaccines and immunisation for the next 10 years.[3]

This strategic document was developed to ensure that the global vision, strategic priorities and goals for vaccination are aligned with country needs. This framework is designed to be tailored by countries to their local context, and to be revised throughout the decade as new needs and challenges emerge. It is important to "leave no one behind" when it comes to vaccination coverage. As stated in the document: "Through collective endeavour, countries and partners will achieve the vision for the decade: A world where everyone, everywhere, at every age, fully benefits from vaccines for good health and well-being."[3]

In addition to its value for health and social wellbeing, vaccination is also one of the most successful and cost-effective health interventions of all time. Although vaccination requires an immediate investment, the economic savings generated through reduced health care costs, lost productivity, and work and school absenteeism due to illness are far higher than the initial cost. Several examples of cost-effectiveness studies can be found in different countries and for different diseases.[4] It is estimated that the annual return on investment for vaccination could be as high as 18% globally.[1]

In terms of safety, no vaccine is 100% safe or effective, as each person reacts to vaccines differently, as also happens with medicines and other health technologies and interventions. Any vaccine can cause side effects, but for the most part they are minor and transient, such as a sore arm or low-grade fever. That being said, vaccines are the best defence strategy we have against infectious diseases, and the decision not to vaccinate involves more serious risks. The benefits of vaccines far outweigh the risks.[5]

Finally, the global threat posed by antimicrobial resistance requires urgent and coordinated actions by all stakeholders to reduce the emergence of multi-resistant pathogens and preserve the effectiveness of antibiotics in our arsenal. Vaccines help reduce the need for antibiotics by reducing the incidence of communicable diseases. They are, therefore, an essential part of the global strategy to address antimicrobial resistance.[6]

1.2 Global burden of vaccine-preventable diseases

The Astana Declaration on Primary Health Care emphasises the critical role of primary health care to ensure that everyone, everywhere can enjoy the highest possible standard of health. This includes prioritising prevention across health policies to reduce the global burden of disease and make health systems more efficient, resilient and sustainable. Vaccination plays a major role in the prevention agenda.[7]

A number of infectious diseases have been eradicated (e.g., smallpox) or have become extremely rare because of vaccination (e.g., poliomyelitis). There are currently great efforts to efficiently diagnose and treat several infectious diseases, preventing between two and three million deaths each year around the world, and to possibly lead to eradication of other diseases.[8]

According to the WHO,[9] there are currently 28 infectious diseases that can be effectively prevented by a vaccine:

Cholera
COVID-19
Dengue
Diphtheria
Haemophilus influenzae type b
Hepatitis A
Hepatitis B
Hepatitis E
Herpes Zoster (shingles)
Human papilloma virus
Influenza
Japanese encephalitis
Malaria
Measles
Meningococcal meningitis
Mumps
Pertussis (whooping cough)
Pneumococcal disease
Poliomyelitis
Rabies
Rotavirus gastroenteritis
Rubella
Tetanus
Tick-born encephalitis
Tuberculosis
Typhoid fever
Varicella (chickenpox)
Yellow fever

Also according to the WHO[9], there are currently 24 diseases for which vaccines are in development. These "pipeline vaccines" are overseen by WHO's Product Development for Vaccines Advisory Committee:

Campylobacter jejuni
Chagas Disease
Chikungunya
Enterotoxigenic *Escherichia coli*
Enterovirus 71
Group B Streptococcus
Herpes simplex virus
HIV-1
Human hookworm disease
Leishmaniasis disease
Malaria
Neisseria gonorrhoeae
Nipah vrus
Nontyphoidal Salmonella disease
Norovirus
Paratyphoid fever
Respiratory syncytial virus
Schistosomiasis disease
Shigella
Staphylococcus aureus
Streptococcus pneumoniae
Streptococcus pyrogenes
Tuberculosis
Universal influenza vaccine

1.3 Key vaccination concepts and vaccine types

Historically, vaccines have played a major role in public health and the prevention of communicable diseases. In 1796, Edward Jenner undertook a well-known experiment on immunisation against smallpox, by inoculating a young boy with matter from fresh lesions from cowpox infection from a dairymaid. A few months later, Jenner inoculated the boy again, this time with matter from a fresh smallpox lesion, and no disease developed.[10] The outcomes of this innovation would be published two years later and coined by Jenner as "vaccination", after the Latin word *vacca* for cow.[11] This marked the start of the vaccine era. In 1980 the WHO declared smallpox an eradicated disease. This was the result of coordinated public health efforts by many people, with vaccination being an essential component.[12]

Immunity is the body's ability to resist disease caused by an infection. The immune system is the group of body organs and processes that provide immunity, through innate immunity (general defences) and adaptive immunity (defence against specific attackers, like viruses). Immunisation is the process whereby an individual becomes immune against an infectious disease either by natural contact with an infectious agent or by vaccination (administration of a vaccine to stimulate immunisation). Community immunity (or herd immunity) is the immunity reached when a large enough majority of a population are immune to an infectious disease, therefore they do not transmit the disease and consequently indirectly protect those people who are not vaccinated. Sometimes this is referred to as herd or community protection.[2]

According to the WHO, “Vaccination is the administration of agent-specific, but safe, antigenic components that in vaccinated individuals can induce protective immunity against the corresponding infectious agent”.[13] These safe components are obtained by attenuating or inactivating the pathogens which cause infectious diseases, their products or derivatives. When inoculated, the antigens induce active, specific immunity protection against the disease caused by the infectious agent from which the antigen is derived. If an immunised person comes into contact with the infectious agent, the body will recognise the antigen and produce defences against the vaccine-preventable disease.[14]

There are various vaccine types in terms of their technology and how they induce immunity. Table 1 presents the main vaccine types and a short definition for each type.

Table 1. Different vaccine types and their definitions[14]

Vaccine type	Definition
A. WHOLE PATHOGEN VACCINES	**Vaccines that use the whole disease-causing pathogen to produce an immune response similar to that seen during natural infection. Using the pathogen in its natural state would cause active disease and could potentially be dangerous to the individual receiving it and risk the disease spreading to others. To avoid this, modern vaccines use pathogens that have been altered.[15]**
1. Live attenuated vaccines	Live attenuated vaccines are produced by weakening a disease producing (“wild-type”) virus or bacterium in the laboratory. The modified strains are able to multiply within the body and trigger a strong immune response. Live attenuated vaccines are generally given in one or two doses.[15]
2. Inactivated (or killed) vaccines	Inactivated vaccines consist of virus particles, bacteria or other pathogens that have been grown in a lab and then killed. Inactivated vaccines often need adjuvants or multiple “booster” injections to provide an effective immune response.[15]
B. SUBUNIT VACCINES	**Subunit vaccines do not use the actual microbe but only the important parts of it: the antigens. This way the antigens stimulate the immune system — polysaccharides (sugars) or proteins from the surface of the microbe that our immune system recognises as foreign. There are several different types of subunit vaccines such recombinant, polysaccharide, conjugate or toxoid vaccines.[16]**
1. Recombinant vaccines	Recombinant vaccines are those whose antigens were produced by genetic engineering technology. A small piece of DNA from the virus or bacterium is inserted into other cells to make them produce large quantities of active ingredient for the vaccine (usually just a single protein or sugar).[16]
2. Polysaccharide vaccines	Polysaccharide vaccines are a unique type of inactivated subunit vaccine composed of long chains of sugar molecules that make up the surface capsule of certain bacteria.[16]
3. Conjugate vaccines	Conjugate vaccines are improvements on polysaccharide vaccines. In conjugate vaccines the polysaccharide is attached to something, usually a protein. The immune system recognises these proteins easily and this helps to generate a stronger immune response than polysaccharide vaccines.[16]
4. Toxoid vaccines	Toxoid vaccines are made with inactivated versions of the toxins produced by the pathogen. They are called “toxoids” because they look like toxins but are not poisonous.[16]
C. NUCLEIC ACID VACCINES	**Nucleic acid vaccines use genetic material from a disease-causing virus or bacterium (a pathogen) to stimulate an immune response against it. Depending on the vaccine, the genetic material could be DNA or RNA; in both cases it provides the instructions for making a specific protein from the pathogen, which the immune system will recognise as foreign (an antigen). Once inserted into host cells, this genetic material is read by the cell’s own protein-making machinery and used to manufacture antigens, which then trigger an immune response.[17]**

Vaccine type	Definition
1. Messenger RNA (mRNA) vaccines	An RNA vaccine consists of an mRNA strand that codes for a disease-specific antigen. Once the mRNA strand in the vaccine is inside the body's cells, the cells use the genetic information to produce the antigen. This antigen is then displayed on the cell surface, where it is recognised by the immune system.[18] RNA vaccines use mRNA inside a lipid membrane. This fatty cover both protects the mRNA when it first enters the body, and also helps it to get inside cells by fusing with the cell membrane. This mRNA typically lasts a few days, but in that time sufficient antigen is made to stimulate an immune response. It is then naturally broken down and removed by the body. RNA vaccines are not capable of combining with the human genetic code (DNA).[15]
2. DNA vaccines	DNA is more stable than mRNA so it does not require the same initial protection. DNA vaccines are typically administered along with a technique called electroporation. This uses low level electronic waves to allow the bodies' cells to take up the DNA vaccine. DNA must be translated to mRNA within the cell nucleus before it can subsequently be translated to protein antigens which stimulate an immune response. By April 2021, there were no licenced DNA vaccines, but there were many in development.[15]
D. **VIRAL VECTORED VACCINES**	**As with nucleic acid vaccines, viral vectored vaccines are a newer technology, using harmless viruses to deliver the genetic code of target vaccine antigens to cells of the body, so that they can produce protein antigens to stimulate an immune response. Viral vectored vaccines are grown in cell lines and can be developed quickly and easily on a large scale. Viral vectored vaccines are significantly cheaper to produce in most cases compared to nucleic acid vaccines and many subunit vaccines.[15]**
1. Replicating	Replicating viral vectors retain the ability to make new viral particles alongside delivering the vaccine antigen when used as a vaccine delivery platform. As with live attenuated whole pathogen vaccines this has the inherent advantage as a replicating virus that it can provide a continuous source of vaccine antigen over an extended period compared with non-replicating vaccines, and so is likely to produce a stronger immune response. A single vaccine may be enough to give protection. Replicating viral vectors are typically selected so that the viruses themselves are harmless, or are attenuated, so while they are infecting the host, they cannot cause disease. Despite this, because there is still viral replication going on there is an increased chance of mild adverse events (reactions) with these vaccines.[15]
2. Non-replicating	Non-replicating viral vectors do not retain the ability to make new viral particles during the process of delivering the vaccine antigen to the cell. This is because key viral genes that enable the virus to replicate have been removed in the lab. This has the advantage that the vaccine cannot cause disease and adverse events associated with viral vector replication are reduced. However, vaccine antigen can only be produced as long as the initial vaccine remains in infected cells (a few days). This means the immune response is generally weaker than with replicating viral vectors and booster doses are likely to be required.[15]

Live attenuated vaccines must replicate (grow) in the vaccinated person to produce an immune response. A relatively small dose of virus or bacterium is administered, which replicates in the body and creates enough of the organism to stimulate an immune response. The immune response to a live attenuated vaccine is virtually identical to that produced by a natural infection. Live attenuated vaccines produce immunity in most recipients with one dose, except those administered orally.[16]

Inactivated vaccines are not alive and cannot replicate. The entire dose of antigen is administered in the injection. These vaccines cannot cause disease, even in an immunodeficient person. Inactivated antigens are less affected by circulating antibody than are live agents, so they may be given when antibody is present in the blood (e.g., in infancy or following receipt of antibody-containing blood products). Inactivated vaccines always require multiple doses. In general, the first dose does not produce protective immunity, but "primes" the immune system. A protective immune response develops after the second or third dose.[16]

1.4 Vaccine components

In terms of their composition, in addition to the active immunogenic elements, vaccines may contain different components such as stabilisers, preservatives and adjuvants.

Stabilisers can be used to maintain either the pH at certain values, or to achieve isotonicity. Preservatives are used to prevent bacterial or fungal contamination of vaccines. Although advances in manufacturing technology have reduced the need for their use, these substances are sometimes still part of the inactivated vaccine production process to ensure that a sterile product is obtained.

Additionally, preservatives are used to prevent accidental contamination of vaccines during use, particularly in multidose vials, which are repeatedly punctured. Contamination of a multidose vial carries a risk of infection or sepsis far higher than the risks associated with the preservatives themselves.

Adjuvants are added to vaccines to enhance and modulate the immunogenicity of the antigen. These substances may contribute to vaccine efficacy through the production of a more potent immune response, reducing the number of doses of the vaccine needed to achieve immunity. Adjuvants may also allow the use of smaller amounts of antigen per vaccine dose, which is particularly useful when production capacity is limited.[19]

1.5 Building safety into vaccine development

Vaccines follow a strict, multiphase process while being developed, including preclinical, clinical and post-licensure phase trials with thousands of volunteers and rigorous protocols for assessing and ensuring the safety, immunogenicity and efficacy of the final licensed product. A profound knowledge of the pathogen structure, biology, associated disease epidemiology and its clinical characteristics informs and determines vaccine design. Continuing monitoring of efficacy and safety in immunised populations is essential to sustain confidence in vaccination programmes.[12]

Manufacturers' quality management processes include a variety of measures: good manufacturing compliance, batch records, laboratory tests and certificates of analyses. There is also a post-licensure monitoring of vaccine safety that includes real world data from large populations and data from healthcare professionals and consumers.[20]

Health professionals, including pharmacists due to their extensive training about medicines, are involved in the safety assessment and monitoring of vaccines, including the preclinical development, clinical development and post-licensure stages.[19]

New approaches to structure-based vaccine design, genetic immunisation platforms and the formulation of recombinant proteins with powerful adjuvants are being used to tackle diseases like tuberculosis and influenza.[21] Vaccine technologies have the potential to produce new and improved vaccines against the world's most impactful infectious diseases and in the development of new vaccines such as the one for HIV.[22]

Highlighting the importance of vaccine safety, the WHO developed a global vaccine safety blueprint in order to optimise the safety of vaccines through effective use of pharmacovigilance principles and methods across different countries and territories around the world.[23]

1.6 Challenges for vaccine access, acceptance and uptake

Challenges for vaccine uptake may have a significant impact on vaccination rates and, consequently, to the incidence and prevalence of vaccine-preventable diseases. These challenges can be understood in the context of three domains: first, individual factors related to vaccine acceptance and vaccine hesitancy; secondly, the vaccination process, which takes into consideration the logistics of, and access to, vaccines; and, thirdly, the vaccination system, which refers to a wider perspective of health systems.

Individual factors that can contribute to decreased vaccine uptake include concerns about side effects or negative effects of the vaccine, lack of perceived need for vaccination, negative beliefs about their effectiveness and safety, fear of injections, communication and cultural barriers and misinformation/ disinformation or lack of understandable information.[24] These factors can be addressed, among other initiatives, by building public trust, keeping the information in an easy-to-understand format and effectively communicating the benefits and risks of vaccination.[25]

Regarding the vaccination process, vaccine uptake can be compromised due to the logistics surrounding vaccination appointments, aspects of immunisation records and reminders to take the next dose, or limited access to local vaccination services.[24] These aspects can be targeted, alongside other actions, by offering vaccinations at multiple locations and times, improving collaboration and partnership between all healthcare professionals and by having better and more robust vaccination record systems.[26]

Pharmacists can greatly contribute to improving vaccine access and uptake through multiple roles, including education, advocacy and promotion of vaccination as described in this handbook.

Last, but not least, aspects related to the vaccination system might include limitations of access to vaccines, vaccine storage or capacity (including distribution), lack of political commitment, or other legislative, regulatory or administrative constraints.[27] This can be tackled with improved vaccination infrastructures, strengthening and improving surveillance and monitoring of vaccination coverage rates and obtaining political commitment to emphasising the importance of vaccination.[26] Equitable access to vaccines around the world is a global health priority and ethical imperative. Vaccination must be an essential component of universal health coverage. However, this is an important and complex challenge linked to vaccine production capacity, vaccine pricing, economic capacity and other factors. Appropriate mechanisms must be in place at global level to ensure that all people have access to these life-saving technologies, regardless of their country of residence or financial capacity, through principles of equity and solidarity.

1.7 Expanding vaccination pathways and providers

In addition to the ethical and equity dimension of universal vaccine access, achieving high vaccination coverage rates is fundamental to achieving herd immunity and ensuring the success of vaccination strategies.

Herd immunity is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or through previous infection. This immunity can only be achieved when a large proportion of the population (at least 70% to 80%) is vaccinated.[28] Understanding that some people may not be vaccinated or cannot develop sufficient immunity to some diseases through vaccination, herd immunity ensures that these vulnerable individuals are protected from the disease by the rest of the community.

As a preventive intervention, vaccination may not be in the minds of many people or be perceived as a priority unless there is a situation of exceptional disease risk or life threat, such as during epidemics or pandemics. This is further emphasised as vaccination strategies throughout the 20th century largely focused on childhood, which produced a common perception that vaccines are not necessary beyond adolescence. Changing this perception is essential both at a policy level and at the individual and community level.

As such, it is important to harness all opportunities to raise awareness about the value of vaccines and to promote and deliver vaccines in the community in the most widespread and accessible manner, and it is paramount to leverage all available health workforce capacity in these efforts.

Countries can ensure adequate uptake of existing immunisation services as a way to indirectly support already pressured health systems, by helping to free up capacity and resources to treat other conditions. This includes harnessing health workforce capacity across all healthcare professions, such as general practitioners, nurses, and pharmacists with the autonomy to prescribe and administer the necessary vaccines to eligible individuals.[29]

Pharmacists are in an ideal position to reach out to the population, being advocates and educators on the benefits of vaccination and thus, helping to reduce the prevalence of vaccine-preventable diseases. They are a valuable, trusted resource in the community through their accessibility, distribution and knowledge.

Pharmacists have an essential public health role as educators and advisers, facilitating and participating in national and global routine immunisation strategies and delivering pharmacy-based vaccinations. All of these roles have already been successfully implemented in various countries around the world and there is a wealth of evidence showing the impact of pharmacists' vaccination-related roles, including vaccine administration. As an example, pharmacists have been shown to help increase the number of pandemic influenza vaccine doses administered, thereby reducing the time to achieve 80% single-dose coverage.[30]

Due to their easy accessibility, pharmacists can more easily identify and target patients who are at higher risk of vaccine-preventable diseases and their complications. As advocates of vaccination, they build trust with the community to establish the crucial nature of vaccines and their benefits. With their knowledge of the vaccine supply chain and cold storage, pharmacists ensure safety and quality of vaccines. They are essential contributors for expanding vaccination coverage and overcoming the challenges necessary to improving vaccination compliance. Several countries, including Australia, Canada, Ireland, New Zealand, Portugal, the UK and the USA, have provided legal rights to pharmacists to administer vaccines, manage patient vaccination schedules, and organise educational and promotional campaigns to increase vaccination rates.[31]

However, in many countries there are still significant barriers for pharmacists to provide such services, including regulatory and policy barriers, the opposition of other vaccination providers, lack of training opportunities, lack of appropriate remuneration models or even some resistance from pharmacists themselves to adopt these new roles.

Other barriers include the requirements in terms of adapting pharmacy premises for the delivery of vaccinations, or the shortage of pharmacy workforce.[32] However, experiences from countries that have introduced pharmacy-based vaccination for several years or decades show that pharmacists can play an important role in contributing to improving vaccination uptake and coverage and in securing routine immunisation even during pandemics, especially in less populated areas or regions with lower access to health care.[33]

1.8 Frequently asked questions

Why is it important to achieve high vaccination coverage rates?
Vaccines are one of the most effective public health interventions, second only to clean water. They save millions of lives every year around the world and provide excellent social value and return on investment for health systems. It is a social, ethical and health imperative to improve vaccination coverage rates across all ages, and it is particularly urgent to expand vaccination pathways beyond infancy, to better protect adults and especially older adults and other vulnerable population groups, such as people with underlying conditions and pregnant women.

Are vaccines safe?
Vaccines follow a strict, multiphase process while being developed and manufactured, including preclinical, clinical and post-licensure phase trials with thousands of volunteers and rigorous protocols for assessing and ensuring the safety, immunogenicity and efficacy of the final licensed product.

What are the main individual factors I should consider regarding vaccine hesitancy?
Individual factors that can contribute to decreased vaccine uptake include concerns about side effects or negative effects of the vaccine, lack of perceived need for vaccination, negative beliefs about their effectiveness and safety, fear of injections, communication and cultural barriers and misinformation/disinformation or lack of understandable information. These factors can be addressed, among other initiatives, by building public trust, keeping the information in an easy-to-understand format and effectively communicating the benefits and risks of vaccination.

What is the difference between natural immunity and vaccine-induced immunity?
One way to acquire active immunity is to survive infection with the disease-causing form of the organism. In general, once people recover from infectious diseases, they will have lifelong immunity to that disease (there are exceptions, such as malaria). The persistence of protection for many years after the infection is known as immunologic memory. Following exposure of the immune system to an antigen, certain memory B-cells continue to circulate in the blood and reside in the bone marrow for many years. Upon re-exposure to the antigen, these memory cells begin to replicate and produce antibodies rapidly to re-establish protection. Another way to produce active immunity is by vaccination. Vaccines contain antigens that stimulate the immune system to produce an immune response that is often similar to that produced by the natural infection. With vaccination, however, the recipient is not subjected to the disease and its potential complications.

2 Community education, advocacy and promotion of vaccination

Expanding vaccination-related roles for pharmacists has been a working topic for FIP in the past few years. The role of pharmacists is especially important in the community, where pharmacists are access points to immunisation services and, at the same time, trusted sources of information for people of all ages and population groups. These characteristics highlight the versatility of the pharmacist in supporting roles related to advocacy and promotion of vaccination.

This chapter focuses on the role pharmacists can play in aiding the expansion of vaccine coverage through aspects related to education and advice. This includes the importance of debunking myths and changing vaccine-related behaviours. On a similar level, this chapter also approaches advocacy-related roles and promotion campaigns specific to vaccination.[6]

Research evidence strongly supports immunisation by pharmacists to improve vaccination rates, regardless of the role the pharmacist played (educator, facilitator, etc).[6, 30, 31, 34-39] Beyond contributing to accessibility, pharmacists also promote the reduction of inequity in immunisation by being able to reach marginalised and isolated individuals and populations.[34]

Pharmacists are positioned favourably regarding vaccination-related topics, provided that there is enough training and adequate resources.[35] Although pharmacists have positive views on vaccination and can play multiple roles, some barriers and limitations to the development of a pharmacist's role in vaccination were identified by FIP and include:[36]

- Lack of confidence by pharmacists;
- Limited access to training opportunities;
- Limited patient demand/acceptance;
- Limited financial support from health system;
- Limited acceptance by other healthcare professionals; and
- Limited acceptance by governments.

In light of these barriers and limitations, FIP supports pharmacists becoming involved in their local communities and at the national level, advocating better immunisation policies, acting as educators and promoting vaccination through campaigns.

2.1 Community education

Pharmacists play an important role in public health and are key players in educating populations about vaccination, due to the frequency of daily encounters that can translate into opportunities for promotion. Through focused education and information resources delivered to patients and the community, pharmacists can increase immunisation rates overall.[37]

The enrolment of pharmacists in immunisation education and recommendation is suggested to improve vaccine coverage among the elderly.[38] Community pharmacies are convenient and patients have established trust in pharmacists. Education for the administration of influenza vaccination or other vaccines in the pharmacy helps to increase vaccination coverage.[39] Disease outbreaks due to low vaccination can increase vaccine uptake immediately thereafter.[40]

Important aspects for the effective communication to the public about vaccines include providing reliable information, gaining the trust of the person, reinforcing understanding of the benefits and risks of vaccines and using patient-friendly language that is accessible, understandable and takes into account the patients' specific barriers to vaccination and health literacy.[41, 42]

Due to the importance of building vaccine trust and addressing vaccine-related concerns and hesitancy at the global level, FIP is addressing this topic in a separate publication and therefore Section 2.1.1 will only focus briefly on the role that the pharmacy workforce can play in dispelling vaccine myths and changing attitudes towards vaccination.

2.1.1 Dispelling vaccine myths

With the increasing availability and ease of access of online health information, there are increasing opportunities for the public to be exposed to misinformation and myths. This is especially true for vaccination and vaccine-related topics, particularly in light of the recent pandemic.[43] Many of those myths include that vaccines can cause autism, that vaccines contain toxic doses of mercury that can act as a neurotoxin, or that different vaccines in children should not be given in the researched time periods.[44] The public is often exposed to misinformation about vaccines because the main benefit is the absence of disease and symptoms. This might lead to deciding to not receive a vaccine and therefore not experiencing any possible negative effects, what might reinforce this feeling of hesitancy for the future.[45]

Vaccine myths are one of the reasons for vaccine refusal and are associated with different patterns of vaccination behaviour. Results suggest that education sessions may overcome vaccine refusal in some cases.[46] Healthcare professionals play an essential part in supporting dissemination of valid information and evidence-based recommendations, resolving doubts and increasing confidence in vaccines. Pharmacists must be prepared to face this challenge of dispelling myths and providing a supporting role in avoiding the spread of false information.[47]

Vaccination acceptance varies along a perception continuum. This continuum can range from people who absolutely refuse to get a vaccine, to intermediate degrees of hesitancy and concerns, and then to people who fully accept and support immunisation. It is important for healthcare professionals to understand where each person stands in the perception continuum and adopt a suitable communication strategy.[48, 49] A summary of tips regarding vaccination communication can be of use for pharmacists when encountering people presenting different types of arguments in the pharmacy. Table 2 presents some actions that can be undertaken regarding vaccination-related myths:[50]

Table 2. Suggested actions for dealing with vaccine myths[50]

Do:	Don't:
• Emphasise facts and use visuals whenever possible • Provide alternative correct explanations, with up-to-date resources • Present only core facts and keep the message simple • Explain the known side effects of vaccination and acknowledge the risks — which are real but rare • Emphasise that it may be a legal requirement for all side effects to be reported (in applicable jurisdictions) • Acknowledge concerns raised by patients (do not dismiss them) • Provide a balanced overview supported by scientific evidence of the facts behind vaccine benefits • Build on existing positive vaccine perceptions	• Repeat myths • Give lengthy explanations • Make explicit warnings • Use strong language that can increase risk perception • Rely only on web-based resources, as they do not allow face-to-face discussion • Emphasise the benefits and withhold information about the risks

Another useful tool for communicating effectively around vaccine misinformation is the "Acknowledge, Bridge, Communicate" framework (Table 3). Using this framework, pharmacists can provide the correct information regarding vaccinations, while maintaining a positive attitude towards the individual and maximising the impact of the information content.[51]

Table 3. "Acknowledge, Bridge, Communicate" framework[51]

Reasons not to vaccinate	Acknowledge	Bridge	Communicate
"Vaccines contain mercury"	That is not fully correct	More accurately	The mercury-based preservative thimerosal, once used to prevent bacterial and fungal contaminations, is no longer used in children's vaccines, except some types of flu shots. The WHO has also concluded that the amount and form of mercury in thiomersal-containing vaccines does not pose a cumulative risk of toxicity.[52]
"Vaccines cause disease"	That's not quite right	Let me explain	Most vaccines cannot cause disease because they do not contain any living virus or bacteria. There are some vaccines that contain weakened live bacteria or virus, but even these have not been described to cause the full onset of a disease, but on very rare occasions, a weaker form of disease with mild symptoms.[53]
"Polio is no longer an issue in this country"	That is not what I know	What I do know is	That reductions in vaccination rates can lead to infectious diseases returning: maintaining high vaccination rates prevents infectious diseases from spreading and protects those still susceptible through herd immunity.[54]
"Vaccines cause autism"	There is no evidence for that	What data show is	That there is extensive evidence that vaccines are not linked to increased incidence of autism.[54]
"No one in my son's school had this disease"	That's true	But the real point is	That it likely happened because most children were vaccinated, and the few who could not be immunised were therefore protected through herd immunity.[54]

2.1.2 Changing vaccination-related attitudes

In the face of emerging vaccine hesitancy, pharmacists are among the most trusted advisors and influencers of vaccination-related decisions in the community. Time constraints, increased workload and limited resources lead to inadequate information or training support to be able to address parents' and other people's questions.[55] Patient-centred interactions, together with emotional support and patient involvement, seems to enhance stronger connections with healthcare professionals and a positive outcome of the communication strategies used by them.[56]

Different evidence-based techniques can be used to effectively communicate the advantages of vaccination. One of these techniques is priming, which consists of pairing one stimulus that will influence a response with a subsequent stimulus, without conscious guidance or intention. Priming by sharing a vaccine information statement prior to vaccination increased vaccine uptake, regardless of its form.[57]

Vaccine communication needs to focus on the positive and emotional aspects of immunisation, including impactful information strategies among different healthcare professionals. However, it is important to consider differences in regional or national contexts that might contribute to a lack of effectiveness of positive messages.[58] The number of adolescent boys who initiated their vaccination increased significantly after reinforcement of the standing official public health recommendation by healthcare professionals to their parents.[59]

Another aspect that pharmacists can focus on is building on favourable intentions through recalls and reminders. These actions aim to increase the likelihood that potential vaccine recipients will keep their previous, positive intents in mind. These can be done via e-mail, postcard, letter, text message or phone calls. The delivered messages should aim to be clear and succinct and provide specific information. Phone calls are the most effective because they allow the recipient to schedule an appointment immediately; however, allowing recipients to choose how to be contacted increases vaccination coverage.[45]

One possible approach is to use incentive or sanction programmes. These incentives do not necessarily have to be financial; rather it is useful to consider what is important to the patient and their motivations, and frame vaccination in that context. For example, if an individual prioritises time with their family, it may be useful to emphasise that vaccination will allow them to keep their family safe, and enable them to have time with their family as everyone is kept safe by the vaccine. Although incentives may help affirm the importance of vaccination, they also might reinforce the impression that vaccination is not the norm. These incentives are useful when put in practice for vulnerable populations. Sanctions like penalties or limitations of access to certain places, are less commonly used as they might be negatively perceived by the population.[45]

2.2 Advocating vaccination

Another important aspect of increasing vaccination coverage is to be an advocate of vaccination at an individual, local and national level. This might include engaging in different promotional campaigns, identifying and advising high-risk patient groups, or even serving or advising in immunisation and safety monitoring committees. Health promotion is a combination of individual and social actions aimed at achieving political commitments, social acceptance and support for health policies and systems for a specific health objective or programme. In this case, promotion focuses on community pharmacy immunisation services and can be achieved through the following actions:[6]

- Participate in or advise international, national or local immunisation committees and groups, including national immunisation technical advisory groups;
- Actively participate in educational processes and provide up-to-date and timely information to patients and the public regarding vaccination;
- Distribute printed or electronic information to patients and the community;
- Educate individuals and communities to promote vaccination uptake; and
- Conduct or participate in national vaccination campaigns.

Pharmacists, due to their medicines expertise and knowledge, should serve on key committees or advisory groups in organised healthcare settings and can promote adequate immunisation delivery among staff and patients by encouraging the development of sound organisational policies on immunisation.[60]

Satisfied individuals are more likely to spread their positive beliefs about vaccination and help reinforce health messaging in their social circles after a positive interaction with a healthcare professional, with sufficient time to ask questions and feeling like they were treated with respect by the professional.[61]

2.3 Frequently asked questions

What can I do to deal with vaccine myths?

- Emphasise facts and use visuals whenever possible
- Provide alternative correct explanations, with up-to-date resources
- Present only core facts and keep the message simple
- Explain the known side effects of vaccination and acknowledge the risks, which are real but rare
- Emphasise that it may be a legal requirement for all side effects to be reported (in applicable jurisdictions)
- Acknowledge concerns raised by patients (do not dismiss them)

What can I do regarding advocacy initiatives at my local level?

- Participate in or advise national or local immunisation committees and groups
- Actively participate in educational processes and provide up-to-date and timely information to patients and the public regarding vaccination
- Distribute printed or electronic information to patients and the community
- Conduct or participate in national vaccination campaigns

3 Pharmacists' roles in vaccine logistics: supply chain management and storage

Pharmacists and pharmacies can contribute to successful vaccination strategies through several logistical roles. These may include the management of the supply of vaccines from manufacturing sites to the end user, ensuring the appropriate storage of vaccines — including cold chain management and other special storage requirements that are critical for vaccine stability and efficacy — and, in some countries, facilitating vaccine appointments for patients.

The roles of pharmacists in increasing access to vaccines and improving immunisation coverage in countries with lower income levels remains a challenge due to limited resourcing and lack of a defined role of pharmacists. The small number of studies identified, and the limited reported role of pharmacists, highlights opportunities to test vaccine-related interventions, to integrate pharmacists in immunisation programmes, and to make sure they can educate, advocate, and remind people who are due for vaccination.[62]

3.1 Vaccine supply chain management

Vaccine supply chain management includes the stages of information, procurement, scheduling, storage, distribution, monitoring and evaluation. In each of these stages, pharmacists should be involved as medicines experts, both nationally and locally. Actions taken include the following:[6]

- Participating in the choice of the vaccines to be provided;
- Participating in the analysis of vaccine supply needs and the allocation of financial resources, in accordance with the objectives and priorities of vaccination;
- Participating in vaccine procurement processes, ensuring that vaccines are procured from reliable sources and are of recognised quality, and to ensure sustainability of supply;
- Establishing and complying with the technical conditions related to the conservation and safety of vaccines;
- Ensuring compliance with technical and regulatory requirements related to the preservation of vaccines at all stages of their distribution and transfer, from manufacture to administration to an individual;
- Ensuring the quality, safety and efficacy of vaccines;
- Participating in the administrative control of the supply process;
- Conducting clinical studies and local audits to determine consumption, costs and impact of vaccines (e.g., increased coverage); and
- Obtaining, analysing and interpreting data pertaining to the vaccine supply process.

Vaccines should be procured from reliable sources that offer a wide selection of vaccines with updated information regarding stock levels and pricing. Policies and procedures should be developed and reviewed to ensure substandard, adulterated, unlicensed and spurious, falsely labelled, falsified or counterfeit vaccines are neither procured nor allowed into the system.[41]

Policies and procedures regarding the procurement of vaccines in the case of shortages, disaster or pandemic preparedness strategies, as well as regarding stock rotation and product recalls should be developed and reviewed.

As an example, researchers have demonstrated that a high level of *Haemophilus influenzae* type b vaccine coverage could be achieved in India through nationwide access to this type of vaccine through community pharmacies. In this study the usefulness of this type of distribution is highlighted as a complement to public sector services.[63]

Appropriately managing vaccine supply is one of the first steps in moving towards more advanced vaccination-related services and development of a pharmacist-led vaccination clinic or service. Not only should there be a consideration about the supply of vaccines but also about vaccine administration paraphernalia, including syringes, needles, alcohol wipes and medical gloves. Other materials that are needed are appropriate equipment for the safe disposal of biohazardous materials, sharps and other medical waste (e.g., a sharps container). There should also always be materials available to treat an anaphylactic episode or other emergency (e.g., anaphylaxis response kit) — see Section 6.3 on guidance for the post-administration phase and the management of anaphylaxis).[6]

3.2 Vaccine storage

Multiple strategies can be employed to ensure proper storage of vaccines that will help with ensuring safe vaccine administration. These include:[64]

- Rotating vaccines to ensure those with the shortest expiry date are used first;
- Checking vaccines frequently for expiration;
- Colour coding vaccines according to type and age;
- Separating paediatric and adult vaccines;
- Using standardised abbreviations on vaccine labels, based on country specific guidelines;
- Separating vaccines that look or sound familiar;
- Not leaving prepared vaccines or containers (either open or closed) for a prolonged time at room temperature; and
- Avoiding storage that may cause the vaccine to freeze (e.g., against the back wall of a refrigerator).

Vaccines are sensitive medical products that require particular care in their handling and storage. They should be stored in a designated area, away from potential sources of contamination (such as food, beverages or high-risk medicines) or potential changes in their storage conditions (such as sources of water, light or extreme temperatures). For refrigerated vaccines, measures should be taken to ensure the integrity of the cold chain. Policies and procedures regarding the management of the cold chain should be developed and reviewed. Refrigeration equipment should provide the necessary temperature regulation system and temperature monitoring capacity. The equipment should also be regularly evaluated to ensure its optimal functioning capacity.[65]

With their knowledge of the vaccine supply chain and storage of cold products, pharmacists can ensure safety and quality of vaccines.[36] Pharmacists must understand the consequences of mishandling vaccines and be aware of the recommended parameters for vaccine handling and storage.[66]

This is even more important for the newest mRNA vaccines, including the COVID-19 ones, that are very delicate and require extra caution when handled.[67]

Some of the parameters to take into account for the adequate storage of vaccines include strictly ensuring and overseeing that all people involved in vaccine logistics follow the recommended storage temperature, and avoid freezing, and thermal and photo degradation.

3.2.1 Cold chain management

A specific aspect of the supply chain when dealing with vaccines is the requirement for many of them to be stored in refrigerators or freezers, highlighting the importance of cold chain management. Vaccines have different heat sensitivities due to the formulation of the vaccine or the components that might be sensitive to temperature.[68]

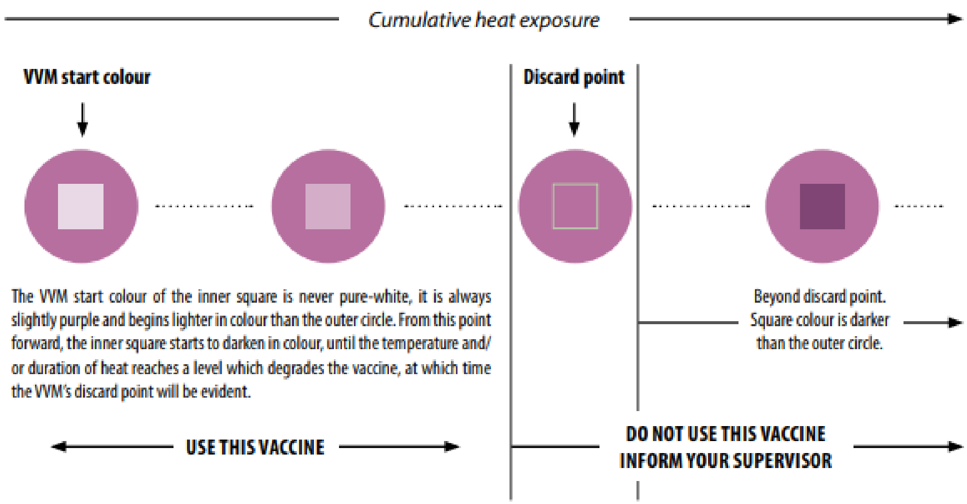
Vaccines can be damaged by heat, whether they are exposed to a lot of heat in a short time (e.g., as a result of keeping the vaccine in a closed vehicle in the sun), or a small amount of heat over a long period (e.g., as a result of the frequent opening and closing of a refrigerator door).[69]

Before reaching a patient, the vaccine travels through a long chain of different handlers. These include the manufacturer, distributers, storage facilities, healthcare centres and pharmacies. The cold chain ensures that vaccines are stored and transported within recommended temperature ranges from manufacture to administration. Loss of vaccine potency may lead to vaccine failure, defined as the occurrence of disease in previously vaccinated individuals.[70]

Effective cold chain management ensures that vaccines are stored and transported within recommended temperature ranges. Vaccines need to be maintained within a specific temperature range, which is usually 2° to 8°C (36° to 46°F) for most liquid vaccines.[71]

Vaccine vial monitors (VVMs) can be a helpful indicator of a vaccine's condition. However, in lower income countries it might still be a challenge to implement the use of VVMs in vaccine management and supply.[72] The VVM consists of one circle and one inner square that has a different start colour. When the difference in colours is no longer visible, it means the vaccine should not be used (Figure 1).

Figure 1. Vaccine vial monitor instructions[68]



To ensure the correct handling and storage conditions of vaccines, specific individuals should be given overall responsibility for managing the cold chain. This includes, but is not limited to, the following actions:[73]

- Checking and recording vaccine temperatures (in the morning and at the end of a session/day);
- Ensuring vaccines, diluents and water packs are stored correctly;
- Overseeing the maintenance of cold chain equipment;
- Keeping vaccines in appropriate vaccine refrigeration equipment;
- Using an appropriate temperature monitoring device to ensure correct temperatures are maintained;
- Transporting vaccines using containers that have been correctly prepared and packed;
- Protecting vaccines against sunlight or artificial light;
- Keeping vaccines in their original packaging until use; and
- Storing vaccines within their specified temperature range.

However, not only heat but also extreme cold can affect the potency and efficacy of some vaccines. Vaccines such as DPT (diphtheria, pertussis and tetanus), hepatitis B and tetanus toxoid vaccines, can be damaged by freezing. A shake test can be used to find out whether this has occurred. The test consists in taking two vaccine vials — the one that you think might have been frozen and another from the same manufacturer which you know has never been frozen — and shaking both of them simultaneously. Immediately after shaking, the vaccine that has never been frozen will look smooth and cloudy, and after 30 minutes it will start to clear and have no sediment. If a vaccine has been frozen and thawed, it will not look smooth and will have some granular particles immediately after shaking, and after 30 minutes it will be clear but with a thick sediment at the bottom of the vial. If a vial fails the shake test, it should be discarded.[69]

Nevertheless, some vaccines may actually require deep freezing for their storage and transportation, as is the case of nucleic acid vaccines, which can be particularly sensitive and thermolabile.

Special attention is given below to the storage conditions of recently developed vaccines against COVID-19, considering the particular relevance and currency of this issue in the management of the current pandemic and also the particular ultra-cold conditions that some of these vaccines require. The information below and other details about COVID-19 vaccines can be found in the FIP document COVID-19 vaccines: Frequently asked questions.

Moderna

- The Moderna COVID-19 vaccine multiple-dose vials are stored frozen between −25° and −15°C (−13° and 5°F). Store in the original carton to protect from light.
- Do not store on dry ice or below −40°C (−40°F).
- Vials can be stored refrigerated between 2° and 8°C (36° and 46°F) for up to 30 days prior to first use. Unpunctured vials can be stored between 8° and 25°C (46° and 77°F) for up to 12 hours.
- After the first dose has been withdrawn, the vial should be held between 2° and 25°C (36° and 77°F). Discard vial after six hours. Do not refreeze.
- A fact sheet for healthcare providers (USA) is available here: https://www.fda.gov/media/144637/download
- You can track expiry dates here: https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup

Pfizer/BioNTech

- Store in a freezer at −80° to −60°C (−112° to −76°F).
- Store in the thermal container at −90 to −60°C (−130° to −76°F). Store in the original package in order to protect from light.
- Once removed from the freezer, the undiluted vaccine can be stored for up to five days at 2° to 8°C (35° to 46°F) and up to two hours at temperatures up to 25°C (77°F) prior to use. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
- After dilution, store the vaccine at 2° to 25°C (36° to 77°F) and use as soon as practically possible and within six hours. The vaccine does not contain a preservative. Discard any unused vaccine.
- Once diluted, the vials should be marked with the dilution time and discarded within six hours of dilution. Do not refreeze.
- A storage and handling summary is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf
- You can track expiry dates here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf
- Information on dry ice safety is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf
- A temperature log for ultra-cold vaccine storage is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-celsius.pdf
- Storage and handling labels can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-handling-label.pdf
- Beyond use date/time tracking labels can be found here: https://www.cdc.gov/vaccines/covid-19/info- by-product/pfizer/downloads/bud-tracking-labels.pdf

- Information for healthcare professionals (UK) is available here: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine
- A fact sheet for healthcare providers (USA) is available here: https://www.fda.gov/media/144413/download

University of Oxford/AstraZeneca

- Unopened multidose vial should be stored in a refrigerator at 2° to 8°C (36° to 46°F). Do not freeze. Keep vials in outer carton to protect from light.
- Information for healthcare professionals (UK) is available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/ 948334/Information_for_UK_healthcare_professionals_on_COVID-19_Vaccine_AstraZeneca.pdf

3.2.1.1 Power outages

In some situations, a power outage might happen and compromise the electricity supply, thereby affecting the refrigeration systems that are used for vaccine storage. In case this happens there are some steps that can be followed:[74]

- Leave the vaccine in the refrigerator with the door closed;
- Place a sign on the refrigerator door saying "Keep fridge door closed. Do not use vaccine until further notice";
- Lock the refrigerator, if possible;
- Transport the vaccine to another temperature-monitored refrigerator in a different location, if possible; and
- Ensure the icebox is monitored with a min/max thermometer or data logger.

When power returns, record the minimum and maximum temperatures for the refrigerator and monitor it closely (e.g., every hour) to ensure that the temperature is stable, then return to once or twice-daily monitoring.

3.3 Frequently asked questions

What are the main tests that can be used to assess the condition of vaccines?

- Ways to understand the condition of a vaccine include recommended temperature, shake test, freezing, and thermal and photo degradation

What are the main aspects to consider about vaccine storage?

- Checking and recording vaccine temperatures (in the morning and at the end of a session/day)
- Ensuring vaccines, diluents and water packs are stored correctly
- Overseeing the maintenance of cold chain equipment
- Transporting vaccines using containers that have been correctly prepared and packed
- Keeping vaccines in their original packaging until use
- Storing vaccines within their specified temperature range

4 Vaccination records and facilitation of vaccination appointments

4.1 Vaccination records

Vaccination records contain information that that can be used by healthcare professionals to support vaccination advocacy to individuals and patient follow-up, therefore contributing to increased vaccination coverage. By having access (reading rights) to patients' vaccination records, pharmacists can assess their vaccination status, identify what vaccines may be missing or require a booster dose, and advise them accordingly.

It is essential for all primary healthcare professionals, including pharmacists, to have access to reliable data about what vaccines a patient has received, to enable them to advise the patient appropriately, and take measures by providing vaccination or referring the patient to another provider. Self-reported vaccination history might not be sufficient or reliable enough for pharmacists to advance vaccination coverage on this basis alone.[36]

Results from a survey conducted by FIP in 2020 indicated that, in around two-thirds of the 99 countries or territories that participated in the study, pharmacists do not have access to vaccination records. From the remaining countries where pharmacists did have access to such records, only one in three had access to all records while the others had access only to some information. The same study also found that in almost half of the responding countries, pharmacists are not authorised to record vaccination details in a shared vaccination record (writing access). [36]

Shared vaccination records are also essential to support collaboration between the various healthcare professionals and to ensure continuity of care by accessing and updating patients' vaccination records and acting upon that information. Naturally, this is sensitive and confidential information that must be managed as such, with the patient retaining control of who should have access to it and how it might be used. Privacy and protection of stored data are essential factors to consider.[75]

By accessing vaccination records, pharmacists have the opportunity to carry out the following actions:[6]

- Review the vaccination status of patients according to the vaccination schedules established in the country;
- Develop vaccination reminder systems to keep the patient's vaccination schedule up to date;
- Assess special health situations and contraindications related to vaccination and, if appropriate, refer the patient to a physician for evaluation;
- Identify and educate risk groups, especially those not covered by national and mandatory vaccination plans;
- Detect, report and follow up on events that have been reported as attributable to vaccines (in other words, suspected adverse reactions to vaccines) to the national and/or regional pharmacovigilance unit; and
- Detect, report and monitor medication errors (prescription, indication, dispensing, administration) related to vaccines.

Also, when vaccinating in the pharmacy is possible and pharmacists are granted writing rights in vaccination records, vaccination details should be carefully recorded, including at least the following elements:[73]

- Name of the patient, date of birth and identification number;
- Name of the vaccine, brand, manufacturer, batch and expiration date;
- Professional identification of the person who administered the vaccine; and
- Date, time, injection site and route of administration.

4.2 Facilitation of vaccination appointments

In some countries where pharmacy-based vaccination is not available or is limited to certain vaccines, pharmacists may play a role in supporting individuals with the scheduling of vaccinations by other providers, including national health systems.

Vaccination appointment programmes allow pharmacists to systematically assess patient vaccination history, schedule appointments and even administer vaccines if allowed.[76] It is also possible to coordinate with different health facilities in the same area to collaborate on the management of vaccination schedules and doses, aiming always to increase vaccination coverage and adequate immunisation of individuals.[77]

4.3 Frequently asked questions

Why is it important for pharmacists to access vaccination records?
Vaccination records contain information that that can be used by healthcare professionals to support vaccination advocacy to individuals and patient follow-up, therefore contributing to increased vaccination coverage. By having access (reading rights) to patients' vaccination records, pharmacists can assess their vaccination status, identify what vaccines may be missing or require a booster dose, and advise them accordingly.

What can pharmacists do to support the logistics around patients' vaccination schedules?
Vaccination appointment programs allow pharmacists to systematically assess patient vaccination history, schedule appointments and even administer vaccines if allowed. It is also possible to coordinate with different health facilities in the same area to collaborate on the management of vaccination schedules and doses, aiming always to increase vaccination coverage.

5 Requirements for vaccine administration

To ensure pharmacists can perform activities related to vaccination services in community pharmacies, it is necessary to have different elements in place. These include an appropriate regulatory framework, an adequately trained pharmacy workforce, and suitable infrastructure. This chapter provides an overview of key elements related to these requirements. More extensive details can be found in previous FIP publications, such as Give it a shot: Expanding immunisation coverage through pharmacists, and Pharmacy based pandemic vaccination programme: Regulatory self-assessment tool

5.1 Regulatory and technical frameworks

As part of the legal and technical framework, it is necessary to have:

- National regulations that identify and define the vaccination activities that may be performed by pharmacists or other authorised professionals in the pharmacy;
- Guidelines and standard operating procedures for every vaccination-related activity performed at the pharmacy, including promotion of vaccination, management of the vaccine supply chain, counselling on a patient's vaccination status, dispensing vaccines, understanding the pharmaceutical indication/recommendation of vaccines, and administering vaccines, either intra- or extramurally, and troubleshooting/problem-solving in the event of unexpected reactions or events; and
- Technical specifications of the professionals required, infrastructure, equipment, materials, management, safety and hygiene, documentation and continuing education that a pharmacy must comply with if it offers vaccine administration services.

These technical specifications should include guidelines or standard operating procedures for:

- Storage and conservation of vaccines in the pharmacy (compliance with cold chain requirements);
- Vaccine administration;
- Registration of vaccines indicated, recommended or administered;
- Registration and reporting of administered vaccines;
- Reporting suspected adverse reactions or medication errors related to vaccines;
- Eliminating hazardous (potentially infectious and contagious) materials and waste products from the administration of vaccines;
- Cleaning the area reserved for the administration of vaccines in the pharmacy; and
- Managing emergencies arising from the administration of vaccines in the pharmacy.

5.2 Pharmacy workforce education and training requirements

The competencies required for vaccination-related services include the following and should be developed through adequately certified undergraduate education or continuing professional development programmes, according to vaccination activities authorised to be carried out in the pharmacy in each country:

- Knowledge about infectious diseases preventable by vaccination, immunisations, types of vaccines available in the country, management of the vaccine supply chain, national vaccination schemes, specific vaccines for the various risk groups, basic considerations in administration of vaccines (oral or injectable), pharmacovigilance of vaccines, handling of materials and infectious waste;
- Communication skills and teamwork with other health professionals and the community; and

- Technical skills for the administration of injectable medicines by the intramuscular, intradermal and subcutaneous routes.

5.3 Infrastructure

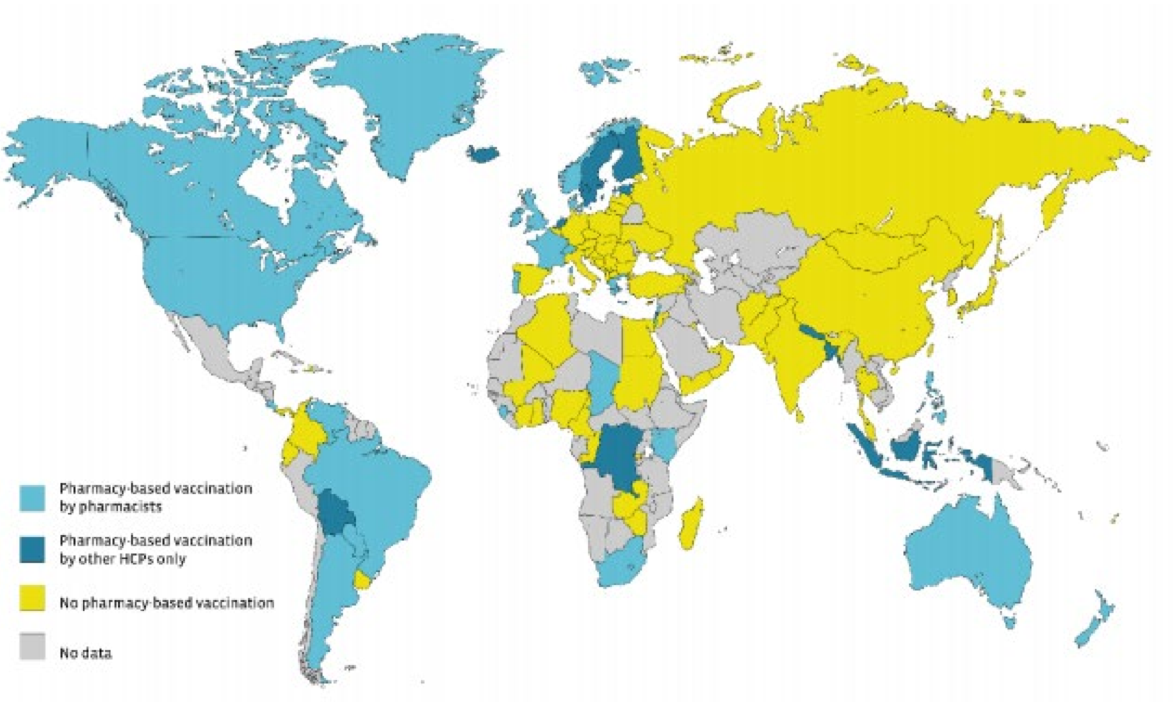
Good pharmacy practice (GPP) is the practice of pharmacy that responds to the needs of the people who use pharmacists' services to provide optimal, evidence-based care. In the context of vaccination, GPP requirements serve to ensure safe, timely and effective immunisation. The following infrastructure requirements relate to the logistics and operational conditions for offering optimal vaccination services:[78]

- Pharmacies should have a suitable and comfortable room in compliance with the technical requirements for the administration of injectable medicines.
- This room should be sufficiently isolated to ensure confidentiality to address patient concerns and administer the vaccine.
- Because vaccination services may require a considerable amount of time, including waiting time after receiving a vaccine to assess for any adverse effects, the waiting area should be sufficiently spacious for all patients to wait comfortably.
- Pharmacies should have a system for record-keeping of vaccines administered, including patient details and other information about vaccines.

6 Vaccine administration

According to the FIP survey on the role of pharmacists in vaccination, as of March 2020, pharmacy-based vaccination was available in at least 36 countries and territories around the world, 16 more than were identified in FIP's previous survey on this topic in 2016 (Figure 2). This meant that nearly 1.8 billion people could access vaccination services at a community pharmacy.[36] These figures have increased since this survey was conducted, because new countries have introduced pharmacy-based vaccination since then, including Italy,[79] Lithuania[80] and Poland.[81]

Figure 2. Vaccine administration in pharmacies at global level as of March 2020



Pharmacy-based vaccination refers to the administration of a vaccine in a community pharmacy by a pharmacist or another authorised member of the pharmacy team or another health professional. Actions related to vaccine administration include:[6]

- Recording and documenting all vaccines administered: recording in the patient's vaccination record (electronic record or vaccination card) and in pharmacy records.
- Reporting vaccines administered to the official national immunisation registry or other as appropriate.
- Managing waste products related to vaccine administration.
- Following up with patients to promote compliance with vaccination schedules.

Pharmacist involvement in immunisation results in increased uptake of immunisations, increasing vaccine coverage.[82, 83] This chapter offers guidance to the appropriate actions to be performed by pharmacists or other pharmacy workforce members in the vaccine pre-administration, administration and post-administration phases. For all three phases, it is essential that pharmacists and other pharmacy workforce members who offer vaccination services to the community comply with regulations in force in their jurisdiction with regard to vaccine administration, and are certified to provide such services after undertaking the required training before starting to administer vaccines.

6.1 Pre-administration phase

The pre-administration phase starts in the dispensing area, when interacting with the individual and acknowledging their intention to be vaccinated. Then follows the evaluation of the patient's eligibility and need to receive the specific vaccine (including administrative criteria and clinical criteria, such as verifying that there are no contraindications), the registration of the vaccination in the appropriate registry, hand hygiene, and the preparation of the materials, which should take place in a separate and private room in the pharmacy. The pharmacist also needs to explain any potential adverse events to the patient before starting the administration phase.

6.1.1 Contraindications

Although the benefits of vaccination normally far outweigh the risks involved, there are some situations or individuals where a vaccine must not be administered. The pharmacist must assess eligibility by accessing the patient's health records where possible and by asking them a set of questions to ascertain if there could be any contraindications. Precise contraindications differ by type of vaccine and could include:[64, 84]

- Severe allergic reaction after a prior vaccination;
- Aged under six weeks;
- Concomitant use of aspirin;
- Pregnancy (although several vaccines are actually recommended during pregnancy);
- Immunodeficiency/family history of immunocompetence (although several vaccines are actually recommended for such patients);
- Encephalopathy not attributable to another cause within seven days of prior vaccination; and
- History of intussusception (a condition in which one segment of intestine "telescopes" inside another, causing an intestinal obstruction or blockage.[85]

Besides the situations where vaccine administration is contraindicated, there are also situations that might imply potential precautions and these include:[64, 84]

- History of Arthus-type hypersensitivity reaction;
- Moderate or severe acute illness with or without fever;
- Pregnancy;
- Progressive neurological disorder;
- Temperature over 40.5°C, collapse or shock-like state, less than 48 hours after prior vaccination; and
- Seizure less than three days after prior vaccination.

It is important always to screen patients for product-specific contraindications and precautions before vaccine administration, even if the patient has previously received the same vaccine.[86] A set of recommendations for the most common conditions or circumstances is set out in Table 4.

Table 4. Conditions to be checked and recommended actions before administering vaccines[86]

Condition/circumstance	Recommended action	Rationale
Anaphylaxis or severe allergic reaction to previous dose of relevant vaccine	Do not vaccinate. Seek further medical advice to confirm causality and to assist with other vaccinations	Anaphylaxis to a previous dose of vaccine is a contraindication to receiving the same vaccine
Acute febrile illness (temp ≥38.5°C) or acute systemic illness	Defer all vaccines until afebrile. All patients with minor illnesses should be vaccinated.	To avoid an adverse event and attributing symptoms to vaccination
Immunosuppression or immunocompromised status	Routine vaccines: influenza and pneumococcal vaccines recommended.	Vaccine safety and effectiveness may be suboptimal in immunosuppressed patients

Condition/circumstance	Recommended action	Rationale
	Live vaccines: contraindicated in severely immunocompromised patients. In general, vaccination is not recommended in patients on corticosteroids.	
In pregnancy	Influenza, pertussis and COVID-19[87] vaccines are broadly recommended for all pregnant women. Live vaccines should be deferred until after delivery	There is insufficient evidence to ensure the safety of administering live vaccines during pregnancy

Misperceptions of contraindications result in missed opportunities to administer recommended vaccines and exacerbates vaccine hesitancy, which can compromise achievement of herd immunity and thus protection of communities. Patients with these conditions should be vaccinated with all recommended vaccines. Conditions commonly misperceived as contraindications to vaccinate include:[88]

- Mild acute illness with or without fever;
- Lack of previous physical examination in a person who appears well;
- Current antimicrobial therapy;
- Convalescent phase of illness;
- Preterm birth (some vaccines are less immunogenic in preterm infants);
- Recent exposure to an infectious disease;
- History of penicillin allergy, other non-vaccine allergies, relatives with allergies or receiving allergen extract immunotherapy;
- History of Guillain-Barré syndrome;
- Local reaction to a previous dose of vaccine or other adverse reactions, such as irritability, drowsiness, febrile convulsion (in children), vomiting, and diarrhoea;
- Acute mild illness, with or without fever (e.g., upper respiratory tract infection, diarrhoea) or convalescence from acute illness;
- Concomitant immunotherapy with allergen extracts;
- Personal or family history of allergies;
- Dermatoses, eczema or localised skin infections;
- Chronic heart, lung, kidney or liver disease;
- Non-evolving neurological diseases, such as cerebral palsy; and
- Down's syndrome or other chromosomal conditions.

6.1.2 Adverse events

Vaccination is not risk-free and adverse events occasionally occur. The prevalence of adverse events is very low as vaccines are given to large populations of healthy people, which also leads to public tolerance of low levels of safety concerns. Pharmacists are well positioned to monitor and detect these events in the community.[89]

Adverse events can occur as a result of product errors, quality defects, vaccination errors (caused by inappropriate vaccine handling, prescribing or administration), over-anxiety about the vaccination procedure, or a coincidental event (caused by something other than the first three). Through correct handling of vaccines and correct use of vaccination protocols, vaccination adverse reactions can be minimised.[19]

Adverse reactions can be linked to individual vaccine components, including antigens, adjuvants, stabilisers and preservatives, or can be caused by a pre-existing susceptibility, linked to genetic variants, environmental exposures or personal behaviours. Thus, it is difficult to predict adverse reactions and establish their causal relationship to the vaccine.[90]

Local or systemic reactions such as pain or fever can occur as part of the immune response. These are generally minor and self-limiting and do not require specific treatment. Localised events might include injection-site hypersensitivity or swelling, redness, warmth or pain. Systemic events might include headache, malaise, loss of appetite, fever, muscle pain or irritability.[91]

Adverse events following immunisation might be related to some specific vaccination errors, and can in some situations be prevented or minimised if the correct guidelines and recommendations are put into practice (Table 5):[89]

Table 5. Possible vaccination errors and adverse events following immunisation[89]

Vaccination error	Possible adverse event following immunisation
NON-STERILE INJECTION Reuse of disposable syringe/needle, leading to contamination of the vial Improperly sterilised syringe or needle Contaminated vaccine or diluent	Local injection site reactions (e.g. abscess, swelling) Sepsis Toxic shock syndrome Blood-borne transmission of disease (e.g., hepatitis B, HIV) Death
RECONSTITUTION ERROR Inadequate shaking of vaccine Reconstitution with incorrect diluent Drug substituted for vaccine or diluent Reuse of reconstituted vaccine	Local abscess Ineffective vaccine* Effect of drug (e.g., insulin, oxytocin, muscle relaxants) Toxic shock syndrome Death
INJECTION AT INCORRECT SITE Bacillus Calmette-Guérin (BCG) vaccine given subcutaneously Diphtheria, tetanus and pertussis(DTP) /diphtheria and tetanus (DT) / or tetanus toxoid (TT) vaccines given too superficially Injection into buttocks	Local reaction (e.g., abscess) Sciatic nerve damage
VACCINE TRANSPORTED/STORED INCORRECTLY Freezing vaccine during transport Failure to keep vaccine in cold chain	Increased local reaction from frozen vaccine Ineffective vaccine*
CONTRAINDICATION IGNORED Vaccination staff ignoring or not becoming familiar with contraindications for a vaccine	Avoidable severe reaction

*Not strictly an adverse event but does represent vaccine failure

6.1.3 Patient engagement

Besides being aware of the main contraindications and adverse events, a pharmacist needs to consider all steps from the moment an individual enters the pharmacy until the vaccine is administered. Being friendly and using an appropriate type of speech are ways to enhance communication, gaining trust and relaxing the patient. It is also important to remember behaviours that may communicate unavailability or indifference to the patient, such as dividing your attention with parallel tasks. For example working on the computer, continuing a previous activity, or talking to colleagues can contribute to a negative first impression, which could influence the rest of the care process. It is important to adopt welcoming behaviours, such as:[84]

- Proactively greeting the patient (e.g., “Good morning, how are you?”);
- Identifying the reason for the visit (e.g., “May I help you?”); and
- Maintaining eye contact.

During patient engagement it is also important to collect patient information. Furthermore, it is advised to have a screening form for patients to fill out and sign. In addition to this information, the patient might be required to fill out other registration sheets for the pharmacy, either in paper or digital format.[64]

An immunisation assessment should be completed at every healthcare visit. This allows the pharmacist to check that the correct time interval has passed since any previous vaccine(s) or any blood products were given. At this point a reassurance can be given to the patient that everything will be fine and the pharmacist can ask if the patient is feeling nervous.[92]

6.1.4 Hand hygiene

In the process of handling vaccine-related supplies and vaccines themselves, correct hand hygiene should be always be a routine procedure. Regardless of the technique chosen, good hand hygiene principles include:[84]

- Remove jewellery and adornments from hands and forearms;
- Keep nails clean, short and free of varnish. Do not use artificial nails;
- Respect the various steps of the hygiene procedure;
- Dry your hands well using disposable paper towels;
- Do not use multiple-use cloth towels;
- Use dermoprotective creams frequently;
- Do not start material preparation or any other activity (e.g., putting on gloves) with wet hands;
- Do not use hot water to wash your hands (increased risk of dermatitis) and
- Do not use antiseptic rub when hands are visibly soiled, use soap and water.

Alcohol-based hand rub should be used before vaccine preparation and between sessions with individual patients. Any time the hands are soiled, or come into contact with bodily fluids, soap and water should be used.

6.1.5 Preparation of materials

Preparation of materials should be carefully done to facilitate the provision of the service. Materials needed include, but are not limited to, the following:[64, 86]

- Injection devices;
- Compresses;
- 70° alcohol;
- Adhesive bandages; and
- A clean table with nothing on it that is not related to the vaccine administration process.

Other considerations include the following:

- Used syringes and needles (do not cut, recap or detach from syringe) should be placed in a puncture-resistant biohazard container;
- Gloves are recommended, especially when contact with potentially infectious body fluids is likely, if the vaccinator has open lesions on their hands. If used, gloves should be changed between sessions with individual patients.
- Protective eyewear is not routinely recommended.
- The use of cotton is not recommended, due to the risk that particles can enter into tissues during puncture.

6.1.6 Step-by-step pre-administration process

A step-by-step process following the initial procedure common to most preparations is presented below:[73] (Steps 1 to 3 only include ampoules, if you are using a vial, start at step 4.)

1. Put on a pair of disposable **gloves**.

2. Gently and quickly **tap the top of the ampoule** until the liquid descends completely into the ampoule body. **Collect the entire volume of liquid**, in order to ensure the exact intended dose is administered.

3. Identify the pressure zone to **break the ampoule** (e.g., coloured dot) and, with a compress around its top, apply pressure quickly and firmly in the opposite direction to the body. This prevents glass splinters from getting attached to the gloves.

4. **Discard the top of the vial** into an appropriate container.

5. Using a sterile syringe and needle, **insert the needle into the ampoule** or vial and carefully **aspirate the entire contents** into the syringe pulling gently on the plunger of the syringe.
   a. Use a **needle with enough length** to reach the bottom of the ampoule; the bevel of the needle must always remain below the level of the liquid;
   b. If necessary, **invert the ampoule or vial** to bring all the liquid within reach of the needle, while preventing aspiration of air.

6. After aspirating all the liquid into the syringe, **remove the needle from the ampoule or vial**. **Discard the ampoule or vial** into an appropriate container. In the case of multi-dose vials place it in the designated area and return it to the refrigerator as soon as possible.

7. **Position the syringe with the needle up**. Pull the plunger a little further and then press it down to **expel excess air**. To eliminate air bubbles inside the syringe:
   a. Hold the syringe upright (needle up);
   b. Tap the syringe barrel, to make the bubbles rise; and
   c. Pull the plunger slightly and then push it ejecting the air to the top of the syringe. Do not eject liquid.

8. **Discard the aspiration needle** into a sharps container.

9. Without removing the protective cap**, attach a new needle to the syringe**.

10. **Place the prepared syringe on a clean tray** or bench.

11. **Proceed immediately to administration**, to minimise microbiological contamination.

6.1.7 Common vaccination errors in the pre-administration phase

During the pre-administration phase, some common errors that can happen are: [64, 86]

- Authentication of patient's vaccination status is not carried out;
- Error in interval between doses, or vaccination before indicated age;
- Incorrect indication;
- Incorrect handling (e.g., reconstitution, spillage);
- Partial doses of vaccine drawn from separate vials to obtain a full dose;
- Failure to inspect and dispose of any vaccines with abnormalities or foreign particulates;
- Injection of a time-expired vaccine or one with prolonged exposure to incorrect temperatures;
- Temperature deviation;
- Confusion of names, date or packaging, leading to injection of the incorrect vaccine; and
- Failure to respect precautions and contraindications specified in the product information.

To ensure safe vaccine administration, use the strategies set out in the following checklist:[84]

1. Check that sufficient quantities of vaccines and diluents are available for the session.
2. Check vials for the following and take appropriate action:
    - Expiry dates;
    - Open vial dates;
    - Vaccine vial monitor status;
    - Freezing status.
3. Place vials in the appropriate place in the immunisation area.
4. Prepare vaccines individually for each patient.
5. Ensure sufficient supplies are available for the session, including:
    - Syringes;
    - Reconstitution syringes;
    - Safety box;
    - Adverse events following immunisation kit; and
    - Immunisation register.
6. Wash your hands with soap and water.

6.1.8 Summary of pre-administration checks

Table 6 summarises key elements that must be checked and actions that must be taken before administering a vaccine to an individual.

Table 6. Key elements to be checked and actions to be taken prior to vaccine administration[73]

Element to be checked	Suggested actions
Right patient	• The patient's immunisation status should be reviewed • All patients should be screened for contraindications and precautions every time a vaccine is administered, even if the patient has previously received a dose of the same vaccine
Right vaccine and diluent	• Always check the label on the vial or box to determine it is the correct vaccine and diluent (if needed) • Each vaccine and diluent (if needed) should be carefully inspected for damage, particulate matter and contamination before using • Verify the vaccine has been stored at proper temperatures
Right time	• This includes administering at the correct age, the appropriate interval and before the vaccine or diluent expires • Check the schedule to ensure the patient is getting the vaccine at the right time and at the appropriate interval • Each vaccine vial should be checked for the expiration date. Expired vaccine or diluent should never be used • Once reconstituted, the vaccine must be administered according to the guidelines or discarded
Right dosage	• Prior to dispensing or administering a vaccine, verify that the dosage is correct • Choose age-specific formulations of vaccines • Make sure you draw the correct amount of liquid when drawing from multidose vials
The right route, needle length, and technique	• Immunisations are administered through the intramuscular (IM), subcutaneous (SC), oral, nasal and intradermal routes • Choose the correct supplies to administer vaccines by injection (syringe and needle size, route and location) • When administering IM injections, it is important to use a needle with the correct length to reach the muscle mass and not seep into SC tissue; the needle should be quickly inserted at a 90° angle • SC injections are administered at a 45° angle, and the SC tissue is pinched up to prevent injection into the muscle
The right site	• Use a separate anatomical site for each injection • Injection sites are chosen depending on the age or size of the patient.
The right documentation	• Vaccine manufacturer • Lot number • Date of administration • Expiration date of the vaccine • Name and business address of the health care professional administering the vaccine • Date that the vaccine information statement is provided together with its publication date • Site of injection (e.g., deltoid area) • Route of administration (e.g., intramuscular)

6.2 Administration phase

6.2.1 Considerations for the elderly

Vaccination rates among older patients remain suboptimal, suggesting poor access and barriers to vaccination. Pharmacists facilitate vaccination in the elderly by providing a convenient point of access, building confidence in vaccination, and actively increasing awareness to reduce complacency.[93]

The reduced effectiveness of vaccines in the elderly (aged over 65 years) is generally attributed to the diminishing effectivity of the immune system. Consequently, older adults are more susceptible to infectious diseases. The best strategies for the elderly should focus on conjugate vaccines with multivalent antigens and should be given before old age to stimulate a strong immunological memory.[73]

Also, the elderly normally have thinner skin and therefore are more likely to have local reactions such as skin breakages or bruises post vaccine. This age group is normally more susceptible to be taking medicines that influence blood coagulation (e.g., blood thinners) and therefore this might rarely also produce local reactions at the administration site.[94]

The most common vaccines studied in this population were pneumococcal and influenza vaccines. Other studies should explore how pharmacists impact access to vaccines beyond vaccination rates, especially with regard to the financial impact on patients.[95]

6.2.2 Considerations for adolescents

Vaccine coverage in early ages is critical to promote life-course vaccination. By expanding the scope of primary care settings to include vaccine delivery, the proportion of children and adolescents receiving on-time doses will undoubtedly increase.[96] Specifically for the human papilloma virus (HPV) vaccine, parents are willing to have their children vaccinated in a pharmacy because they recognise the pharmacist as a capable healthcare professional.[97]

There are still many adolescents who are not aware of the possibility of being vaccinated for diseases like HPV and pharmacists can play a role in increasing the coverage in this age group.[98] Pharmacists, specifically those who have been in practice for few years, had positive perceptions about adolescent vaccination administration but their perceptions were strengthened with additional training.[99]

Adolescent immunisation services in pharmacies have the potential to expand in the next years, although there are still concerns about vaccine supply and availability and clarification on consent for vaccines in the case of minors.[100]

6.2.3 Administration routes

Before administering a vaccine, pharmacists must be aware of the appropriate administration route for each vaccine and be familiar with the administration technique. The route of administration of vaccines is determined during the pre-approval phase, based on their composition and immunogenicity. Vaccines should be administered at sites where they induce an adequate immune response and where the possibility of injury (local, neurological or vascular) is minimal. To avoid local or systemic adverse reactions and to ensure an adequate immune response, manufacturers' recommendations for administration, including those regarding the anatomical site, should be followed.[73]

Administration of vaccines via deep intramuscular injection is generally recommended, because subcutaneous or intradermal administration may cause marked irritation, induration, skin discoloration and granuloma formation. The subcutaneous route presents risk of neurovascular damage, and is therefore recommended for vaccines that are less reactive.[73]

A summary of administration routes is set out in Table 7.

Table 7. Administration routes and technique details[64]

Route	Where to administer	How to administer	Needle gauge and length
Oral	Mouth	Administer the liquid slowly down one side of the inside of the cheek or tongue depending on administered vaccine. Never administer the vaccine directly into the throat.	N/A
Intranasal	Nose	The patient should be seated in an upright position with the head tilted back and a provider's hand supporting the back of the head. Insert the tip of the sprayer and spray half of the content into the nostril. Remove the dose-divider clip and repeat the procedure in the other nostril.	N/A
Subcutaneous	<12 months old: thigh ≥12 months old: upper outer triceps	Pinch up tissue at site. Insert the needle at a 45° angle and inject the vaccine. Withdraw the needle and apply light pressure to the injection site for several seconds with a gauze pad.	23- to 25-gauge, 5/8inch
Intramuscular	≤3 years old: anterolateral thigh >3 years old and adults: deltoid muscle	Spread the skin of the injection site taut between the thumb and forefinger. Insert the needle fully into the muscle at a 90° angle and inject the vaccine. Withdraw the needle and apply light pressure to the injection site for several seconds with a gauze pad.	Up to 18 years old: 22- to 25-gauge, 5/8- to 1-inch >18 years old: 23- to 25-gauge, 5/8- to 1.5inch (based on gender and weight)
Intradermal	Deltoid region of upper arm	The patient should be seated with the arm bent at the elbow and the hand on the hip. Insert the needle into the dermal layer of the skin and inject the vaccine.	30-gauge (typically a prefilled syringe)

6.2.4 Intramuscular vaccination for adolescents and adults

Intramuscular (IM) administration deposits the drug directly into the deep muscle tissue. Striated muscle is highly vascularised, which results in a faster absorption of the drug compared with subcutaneous tissue, leading to faster systemic action. The IM route is the preferred route for administration of vaccines and is typically less irritating as the muscle is less innervated by sensory fibres and therefore less sensitive. The IM route allows for the absorption of relatively high volumes of vaccine dose because muscle tissue is endowed with a large vascular area, which allows for quick absorption. Some muscles are specifically used as injection sites because they present, in relation to other muscles, a lower risk of injury to underlying anatomical structures, namely large vessels, bones and nerve structures, the muscles identified as the most suitable and safe for drug administration are:[73]

- Deltoid (outer side of the shoulder);
- Gluteus maximus (the outermost muscle of the buttocks);
- Gluteus medius (located on the outer surface of the pelvis) and minimus (located immediately beneath the gluteus medius);
- Vastus lateralis (anterolateral thigh)

In the deltoid or vastus lateralis muscles, the absorption rate is faster compared with the same administration in the gluteus. This is due to generally greater amounts of subcutaneous fat being present in the gluteus and this region having less perfusion. This is the reason for vaccines usually being administered in the deltoid. [64] The selection of the intramuscular administration site should consider:

- The size of the muscle, which should be bulky and well developed;

- The muscle condition of the patient (e.g., the presence of stiffness, laxity hernias, paraesthesia or atrophy);
- The volume of the drug to be administered (individuals of average height can carry more volume than thin individuals or children); and
- The patient's preference (this does not override the indications contained in the summary of product characteristics).

The IM route also presents a risk of complications which should be taken into consideration:

- Intravascular administration by accidental vessel perforation, when there is proximity large calibre vessels;
- Nerve injury from trauma or accidental compression, with eventual muscle paralysis (e.g., sciatic nerve);
- Muscle inflammatory injury, due to administration of irritating substance or large volume administration;
- Bone injury during needle insertion;
- Appearance of non-specific infections or sterile or septic abscesses, nodules fibrosis or hematoma; and
- Administration of the drug outside the muscle tissue, due to the size of the subcutaneous layer.

If multiple injections are administered during a single visit, administer each injection at a different injection site.

6.2.5 Step-by-step procedure for the administration of vaccines

The following administration method is based in different recommendations and provides a step-by-step procedure for the administration of vaccines: [64, 73, 84]

1. Make sure the patient is comfortably sitting and bend the arm over the lap, to maintain the relaxation of the muscle.
2. Create a calm and safe atmosphere, and inform the individual about the procedure, keeping the syringe/needle out of their angle of vision to minimise anxiety.
3. Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.
4. With your palm resting on their shoulder, hold the injection site gently with thumb and forefinger. An indicated locale for the injection is the centre of the deltoid approximately 5cm below the acromion (the outer end of the shoulder blade that forms the highest part of the shoulder and to which the collarbone is attached).
5. Holding the barrel of the syringe and, using a dart-like (quick, smooth) action, insert the needle at a 90° angle all the way down through the skin and into the muscle.
6. Depress the plunger smoothly, taking care not to move the needle under the skin.
7. Pull the needle out quickly and smoothly at the same angle as it went in.
8. Perform local asepsis of the application. Do not rub or massage the area.
9. Discard the needle and syringe straight into the safety box.

Besides the steps described above, some additional points to be considered are:

- Watch for signs of anxiety, and reassure and comfort the vaccine recipient;
- Allow time for discussion about the vaccine and the disease;
- Talk quietly and be patient;
- Provide privacy during vaccination; and
- Explain how the vaccine will be administered and how it might feel.

6.2.6 Reducing procedural pain

Pain associated with injections is a source of distress for patients and carers. The following evidence-based strategies to reduce procedural pain might be used:[101]

- Inject vaccines rapidly without aspiration;
- Avoid telling the patient that the injection will hurt or telling them "sharp prick coming", because this could prime them to be more anxious and have more pain;
- Reassure patients that any pain is only short-lasting;
- Use topical anaesthetics or analgesics;
- Use sweet-tasting liquids;
- Inject the most painful vaccine last;
- Use distraction techniques;
- Apply skin cooling at the site of injection, without rubbing the injection site;
- Position the patient appropriately;
- Administer vaccines that may be more likely to cause a local reaction in different limbs;
- Separate injection sites by 2.5cm or more; and
- Use combination vaccines, if appropriate, to decrease the number of injections.

6.2.7 Common vaccination errors in the administration phase

During the administration phase, some common errors that can happen include: [64, 86]

- Injection speed too slow or too fast;
- Inadequate pain management techniques;
- Insufficient patient preparation;
- Administration route or site error;
- Incorrect preparation of vaccine or syringe;
- Incorrect or forgotten procedure (e.g., unsuitable needle selection);
- Clumsiness, leading to incorrect administration; and
- Distraction due to an external event.

To ensure safe vaccine administration, use the strategies set out in the following checklist:[84]

1. Greet the patient and caregiver.
2. Review the patient's immunisation card.
3. Determine vaccine eligibility based on the national schedule, patient's age and possible contraindications.

4. Reconstitute each vaccine with its matched diluent (for lyophilised vaccines).
5. Fill syringes just before administration using aseptic technique.
6. Administer each vaccine according to the recommended technique and correct injection site.
7. Immediately dispose of needles and syringes in safety boxes after each injection.
8. Record all vaccinations in the appropriate registry documents.
9. Communicate key messages, including potential adverse reaction and date of next visit.

6.3 Post-administration phase

After the administration of any injectable product, it is necessary to watch out for possible acute reactions. Recipients of any vaccine should be observed for immediate adverse reactions. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration. Therefore, as an extra safety measure, vaccine recipients should be kept under observation for at least 15 minutes after immunisation so they can be quickly treated if necessary; 30 minutes is a safer interval when there is a specific concern about possible vaccine allergy.[102]

Patients who during, or after, the administration of an injectable complain of dizziness should be advised to lie down until they feel an improvement, as there is a risk of falling and possible trauma. The following general recommendations can be followed to ensure patient safety in the period after the administration of a vaccine:[84]

- Dispose of used vaccine vials and injection equipment safely;
- Cover the injection site quickly with dry gauze, apply pressure for 1 to 2 minutes, then remove it and leave the injection site exposed to the air;
- Leave the environment clean and tidy;
- Document the vaccination (including date of administration, batch number, name of vaccinator);
- Manage immediate adverse events following vaccination (e.g., anaphylaxis, vasovagal episode); and
- Follow the recommendation that a vaccinated person and parent or carer remain in the vicinity of the place of vaccination for at least 15 minutes after the procedure.

6.3.1 Anaphylaxis

Anaphylaxis is an acute, potentially fatal, systemic hypersensitivity reaction with variable mechanisms, clinical presentation and severity, resulting from the sudden release of mediators from mast cells and basophils.[103]

Signs and symptoms that might indicate anaphylaxis include erythema (redness of the skin), urticaria (skin rash with red, raised, itchy bumps) and angioedema (swelling under the skin), wheezing and drop in blood pressure, and shock with a concomitant distributive (i.e., resulting from excessive vasodilation and the impaired distribution of blood flow) and hypovolaemic component (i.e., involving loss of bodily fluids due to fluid extravasation).[104] Gastrointestinal smooth muscle contraction can cause nausea, vomiting and diarrhoea. Swelling of the conjunctiva and lips, tongue or throat can also happen.[105]

The exact incidence of anaphylaxis is unknown. The incidence rate "all-cause" ranged from 1.5 to 7.9 per 100,000 people per year in Europe.[106] This might indicate that approximately one in 300 people suffer one anaphylaxis episode in their lifetime. Note, however, that estimates vary between age groups and between geographical regions. The authors of the cited study identified fatality rates associated with anaphylaxis of 0.0001% or less. Regardless of the estimates, it is important to note anaphylaxis as a serious matter and preparations to act upon these types of reactions must be considered.

Prompt administration of adrenaline should be done when an anaphylactic reaction is suspected in order to minimise the release of mediators and escalation of clinical manifestations. Failure to rapidly administer adrenaline has been associated with fatalities, encephalopathy (due to hypoxia or ischemia) and the onset of biphasic anaphylaxis.[89]

Regarding anaphylaxis, it is important for pharmacists to be aware of the issues with patients during vaccination and be prepared to act if needed. Training in first-aid and cardiopulmonary resuscitation might be a useful asset for pharmacists when dealing with an event like this.

6.3.2 Vasovagal episodes

A vasovagal episode or vasovagal syncope is the most common form of reflex syncope. Reflex syncope describes any form of syncopal episode caused by a failure in the autoregulation of blood pressure, and ultimately, a drop in cerebral perfusion pressure resulting in a transient loss of consciousness.[107]

Patients who may be prone to this type of episodes (or with a history of such episodes) should be instructed to drink fluids to improve their volume status and to change positions slowly. Patients should be aware of the "warning signs" of a vasovagal event and be instructed to lie down if they perceive that an episode may be starting. This may prevent the actual episode to happen, or at least reduce the risk of harm from falling.[107]

6.3.3 Common errors during the post-administration phase

During the post-administration phase, some common errors that can happen include: [64, 86]

- Waste not disposed of immediately, leading to reuse of equipment (e.g., syringes);
- Incorrect disposal of waste (e.g., medical sharps);
- Failure to monitor the vaccine recipient (e.g., potential for vasovagal syncope and rare anaphylactic events);
- Failure to register the procedure on medical records;
- Incorrect patient information recorded;
- Failure to record vaccination date;
- Failure to recognise early signs of side effects.

To ensure safe vaccine administration, use the strategies set out in the following checklist: [84]

1. Correctly assess if open vials can be used in the next session in accordance with national multi-dose vial policy.
2. Discard open vials that should not be reused.
3. Record the date of opening on vials that can be reused and place them in the “use first” box in the refrigerator.
4. Return unopened vials to the refrigerator.
5. Complete the session summary report.
6. List the names of people who missed vaccination and require follow up.
7. Handle full safety boxes correctly.
8. Take appropriate action to ensure sufficient vaccine stock for the next session.
9. Inform individuals of the date and time of the next session.

6.4 Frequently asked questions

What are some important things to remember before administering vaccines?

- Identify contraindications in patients.
- Identify potential precautions.
- Educate patients about common misperceived contraindications.
- Discuss potential common local or systemic reactions.
- Engage positively with patients.
- Check the vaccines themselves, get set up appropriately .

What are some things to remember when administering vaccines?

- Determine the appropriate route of administration.
- If giving multiple vaccines, use different administration sites.
- A positive experience for adolescents can promote life-long vaccination.
- Encourage vaccination before older age to stimulate a strong immunological memory.
- Use conjugate vaccines in the elderly.

What are some important things to remember after administering vaccines?

- Dispose of waste early.
- If the patient is showing early warning signs of an anaphylactic reaction, administer adrenaline.
- After vaccination, the patient must remain for a minimum of 15 minutes in the vicinity. This time interval can be extended to 30 minutes if there is a specific concern.

7 Conclusion

FIP supports the spread of vaccination coverage across the globe by expansion and development of the roles of pharmacists. Pharmacists are trusted healthcare professionals in all communities. They have key expertise in public health, health promotion and education and work to provide evidence-based, trusted advice through the relationships they establish with the communities they attend to.

Advocating vaccination should be part of the daily practice of community pharmacists, making every contact count. Due to increasing levels of vaccine hesitancy, pharmacists should be equipped with proper training and tools to effectively communicate and provide evidence-based recommendations to populations in order to support vaccine uptake.

With regard to vaccine supply and storage, pharmacists can play a significant role in providing access to vaccines, managing stocks, and assuring vaccine efficacy and safety through appropriate cold chain management.

Another important aspect of the role of the pharmacist in vaccination is the management of vaccination records and facilitation of vaccination appointments. Access to vaccination records by pharmacists is still not mainstream practice worldwide, so could remain a barrier to providing adequate reminders and referrals to health systems.

Vaccine administration in community pharmacies, in particular, opens an opportunity to make vaccination more accessible and timelier across the life course, especially for adults and older adults. Appropriately trained and certified pharmacists can deliver value both to individuals and society through this service that, without a doubt, contributes to improving vaccination coverage and uptake.

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