

FIP knowledge and skills reference guide for professional development in vaccination services

2025



FIP Development Goals



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PHARMACY
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1 Introduction

1.1 Rationale for expanding on the FIP knowledge and skills reference guide for vaccination

Since the publication of the FIP vaccination reference guide in 2022¹, which outlines the knowledge and skills to support professional development and inform pharmacy education in vaccination, the healthcare landscape has continued to evolve significantly, especially in the wake of the COVID-19 pandemic. This period has marked a turning point for pharmacy-based vaccination, demonstrating the essential role of pharmacists in public health and highlighting the ongoing need for updated education and training resources to support their expanding responsibilities. Reflecting this, the guide has been revised and updated in 2025 to respond to the dynamic changes in healthcare and pharmacy practice. This update also aligns with broader global strategies and goals. Among the 21 [FIP Development Goals \(DGs\)](#) introduced in September 2020, vaccination is connected to 17, underscoring its strategic importance not only for pharmacy and FIP but also for global health. [Development Goal 16 \(Communicable Diseases\)](#) is directly tied to disease prevention, with vaccination playing a central role. FIP has also developed several vaccination-related resources, available on the [FIP Prevention webpage](#).

These developments, along with other key factors, have driven the need to revisit and expand on the original 2022 guide:

- The pandemic accelerated advancements in vaccine development, distribution, and administration, with pharmacists at the forefront of these initiatives.
- The role of pharmacists in vaccination has grown considerably, supported by robust evidence demonstrating their impact on improving vaccination rates and access to vaccination. As trusted healthcare professionals, pharmacists are increasingly recognised as integral to vaccination campaigns and public health initiatives.
- Taking into account recent challenges, including decreased vaccine confidence, the introduction of artificial intelligence (AI) in healthcare, the spread of misinformation, evolving regulatory frameworks, and the disparities in vaccine access, there is a pressing need to equip pharmacists with the necessary knowledge and skills to navigate this evolving landscape.
- As the scope of pharmacy practice expands, so too must the education and training that underpins it. There is an urgent need to embed vaccination education and training into undergraduate pharmacy curricula worldwide. This document is an updated knowledge and skills guide to optimise pharmacy-based vaccination and emphasises the importance of continuous education to ensure pharmacists remain well-equipped to deliver high-quality vaccination services.

Among the many resources on vaccination that FIP has published is the [FIP policy statement on the role of pharmacy in life-course vaccination](#),² which highlights FIP's commitment to support pharmacists in their role in vaccination, particularly in achieving life-course immunisation and expanding vaccination schedules and strategies beyond infancy to ensure access to vaccines for all age groups. Pharmacists should be integrated into patient immunisation pathways and provide vaccines to special-risk groups, such as those with long-term conditions, pregnant individuals, healthcare professionals, underserved populations and caregivers.

1.2 Pharmacists' expanding role and the need for relevant continuing professional development

Pharmacists are increasingly recognised as key players in immunisation, taking on vital roles that extend beyond traditional pharmacy services. As trusted healthcare professionals, in many countries they are uniquely positioned as the first point of contact for patients seeking advice on health information, such as vaccination. In many countries, pharmacists now dispense, prescribe and administer vaccines. They are actively involved in promoting vaccination, educating patients about its benefits, and dispelling myths and misinformation that contribute to vaccine hesitancy. By fostering trust and providing evidence-based guidance, pharmacists help improve vaccine uptake, particularly in underserved and high-risk populations. Pharmacists also play a crucial role in managing the supply chain of vaccination, including the proper storage, handling, and distribution of vaccines. These responsibilities became more critical during the COVID-19 pandemic, which highlighted the importance of maintaining public confidence in vaccination through efficient and safe delivery systems. In addition, pharmacists take part in conducting vaccine research, development, production, quality control, and regulatory activities related to vaccines (see Figure 1).^{3,4}

Beyond individual pharmacists, the broader pharmacy workforce—including pharmacy technicians, assistants, interns, and students—contributes significantly to immunisation efforts. In some regions, these professionals are trained and certified to provide vaccine-related services, further enhancing the capacity of pharmacies to support public health initiatives. Working collaboratively, pharmacists and their teams help to remove barriers to vaccination, strengthen healthcare systems, and ensure equitable access to life-saving vaccines.

The expanding role of pharmacists in immunisation reflects a broader recognition of their potential to overcome global health challenges. By continuing to embrace and develop this role, pharmacists play a pivotal part in achieving higher vaccination rates and improving public health outcomes worldwide. As the role of pharmacists in vaccination expands, it is essential that education and training keep pace to support this evolution. Beginning at the undergraduate level, there is a pressing need to embed vaccination education and training into pharmacy curricula globally. This foundational education must be complemented by ongoing professional development to address emerging challenges and advancements in immunisation practices.

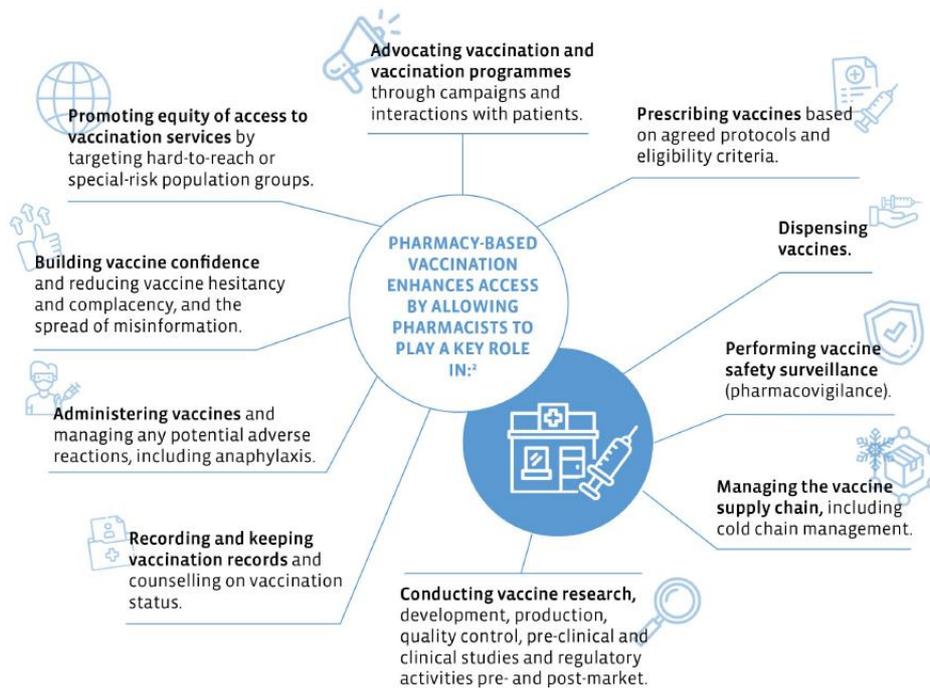


Figure 1: The role of pharmacists in vaccination ⁴

1.3 Purpose and scope of the reference guide

This guide is a valuable resource that reinforces FIP’s commitment to supporting pharmacists in their role in vaccination. It builds on existing data and FIP resources to enhance pharmacists’ training and education in pharmacy-based vaccination. By leveraging insights from recent FIP initiatives, case studies, and emerging evidence, this document provides useful guidance for identifying and addressing education and training needs in this area.

It outlines the key knowledge and skills that pharmacists require to optimise vaccination services, ensuring they can meet the evolving demands of healthcare systems and public health needs. As such, it serves as a useful guide for practitioners, educators, students and regulators.

2 FIP global competency and professional development frameworks, and knowledge and skills reference guides

As medicines experts, pharmacists are essential members of the healthcare team. Through continuing professional development (CPD), pharmacists are required to maintain and further their competence to practise and remain responsive to increasingly complex healthcare environments and requirements such as the recent COVID-19 pandemic. FIP defines CPD as “the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers”.

One approach to developing and maintaining competence is competency-based training and assessment, a structured method focused on achieving specific outcomes. As such, pharmacists must be assisted to acquire the skills and knowledge to enable them to perform a task to a specified standard under certain conditions, either by guidance, toolkits, CPD or professional development programmes. Competency-based training involves clear learning objectives, so that learners understand exactly what they need to accomplish, trainers are aware of the required training or learning to be provided, and organisations can identify the necessary skill levels. This approach emphasises practical application (“performing”) rather than theoretical knowledge (“knowing”).

With the wide acceptance of implementing competency-based training and education in health professions, competency frameworks are useful in organising educational curricula, regulating career entry, benchmarking standards of practice, and facilitating expertise development. FIP has developed two global frameworks that describe generic competencies for both foundation and advanced pharmacy practice:

- The [FIP Global Competency Framework](#) (GbCF), updated in 2020, is a set of competencies and core behavioural statements designed for the global pharmacy workforce, particularly targeting early career (foundation-level) pharmacists. It includes 124 behavioural statements grouped under 23 competency domains and four broad competency clusters: pharmaceutical public health, pharmaceutical care, organisation and management, and professional and personal competencies.
- The [FIP Global Advanced Development Framework](#) (GADF), published in 2020, complements the GbCF by supporting professional development and recognition for pharmacists and pharmaceutical scientists. It maps broad-based stages of advanced practice across six developmental competency clusters: expert professional practice; working with others; leadership; management; education, training, and development; and research and evaluation.

Both the GbCF and GADF are intended to act as mapping tools to guide individuals towards achieving effective and sustained performance, paving the way for advanced and specialist practice. FIP recommends that pharmacists, pharmaceutical scientists and educators use the wide-ranging knowledge and skills reference guides in conjunction with the FIP competency and development frameworks to identify the knowledge, skills and behaviours relevant to their professional growth (see Figure 2). Pharmacists should draw on their existing knowledge, skills, attitudes and values, which may intersect with other competency areas, to deliver patient-centred services.

FIP reference guides offer specific guidance on the knowledge and skills required for particular topics, fostering cross-learning and the transfer of key competencies. These resources, including competency frameworks and knowledge and skills reference guides, support CPD, self-assessment for registration or licensing, professional development, and self-directed learning, as well as guidance for CPD and training programme providers.

To access FIP's collection of knowledge and skills reference guides, follow this [link](#).

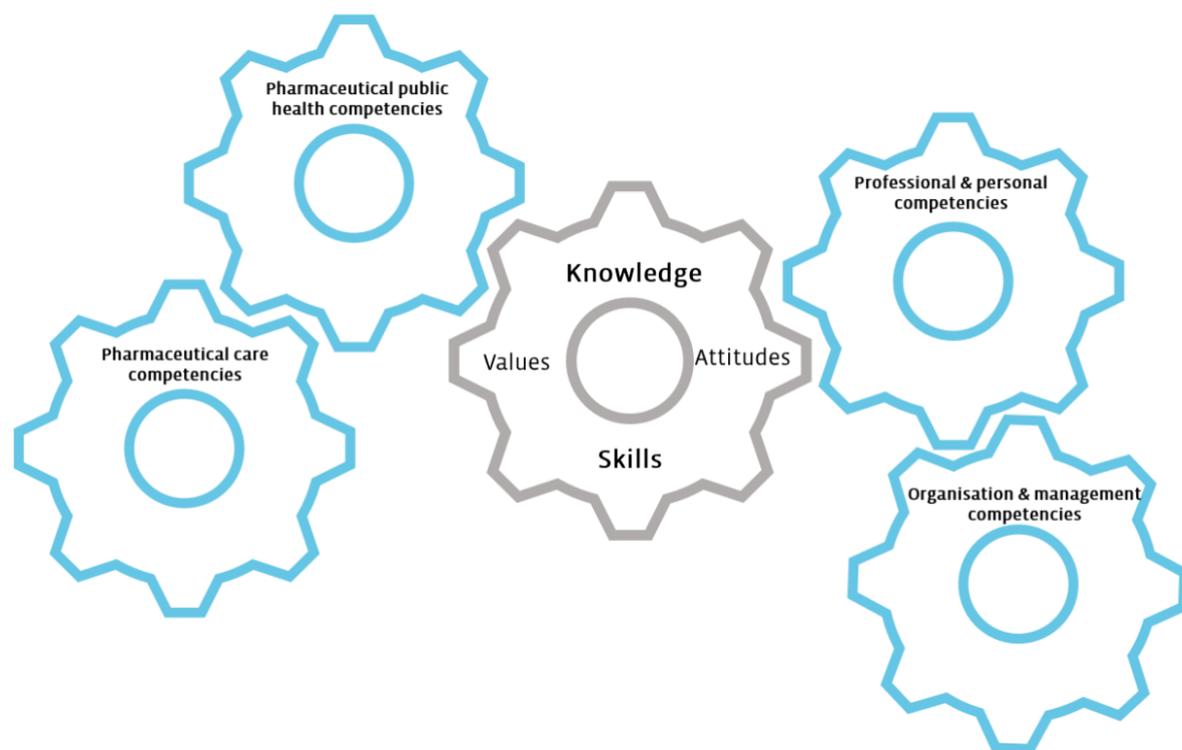


Figure 2: Competencies encompass an array of knowledge, skills, attitudes and values to enable effective performance. Competency clusters are based on the FIP Global Competency Framework

About the guide content

The reference guide provides a comprehensive list of required knowledge and skills to support practitioners to develop, upskill and refresh knowledge in vaccination and related roles in pharmacy. This reference guide is intended to guide practice in the area of vaccination rather than to be a prescriptive list that has to be adhered to in all cases.

How is the information organised?

The guide is organised in three main parts:

The first part (Table 1) outlines the knowledge required for practitioners involved in vaccination and vaccination-related roles. In the knowledge guide, topics are grouped into three categories (Figure 3):

- Broad topic area — includes fundamental concepts such as body systems, medicines supply and use, patient and disease, patient and pharmaceutical care, and advocacy, ethics and collaborations.
- Core topics — highlights key knowledge areas related to the roles and services provided in vaccination.
- Specific topics — details specific subjects that expand on the core topics.

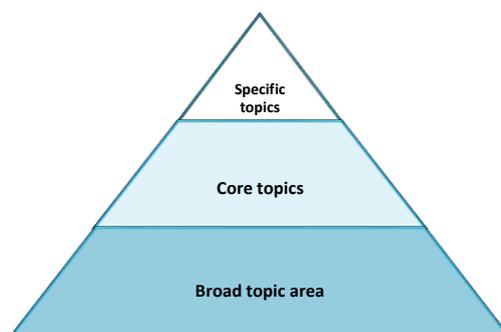


Figure 3. Hierarchy of topic grouping in the knowledge guide

The second part (Table 2) describes skills required by practitioners in vaccination and vaccination-related roles.

Who is it for?

- It is relevant to pharmacists focusing on a specific area or areas of practice and may be relevant at any stage of professional development, depending on the pharmacist's role.
- This guide is also for pharmacy educators and academics to support the development of undergraduate courses and programmes on vaccination.
- Additionally, it serves as a valuable resource for CPD providers to design and deliver continuing professional development programmes that enhance pharmacists' knowledge and skills in vaccination.

How to use it?

This reference guide can be used in the following ways:

- To support practitioners in upskilling in vaccination as part of their career development journey.
- To assist pharmacists interested in providing vaccination-related services in practice.
- To guide the design and delivery of education and training programmes for continuing professional development.
- To inform the development of education and training curricula in undergraduate and postgraduate pharmacy education.
- To support students in identifying knowledge gaps and training needs in vaccination.
- To provide a framework for setting standards, accreditation, and certification requirements related to vaccination services.

Contextualisation, regulatory and training requirements

It is crucial to recognise that practitioners must adhere to their local, national and jurisdictional requirements for training, certification and regulatory, professional and ethical standards to fulfil their specified roles in vaccination. These may include:

- Legislation
- Codes of conduct
- Nationally developed certificate training programmes
- Registration or licensure status.

3 Emerging knowledge and skills in pharmacist-led vaccination services

The 2025 FIP vaccination knowledge and skills reference guide reflects the latest developments in pharmacist-led vaccination, incorporating additional competencies identified through FIP's ongoing work in this area. These have been informed by a range of FIP activities, including digital events, insight boards, global summits, and literature reviews. The following key areas have been identified as priorities for advancing vaccination services through pharmacy.

3.1 Enhancing knowledge on advances in vaccine technology

The rapid development and deployment of new vaccines in recent years, such as the mRNA vaccines developed during the COVID-19 pandemic, have highlighted the need for healthcare professionals, including pharmacists, to stay informed and equipped to manage these new innovations. In return, this enables them to better educate patients, address concerns, manage immunisation schedules, and ensure the safe and efficient handling, storage, and delivery of vaccines, ultimately improving patient outcomes and supporting global health efforts. This chapter highlights the specific knowledge and skills pharmacists need to remain actively engaged in the evolving landscape of vaccine technology.

Advances in vaccine technology	Demonstrates knowledge and understanding of:
	Emerging vaccine technologies, including mRNA vaccines.
	Novel delivery methods such as skin patches, microneedles, or oral vaccines.
	Mechanisms of action of new vaccines, including their development, immune responses and applications.
	Manufacturing, regulatory, and approval processes for new vaccines.
	Associated skills:
	Addresses vaccine hesitancy and misinformation related to emerging technologies.
	Evaluates emerging data on new vaccines to inform better evidence-based decision-making.
	Facilitates or participates in the manufacturing, testing, storage, and transport of vaccines, particularly new vaccines, and ensures compliance with regulatory standards.

3.2 Strengthening supply chain management

Effective vaccine supply chain management is essential to ensuring that vaccines remain safe, effective, and accessible to patients. This requires a comprehensive understanding of processes from procurement to distribution and delivery. By maintaining proper transport, storage, and temperature control, pharmacists play a critical role in safeguarding vaccine quality and supporting successful immunisation programmes.⁵ Below are the knowledge and skills pharmacists need to ensure safe and efficient supply chain management of vaccines.

Supply chain management	Demonstrates knowledge and understanding of:
	Vaccine supply chain management, from procurement to distribution and delivery.
	Vaccine logistics, including ordering, inventory management, and cold chain requirements, ensuring proper transport, storage, and administration of temperature-sensitive vaccines to maintain quality from manufacture to administration.
	Associated skills:
	Facilitates the procurement and distribution of vaccines.
	Utilises technology to track and monitor vaccines storage conditions.
	Identifies and mitigates risks associated with cold chain disruptions.

3.3 Strengthening pharmacovigilance in vaccines

Pharmacovigilance plays a critical role in monitoring the safety of medicines and vaccines, ensuring that potential risks are identified, assessed, and managed appropriately. For pharmacists, staying informed about the latest vaccine pharmacovigilance practices is essential to guarantee patient safety and maintain public trust in immunisation programmes. This chapter outlines the knowledge and skills pharmacists need to enhance and maintain vaccine pharmacovigilance.

Pharmacovigilance for vaccine safety	Demonstrates knowledge and understanding of:
	The basics of pharmacovigilance and its role in ensuring vaccine and patient safety.
	Potential adverse events following vaccination, their causes and their likelihood.
	Methods to assess and manage adverse events when they occur.
	Associated skills:
	Detects, monitors, reports, and follows up on vaccine-related side effects and adverse events through regional or national pharmacovigilance systems.
	Responds to and manages adverse events effectively, providing appropriate care, monitoring, and referral when necessary.
	Counsels patients about potential side effects, what to expect after vaccination, and when to seek medical attention.

3.4 Enhancing digital literacy and access to data and immunisation records

Digital literacy has become a crucial skill in modern healthcare as digital tools and technologies continue to transform service delivery. In immunisation, it enables healthcare professionals, including pharmacists, to access, manage, and share patient records, ensuring seamless care coordination and accurate, up-to-date information. With access to vaccination records, pharmacists can provide personalised vaccine recommendations, register administered vaccines, identify vaccination gaps, and advise against certain vaccines when contraindications are present. They can also refer patients to physicians when needed, counsel them remotely through digital platforms, and develop systems to remind patients about overdue vaccinations.

Equally important is digital health literacy, which is the ability to access, understand, and use digital tools and health-related information to make informed health decisions. Empowering pharmacists with the skills and knowledge to enhance their patients' digital health literacy is crucial for improving access to information, fostering better self-care, and supporting more informed healthcare decisions.

This chapter highlights the importance of digital health literacy and access to vaccination records in pharmacy practice, outlining the knowledge and skills pharmacists need to navigate digital health systems and leverage technology to improve patient care.

Artificial intelligence (AI), digital health literacy and electronic vaccination records	Demonstrate knowledge and understanding of:
	AI's role in vaccine research, discovery, development and manufacturing.
	The role of digital literacy in improving access to healthcare and health information.
	Digital literacy disparities and strategies to support equitable access to patient records and health information.
	Digital health systems for accessing, managing, and updating patient records, particularly immunisation records.
	Patient rights, data privacy, and security regulations related to digital health records.
	Interprofessional collaboration to ensure consistent access to patient records and improve patient care.
	Associated skills:
	Efficiently navigates electronic vaccination records and digital health systems to retrieve, update, and record vaccination data in line with regulatory requirements.
	Collaborates with other healthcare providers to ensure seamless data sharing as well as accurate reporting of discrepancies or gaps in patient records.
	Uses reminder or recall systems, where available, for patient follow-up.

	Supports and educates patients in developing digital health literacy skills, enabling them to confidently access, navigate, and understand electronic health records and reliable health information sources.
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3.5 Preparing pharmacists for future health emergencies: preparedness, response, and recovery

In times of health emergencies, such as the COVID-19 pandemic, pharmacists play a critical role in safeguarding public health and ensuring the continuity of care. Their responsibilities extend far beyond medication dispensing and providing patient care. Pharmacists play a crucial role in immunisation efforts by providing patient education, prescribing and administering vaccines, and managing vaccine supply chain, including overseeing the cold chain storage and distribution of vaccines.⁵ This section examines the importance of preparing the pharmacy workforce for these vital tasks, focusing on the knowledge and skills needed to enhance pharmacy preparedness, response, and recovery during health crises. By equipping pharmacists with the right knowledge and skills, they can help ensure efficient vaccine delivery, manage vaccine supply chains, and reduce the impact of emergencies, ultimately strengthening healthcare resilience and improving public health outcomes.

Pandemic preparedness and emergency response	Demonstrate knowledge and understanding of:
	The role pharmacists can play in the response, recovery, and preparedness to health emergencies.
	Infectious disease transmission, containment strategies and outbreak management.
	Vaccine storage, especially during emergencies where infrastructure may be compromised.
	Clear, simple communication methods to provide patients and the public with the right health information during crises.
	The use of digital health tools and platforms for accurate information dissemination and remote patient management.
	Associated skills:
	Access to vaccination records via available online portals, electronic health records, mobile applications, or immunisation information systems. ⁶
	Maintain privacy and security of personal health information. ⁷
	Coordinates the procurement, storage, and distribution of essential medicines, vaccines, and medical supplies.
	Participates in mass vaccination campaigns during pandemics through advocacy or vaccine dispensing, prescribing, administering.
	Tracks disease trends and reports data to public health authorities to support response efforts.
	Utilises digital tools to record and manage patient data efficiently.
	Leverages digital platforms to raise awareness and disseminate accurate public health information.
Adapts to constantly changing or unclear government guidance.	
Addresses vaccine hesitancy and misinformation, especially in the context of emergencies.	

3.6 Strengthening vaccine confidence and addressing hesitancy

As trusted healthcare professionals, pharmacists play a crucial role in promoting vaccines and addressing vaccine hesitancy. Their involvement in this area requires a robust understanding of the complex factors influencing patient health literacy and vaccine confidence levels as well as the ability to apply effective communication and counselling strategies to enhance them.⁸ Being the most accessible healthcare providers, pharmacists are uniquely positioned to foster trust and empower individuals to make informed decisions about their health, including those regarding vaccination. This section outlines the essential knowledge and skills pharmacists need to navigate the challenges associated with vaccine hesitancy, structured into four key areas: the science of vaccine hesitancy; communication and counselling skills; addressing misinformation; and, cultural competency.

The science of vaccine hesitancy	Demonstrate knowledge and understanding of:
	The definition of vaccine hesitancy, and its complexity, causes, and trends.

	<p>The impact of vaccine hesitancy on vaccine uptake rates.</p> <p>Factors influencing vaccine hesitancy, such as cultural, psychological, or socio-economic factors.</p> <p>Methods to reach and engage high-risk and underserved populations.</p> <p>Associated skills:</p> <p>Stays up to date with the latest advancements in vaccine science, trends, and hesitancy levels.</p> <p>Evaluates any emerging scientific evidence to stay up to date on vaccine safety and efficacy as well as to identify any key areas for intervention.</p> <p>Researches and interprets new evidence to stay up to date with vaccine hesitancy trends and public health recommendations.</p>
<p>Communication and counselling skills</p>	<p>Demonstrate knowledge and understanding of:</p> <p>Best practices for effective communication, maintaining clarity, empathy, and transparency.</p> <p>Behavioural science and behavioural change theories to understand and effectively influence patient attitudes and behaviours towards vaccines.</p> <p>Strategies to assess patients' health literacy, gauge their vaccine confidence, and identify ways to strengthen it to improve vaccine uptake.</p> <p>Methods to ensure health information delivery is tailored to match patient health literacy levels and specific needs.</p> <p>New and emerging communication and counselling techniques to better engage patients, address vaccine hesitancy, and build trust, ultimately enhancing health literacy and vaccine confidence.</p> <p>Associated skills:</p> <p>Expresses interest in patient concerns.</p> <p>Actively listens to understand patient concerns and allow for an open dialogue.</p> <p>Uses best techniques to assess patient health literacy and vaccine confidence levels.</p> <p>Tailors communication and adapts language to match patients' level of literacy, particularly for high-risk and underserved populations.⁹</p> <p>Offers clear, evidence-based advice on vaccines, encouraging patients to consider receiving the vaccine and ensuring they leave with increased vaccine confidence.</p>
<p>Addressing misinformation</p>	<p>Demonstrate knowledge and understanding of:</p> <p>Common vaccine related myths and misconceptions spread within communities or through social media.</p> <p>Credible sources of accurate vaccine information such as the World Health Organization (WHO).</p> <p>The preferred information sources or platforms for different age groups.</p> <p>The impact of social media on health literacy and vaccine confidence.</p> <p>Associated skills:</p> <p>Identifies inaccurate vaccine information and corrects it with evidence-based data.</p> <p>Understands how to use different social media platforms to identify sources of misinformation and counter them effectively.</p> <p>Uses appropriate communication methods to correct misinformation while minimising patient resistance and fostering a collaborative dialogue.</p> <p>Guides patients to credible sources of information to retrieve accurate health information.</p>
<p>Cultural competency</p>	<p>Demonstrate knowledge and understanding of:</p> <p>Cultural, religious, and community values that may influence health behaviours and perceptions of vaccination.</p> <p>Possible causes of mistrust in the healthcare system within certain communities or cultures.</p> <p>Common beliefs or myths about vaccines within different cultures.</p> <p>Language preferences within a community.</p> <p>The influence and engagement of local leaders and faith groups within a community to support vaccination efforts.</p> <p>Associated skills:</p> <p>Demonstrates genuine understanding and respect for cultural concerns to build trust.</p>

	Adapts communication styles to respect and align with the cultural and religious values of different communities.
	Establishes meaningful relationships with local leaders, faith groups, and community representatives to promote trust and encourage vaccination advocacy.
	Actively listens to understand patients' cultural concerns and health beliefs without imposing personal biases.
	Respectfully debunks vaccine myths while acknowledging the cultural context in which they arise.
	Offers information in the community's preferred language and uses professional translation services when necessary.

3.7 Strengthening research skills

In the context of vaccination services, research skills are critical for pharmacists to ensure that practices are rooted in the latest scientific evidence. Pharmacists must be able to assess and interpret current research to inform and improve their vaccination practices in all their aspects, identify gaps in knowledge on vaccination, and contribute to advancing vaccine-related research. This chapter outlines the knowledge and skills required to enhance pharmacists' research skills in the area of vaccination.

Research strategies in pharmacy	Demonstrate knowledge and understanding of:
	The science of vaccines, vaccine-preventable diseases, vaccine effectiveness, and their impact on public health.
	Health data analytics and interpretation of vaccine-related data, such as coverage rates and adverse events.
	Current trends, opportunities, and challenges in (pharmacist-led) immunisation efforts.
	Associated skills:
	Critically assesses scientific literature on vaccine safety, efficacy, and new developments.
	Designs and conducts studies to evaluate vaccination programmes and their outcomes, particularly pharmacist-led programmes.
Keeps track of emerging evidence and data that could enhance pharmacist-led immunisation efforts.	

3.8 Developing economic and business skills

Pharmacists require strong economic and business skills to ensure the sustainability and efficiency of their services. Whether operating in community, hospital, or other healthcare settings, financial management, strategic planning, and an understanding of market dynamics are essential for optimising resources, expanding services, and maintaining high-quality patient care. For vaccination services specifically, pharmacists must understand remuneration schemes, reimbursement pathways, and strategies to be able to participate in vaccination efforts whilst ensuring financial sustainability, optimising service delivery, and maintaining patient accessibility.^{10,11} This section outlines the key knowledge and skills pharmacists need to build a strong business foundation for vaccination services, enabling them to deliver high-quality, financially sustainable immunisation programmes.

Economic and business considerations	Demonstrate knowledge and understanding of:
	The economic impact of vaccination programmes on healthcare spending.
	Funding pathways, government schemes, and private insurance reimbursement for vaccination services.
	Factors that impact patient access to vaccines, including pricing structures and reimbursement mechanisms.
	Workflow models that enhance the pharmacist's productivity, reduce waste, and improve patient outcomes.
Financial and operational risks, such as vaccine shortages and regulatory changes, and developing contingency plans.	

	Leadership and human resources management to ensure efficient team coordination and staffing, skill development, and cost-effective vaccine service delivery.
	Efficient time management to optimise workflow and service delivery.
	Associated skills:
	Navigates reimbursement processes to secure funding from government schemes and private insurers.
	Designs pricing models that balance affordability with financial sustainability.
	Manages time and coordinates staff efficiently to streamline vaccination services and improve overall efficiency without compromising service quality, patient safety, or staff workload.

3.9 Enhancing knowledge on regulatory affairs

Pharmacists involved in vaccination services must have a strong understanding of regulatory requirements to ensure compliance with local and international guidelines. Navigating the complex regulatory landscape is essential to maintaining high standards of safety, efficacy, and quality in vaccine administration.¹² By enhancing their knowledge on the evolving regulations on vaccination programmes, pharmacists can ensure their services are both legally compliant and aligned with public health objectives. This chapter outlines the knowledge and skills pharmacists need with regards to regulatory affairs to manage and optimise their role in vaccination services.

Regulatory affairs	Demonstrate knowledge and understanding of:
	Regulatory requirements of vaccine manufacturing, storage, transport, and administration.
	Regulatory pathways for vaccine licensure, clinical trial guidelines, and quality assurance standards. ¹³
	Safety regulations and compliance standards for vaccine transportation, storage, and handling to ensure quality.
	Safety protocols to ensure timely reporting and good management of adverse events in line with regulatory requirements.
	Associated skills:
	Ensures regulatory compliance as well as safety and quality standards from vaccine manufacturing to administration.
	Manages vaccine supply chain safety and compliance, overseeing storage, handling, and distribution according to regulatory standards.
	Implements efficient adverse event reporting, ensuring adherence to regulatory safety and compliance requirements.

3.10 Enhancing collaborative practice

Collaboration with other healthcare professionals is essential to ensure the optimal delivery of vaccination services and enhance patient outcomes. A thorough understanding of how to work within multidisciplinary teams is crucial for pharmacists to contribute meaningfully to vaccination efforts. This section outlines the key knowledge and skills pharmacists need to foster interprofessional collaboration and ensure effective vaccination service delivery through teamwork.

Collaborative practice	Demonstrate knowledge and understanding of:
	National and international guidelines on collaborative practice, including those specific to vaccination services.
	Roles and contributions of various healthcare professionals in vaccination services, including physicians, nurses, and public health officials.
	Effective communication and coordination between team members to deliver safe and efficient vaccination services.
	The impact of interprofessional collaboration in enhancing patient care and public health outcomes.
	Associated skills:
	Fosters open communication and mutual respect among healthcare team members.

	Understands and follows collaborative practice guidelines to support effective teamwork and delivery of vaccination services.
	Coordinates roles and responsibilities within the pharmacy team to ensure a seamless vaccination service.
	Advocates for the inclusion of pharmacists in immunisation efforts, promoting their integration as key members of the healthcare team working on vaccination initiatives.
	Facilitates interprofessional education opportunities that build knowledge and teamwork among healthcare professionals involved in vaccination efforts.

4 Essential knowledge and skills for pharmacists in vaccination

Outlined below are the essential knowledge and skills required for pharmacists in vaccination. These frameworks are designed to support pharmacists in actively participating in immunisation practices and to equip them to contribute effectively to public health efforts.

Table 1. Knowledge guide for practising pharmacists in the area of vaccination

Body systems	
Immune system	Demonstrates knowledge and understanding of:
Immunology ¹⁴	<ul style="list-style-type: none"> The basic immunological concepts and mechanisms of the immune system in allergic reactions, autoimmune diseases and transplantation survival. The different types of immunity (passive immunity and active immunity, including natural immunity and vaccine-induced immunity). Key terms (immunity, vaccine, vaccination, immunisation).
Vaccines	Demonstrates knowledge and understanding of:
Medicines: common vaccinations	<ul style="list-style-type: none"> All aspects of common vaccinations, including: indications; mechanism of action; pharmacology; pharmacokinetics; pharmaceutical aspects; adverse effects, contraindications, precautions and interactions; usual doses and routes of administration; place in therapy; and, monitoring requirements.
Medicines: anaphylaxis medicines	<ul style="list-style-type: none"> All aspects of antihistamines, corticosteroids, bronchodilators, adrenergic agonists and vasoconstrictors, including: mechanism of action; pharmacology; pharmacokinetics; pharmaceutical aspects; adverse effects, contraindications and interactions; usual doses and routes of administration; place in therapy; and, monitoring requirements.
Common vaccinations	<ul style="list-style-type: none"> The main types and groups of vaccines; the differences between live and inactivated vaccines; childhood vaccinations; an ability to advise on the most appropriate vaccination regimens; protocols for supply; and, the precautions that need to be observed with respect to timing when administering more than one vaccine from the same group or different groups.
Advances in vaccine technology	<ul style="list-style-type: none"> Emerging vaccine technologies, including mRNA vaccines. Novel delivery methods such as skin patches, microneedles, or oral vaccines. Mechanisms of action of new vaccines, including their development, immune responses, and application. Manufacturing, regulatory, and approval processes of new vaccines.
Vaccine-preventable diseases	Demonstrates knowledge and understanding of:
Aetiology, transmission & diseases	<ul style="list-style-type: none"> Aetiology; toxin mechanism of action; types; risks; pathogenesis and virulence; clinical features; epidemiology; transmission; and, diseases and complications caused by common vaccine-preventable diseases. Common vaccine-preventable diseases, including cholera, diphtheria, haemophilus influenza, hepatitis A and B, human papilloma virus, influenza,

	measles, meningococcal disease, mumps, pertussis, pneumococcal disease, poliomyelitis, rabies, rotavirus, rubella, tetanus, typhoid, varicella (chickenpox), zoster (shingles), yellow fever, some cancers, tuberculosis and malaria.
History of vaccines and vaccination	<ul style="list-style-type: none"> The history of vaccines and how vaccination has mitigated or eradicated many infectious diseases, e.g., smallpox.
Vaccine development	<ul style="list-style-type: none"> The main steps involved in the development, production and pharmaceutical regulation of vaccines.
Vaccine use	Demonstrates knowledge and understanding of:
Timing and spacing of vaccines	<ul style="list-style-type: none"> The differing actions of available vaccines and which vaccine is appropriate for the patient. Timing and spacing of vaccines, including interval between doses of the same vaccines, and simultaneous and non-simultaneous vaccine administration.
Vaccine pharmacology	<ul style="list-style-type: none"> Appropriate vaccine doses and dosage forms used to prevent disease. Vaccine-drug interactions and corresponding warnings associated with their use. Appropriate considerations for special population groups, e.g., pregnant persons, people with co-morbidities, children, etc. The side effects associated with vaccines. Vaccine additives that may trigger allergic reactions in susceptible patients. Vaccine administration routes, e.g., oral, intranasal, subcutaneous, intramuscular, intradermal, and the corresponding appropriate administration techniques.
Patient screening	<ul style="list-style-type: none"> The need for pre-screening and patient consent prior to receiving vaccination. The patient screening process in identifying eligible candidates for vaccination. This includes understanding the inclusion and exclusion criteria for patients through familiarity with the patient group directives. The need for patient counselling before vaccination.
Public health	<ul style="list-style-type: none"> Demonstrates knowledge and understanding of local and national vaccination and immunisation schedules and regimens.
Vaccine information	Demonstrates knowledge and understanding of:
Answering vaccine information enquiries	<ul style="list-style-type: none"> The use of common information sources used when answering enquiries about immunisation programmes in the country, and health protection for persons travelling abroad, including their advantages and disadvantages. Standard questions to ask to obtain the relevant background information when answering enquiries about immunisation programmes in the country and health protection for persons travelling abroad.
Vaccine supply	
Vaccine production	Demonstrates knowledge and understanding of:

<p>Vaccines manufacturing and regulation</p>	<ul style="list-style-type: none"> • Vaccine manufacturing and quality control processes. • Standardisation of starting materials, production and quality control testing to guarantee vaccine identity, purity, sterility, efficacy and safety. • The regulatory requirements of the entire manufacturing process from start to finish. • Vaccines formulation and active ingredient manufacturing. • Vaccines filling, packaging and lot release processes. • The good manufacturing practices for vaccines.
<p>Vaccine storage and handling</p>	<p>Demonstrates knowledge and understanding of:</p>
<p>Vaccine cold chain</p>	<ul style="list-style-type: none"> • Vaccine cold-chain and how it may affect vaccine efficacy. • Vaccine storage and handling standard operating procedures. • Quality control aspects of vaccines at multiple levels (pre-approval, quality control testing, good manufacturing practice and pharmacovigilance), e.g., potency assays, in-process testing, immunogenicity tests, quantitative polymerase chain reactions, and post-approval clinical studies. • Vaccine supply chain management, from procurement to distribution and delivery.
<p>Transport, storage and handling</p>	<ul style="list-style-type: none"> • Vaccine logistics, including ordering, inventory management, and cold chain requirements, ensuring proper transport, storage, and administration of temperature-sensitive vaccines to maintain quality from manufacture to administration. • Vaccine storage and temperature monitoring equipment, including refrigerators and freezers, temperature monitoring devices, storage unit setup, stabilising temperatures, power supply, and equipment maintenance. • Vaccine transport and inventory management. • Organising and storing vaccines in storage units. • Stability of vaccines. • Vaccine delivery systems.
<p>Administration</p>	<p>Demonstrates knowledge and understanding of:</p>
<p>Pre-administration phase</p>	<ul style="list-style-type: none"> • The timing and spacing of vaccines. • Assessment for the needed vaccines. • Consent prior to vaccination according to the requirements of the state, territory or region of practice. • Pre-administration precautions. • Good pharmacy practice in the pharmacy, which includes having a vaccination-specific place or room, a refrigerator specifically for vaccines, a temperature monitor, a portable refrigerator in case of power failure, an anaphylaxis response kit, an anaphylaxis management poster or guidance, a safety box, a medical waste bin, and materials for hand sanitisation and surface cleaning.
<p>Administration phase</p>	<ul style="list-style-type: none"> • Administration site recommendations for infants, toddlers, children, adolescents and adults. • Contraindications to vaccination and associated adverse events following vaccination. • The risks of complications when administering vaccines via specific routes.

	<ul style="list-style-type: none"> • Infection control during vaccine administration including aspects of personal protective equipment; proper vaccine preparation to maintain integrity; vaccine inspection; and selection of supplies for administering vaccines. • Administration considerations for specific risk groups, including barriers to access to vaccination; effectiveness of vaccines and strategies to improve effectiveness. • Pain management during the vaccination procedure.
Post-administration phase	<ul style="list-style-type: none"> • Patient care after vaccine administration, including possible acute reactions and vasovagal episodes. • Common errors in the post administration phase; errors that require re-vaccination. • Strategies to ensure safe vaccination, and how to report vaccine administration errors. • Correct handling of sharps and prevention of needle stick injuries. • Proper documentation and vaccination records, including electronic universal health records. • Creation and implementation of quality improvement programmes. • Patient follow-up strategies such as the recall system, standing orders and automatic reminders.
Vaccine safety	Demonstrates knowledge and understanding of:
Pharmacovigilance & adverse events following immunisation (AEFI)	<ul style="list-style-type: none"> • Basics of pharmacovigilance and its role in ensuring vaccine and patient safety. • Potential adverse events following vaccination, their causes and their likelihood. • Assessment of causality. • Assessment and monitoring of vaccine safety. • Adverse drug reaction notifications to pharmacovigilance specialised authorities and vaccine safety programmes in ensuring vaccine safety.
Emergency management of AEFI	<ul style="list-style-type: none"> • Methods to assess and manage adverse events when they occur. • Management of anaphylaxis and allergies. • First aid procedures and basic life support, including use of an automated external defibrillator.
Vaccination provider's role	<ul style="list-style-type: none"> • Vaccination provider's role in ensuring safety and efficacy of vaccines, including benefit and risk communication and managing ADRs after vaccination.
Patient/pharmaceutical care	
Special population groups	Demonstrates knowledge and understanding of:
Adults	<ul style="list-style-type: none"> • Vaccines needed by all adults regardless of whether they were received during childhood (e.g., hepatitis B, influenza, varicella, MMR, and DPT vaccines). • Changes in susceptibility of contracting vaccine-preventable diseases in adulthood. • Reminder and recall systems and standing orders in enhancing access to immunisation. • Methods of dealing with vaccine hesitancy.

Elderly	<ul style="list-style-type: none"> • The need for additional vaccines for people who are aged 65 and older, including COVID-19, influenza, pneumococcal, and zoster, and the scheduling regimen and frequency. • Patient considerations taken during screening and vaccine administration among the elderly because of reduced vaccine effectiveness and multimorbidity. • The difference in vaccine adjuvants (composition) for the elderly. • Methods of dealing with vaccine hesitancy among the elderly.
Immunocompromised patients	<ul style="list-style-type: none"> • Contraindications and precautions for vaccines in immunocompromised patients (e.g., HIV/AIDS, chemotherapy, autoimmune disease, primary or secondary immune deficiency) and those with medical conditions that weaken the immune system (cancer, sickle cell disease) or on immunosuppressants, including steroids. • The reduced effectiveness of vaccines in immunocompromised patients depending on the type of vaccine and the degree of immune dysfunction.
Immigrants	<ul style="list-style-type: none"> • Aspects related to the vaccination status of immigrants as vaccination may be incomplete and documentation missing, and the need to begin catch-up vaccination in children.
Healthcare providers	<ul style="list-style-type: none"> • The need for healthcare providers to be vaccinated annually against influenza, be up to date with vaccines in the national immunisation programme to protect themselves and their patients. Other vaccines and booster doses include tetanus toxoid, diphtheria toxoid, measles, mumps, rubella, varicella and hepatitis. • Methods of dealing with vaccine hesitancy.
Pregnant or lactating women	<ul style="list-style-type: none"> • Immunisation routinely recommended for women during pregnancy including inactivated trivalent influenza vaccine. • The need for women to receive all recommended vaccines that could not be or were not administered during pregnancy. • Valid contraindications and precautions for immunising pregnant women.
Travellers	<ul style="list-style-type: none"> • Immunisation requirements and recommendations for travellers.
Patient education	Demonstrates knowledge and understanding of:
Communication and counselling skills	<ul style="list-style-type: none"> • Best practices for effective communication, maintaining clarity, empathy, and transparency. • Behavioural science and behavioural change theories to understand and influence patient attitudes and behaviours towards vaccines effectively. • Strategies to assess patients' health literacy, gauge their vaccine confidence, and identify ways to strengthen it to improve vaccine uptake. • Methods to ensure health information delivery is tailored to match patient health literacy levels and specific needs. • New and emerging communication and counselling techniques to better engage patients, address vaccine hesitancy, and build trust, ultimately enhancing health literacy and vaccine confidence.

Addressing misinformation	<ul style="list-style-type: none"> • Common vaccine related myths and misconceptions spread within communities or through social media, e.g., the ABC (acknowledge, bridge, communicate) framework. • Credible sources and ways of dissemination of accurate vaccine information such as the World Health Organization (WHO). • The preferred information sources or platforms for different age groups. • The impact of social media on health literacy and vaccine confidence.
Cultural competency	<ul style="list-style-type: none"> • Cultural, religious, and community values that may influence health behaviours and perceptions of vaccination. • Possible causes of mistrust in the healthcare system within certain communities or cultures. • Common beliefs or myths about vaccines within different cultures. • Language preferences within a community. • The influence and engagement of local leaders and faith groups within a community to support vaccination efforts.
System-based barriers	<ul style="list-style-type: none"> • System-based barriers to vaccination, including missed opportunities, limited access to healthcare, low awareness on vaccines and their benefits, complicated adult immunisation schedules, and vaccine cost and reimbursement.
Vaccine hesitancy	<ul style="list-style-type: none"> • Reasons for vaccine hesitancy, including safety concerns, efficacy concerns, moral or philosophical concerns, and misinformation. • Methods of addressing vaccine hesitancy, including adjusting communication styles, communication content, and addressing and preventing misinformation. • Patient-focused strategies that improve patient confidence such as strong vaccination recommendations, taking time to answer questions, and adopting the SHARE (share, highlight, address, remind, explain) framework.¹⁵ • Practice-focused strategies that are designed to overcome physical and psychological barriers. • The definition of vaccine hesitancy, its complexity, causes, and trends. • The impact of vaccine hesitancy on vaccine uptake rates. • Factors influencing vaccine hesitancy, such as cultural, psychological, or socio-economic factors. • Methods to reach and engage high-risk and underserved populations.
Public health	Demonstrate knowledge and understanding of:
Advocacy	<ul style="list-style-type: none"> • Methods of advocacy relevant to their area of practice. • Advocacy strategy development, including situational analysis tools, stakeholder onboarding, implementation of vaccine services, monitoring implementation and progress, and developing a remuneration model for the service.
Health promotion	<ul style="list-style-type: none"> • Health promotion strategies through immunisation quality improvement projects. • Developing strategies to address public health needs and disease prevention. • Common public health strategy theories, and the ability to critically appraise strategies around public health.

Pandemic preparedness and emergency response	<ul style="list-style-type: none"> • The role pharmacists can play in the response, recovery, and preparedness to health emergencies. • Infectious disease transmission, containment strategies and outbreak management. • Vaccine storage, especially during emergencies where infrastructure may be compromised. • Clear, simple communication methods to provide patients and the public with the right health information during crises. • The use of digital health tools and platforms for accurate information dissemination and remote patient management.
Multidisciplinary care	Demonstrate knowledge and understanding of:
Patient-centred interactions and patient involvement	<ul style="list-style-type: none"> • The need for consistent patient education and counselling on vaccines and vaccination. • Culture- and religion-appropriate language when communicating to patients on vaccination. • The benefits of patient-centred interaction and involvement in improving healthcare intervention outcomes and building patient confidence.
Individualisation of vaccine therapy	<ul style="list-style-type: none"> • Vaccine therapy individualisation based on age, sex, patient history and immune state.
Professional development in an interdisciplinary approach	<ul style="list-style-type: none"> • The need for continuous education on vaccination and professional development. • Interdisciplinary efforts in improving immunisation coverage and building patient confidence and trust in vaccination.
Ethical practice	Demonstrate knowledge and understanding of:
Pharmacy code of ethics	<ul style="list-style-type: none"> • How pharmacy codes of ethics apply to pharmacist-patient interactions, patient informed consent, and access to patient data. • Ways to deal or interact with patients of varying health literacy levels.
Collaborative practice	Demonstrate knowledge and understanding of:
Interprofessional collaboration	<ul style="list-style-type: none"> • National and international guidelines on collaborative practice, including those specific to vaccination services. • Roles and contributions of various healthcare professionals in vaccination services, including physicians, nurses, and public health officials. • Effective communication and coordination between team members to deliver safe and efficient vaccination services. • The impact of interprofessional collaboration in enhancing patient care and public health outcomes.
Policies, regulations and guidelines	
Vaccine policies and regulations	Demonstrate knowledge and understanding of:
Government-funded vaccination programmes	<ul style="list-style-type: none"> • Government-funded vaccination programmes in their area of practice.

	<ul style="list-style-type: none"> Government-supported and other funded programmes that cover the cost of vaccines and their administration for people who do not have adequate resources.
Paediatric vaccination schemes and schedules	<ul style="list-style-type: none"> Paediatric immunisation schedules as recommended by government health ministries or other national and international expert bodies, e.g., the World Health Organization. Recommended minimal intervals between vaccine doses for children.
Geriatric vaccination schemes and schedules based on comorbidities	<ul style="list-style-type: none"> Recommended geriatric vaccination schedules in the context of existing comorbidities such as cancer, chronic kidney disease, chronic liver disease, chronic kidney disease, heart conditions, dementia and diabetes.
Mandatory vaccines	<ul style="list-style-type: none"> Contexts where vaccination is mandatory as required by laws or government directives, e.g., before international travel.
Pharmacovigilance of vaccines in monitoring and management	<ul style="list-style-type: none"> Pharmacovigilance and vaccine safety programmes in ensuring vaccine safety.
Artificial intelligence (AI), digital health literacy and electronic vaccination records	<ul style="list-style-type: none"> AI's role in vaccine research, discovery, development and manufacturing. Role of digital literacy in improving access to healthcare and health information. Digital literacy disparities and strategies to support equitable access to patient records and health information. Digital health systems for accessing, managing, and updating patient records, particularly immunisation records. Patient rights, data privacy, and security regulations related to digital health records. Interprofessional collaboration to ensure consistent access to patient records and improve patient care.
Regulatory affairs	<ul style="list-style-type: none"> Regulatory requirements of vaccine manufacturing, storage, transport, and administration. Regulatory pathways for vaccine licensure, clinical trial guidelines, and quality assurance standards.¹³ Safety regulations and compliance standards for vaccine transportation, storage, and handling to ensure quality. Safety protocols to ensure timely reporting and good management of adverse events in line with regulatory requirements.
Research strategies in pharmacy	
	Demonstrates knowledge and understanding of:
Research and analytical skills	<ul style="list-style-type: none"> The science of vaccines, vaccine-preventable diseases, vaccine effectiveness, and their impact on public health. Health data analytics and interpretation of vaccine-related data, such as coverage rates and adverse events. Current trends, opportunities, and challenges in (pharmacist-led) immunisation efforts.
Economic and business considerations	
	Demonstrates knowledge and understanding of:

Economic considerations	<ul style="list-style-type: none"> • Economic impact of vaccination programmes on healthcare spending. • Funding pathways, government schemes, and private insurance reimbursement for vaccination services. • Factors that impact patient access to vaccines, including pricing structures and reimbursement mechanisms. • Financial and operational risks, such as vaccine shortages and regulatory changes, and developing contingency plans.
Business management	<ul style="list-style-type: none"> • Workflow models that enhance the pharmacist's productivity, reduce waste, and improve patient outcomes. • Leadership and human resources management to ensure efficient team coordination and staffing, skill development, and cost-effective vaccine service delivery. • Efficient time management to optimise workflow and service delivery.

Table 2. Skills, techniques, and procedures in vaccination (shaded rows indicate updates)

Vaccination-related role or service	Skills, techniques, quality assurance and procedures
Patient education, health literacy and vaccine hesitancy	<ul style="list-style-type: none"> • Cordially welcomes patients, establishes rapport and answers any questions they may have. • Provides an explanation of the vaccine and how it will be administered. • Adequately accommodates any language, literacy, cultural or religious barriers, including any special needs that the patient or carer may have to help them feel comfortable and informed about the procedure. • Verifies that the patient has received the vaccine information statements for indicated vaccines. • Conducts screening for contraindications. • Reviews comfort measures and aftercare instructions with the patient, allowing for any questions. • Uses the ABC framework to dispel vaccination myths. • Adopts the SHARE framework¹⁵ in tackling vaccine hesitancy. • Stays up to date with the latest advancements in vaccine science, trends, and hesitancy levels. • Evaluates any emerging scientific evidence to stay up to date on vaccine safety and efficacy as well as to identify any key areas for intervention. • Researches and interprets new evidence to stay up to date with vaccine hesitancy trends and public health recommendations.

Vaccination-related role or service	Skills, techniques, quality assurance and procedures
Patient advocacy and communication	<ul style="list-style-type: none"> • Expresses interest in patient concerns. • Actively listens to understand patient concerns and allow for an open dialogue. • Uses suitable techniques to assess patient health literacy and vaccine confidence levels. • Tailors communication and adapts language to match patient's level of literacy, particularly for high-risk and underserved populations.⁹ • Offers clear, evidence-based advice on vaccines, encouraging patients to consider receiving the vaccine and ensuring they leave with increased vaccine confidence. • Builds trust and confidence with the community and establishes the crucial nature of vaccines. • Advises immunisation committees and engages in multidisciplinary vaccination campaigns. • Applies health promotion and disease state management aspects in vaccination advocacy and education. • Addresses vaccination concerns and beliefs in a respectful manner and develops group-specific materials to address patients' concerns. • Participates in or conducts regular assessments of immunisation coverage rates in their area of practice.
Addressing misinformation	<ul style="list-style-type: none"> • Identifies inaccurate vaccine information and corrects it with evidence-based data. • Understands how to use different social media platforms to identify sources of misinformation and counter them effectively. • Uses appropriate communication methods to correct misinformation while minimising patient resistance and fostering a collaborative dialogue. • Guides patients to credible sources of information to retrieve accurate health information.
Cultural competency	<ul style="list-style-type: none"> • Demonstrates genuine understanding and respect for cultural concerns to build trust. • Adapts communication styles to respect and align with the cultural and religious values of different communities. • Establishes meaningful relationships with local leaders, faith groups, and community representatives to promote trust and encourage vaccination advocacy. • Actively listens to understand patients' cultural concerns and health beliefs without imposing personal biases. • Respectfully debunks vaccine myths while acknowledging the cultural context in which they arise.
Medical protocols	<ul style="list-style-type: none"> • Offers information in the community's preferred language and uses professional translation services when necessary.
Vaccine handling	<ul style="list-style-type: none"> • Checks vial expiration date before administration. • Monitors vaccine vial monitor thermochromic labels to ensure vaccine vials are kept in their safe temperature range. • Double checks vial label and contents before drawing up and carries out visual inspection of vaccine for any obvious defects. • Maintains aseptic techniques throughout the administration process. • Shakes vaccine vial or reconstitutes with diluent supplied. Also inverts vial and draws up the correct dose of vaccine. • Labels each filled syringe or uses a labelled tray for ease of identification. • Handles vaccine properly, including protection from light where necessary, and adequately logs refrigerator temperature.

Vaccination-related role or service	Skills, techniques, quality assurance and procedures
Client assessment	<ul style="list-style-type: none"> • Conducts appropriate client assessment before vaccination, including health status, vaccine history, contraindications, and adverse event history. • Determines high-risk eligibility for additional vaccines. • Identifies and responds to unique immunisation needs of special population groups, e.g., children, immunocompromised patients, elderly, pregnant/lactating persons. • Obtains appropriate consent from patients aged 18 years of age and over to receive the vaccine. For paediatric patients, appropriate consent has to be obtained from a parent or legal guardian.
Administering vaccines	<ul style="list-style-type: none"> • Rechecks prescription or schedule against prepared syringes. • Washes hands and puts on disposable gloves to maintain aseptic techniques. • Identifies the appropriate route of administration for each vaccine. • Positions patient and locates anatomical site specific for the route of administration. • Prepares the administration site with alcohol wipes and allows the alcohol to dry. • Controls disinfected area with free hand and inserts needle quickly and straight into the skin. Aspires, and slowly injects content of the syringe into the skin before taking the needle out quickly and disposing of it in the sharps bin. • Uses steady pressure to inject vaccine and withdraw needle at the angle of insertion. • Properly disposes of needle and syringe in sharps container. • Properly disposes of vaccine vial. • Encourages comfort measures before, during, and after the procedure. • Makes use of screening tools such as questionnaires to identify vaccination opportunities in patient populations.
Documentation	<ul style="list-style-type: none"> • Fully documents each immunisation in patient's chart, including date, lot number, manufacturer, site, date, and name or initials. • Makes use of computers to call up patient records, assess what is due and update computer immunisation history. • Asks for and updates patient's record of immunisation and reminds them to bring it to each visit or access their electronic immunisation records. • Adequately uses reminder and recall systems where available for patient follow-up.
Multidisciplinary patient-centred care	<ul style="list-style-type: none"> • Effectively communicates and works with other healthcare providers to promote vaccination uptake and immunisation coverage. • Individualises vaccination therapy through administration of standardised questionnaires to patients. • Identifies and targets patients who are at high-risk of vaccine-preventable diseases and their complications. • Works collaboratively with other healthcare professionals to improve patient outcomes. This includes assessing and recommending appropriate vaccines, administering the vaccine, and reporting administered vaccine to primary care providers or vaccination recording systems.

Vaccination-related role or service	Skills, techniques, quality assurance and procedures
Ensuring vaccine safety	<ul style="list-style-type: none"> • Detects, monitors, reports, and follows up on vaccine-related side effects and adverse events through regional or national pharmacovigilance systems. • Responds to and manages adverse events effectively, providing appropriate care, monitoring, and referral when necessary. • Counsels patients about potential side effects, what to expect after vaccination, and when to seek medical attention. • Adequately handles adverse reactions to vaccines. • Identifies the cause of the most common adverse reactions post-administration. • Reports any significant adverse effect to the national or regional pharmacovigilance units. • Implements good pharmacy practice standards throughout the vaccination process
Ethical service provision	<ul style="list-style-type: none"> • Serves the healthcare needs of patients and contributes to efficient health systems while considering professional ethics as a guide to access use patient data.
Vaccine policies and regulations	<ul style="list-style-type: none"> • Ensures regulatory compliance as well as safety and quality standards from vaccine manufacturing to administration. • Manages vaccine supply chain safety and compliance, overseeing storage, handling, and distribution according to regulatory standards. • Implements efficient adverse event reporting, ensuring adherence to regulatory safety and compliance requirements. • Facilitates or participates in national and global routine immunisation programmes and practices. • Contributes to research projects related to vaccines through data sharing, data collection and other methods. • Makes use of available vaccine financing programmes, minimising patient out-of-pocket expenses.
Vaccine production and regulation	<ul style="list-style-type: none"> • Facilitates or participates in vaccines manufacturing and quality control testing processes. • Implements good manufacturing practice standards throughout the vaccine production processes. • Provides regulatory oversight to the entire manufacturing process from start to finish.
Advances in vaccine technology	<ul style="list-style-type: none"> • Addresses vaccine hesitancy and misinformation related to emerging technologies. • Evaluates emerging data on new vaccines to inform better evidence-based decision-making. • Facilitates or participates in the manufacturing, testing, storage, and transport of vaccines, particularly new vaccines, and ensures compliance with regulatory standards.
Vaccine supply chain management	<ul style="list-style-type: none"> • Facilitates the procurement and distribution of vaccines. • Utilises technology to track and monitor vaccines storage conditions. • Identifies and mitigates risks associated with cold chain disruptions.

Vaccination-related role or service	Skills, techniques, quality assurance and procedures
Artificial intelligence (AI), digital health literacy and electronic vaccination records	<ul style="list-style-type: none"> • Efficiently navigates electronic vaccination records and digital health systems to retrieve, update, and record vaccination data in line with regulatory requirements. • Collaborates with other healthcare providers to ensure seamless data sharing as well as accurate reporting of discrepancies or gaps in patient records. • Uses reminder or recall systems, where available, for patient follow-up. • Supports and educates patients in developing digital health literacy skills, enabling them to confidently access, navigate, and understand electronic health records and reliable health information sources.
Pandemic preparedness and emergency response	<ul style="list-style-type: none"> • Accesses vaccination records via available online portals, electronic health records, mobile applications, or immunisation information systems.⁶ • Maintains privacy and security of personal health information.⁷ • Coordinates the procurement, storage, and distribution of essential medicines, vaccines, and medical supplies. • Participates in mass vaccination campaigns during pandemics through advocacy or vaccine dispensing, prescribing, or administering. • Tracks disease trends and reports data to public health authorities to support response efforts. • Utilises digital tools to record and manage patient data efficiently. • Leverages digital platforms to raise awareness and disseminate accurate public health information. • Adapts to constantly changing or unclear government guidance. • Addresses vaccine hesitancy and misinformation, especially in the context of emergencies.
Research skills	<ul style="list-style-type: none"> • Critically assesses scientific literature on vaccine safety, efficacy, and new developments. • Designs and conducts studies to evaluate vaccination programmes and their outcomes, particularly pharmacist-led programmes. • Keeps track of emerging evidence and data that could enhance pharmacist-led immunisation efforts.
Economic and business skills	<ul style="list-style-type: none"> • Navigates reimbursement processes to secure funding from government schemes and private insurers. • Designs pricing models that balance affordability with financial sustainability. • Manages time and coordinates staff efficiently to streamline vaccination services and improve overall efficiency without compromising service quality, patient safety, or staff workload.
Interprofessional collaboration	<ul style="list-style-type: none"> • Fosters open communication and mutual respect among healthcare team members. • Understands and follows collaborative practice guidelines to support effective teamwork and delivery of vaccination services. • Coordinates roles and responsibilities within the pharmacy team to ensure a seamless vaccination service. • Advocates for the inclusion of pharmacists in immunisation efforts, promoting their integration as key members of the healthcare team working on vaccination initiatives. • Facilitates interprofessional education opportunities that build knowledge and teamwork among healthcare professionals involved in vaccination efforts.

5 Identifying policy enablers for workforce qualification and participation

To advance workforce training and education in vaccination, the key policy enablers outlined in the table below, aligned with the FIP DGs, can support the transformation of vaccination in pharmacy and can serve as an action plan that regions and countries worldwide can adopt and adapt.

Table 1. Summary of the key policy enablers for workforce and education to transform vaccination

FIP Development Goal	Workforce and education policy enabler to transform vaccination
 <p>1 A ACADEMIC CAPACITY</p>	<p>Engagement with pharmaceutical higher education development policies and ready access to leaders in all sectors of pharmacy practice and pharmaceutical science, in order to support supply-side workforce development in the areas of vaccination training and service delivery</p>
 <p>2 A EARLY CAREER TRAINING STRATEGY</p>	<p>Foundation training infrastructures in place for the early post-registration (post-licensing) years of the pharmaceutical workforce, serving as a basis for consolidating initial vaccination education and training and progressing the workforce towards qualification in vaccination service delivery</p>
 <p>3 A QUALITY ASSURANCE</p>	<p>Transparent, contemporary and innovative processes for the quality assurance of needs-based education and training systems and service delivery, and for maintaining competence in vaccination delivery by pharmacists</p>
 <p>4 A ADVANCED AND SPECIALIST DEVELOPMENT</p>	<p>Education and training infrastructures in place for the recognised advancement of the pharmaceutical workforce as a basis for enhancing patient care and competency of existing pharmacist workforce in the area of vaccination delivery</p>
 <p>5 A COMPETENCY DEVELOPMENT</p>	<p>Clear and accessible developmental frameworks describing competencies and scope of practice for pharmacist vaccinators at all stages of professional careers</p>
 <p>6 A LEADERSHIP DEVELOPMENT</p>	<p>Strategies and programmes in place that develop professional leadership skills (including clinical and executive leadership) for all stages of career development relevant to the delivery and promotion of vaccinations</p>

FIP Development Goal	Workforce and education policy enabler to transform vaccination
 <p>7  ADVANCING INTEGRATED SERVICES</p>	<p>A patient-centred and integrated health services foundation for workforce development, relevant to social determinants of health and needs-based approaches to workforce development for the implementation of pharmacist-delivered vaccination services</p>
 <p>8  WORKING WITH OTHERS</p>	<p>Clearly identifiable elements of collaborative working and interprofessional education and training which should be a feature of all workforce development programmes and policies, including vaccination service delivery</p>
 <p>9  CONTINUING PROFESSIONAL DEVELOPMENT STRATEGIES</p>	<p>All professional development activity clearly linked with needs-based health policy initiatives and pharmaceutical career development pathways to deliver vaccination services in relevant settings</p>
 <p>10  EQUITY & EQUALITY</p>	<p>Clear strategies for addressing equity and diversity inequalities in pharmaceutical workforce development, continued education and training, and career progression opportunities in the areas of vaccination service delivery</p>
 <p>11  IMPACT & OUTCOMES</p>	<p>Evidence of the impact of the pharmaceutical workforce within health systems and health improvement in the delivery of vaccination services by pharmacists</p>
 <p>12  PHARMACY INTELLIGENCE</p>	<p>A national strategy and corresponding actions to collate and share workforce data and workforce planning activities (skill mixes, advanced and specialist practice, capacity) that promotes the development and implementation of pharmacist-delivered vaccination services. Without workforce intelligence data there can be no strategic workforce development.</p>
 <p>13  POLICY DEVELOPMENT</p>	<p>Clear and manageable strategies to implement comprehensive, needs-based development of the pharmaceutical workforce throughout the entire professional career life cycle to support pharmacist-delivered vaccination services and address regulatory and attitudinal barriers to their implementation</p>
 <p>14  MEDICINES EXPERTISE</p>	<p>Strategies and systems in place to prepare and train a workforce that can deliver quality medicines expertise including vaccines and pharmacist-delivered vaccination services</p>

FIP Development Goal	Workforce and education policy enabler to transform vaccination
 <p>15  PEOPLE-CENTRED CARE</p>	<p>Strategies in place to develop pharmaceutical education and the workforce to support the delivery of people-centred care in practice, with particular focus on debunking misinformation and disinformation about vaccination</p>
 <p>16  COMMUNICABLE DISEASES</p>	<p>Education and training infrastructures in place to develop a workforce prepared to deliver quality services around communicable and vector-borne diseases through the development of pharmacist-delivered vaccination services</p>
 <p>17  ANTIMICROBIAL STEWARDSHIP</p>	<p>Strategies and systems in place to develop a pharmaceutical workforce prepared to deliver quality vaccination services as a supportive process to delivering antimicrobial stewardship through the prevention or eradication of vaccine-preventable infections</p>
 <p>18  ACCESS TO MEDICINES, DEVICES & SERVICES</p>	<p>Strategies in place to widen access to vaccinations through pharmacist-delivered vaccination services, utilising a responsive, capable, available and well-distributed pharmaceutical workforce</p>
 <p>19  PATIENT SAFETY</p>	<p>Workforce and education strategies that support patient safety mechanisms and reduce medication-related harm in the delivery of pharmacist-led vaccination services</p>
 <p>20  DIGITAL HEALTH</p>	<p>Enablers of digital transformation within the pharmacy workforce and effective processes to facilitate the development of a digitally literate pharmaceutical workforce accessing and contributing to shared digital health records, assisting with the efficient utilisation of pharmacist-delivered vaccination services</p>
 <p>21  SUSTAINABILITY IN PHARMACY</p>	<p>Strategies and systems in place that utilise the workforce to enhance sustainable pharmacist-delivered vaccination services</p>

This reference guide serves as a tool to support the implementation of key enablers through capacity building and professional development of the pharmaceutical workforce, particularly in relation to DG 1 (Academic capacity), DG 2 (Early career training strategy), DG 5 (Competency development) and DG 9 (Continuing professional development strategies).

FIP recognises the diverse legal, political and governance structures across countries and regions. As such, these drivers and mechanisms can be adopted and adapted by pharmacy leaders to align with local contexts and needs. FIP works closely with its members not only to identify priorities and barriers, including challenges related to policy enablement, and to explore strategies to overcome them. These insights, coupled with policy enablers, can provide a powerful mechanism to transform vaccination locally, regionally and globally.

6 Advancing pharmacy-based vaccination through education and training: Global trends and recommendations

In 2024, FIP conducted a comprehensive global survey-based study with the aim of monitoring the recent advances in the area of vaccination in pharmacy practice. The results were published in the [‘Leveraging pharmacy to deliver life-course vaccination: An FIP global intelligence report’](#).³ Data from 115 countries and territories provided insights into the status of vaccination education and training for pharmacists.

According to this study, vaccination training for pharmacists is available in over half of the countries surveyed, including some where pharmacists are not yet authorised to vaccinate. All countries where pharmacists have vaccination authority provide corresponding training.

Since 2016, the availability of vaccination training for pharmacists has increased significantly, with countries reporting such training rising from 12 to 64 (+433%). Undergraduate education and training have expanded from 6 to 19 countries, while post-registration or professional development training has grown from 11 to 41 countries. Training is now mandatory in 22 countries, with renewal requirements in 17. As more pharmacists gain vaccination authority, ongoing training and certification renewal are critical to maintaining the quality and safety of services.

Expanding immunisation education and training across all levels of pharmacy practice is essential to ensure pharmacists are well-equipped to deliver vaccination services. Strengthening undergraduate and pre-service education by integrating immunisation content into pharmacy curricula helps build foundational competencies early in pharmacists' careers. Continuing professional development (CPD) frameworks should incorporate structured training to keep practising pharmacists updated on immunisation guidelines, emerging vaccine technologies, and service delivery models.

Interprofessional education (IPE) also plays a key role, enabling pharmacists to collaborate effectively with other healthcare professionals in immunisation efforts, ultimately improving patient access and vaccine confidence. To further enhance pharmacists' development, competency-based education models should be designed to ensure they acquire the necessary skills for safe and effective vaccination service delivery. Adopting international best practices, including hands-on workshops and simulation-based learning, can strengthen practical skills and confidence.

Additionally, structured micro-credentialing and certification pathways can provide a recognised framework for validating pharmacists' vaccination competencies, ensuring standardised and high-quality service provision across different healthcare settings. To further assure the quality and alignment of vaccination-related education and training with global standards, FIP encourages the use of the [FIP Seal](#) by CPD providers and accreditation agencies. As outlined in the [FIP Statement of Policy on Continuing Professional Development \(2021\)](#)¹⁶, the FIP Seal serves as a tool for self-assessment and recognition of programmes that are aligned with FIP's global mission to advance pharmacy worldwide. Integrating the FIP Seal into vaccination training initiatives can enhance consistency, promote excellence, and strengthen professional confidence in the quality of education and training programmes in this area.

In conclusion, FIP recommends referring to its [FIP policy statement on the role of pharmacy in life-course vaccination](#)² for further insights and strategic guidance.

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