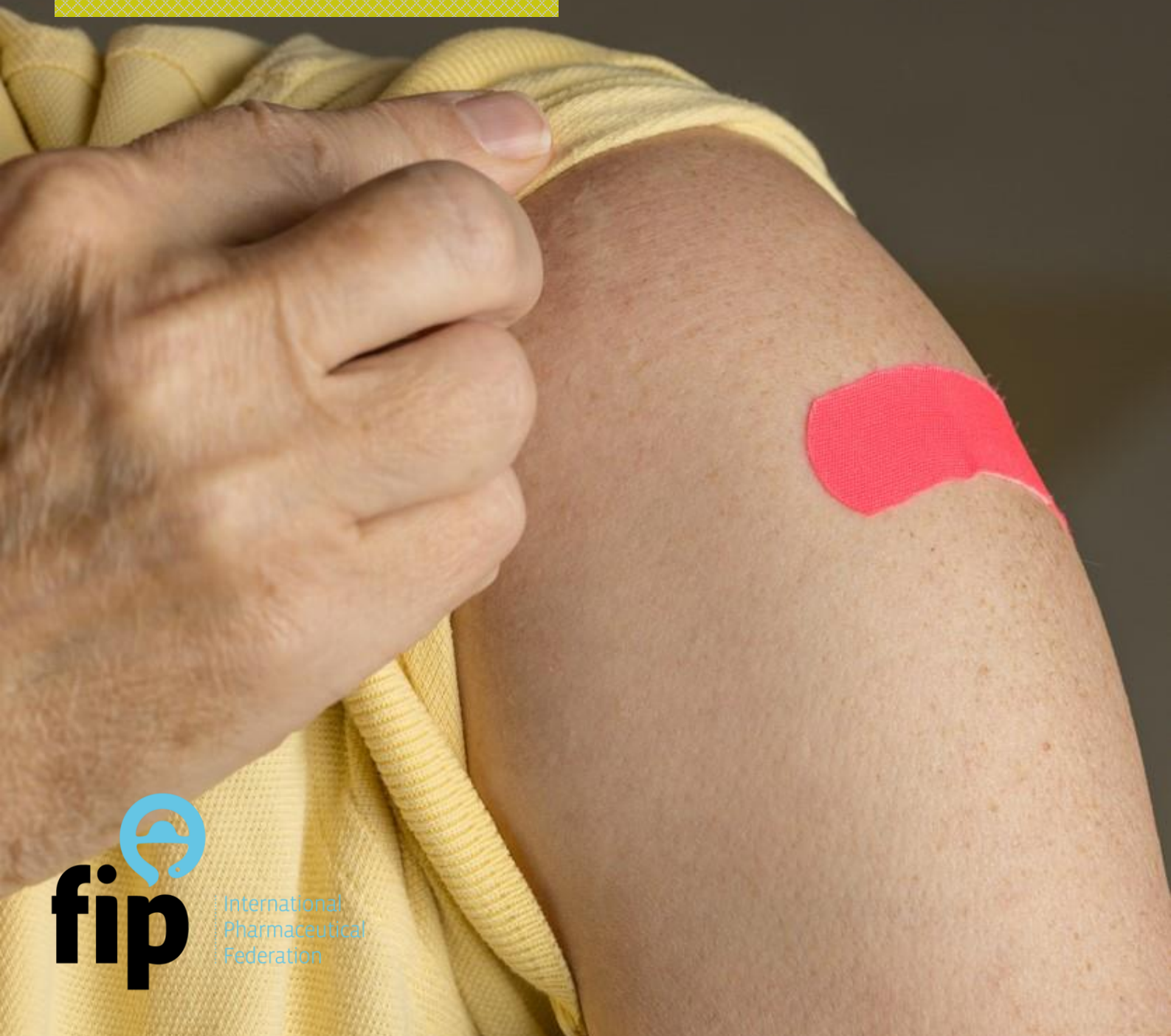


FIP global vaccination advocacy toolkit

Supporting and
expanding immunisation
coverage through
pharmacists

2019



International
Pharmaceutical
Federation

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1 Introduction

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1.1 The value, safety and cost-effectiveness of vaccines

Vaccines are proven to control and eliminate otherwise life-threatening diseases, preventing between two and three million deaths each year around the world.¹ In fact, vaccination is one of the most successful and cost-effective health interventions of all time, second only to clean water.² Vaccines are responsible for numerous accomplishments in public health, including the elimination of smallpox in 1980, one of the world's most feared diseases. This is considered one of the biggest achievements in international public health history.³ Vaccines have also saved countless lives by nearly eliminating the polio virus by reducing cases by 99%. In addition, the number of people who experience illness, disability or death from diphtheria, tetanus, whooping cough, measles, *Haemophilus influenzae* type b disease, and epidemic meningococcal A meningitis is at an all-time low.³

The influenza vaccine prevents millions of illnesses and flu-related physician office visits each year, prevents tens of thousands of hospitalisations, and prevents serious medical events associated with chronic conditions. It also reduces the risk of certain complications in women during and after pregnancy, reduces the risk of a child dying of influenza, and protects people around those who are vaccinated, especially young children and the elderly.⁴

The only way to protect against shingles and postherpetic neuralgia, the most common complication from shingles, is the shingles vaccine. The risk of shingles and postherpetic neuralgia increases with age, so protection is especially important.

The human papillomavirus (HPV) vaccine is also extremely effective as it decreases the prevalence of HPV infection and genital warts. Decreases in vaccine-type prevalence, genital warts and cervical dysplasia have also been observed in various countries with HPV vaccination programmes.⁶

Vaccines are effective not only from a public health perspective, but also from an economic perspective: they are one of the most cost-effective health investments. Although vaccination requires an immediate investment, the economic savings they generate through reduced health care costs, lost productivity, and work and school absenteeism due to illness are far higher than the initial cost. According to Ozawa and collaborators, for every US\$1 spent on immunisation, an estimated \$16 is saved from childhood immunisation in low- and middle-income countries over a decade. With the broader benefits of people living longer and healthier lives, the return on investment rises to \$44 per \$1 spent.⁷

In the United States, for every \$1 spent on childhood vaccinations, the country saves over \$10. Since 1994, vaccination in children has saved the US nearly \$406 billion in direct medical costs and \$1.88 trillion in total society costs.⁸ In Brazil, the universal childhood vaccination programme against hepatitis A could be a cost-saving strategy in all regions of the country. At \$7.23 per dose, there was a 64% reduction in the number of cases of icteric hepatitis, a 59% reduction in deaths from the disease, and a 62% decrease of life years lost.⁹ In China, publicly financed HPV vaccination to prevent cervical cancer is cost-effective across all income groups when the cost is less than \$50 per vaccinated girl.¹⁰

Vaccines are tested extensively by scientists to ensure they are effective and safe. No vaccine is 100% safe or effective for everyone as each person's body reacts to vaccines differently. However, vaccines are the safest they have ever been and pass multiple levels of quality control procedures and safety evaluations before they reach the public. As vaccine-preventable infectious diseases become less common, we hear less about the serious consequences of such diseases and more about the risks associated with vaccines. 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. As

vaccines are the best defence we have against infectious diseases, the decision not to vaccinate involves much more serious risks. Not vaccinating may jeopardise not only that individual but also others who come into contact with him or her because they are at risk of contracting a potentially deadly disease. In reality, the benefits of vaccines far outweigh the risks.

1.2 Life-course vaccination: healthy ageing and adult immunisation

Life expectancy has risen dramatically in the past century, with issues specific to an ageing population becoming a priority. Increased susceptibility to vaccine-preventable diseases and increased likelihood of living with one or more chronic conditions are some of the issues that must be addressed. Vaccine-preventable diseases such as influenza, pneumococcal diseases, herpes zoster, and pertussis are a significant cause of morbidity, loss of quality of life and mortality in older people.

Along the disease burden of vaccine-preventable diseases, there is a gradual deterioration of the immune system brought on by increased age.¹¹ The progressive decline includes both innate and adaptive immunity, thus contributing to the increased incidence and severity of infections in older adults.¹² These severe infections are associated with long-term effects, such as impairments in activities of daily living, onset of frailty or the loss of independence.

Life-long vaccination programmes and the importance of vaccination for the elderly are often underestimated.¹³ It is of paramount importance to increase the focus on vaccination throughout the life course and ensure access to vaccines that are relevant for each age group, namely, adolescents, adults and older persons.

1.3 Targeting specific adult populations: pregnant women, healthcare professionals and women as caregivers

It is paramount to increase vaccination coverage of specific adult groups, such as pregnant women and health workers. With regard to pregnancy, the World Health Organization indicates that there is no evidence of adverse pregnancy outcomes from the vaccination of pregnant women with inactivated virus, bacterial vaccine or toxoid. Therefore, pregnancy should not preclude women from immunisation with these vaccines, if medically indicated. The use of selected vaccines in pregnancy is an important aspect of prenatal care which not only protects maternal health but also benefits the neonate. The WHO specifically recommends that pregnant women are vaccinated against seasonal influenza, tetanus and meningococcal infections.¹⁴

With regard to health workers — including all persons involved in patient care such as healthcare professionals, residents, students, laboratory staff, administrative and service staff, as well as persons in public health such as field workers, epidemiologists, laboratory staff and community health workers — the WHO recommends that they are vaccinated against multiple diseases, including influenza.¹⁵ Community pharmacists and pharmacy support personnel may be particularly exposed to influenza and it is recommended not only that they protect themselves from the disease, but also that they avoid becoming a vector for further disease transmission. In some countries, vaccination of healthcare professionals against influenza is mandatory, and this has raised concerns over the ethical obligation versus the autonomy of individual health professionals to be vaccinated. On this note, an article by Perl and Talbot suggests that, although it is important to recognise these arguments, it is also important to place them within the context of a healthcare professional's ethical duty to protect patient safety. This duty consists of acting in the patient's interest, working to protect vulnerable patients, and not placing patients at undue risk of harm. Furthermore, it is key to understand that up to 50% of influenza infections in healthcare professionals are asymptomatic, paucisymptomatic or simply unrecognised.¹⁶

Another group for whom vaccination advocacy is particularly important is women. Women are the non-professional caregivers closest to healthcare professionals; it is often women who encourage family members to visit healthcare professionals and who make sure they take medicines and understand their treatment. With an ageing population, women are increasingly volunteering or being asked to care for their elderly family members.¹⁷ As such, women are key allies in building trust in vaccines and improving vaccination coverage not only of young children and adolescents, but also of adults and older adults.

Pharmacists are in a unique position to reach out to these groups, inform them and advocate the benefits of vaccination and thus reduce the prevalence of vaccine-preventable diseases. They are a valuable, trusted resource in the community through their accessibility, distribution and knowledge.

1.4 Increasing vaccination coverage and uptake: a global imperative

At the Global Conference on Primary Health Care in October 2018, organised by the WHO in Astana, Kazakhstan, the Astana Declaration on Primary Health Care was endorsed. This declaration emphasises the critical role of primary health care around the world and aims to refocus efforts on primary health care to ensure that everyone everywhere is able to enjoy the highest possible standard of health.¹⁸ This includes prioritising prevention across health policies, in order 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.

In addition, 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 this global strategy to address antimicrobial resistance.

While the effectiveness of vaccinations is well documented, barriers to immunisation exist and have a significant impact on vaccination rates and the incidence and prevalence of vaccine-preventable diseases. These barriers affect the implementation of effective strategies for vaccination, thus hindering national and global immunisation rates. Misinformation regarding vaccines, lack of understanding regarding their important benefits, and limiting fears and beliefs are factors that present challenges to vaccination. The amount of misinformation about vaccines circulating on the Internet in recent years has generated a worrying level of hesitancy or outright opposition to the use of vaccines by growing anti-vaccination groups in many countries. This has been associated with the return or increase of diseases such as measles and whooping cough.¹⁹

Another set of barriers is with vaccination administration and record processes along with their accessibility and distribution, including supply and storage. Other challenges include political, legal, financial and administrative constraints to vaccination provision, namely by pharmacists, in many countries.²⁰

1.5 Pharmacists' contribution to vaccination

Pharmacists play a role in overcoming these barriers through education, providing evidence-based information and advice to overcome misbeliefs and misconceptions regarding vaccinations. Pharmacists have an essential public health role by acting as educators and advisers, facilitating and participating in national and global routine immunisation strategies and practices and/or delivering pharmacy-based vaccinations. All these roles have already been successfully implemented in various countries around the world and there is a wealth of evidence of the impact of pharmacists' vaccination-related roles, as included in this publication.

The accessibility and distribution of community pharmacies usually makes them a first point of contact for patients and the public in general, providing the opportunity to promote and increase vaccination services. 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 for 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 storage of cold products, pharmacists ensure safety and quality of vaccines.²¹ They are essential contributors for expanding vaccination coverage and overcoming the challenges necessary to improving vaccination compliance.

1.6 Aims of this publication

Based on the conviction that pharmacists should be involved in vaccination strategies in a multitude of roles everywhere around the world, FIP has given high priority to this area for a number of years. In 2016, FIP conducted a survey of its member organisations to identify the roles that pharmacists play in immunisation and the impact of these activities. This led to the publication of the landmark report “An overview of current pharmacy impact on immunisation”.²¹ Since then, FIP has organised several policy meetings and congress sessions on this subject, including the seminar “Pharmacists’ role in immunisation — advocacy approaches”²² in January 2018, in Amsterdam, the Netherlands, and the policy conference “Improving access, coverage and trust in vaccination: Harnessing the role of pharmacists”, for FIP member organisation leaders at the FIP congress in Glasgow, in September 2018.

We have also advocated for the removal of barriers to vaccination by pharmacists through statements at meetings of the WHO²³ and several other global, regional and national forums, where we have advocated for pharmacists’ multiple roles in vaccination.

In recent years, the number of countries that have introduced vaccination by pharmacists or at community pharmacies has increased at an accelerated pace, establishing what seems to be a growing and sustained trend. However, the number of countries that still face barriers and opposition to this expansion of pharmacists’ scope of practice remains very high.

With this new publication, FIP aims to provide its member organisations with a guidance toolkit for achieving or expanding the roles of pharmacists in increasing vaccination coverage and uptake.

[#FIP4vaccination](#) / [#VaccinesWork](#) / [#pharmacists](#)

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2 Making the case for pharmacy-based vaccination

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2.1 Pharmacists' roles in vaccination: a global overview

The role of pharmacists in immunisation and vaccination varies across the world. In some countries pharmacists are primarily involved in ensuring the safe supply and dispensing of vaccines, as well as advocating for immunisation, while in other countries they are empowered to play a more active role, as they are legally authorised to organise vaccination activities and campaigns.

It is estimated that 10 million lives per year could be saved by increasing access to medicines and vaccinations.¹ Community pharmacists are therefore in a strong position to provide a major contribution to public health due to their accessibility, distribution and available medicines expertise. Pharmacists are also highly trusted healthcare professionals and can therefore significantly improve communication channels and provide public reassurance on product quality. Pharmacists can also more easily identify patients at higher risk and specific target groups for vaccination, providing the necessary advice and actively participating in reminder and recall systems to ensure that vaccination schedules are met and regional/global goals achieved.²

In 2016, FIP published “An overview of current pharmacy impact on immunisation: A global report” presenting the results of a survey and a collection of case studies on vaccine-related roles by pharmacists. A year later, FIP dedicated a section of the report “Pharmacy — A global overview. Workforce, medicines distribution, practice, regulation and remuneration” to presenting the results of another survey of FIP member organisations about pharmacy-based vaccination practices.³

The high accessibility and distribution of community pharmacies make them a first point of contact for patients, providing an excellent opportunity to expand and increase access to immunisation services. This is particularly important in rural, isolated and medically underserved areas, where access to vaccination points can be challenging. Also, in the event of emergencies or outbreaks of communicable diseases, pharmacists should be considered as invaluable contributors, together with other healthcare professionals, in the delivery, access and administration of vaccines.

The opening hours of pharmacies mean easy and convenient access to vaccination services both for working and non-working individuals. It is worth noting that a large-scale US study of 7,800 pharmacies found that 30.5% of vaccines were administered outside of the usual opening hours of physician's offices. The study concluded that a large proportion of adults being vaccinated receive their vaccines during evening, weekend, and holiday hours at the pharmacy, when traditional vaccine providers are likely unavailable.⁴

On the technical side, community pharmacists and pharmacies may provide the infrastructure and medicines expertise required by the vaccines supply chain and storage of cold-chain products, and the safety and quality assurance that society demands of vaccines.

Pharmacists are highly trusted healthcare professionals who can offer evidence-based information and advice, which helps build individual and societal trust in vaccines as essential medicines.

According to current FIP data, pharmacists play a role as vaccination advocates and patient educators in at least 34 countries, representing approximately half of the world's population, and they have an active role as immunisers in 27 countries and territories — and these figures have steadily and rapidly increased in recent years.

The following Figures provide an illustration of the extent of the involvement of pharmacists and community pharmacies in expanding vaccination coverage. Figure 1 indicates where pharmacists play a variety of roles

related to vaccination promotion and advocacy. These may include providing evidence-based information and advice, distributing leaflets/posters, engaging in campaigns (including multidisciplinary campaigns), identifying and advising high-risk patient groups and serving or advising immunisation committees.

Figure 1. Countries and territories where pharmacists play a role in the promotion of vaccination and other vaccine-related advocacy activities (34 countries; 2017)



When it comes to a direct role in vaccine administration, Figure 2 shows the 27 countries (based on current FIP data) where pharmacy-based administration of vaccines is legally authorised, including different regulatory scenarios in terms of vaccine administration authority.

Figure 2. Countries where pharmacy-based administration is regulated (27 countries; 2017)

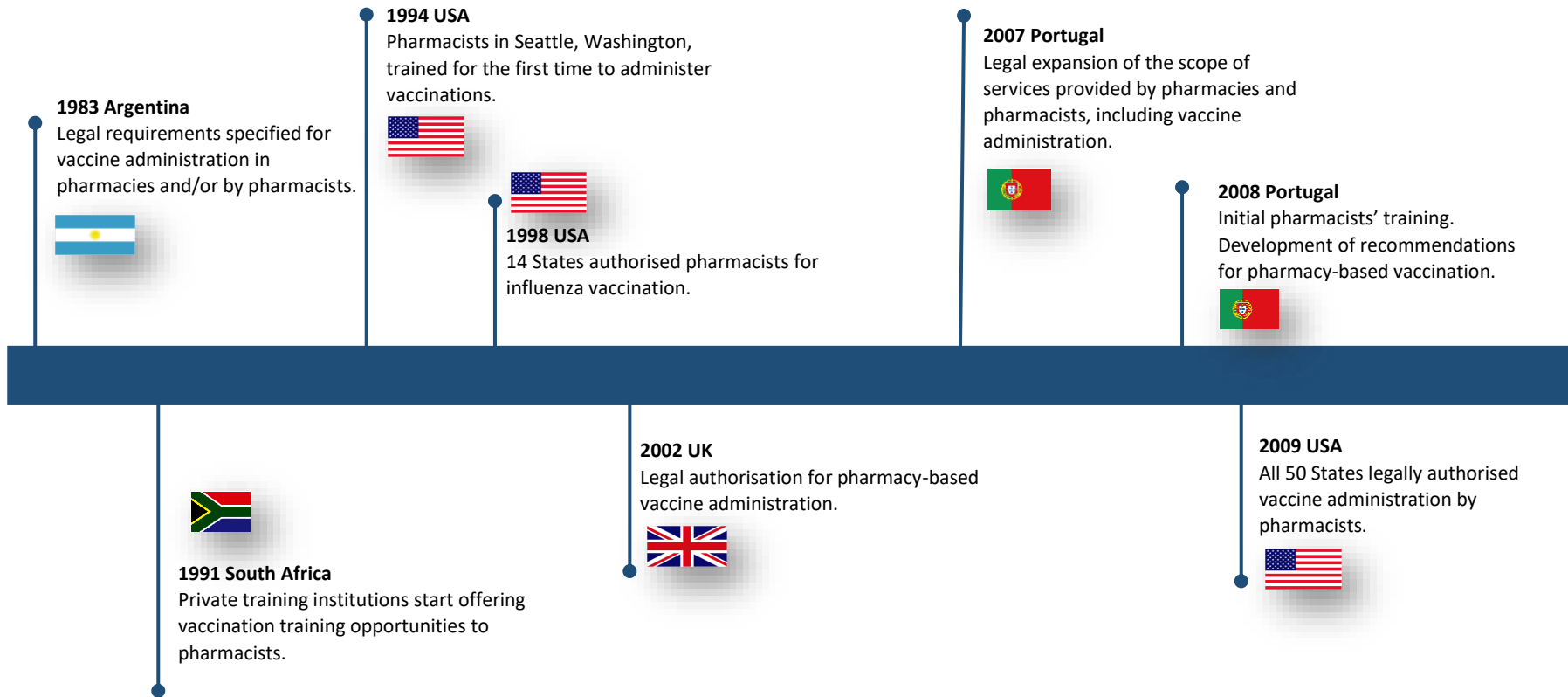


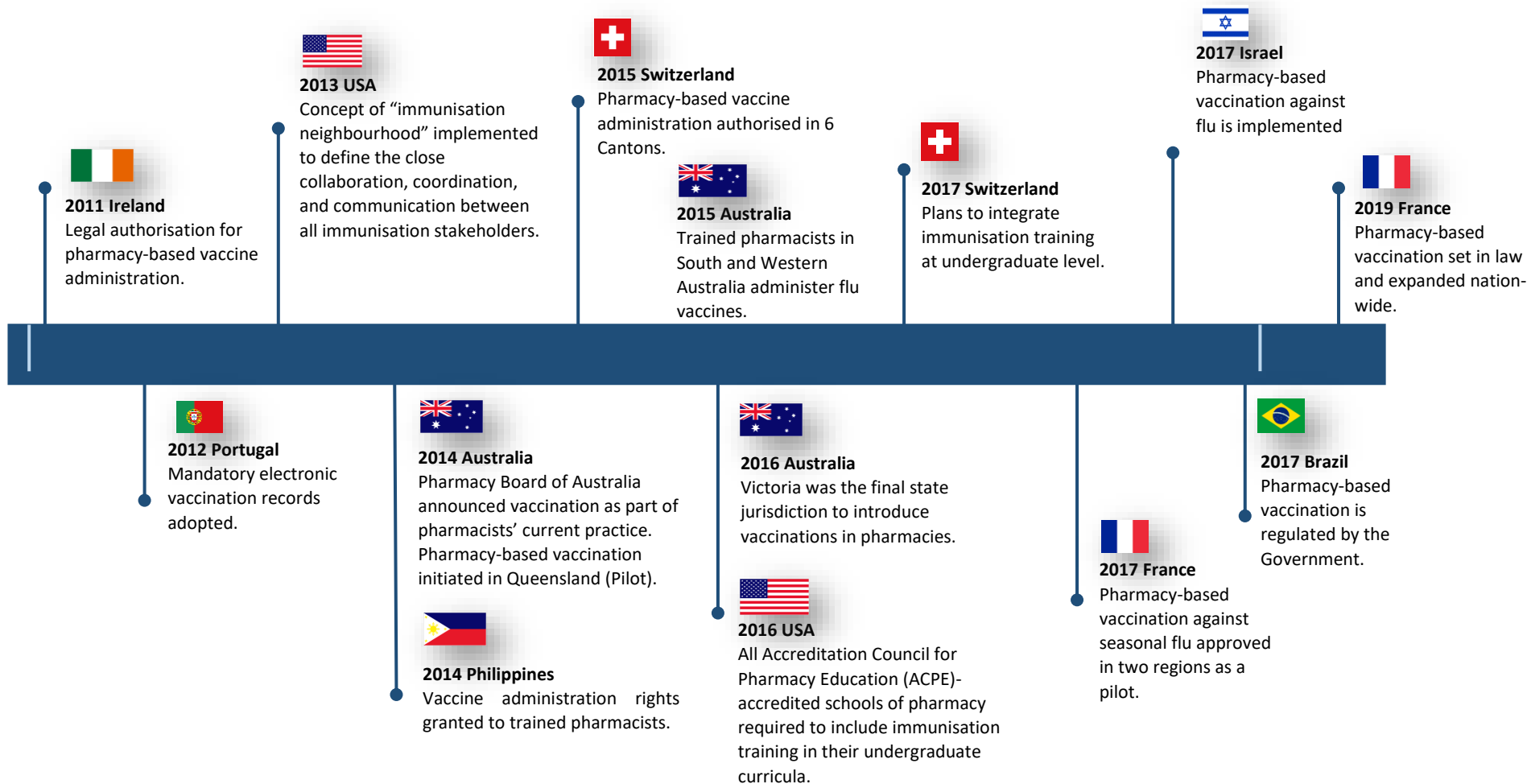
It should be noted that our study from 2016 listed 20 countries. By updating that list with the data collected through our survey from 2017 and a subsequent approach to those countries that reported having pharmacy-based vaccination, we arrived at this list of 27 countries. Brazil, France and Israel regulated pharmacy-based vaccination in 2017. Madagascar, Nepal, Panama and Paraguay reported having pharmacy-based vaccination in our recent survey, but no further details could be obtained.

With regard to pharmacists being legally authorised to administer vaccines, the list includes 21 countries. This list differs from the previous one because in six countries (Bolivia, the Democratic Republic of Congo, Finland, Iceland, the Netherlands and Pakistan), vaccines may be administered at pharmacies but only by other legally authorised healthcare professionals.

Although the regulation of pharmacy-based vaccination has rapidly expanded in the past decade, this is by no means a recent phenomenon. In Argentina, pharmacists have been legally authorised to vaccinate since 1983, and in both South Africa and the United States pharmacies have offered vaccination services for more than 25 years. Figure 3 provides a selection of landmark events in an international timeline of pharmacy-based vaccination.

Figure 3. International timeline of landmark events related to pharmacy-based vaccination





Adapted from Rosado H, Bates I and Pyzik O, *An overview of current pharmacy impact on immunisation: A Global Report*, Presentation at the 76th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Buenos Aires, September 2016)



Aside from the international diversity of scenarios with regard to the legal authority of pharmacists and pharmacies to administer vaccines, there are also important differences across countries (or even across sub-national jurisdictions in federal states) in terms of the range of vaccines that pharmacies may administer (see Table 1). In a few countries (such as Argentina, Canada, Costa Rica, Portugal, the UK and the USA), pharmacies are authorised to administer a broad range of vaccines, while in several others the range is more limited. Vaccination against seasonal influenza is the one most commonly administered by pharmacies and is present in all countries where pharmacy-based vaccination is allowed and which have shared data on the range of vaccines with FIP.

The rapid increase in the number of jurisdictions that have regulated pharmacy-based vaccination in recent years or expanded the range of age groups and/or vaccines that pharmacists can administer seems to indicate that governments and policy-makers in general understand that increasing vaccination coverage is a public health imperative and that pharmacists should be part of the solution.

The wealth of evidence available that demonstrates the impact of pharmacy-based vaccination on immunisation coverage and the economic impact it has for individuals, families, communities and health systems is growing year after year, and this has been crucial to support well-informed policy decisions that recognise and support these expanded roles for pharmacists.

2.2 Building the case: The arguments used for (and against) pharmacy-based vaccination

Considering not only the imperative of improving vaccination coverage but also the overall evolution of pharmacy as a profession towards a broader role primary health care, health promotion and disease prevention, it seems logical to expand the scope of practice of pharmacists to include a series of vaccine-related roles and particularly the administration of vaccines.

However, this is an evolution that might not be immediately and universally understood or welcomed by several groups, including other health professions, the public or even some pharmacists themselves.

FIP organised a seminar on “Pharmacists’ role in immunisation — Advocacy approaches” in January 2018 in Amsterdam, the Netherlands. This included a brainstorm session and role play workshop between advocates and opponents of pharmacy-based vaccination, with participants split into two groups to prepare arguments for their representatives to use in the subsequent discussion. Based on the experience of several organisations that have successfully gone through the process of advocating for the regulation of pharmacy-based vaccination, a list of arguments and concerns frequently expressed by opponents to pharmacists vaccinating were identified. Another list of reasons and motivations of why pharmacists should be authorised to vaccinate was put forward not only in response to the former but, above all, to explain and support the case for vaccination by pharmacists.

Being aware of these arguments (see Sections 2.2.1 and 2.2.2 below) and adapting them to your national scenario and stakeholders’ landscape may help you build a strong advocacy strategy. Naturally, this is not an exhaustive list, but it identifies several points that have emerged in multiple nations.

Table 1. Range of vaccines authorised for pharmacy-based administration per country

	Flu	HZV	Pneumoco	Travel vac.	HPV	DTP	MMR	HepB	HepA	Hib	Meningoc.	Other
Argentina	Y	ND	Y	Y	Y	Y	Y	Y	Y	Y	ND	Rotavirus
Australia*	Y	N	N	N	N	Y	Y	N	N	N	N	N
Bolivia	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Brazil	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Canada*	Y	Y	Y	ND	Y	Y	ND	Y	Y	ND	ND	Rabies
Congo (DR)	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Costa Rica	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	ND	Dengue, Polio
Denmark	Y	N	N	Y	N	N	N	N	N	N	N	N
Finland	Y	N	N	N	N	N	N	N	N	N	N	N
France	Y	N	N	N	N	N	N	N	N	N	N	N
Iceland	Y	N	N	N	N	N	N	N	N	N	N	N
Ireland	Y	Y	Y	N	N	N	N	N	N	N	N	N
Israel	Y	N	N	N	N	N	N	N	N	N	N	N
Lebanon	Y	N	N	N	N	N	N	N	N	N	N	N
Madagascar	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Nepal	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Netherlands	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
New Zealand	Y	Y	N	N	N	Y	N	N	N	N	Y	Cholera, Enterotoxigenic <i>E. coli</i> .
Pakistan	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Panama	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Paraguay	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Philippines	Y	N	Y	N	N	N	N	N	N	N	N	N
Portugal	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Rabies, Rotavirus
South Africa	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Polio, BCG, Rotavirus,
Switzerland*	Y	N	N	N	N	N	Y	Y	Y	N	N	Tick-borne encephalitis
United Kingdom	Y	Y	Y	Y	Y	Y	Y	Y	Y	ND	Y	Polio, Cholera, Tick-borne encephalitis. Rabies
United States*	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	

*Varies per state/province/canton

Legend: Flu – Seasonal influenza; HZV – Herpes-Zoster Virus: Varicella or Shingles vaccines; HPV – Human Papilloma Virus; DTP – Diphtheria, Tetanus and Pertussis; MMR – Measles, Mumps and Rubella; HepA – Hepatitis A; HepB – Hepatitis B; Hib – Haemophilus influenzae type B

2.2.1 Arguments used against pharmacists gaining vaccination authority

Arguments used by other healthcare professions

1. Fragmentation of care
 - It would lead to incomplete medical records/incomplete patient history
 - Health care should be led by general practitioners
 - Doctors will have to manage the ill effects of pharmacist vaccination
 - It would only shift the demand but not improve vaccination coverage
2. It would be a lost opportunity for a holistic health care approach by doctors
3. Vaccination payments sustain general practice services
4. There is a finite supply of vaccines that would be spread too thinly across vaccination providers
 - This would disadvantage patients
 - Pharmacists would waste vaccines on healthy people
5. It is too costly to extend national cold-chain distribution service to pharmacies
6. Lack of competence of pharmacists:
 - Pharmacists are not trained in anatomy or public health
 - Pharmacists have no experience in managing anaphylaxis
 - Pharmacists cannot provide confidentiality
 - There would be no follow-up of patients
 - Pharmacists have no such training at undergraduate level
 - It is outside the scope of practice of pharmacy
 - Theoretical training is no substitute for real-life experience
 - The public cannot trust quality or competence in pharmacy
 - There would be an increased risk of shoulder injuries from incompetent vaccinators
7. Inappropriate facilities/lack of privacy in pharmacy
8. Pharmacies are profit-driven corporations
 - Pharmacy is retail, not health care
 - Waste of limited supplies on inappropriate patient groups
9. Vaccination rates are as good as anywhere — pharmacy participation is not necessary
10. There is no evidence that pharmacist vaccination improves overall coverage

Arguments used by pharmacists

1. Vaccine administration is outside our scope of practice — pharmacists reluctant to touch patients
2. Vaccination cannot be integrated into the pharmacy workflows
3. It would introduce a distraction from core function of dispensing and medicines management services
4. It is economically unsustainable
5. It requires too much upfront investment in consultation room, fridge space, training, adrenaline pens etc

Arguments used by the public/media

1. Vaccines do not work
2. The urge to improve vaccination coverage is a conspiracy driven by the pharmaceutical industry
3. The side effects of vaccine are worse than the illness being prevented

2.2.2 Arguments used to gain and support pharmacy vaccination rights

1. Health care should be multidisciplinary and interdisciplinary — and have the patient's best interest at its centre.
2. There is no "fragmentation of care", because pharmacies are an extension of healthcare systems and part of the healthcare team attending to each patient. The important element is that pharmacists have read-and-write access to patients' immunisation records, as this enables them to record vaccinations and monitor vaccination coverage, and to measure the impact of their services. Also, when pharmacists have access to vaccination

records, they can remind patients of their next vaccination needs, even when patients visit the pharmacy for other reasons.

3. Pharmacists are knowledgeable about communicable diseases, vaccines and immunology, and can offer information and education to patients, and actively dispel myths and prejudices against vaccines through evidence-based advice.
4. Pharmacists are competent to administer vaccines and will only provide the service once they have received certified training for doing so. This includes the management of potential adverse events, such as anaphylaxis. In addition, anaphylaxis is an extremely rare reaction, and some countries where pharmacy-based vaccination has been available for several years have never had a single case of anaphylaxis.
5. Pharmacists who receive certified training for administering vaccines are at least as competent as other healthcare professionals to deliver this service and manage any potential adverse events.
6. Pharmacy is a well organised and dynamic profession, and its professional organisations have the capacity to reach out to practitioners, train and certify them, and engage practitioners to adopt this new role.
7. The role and scope of practice of community pharmacists is increasing to include a number of health promotion, disease prevention and disease state management services, aside from dispensing medicines and ensuring their responsible use. Community pharmacies function as a gateway and an integral part of healthcare systems. Their services contribute to improving the efficiency and sustainability of health systems, namely by preventing the saturation of other parts of the system, such as GP offices and emergency rooms. When necessary, they refer patients to other healthcare professionals or facilities.
8. Pharmacists are experts in medicines and in conveying advice in lay language and using different communication methods (e.g., oral, written, pictograms, different languages, etc.)
9. Pharmacists are familiar with the religious and cultural diversity of their communities. They address concerns and beliefs in a respectful manner and even develop materials addressing specific groups in the community.
10. Pharmacists can organise community reach-out activities and campaigns to inform and advise about vaccines in schools, community centres, workplaces, etc.
11. Pharmacists are highly trusted professionals, and one of the most accessible health care providers, with widespread presence across territories and convenient opening hours for both working and non-working patients.
12. Pharmacists are bound by a code of ethics: not only are their priorities to serve the healthcare needs of patients and contribute to the efficiency of health systems, but their professional ethics guide their access to and use of sensitive patient data.
13. Pharmacies follow good practice standards with regards to their facilities, ensuring patient privacy and appropriate storage conditions for all medicines, including those that require strict cold-chain management. In addition, pharmacies have the infrastructure, equipment and logistics in place to store and handle such products.
14. In many places, pharmacies are connected via electronic network systems that allow them to receive and access instantly information about vaccines, notifications of quality problems or recalls, shortages of vaccines, etc.
15. Patients value the ease of access to pharmacies when they need to be vaccinated and informed, and are often willing to pay for the service if it saves queuing, waiting times and taking time off work to visit a health care centre or GP. In addition, people visit a pharmacy far more often than they visit a physician's office, which offers more opportunities to be reminded about vaccination and actually be vaccinated, and particularly to identify risk group patients.
16. The high accessibility of community pharmacies is not only about their territorial distribution, but is also about the close relationship they establish with the surrounding community.
17. Pharmacy-based vaccination is not a speculative or risky project with no evidence regarding its social value: it exists in at least 27 countries around the world and has been well-established in some of them for several years, with a vast amount of published outcomes. In fact, in at least seven countries, pharmacists are remunerated by public and/or private third-party payers for this valuable service. In addition, pharmacists play a role as vaccination advocates and educators in at least 34 countries.

18. There is evidence that pharmacy-based vaccination increases coverage, and that a number of patients who choose to be vaccinated at a pharmacy had never been vaccinated before (against influenza) — check the selection of published evidence included in this toolkit.
19. There is evidence that pharmacy-based vaccination has high rates of patient satisfaction, and increases access to vaccination and professional advice on vaccines. It is appropriate, fair and cost-effective that community pharmacies are remunerated for a service that delivers value for patients and health care systems, and generates savings through reduced GP visits, hospital admissions, disease care burden, work absenteeism and loss of productivity.
20. Extending vaccination rights to pharmacists contributes to a country's preparedness for pandemics and emergencies (natural or man-made) that may require mass vaccination or administration of injectable medicines.
21. Improving vaccination coverage contributes to fighting antimicrobial resistance as lower incidence rates of communicable diseases implies lower needs for antibiotics.
22. The effectiveness of the influenza vaccine may vary, but there is evidence that taking the vaccine makes the symptoms at least milder and reduces the impact of the disease.

2.3 Supporting evidence and bibliography on the impact of pharmacy-based vaccination

Editor:

Blake Barta, University of North Carolina, USA

This section includes a selection of abstracts of published studies that demonstrate the impact of pharmacy-based vaccination.

2.3.1 Vaccinations in community settings could improve uptake, public health report finds

Date of publication: January 2019

Study location: United Kingdom

Objectives:

To provide a snapshot of public and professional attitudes to vaccinations.

Method:

A narrative literature review of relevant articles and three public surveys: one with 2,000 UK adults aged 18 years and over; one with 2,622 UK parents; and one with 216 healthcare professionals working to deliver vaccination programmes in the UK.

Results:

- While the public trusts healthcare providers, misinformation regarding vaccinations in the media could be affecting vaccination uptake across the UK.
- Timing, availability and location of appointments are all barriers to vaccination uptake.
- The findings show that improving access to vaccinations is crucial to tackling inequalities in uptake, particularly those related to ethnicity or socio-economic status.

Conclusions:

The Royal Society for Public Health has called for a multi-pronged approach to help improve and maintain uptake of vaccination in the UK, including efforts to protect the public from fake news and negative messages on social media and to offer vaccinations in a more diverse range of locations, such as gyms and high-street pop-ups.

Bibliographical reference:

Robinson J. Vaccinations in community settings could improve uptake, public health report finds [Internet]. *Pharmaceutical Journal*; 2019 [cited 2019 Jul 16]. Available from: <https://www.pharmaceutical-journal.com/news-and-analysis/news/vaccinations-in-community-settings-could-improve-uptake-public-health-report-finds/20206041.article?firstPass=false>

2.3.2 Evidence for pharmacist vaccination

Date of publication: September/October 2018

Study location: Most studies were completed in the United States and one was completed in Canada

Objectives:

To carry out a systematic review and meta-analysis of the impact of pharmacists in their various immunisation roles.

Method:

The research methods (search strategy, study selection and data extraction) and results are available in detail in the original publication. Briefly, PubMed, EMBASE, Cochrane Libraries, Cumulative Index to Nursing and Allied Health Literature, International Pharmaceutical Abstracts and Google Scholar were searched from inception until October 2015. Grey literature searches and hand searches of journals and publications of interest were also completed. Inclusion criteria were clinical or epidemiologic studies in which pharmacists were involved in the immunisation process.

Results:

- All studies demonstrated an increase in vaccine coverage when pharmacists were involved in the immunisation process, regardless of role (educator, facilitator, administrator), setting or vaccine administered, compared with vaccine provision by traditional providers without pharmacist involvement. Pooled analysis of the four randomised controlled trials evaluating pharmacists as educators and facilitators demonstrated a statistically significant increase in immunisation rates with the addition of pharmacists (relative risk [RR] 2.96; 95% confidence interval [CI] 1.02–8.59), with similar results seen in the two randomised controlled trials evaluating pharmacists as vaccine administrators (RR 2.64; 95% CI 1.81–3.85). Pooled analysis of all six randomised controlled trials demonstrated a statistically significant increase in immunisation rates with the addition of pharmacists as educators, facilitators and administrators (RR 2.74; 95% CI 1.58–4.74).
- Other outcomes of interest, such as safety and incidence of vaccine-preventable morbidity and mortality, were evaluated by very few studies. Four studies evaluated adverse events following immunisation and reported no change in adverse events with the addition of pharmacists. One study evaluated clinical outcomes and found a decreased risk of self-reported influenza-like illness with the addition of pharmacists as immunisation educators and/or facilitators.

Conclusions:

Research evidence strongly supports immunisation by pharmacists to improve vaccination rates. The positive effects were seen regardless of the role played (educator, facilitator and administrator), the vaccine administered or the setting. Expanding the range of publicly funded vaccines that can be administered by pharmacists has potential to reduce vaccine-preventable diseases and complications through increased uptake. Further study is needed in this area in Canada.

Bibliographical reference:

Isenor JE, Bowles SK. Evidence for pharmacist vaccination. *Can Pharm J* [Internet]. 2018 Jun [cited 2019 Jul 16];151(5):301-4. Available from: <https://journals.sagepub.com/doi/abs/10.1177/1715163518783000> DOI: 10.1177/1715163518783000

2.3.3 Vaccination in the pharmacy: Review and experience of the pharmacies

Date of publication: August 2018

Study location: Switzerland

Objectives:

To provide a comprehensive assessment of the distribution, design, use and implementation of flu vaccine administration by pharmacies in Switzerland.

Method:

- The database consists of vaccination data from pharmacies (phS-net database) for the 2016–17 and 2017–18 influenza seasons, the tariff pool of the Health insurer and CSS Insurance data.
- Supplementary information was collected from pharmacies in the vaccination cantons by means of online surveys. Various statistical approaches were used in the evaluation, taking particular account of the fact that only a partial survey is available.

Results:

- The number of vaccinations offered by pharmacies and their use increased significantly between the 2016–17 and 2017–18 influenza seasons: the number of vaccination pharmacies rose from 316 to around 470 (+48%) and the number of influenza vaccinations carried out from 8,366 to 19,648 (+135%)
- The 56% increase in the number of vaccinations per pharmacy indicates that the offer has become better known among customers. The results show that the introduction of the vaccination service increased the overall vaccination coverage rate.
- There are no valid indications of major shifts from doctors' offices to pharmacies: the number of flu vaccinations carried out in doctors' surgeries in 2016 was even slightly higher than in 2014.
- Another relevant result is that the information campaign and the assumption of costs by CSS Insurance led to significantly more flu vaccinations, but the effect of the vaccination on the cost of illness was not sufficiently precise, hence no statistically reliable statements are possible.
- The survey of pharmacies shows that the cost of influenza vaccination on average is around 38 Swiss francs.
- Around 80% of all vaccinations carried out in pharmacies are against influenza; however, many pharmacies also offer vaccinations against early summer meningoencephalitis (TBE), hepatitis A and B and other diseases. The most important reasons given by pharmacies for introducing vaccination are the improvement of the range of services, positioning in prevention, better customer loyalty and an increase in vaccination coverage. The most common obstacles and difficulties cited are training, high infrastructure costs and restrictions imposed by cantonal authorisations, which are perceived as rather costly.
- Pharmacists cite the expansion to additional target groups (above all people with well treatable underlying diseases and chronically ill people) and the inclusion of further vaccines (above all TBE and diphtheria tetanus) as the thrust for further development of the range.
- The survey of non-vaccination pharmacies in vaccination cantons showed that around 30% would like to introduce a vaccination range by the 2019–20 vaccination season, so the number of vaccinations in pharmacies should continue to increase in the coming years. In addition, the number of vaccination pharmacies should also continue to rise.

Conclusions:

- The study shows that the still young "Vaccination in pharmacies" service has already achieved a high degree of penetration and meets a customer need.

- The introduction of the vaccination service is expected to have led to a slight overall increase in influenza vaccination coverage, thereby contributing to the health policy vaccination strategy.
- Although the introduction of the vaccination service was or is partly associated with challenges, pharmacies are very positive about the new service and show interest and willingness to further develop the existing service
- Due to the amendment of the Medical Profession Act of 2015, pharmacists will in the future acquire the vaccination competence already in the basic university training. This will simplify the training, which is currently perceived as expensive.
- It is important to mention that the vaccines that pharmacists are currently allowed to supply vary from canton to canton. In some cantons TBE vaccination is already possible; in others it is not.
- In May 2018, another canton (Basel Stadt) introduced vaccination in pharmacies without a medical prescription. Further cantons are expected to follow.
- The aim is to expand the scope of our activities in the field of vaccines and vaccine groups if the regulatory framework conditions are created for this purpose.

Bibliographical reference:

B,S,S. Volkswirtschaftliche Beratung AG and CSS Institut. Impfen in der Apotheke: Bestandsaufnahme und Erfahrungen der Apotheken; 2018. Available from: <https://www.pharmasuisse.org/fr/?Article=1478246>

2.3.4 An economic analysis of flu vaccination

Date of publication: July 2018

Study location: England

Objectives:

- To chart, using available evidence, some of the challenges faced by society in the face of seasonal influenza, as well as document the key areas where flu outbreaks have tangible economic costs.
- To model a cost-benefit analysis of flu vaccination. There are a number of approaches taken within the literature, each with its own strengths and weaknesses.
- To estimate the number of cases averted due to vaccination.

Method:

- This report's critical contribution is to outline findings from a new economic model of the costs and benefits from flu vaccination in England using actual recent efficacy data. It did so by producing a conservative, static model which provides a partial cost-benefit analysis of vaccination under various scenarios. The model allows the creation of a cost-benefit analysis under different plausible scenarios for vaccine efficacy, the vaccination rate and the cost of the vaccine as it applies to various risk groups.

Results:

- Our findings underscore the importance of 1) raising efficacy among older age groups in particular and 2) better evidence on actual efficacy values, particularly for older people and those with underlying health conditions
- It cannot be taken for granted that flu vaccination will generate economic benefits that exceed the cost of vaccination, but if efficacy and coverage were to both improve beyond recently recorded rates, the potential for cost savings are significant as well as benefits which are not monetary.
- Vaccination can play a vital role in saving lives and relieving some of the burden that falls upon the NHS in winter.
- To allow comparison with the wider literature, the headline vaccination costs per death averted were calculated. Where the vaccine is well-matched, results suggest that it is likely to be cost effective (ranging between £20,000 and £30,000 per death averted).

Conclusions:

- Public policy should focus on increasing coverage rates among young people (0–15) where efficacy and incidence are higher as this would seem to be the most efficient approach to improving overall benefits relative to costs.

- The efficacy of the vaccine among individuals over 65 years old is a significant issue. High levels of demand for the vaccine among this age group combined with recent low efficacy rates means that the costs of delivering the vaccine outweigh the benefits in the model. More research and innovation are needed to specifically explore vaccination efficacy for this age group.
- Overall, the cost-benefit analysis is highly sensitive to vaccine administration costs. If the health service can take advantage of economies of scale to reduce the unit cost for delivering the vaccine (critically, without it affecting the efficacy), this would also support improving the potential benefits relative to the costs.
- The wider societal costs of premature death from flu, such as lost years of work and care, account for the largest component of total costs.

Bibliographical reference:

Franklin B, Hochlaf D. An economic analysis of flu vaccination [Internet]. UK: International Longevity Centre; 2018 [cited 2019 Jul 16]. Available from: <https://ilcuk.org.uk/an-economic-analysis-of-flu-vaccination/>

2.3.5 The organisation and delivery of vaccination services in the European Union

Date of publication: 2018

Study location: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

Objectives:

To conduct an overview of systematic reviews, supplemented by European reports and reviews, that evaluate health system components, barriers and facilitators to establishing effective childhood immunisation and influenza vaccination programmes at health system and health service level. To identify gaps in the evidence and make recommendations for future research.

Method:

- A search of systematic reviews of health system factors affecting the implementation of immunisation programmes, including barriers and facilitators. European reports and reviews (including non-Cochrane systematic reviews) were incorporated to supplement the results of the search. A protocol was registered beforehand on PROSPERO, an international database of prospectively registered systematic reviews in health and social care (<https://www.crd.york.ac.uk/prospero>).
- A search of electronic databases, including the Cochrane Database of Systematic Reviews (CDSR), Ovid Medline, Ovid Embase, Web of Science, PsychInfo and Google Scholar), using a pre-defined search strategy. European health organisation websites were also searched, and any relevant publications retrieved (for example: WHO Regional Office for Europe, ECDC (European Centre for Disease Prevention and Control), VENICE (Vaccine European New Integrated Collaboration Effort) Project, European Council, European Commission, VaccinesEurope.eu). The investigators also searched the London School of Hygiene and Tropical Medicine database of all systematic reviews for vaccines, created for the WHO (www.nitag-resource.org) (reported in Fernandes *et al* 2018 in the bibliographical reference below). Reference lists of included reports and reviews were manually searched to identify any additional reviews from the grey literature. Papers with abstracts published in English, French or German between January 2000 and May 2018 were considered for inclusion in order to provide the most up-to-date evidence.

Results:

- In all EU member states, vaccination programmes are organised at the national level, whereas the regional level tends to be charged with overseeing implementation of vaccinations and monitoring vaccination coverage. However, there are some countries where the regional level has latitude to modify national vaccination programmes and recommendations to local needs. This includes Denmark, Germany, Spain and Sweden.
- In nine EU member states (Bulgaria, Croatia, Czech Republic, France, Hungary, Italy, Poland, Slovakia and Slovenia), vaccinations against measles are mandatory for children, while in the remaining 19 states they are voluntary, but recommended by the relevant authorities. However, the distinction between voluntary and mandatory

immunisation is not always clear-cut. In three countries (Cyprus, Germany and Greece) vaccinations are formally voluntary, but vaccination certificates are required for the enrolment of children in schools or kindergartens.

- In contrast, vaccinations for adults against influenza are voluntary in almost all EU member states. The sole exception is Slovakia, where vaccination against influenza is mandatory for any person living in social care facilities, as well as for any person at increased risk of infection due to living or working in an area where avian influenza is present.
- EU countries have embraced a mix of incentives and sanctions to improve vaccination coverage. These include awareness campaigns, financial rewards for parents or healthcare providers, and financial sanctions or denying school or kindergarten entry for those who refuse (mandatory or even voluntary) vaccinations.
- Specific targeted measures for vulnerable groups of the population are adopted in a number of countries (including Croatia, Finland, Germany, Greece, Ireland, Luxembourg, Malta, the Netherlands, Portugal, Romania, the United Kingdom). These include, in particular, actions for refugees and asylum-seekers, often as part of routine medical screening upon entry to the country. Some countries (including Croatia, the United Kingdom, Ireland and Romania) also offer targeted measures for minority ethnic groups, such as the Roma and traveller communities.

Conclusions:

This report documents the sustained efforts undertaken by EU member states in addressing vaccine-preventable diseases. They provide an insight into what has been achieved, but also where further improvements could be made. The main perceived barriers for improved vaccination coverage are vaccine hesitancy and lack of awareness not only in the general population, but also among health workers. However, the country profiles also identify many other actions that health systems can take to improve coverage. These include a mix of incentives and sanctions, targeted measures and outreach services for vulnerable population groups, and an expansion of public financing for vaccinations against influenza, as well as the removal of administrative barriers.

Bibliographical reference:

Rechel B, Richardson E, McKee M. The organization and delivery of vaccination services in the European Union (2018) [Internet]. World Health Organization; 2018 [cited 2019 Jul 16]. Available from: <http://www.euro.who.int/en/publications/abstracts/the-organization-and-delivery-of-vaccination-services-in-the-european-union-2018>

2.3.6 Repeated influenza vaccination for preventing severe and fatal influenza infection in older adults: A multicentre case-control study

Date of publication: January 2018

Study location: Spain

Objectives:

To evaluate the effectiveness of influenza vaccination on preventing admissions to hospital for influenza and reducing disease severity.

Method:

The researchers conducted a case-control study in 20 hospitals in Spain during the 2013–14 and 2014–15 influenza seasons. Community-dwelling adults aged 65 years or older who were admitted to hospital for laboratory-confirmed influenza were matched with inpatient controls by sex, age, hospital and admission date. The effectiveness of vaccination in the current and three previous seasons in preventing influenza was estimated for inpatients with non-severe influenza and for those with severe influenza who were admitted to intensive care units (ICUs) or who died.

Results:

The researchers enrolled 130 inpatients with severe influenza and 598 with non-severe influenza who were matched to 333 and 1,493 controls, respectively. Compared with patients who were unvaccinated in the current and three previous seasons, adjusted effectiveness of influenza vaccination in the current and any previous season was 31% (95% CI 13%–

46%) in preventing admission to hospital for non-severe influenza, 74% (95% CI 42%–88%) in preventing admissions to ICU and 70% (95% CI 34%–87%) in preventing death. Vaccination in the current season only had no significant effect on cases of severe influenza. Among inpatients with influenza, vaccination in the current and any previous season reduced the risk of severe outcomes (adjusted OR 0.45; 95% CI 0.26–0.76).

Conclusions:

Among older adults, repeated vaccination for influenza was twice as effective in preventing severe influenza compared with non-severe influenza in patients who were admitted to hospital, which is attributable to the combination of the number of admissions to hospital for influenza that were prevented and reduced disease severity. These results reinforce recommendations for annual vaccination for influenza in older adults.

Bibliographical reference:

Casado I, Domínguez Á, Toledo D, Chamorro J, Astray J, Egurrola M, et al. Repeated influenza vaccination for preventing severe and fatal influenza infection in older adults: a multicentre case-control study. *CMAJ* [Internet]. 2018 Jan [cited 2019 Jul 16]; 190(1):E3-12. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29311098>

2.3.7 Population characteristics associated with pharmacy-based influenza vaccination in United States survey data

Date of publication: November/December 2017

Study location: United States of America and Puerto Rico

Objectives:

To examine the population characteristics associated with the health behaviour of receiving an influenza vaccine from a pharmacy-based setting.

Method:

Secondary analysis of data from states that participated in an optional influenza module in the 2014 Behavioural Risk Factor Surveillance System, a state-based observational survey of US adults.

Results:

Multinomial logistic regression results showed that environmental, predisposing, enabling, and need factors in the Andersen model were salient features associated with odds of using pharmacy-based influenza vaccination settings instead of a doctor's office. Residents of states that allowed pharmacists as immunisers before 1999 reported greater use of pharmacy-based store settings (Odds ratio [OR] 1.31). Compared with young adults, individuals 65 years of age and older were more likely to choose a pharmacy-based store than a doctor's office (OR 1.41) and less likely to use other community settings (OR 0.45). Compared with non-Hispanic whites, black respondents were less likely to use pharmacy-based store vaccination (OR 0.51), and multiracial and Hispanic respondents were more likely to use other settings (OR 1.47 and 1.60, respectively). Enabling and need factors were also associated with the setting.

Conclusions:

Based on this dataset of selected states from 2014, almost a quarter of US adults who reported receiving an annual influenza vaccination did so from a pharmacy-based store; 35% reported using other community-based settings that may enlist pharmacists as immunisers. There were striking disparities in use of non-traditional vaccination settings by age and race or ethnicity. Pharmacists and pharmacies should address missed opportunities for vaccination by targeting outreach efforts based on environmental and predisposing characteristics.

Bibliographical reference:

Inguva S, Sautter JM, Chun GJ, Patterson BJ, McGhan WF. Population characteristics associated with pharmacy-based influenza vaccination in United States survey data. J Am Pharm Assoc [Internet]. 2017 Nov [cited 2019 Jul 22];57(6):654-60. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28830660>

2.3.8 Pharmacy influenza vaccination service review

Date of publication: September 2017

Study location: Ireland

Objectives:

To review the pharmacy influenza vaccination service and look at other vaccinations suitable for community pharmacy provision.

Results:

- 84% of respondents said they had received the flu vaccination before. Overall, almost a third indicated it was their first time receiving the flu vaccine in a pharmacy.
- 19 out of 20 respondents said they were very satisfied with the amount of information received at the time of vaccination.
- 99% said that they would be likely to go to the pharmacist for their flu vaccination again.
- Patient satisfaction with the pharmacy-delivered flu vaccination service is high; 79% of respondents rated their overall satisfaction as 10 out of 10; 93% rated overall satisfaction as 9 or 10 out of 10; 99% of respondents rated their overall satisfaction as either 8, 9 or 10 out of 10.

Conclusions:

The ability to monitor vaccination coverage is a key component of any vaccination programme. In order to identify gaps and weaknesses, all EU member states need to reconsider their approach in order to collect more comprehensive and accurate information on vaccination coverage for all of those population groups that are targeted for seasonal influenza vaccination, in order to enable public health organisations to track their progress and identify obstacles to achieving national and EU targets. The Health Service Executive (HSE) vaccination portal, which pharmacists use to record all vaccines administered, could form the basis of such a system and supports the appropriateness of pharmacies as a location for receiving vaccinations. There is still great potential for the pharmacy vaccination service to grow. The HSE estimates that, between older people and at-risk people, over one million people should be vaccinated in Ireland. As the population ages and chronic disease rates keep increasing, this cohort will continue to grow.

Bibliographical reference:

Pharmacy influenza vaccination service review [Internet]. IPU Review; 2017 [cited 2019 Jul 16].

2.3.9 Relationship between pharmacist density and adult influenza vaccination after controlling for individual and neighbourhood effects

Date of publication: July/August 2017

Study location: United States of America

Objectives:

Since 2009, all 50 states have passed legislation to allow pharmacists to administer influenza vaccinations. Pharmacies have become the second most common place for influenza vaccination, after a doctor's office. The aim of this study was to provide nationally representative results on the relationship between pharmacist density and influenza vaccination after controlling for both individual- and county-level characteristics.

Method:

Retrospective data analysis with the use of merged individual data from the 2008–2012 Behavioural Risk Factor Surveillance System (BRFSS) and county data from the 2010 Area Health Resources Files. Sample-weighted multivariate logistic models were estimated to predict influenza vaccinations with the use of number of pharmacists per 1,000 population as the key predictor.

Results:

The number of pharmacists per 1,000 population was associated with higher odds of influenza vaccination (adjusted odds ratio [AOR] 1.13, 95% CI 1.11–1.15) and was significant for non-Hispanic whites (AOR 1.06, 95% CI 1.04–1.08) and Hispanics (AOR 1.35, 95% CI 1.24–1.48). It varied across county types and employment status. The largest effects were found in urban counties (AOR 1.16, 95% CI 1.11–1.21) and among the self-employed (AOR 1.18, 95% CI 1.10–1.26), homemakers (AOR 1.18, 95% CI 1.10–1.26), and the retired (AOR 1.18, 95% CI, 1.14–1.22).

Conclusions:

Pharmacists play an important role in influenza vaccination and are an important alternative to traditional settings such as doctors' offices and health clinics. Future research is needed to investigate reasons and barriers behind their different effects in different regions and population groups. By covering in-pharmacy vaccinations in health plans and removing other barriers, pharmacists can help to alleviate the shortage of other healthcare providers and help increase vaccination rates.

Bibliographical reference:

Gai Y, Feng L. Relationship between pharmacist density and adult influenza vaccination after controlling for individual and neighborhood effects. *J Am Pharm Assoc [Internet]*. 2017 Jul [cited 2019 Jul 22];57(4):474-82.e2. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28479195>

2.3.10 Seasonal influenza vaccination in Europe

Date of publication: July 2017

Study location: 28 EU countries, Norway, Iceland, Liechtenstein

Objectives:

To update data on seasonal influenza immunisation policies (collected in previous VENICE surveys) and obtain vaccination coverage rates in EU/EEA member states for the 2012–13 influenza season in order to monitor progress — or lack thereof — towards the 2014–2015 EU target of 75% in all at-risk or targeted groups.

Method:

The survey was carried out through a web-based platform with protected access restricted to nominated experts from each EU/EEA member state. This survey was a collaborative study between the European Centre for Disease Prevention and Control (ECDC), the Vaccine European New Integrated Collaboration Effort (VENICE) Project, and the EU/EEA member states. Currently, 28 EU and three EEA (Iceland, Norway, and Liechtenstein) member states participate in VENICE. Croatia and Liechtenstein participated for the first time. The survey was conducted in March 2014.

Results:

- Of 31 responding member states, 30 recommended influenza vaccination for healthcare workers (HCWs); 25 of these had recommendations to vaccinate all HCWs; four recommended vaccination for only some HCWs. In the United Kingdom countries of Northern Ireland and Scotland, vaccination was offered to all HCWs; while in England and Wales only some HCWs were recommended vaccination.
- In all member states people with immunosuppression due to diseases or treatment, metabolic disorders, chronic pulmonary, cardiovascular and renal diseases were recommended influenza vaccination. Twenty-eight member states recommended vaccination of individuals with hepatic disease or HIV/AIDS. Fifteen recommended vaccination

for those on long-term aspirin use (children <18 years old). Fifteen had recommendations to vaccinate those with morbid obesity.

- Of 31 responding member states, 28 recommended vaccination of pregnant women. Twenty-six member states recommended vaccination of all pregnant women; two recommended vaccination only for those pregnant women with chronic medical conditions. Nineteen recommended influenza vaccination for pregnant women in any trimester of pregnancy.
- Vaccination coverage rates, which were measured by analysis of administrative returns or estimated by survey methods, were known in 24 member states for older target populations and ranged from 1.0% to 77.4% (median 44.7%) in 2012–13. The coverage among HCWs was known in 13 member states, ranging from 9.5% to 75% (median 28.6%). The coverage for chronic medical conditions was provided by seven member states and ranged from 28% to 80.2% (median 45.6%) in 2012–13. The coverage for pregnant women was known in seven member states, ranging from 0.2% to 64.6% (median 25.5%) in 2012–13. Three member states were able to report vaccination coverage rates for residents of long-stay care facilities (73% in Ireland, 71.1% in Slovakia, and 89% in Portugal).

Conclusions:

- The results of the survey indicate that recommendations for influenza vaccination exist in most of the member states for all population groups targeted for seasonal influenza vaccination — those with chronic medical conditions, pregnant women, older age groups and HCWs. However, there was a notable discrepancy between having recommendations and the ability to monitor, and report on, vaccination coverage among those with chronic medical conditions and pregnant women. Data on vaccination for these groups was only available for less than 25% of the member states. With regard to HCWs, less than half of the member states were able to report on vaccination coverage in this group.
- Although there has been widespread consensus for many years that the older age groups should be vaccinated, the EU target of 75% was reached in only two member states in the 2012–13 season.
- The ability to monitor vaccination coverage is a key component of any vaccination programme. In order to identify gaps and weaknesses, all member states may need to reconsider their approach in order to collect more comprehensive and accurate information on vaccination coverage for all of those population groups that are targeted for seasonal influenza vaccination.

Bibliographical reference:

Mereckiene J. Seasonal influenza vaccination in Europe [Internet]. European Centre for Disease Prevention and Control. 2017 [cited 2019 Jul 22]. Available from: <https://ecdc.europa.eu/en/publications-data/seasonal-influenza-vaccination-europe-vaccination-recommendations-and-coverage-2007-2015>

2.3.11 Implementation of a vaccine screening programme at an independent community pharmacy

Date of publication: March/April 2017

Study location: North Carolina, United States of America

Objectives:

To implement a comprehensive vaccine screening programme and to identify best practices in workflow for such a programme.

Method:

- A pharmacy team member used a screening tool to identify vaccination opportunities in the patient population. Patients aged 18 years or older who entered the pharmacy workflow process were eligible for screening.
- If pharmacy staff identified needed vaccinations for a patient, a pharmacist evaluated the screening and recommended immunisation(s) to the patient. If the recommendation was accepted, the vaccine was administered. If the patient declined vaccination, a brief reason was designated from a predefined selection of choices.

Results:

During the 30-day study period, 631 screenings were performed. Pharmacy technicians and pharmacists performed 95.4% and 4.6% of screenings, respectively. Of completed screenings, 81.5% were completed at data entry, 13.9% at the fill station, 4.1% at prescription verification, and 0.5% during a clinical consultation. As a result of this study the following vaccines were administered: influenza (n=11), pneumococcal conjugate (n=5), pneumococcal polysaccharide (n=1), Tdap (n=5), and zoster (n=6).

Conclusions:

A comprehensive vaccine screening tool was successfully used by pharmacy technicians and pharmacists at data entry and fill station during the traditional workflow at an independent community pharmacy.

Bibliographical reference:

Rhodes LA, Branham AR, Dalton EE, Moose JS, Marciniak MW. Implementation of a vaccine screening program at an independent community pharmacy. *J Am Pharm Assoc* [Internet]. 2017 Mar [cited 2019 Jul 22];57(2):222-8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27964886>

2.3.12 Impact of pharmacists as immunisers on vaccination rates: A systematic review and meta-analysis

Date of publication: November 2016

Study location: Various

Objectives:

To complete a systematic review of the literature on the impact of pharmacists as educators, facilitators, and administrators of vaccines on immunisation rates.

Method:

The study identified 2,825 articles searching the following databases from inception until October 2015: PubMed, EMBASE, Cochrane Libraries, Cumulative Index to Nursing and Allied Health Literature, International Pharmaceutical Abstracts, Google Scholar. Grey literature was identified through use of the Canadian Agency for Drugs and Technology in Health “Grey Matters” search tool. Content from relevant journals and references of included studies were also searched. Inclusion criteria were clinical or epidemiologic studies in which pharmacists were involved in the immunisation process. Studies were excluded if no comparator was reported. Two reviewers independently completed data extraction and bias assessments using standardised forms.

Results:

Thirty-six studies were included in the review; 22 assessed the role of pharmacists as educators and/or facilitators and 14 assessed their role as administrators of vaccines. All studies reviewed found an increase in vaccine coverage when pharmacists were involved in the immunisation process, regardless of role (educator, facilitator, administrator) or vaccine administered (e.g., influenza, pneumococcal), when compared with vaccine provision by traditional providers without pharmacist involvement. Limitations of the results include the large number of non-randomised trials and the heterogeneity between study designs.

Conclusions:

Pharmacist involvement in immunisation, whether as educators, facilitators, or administrators of vaccines, resulted in increased uptake of immunisations.

Bibliographical reference:

Isenor JE, Edwards NT, Alia TA, Slayter KL, MacDougall DM, McNeil SA, et al. Impact of pharmacists as immunizers on vaccination rates: a systematic review and meta-analysis. *Vaccine* [Internet]. 2016 Nov [cited 2019 Jul 22]; 34(47):5708-23. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27765379>

2.3.13 Patient feedback on the flu vaccination service provided in pharmacies

Date of publication: 2016

Study location: Ireland

Objectives:

To gain feedback, through a Pharmaceutical Society of Ireland survey, from a large number of patients on their experience of the seasonal influenza vaccination service in pharmacies across Ireland.

Method:

- A random sample of 300 pharmacies participating in the flu vaccination service were selected from the pharmacy register. The supervising pharmacist from each of these pharmacies was contacted and asked to invite people who had been vaccinated in the pharmacy to provide feedback on their experience. If the person was willing to do so, they were asked to sign a consent form and provide their telephone number so that they could be contacted by Behaviours & Attitudes for a short telephone interview.
- A total of 571 patient consent forms were returned to Behaviours & Attitudes and from this a total of 374 patient telephone interviews were completed.

Results:

- One in six respondents were receiving the flu vaccine for the first time and a third of respondents had not received the vaccine from a pharmacy before.
- Satisfaction with the service is high: 79% of respondents rated their overall satisfaction with the pharmacy-delivered service as 10 out of 10, 93% as 9 or 10 out of 10, and 99% as 8, 9 or 10 out of 10.
- Respondents stated that the primary motivation for attending a pharmacy for the flu vaccination in 2015 was the convenience and efficiency of availing of it there (longer opening hours, no need for appointments etc.) with the add-on benefit of perceived better value/lower expense.

Conclusions:

Most respondents are keen to access other services from pharmacies, and this underscores the level and extent of satisfaction with the flu vaccine service.

Bibliographical reference:

Patient feedback on the flu vaccination service provided in pharmacies [Internet]. Evaluation of the seasonal influenza vaccination service. PSI; 2016 [cited 2019 Jul 16]. Available from: https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/PharmacyServices/Vaccination_Service/

2.3.14 Impact of pharmacists providing immunisations on adolescent influenza immunisation

Date of publication: July/August 2016

Study location: Oregon, United States of America

Objectives:

To determine if the Oregon law change in 2011 to allow pharmacists to immunise adolescents aged 11 to 17 years increased influenza immunisations or changed existing immunisation venues.

Method:

With the use of Oregon's ALERT Immunisation Information System (IIS), two measures of impact were developed. First, the change in adolescent age 11–17 influenza immunisations before (2007–10) and after (2011–14) the pharmacy law change was evaluated against a reference cohort (aged 7–10) not affected by the law. Community pharmacies were also compared with other types of influenza immunisation sites within one of the study influenza seasons (2013–14).

Results:

From 2007 to 2014, adolescent influenza immunisations at community pharmacies increased from 36 to 6,372 per year. After the 2011 pharmacy law change, adolescents aged 11 to 17 were more likely to receive an influenza immunisation compared with the reference population (odds ratio 1.21; 95% CI 1.19–1.22). Analysis of the 2013–14 influenza season suggests that community pharmacies immunised a different population of adolescents than other providers.

Conclusions:

The 2011 change in Oregon law allowed pharmacists to increase the total of influenza immunisations given to adolescents.

Bibliographical reference:

Robison SG. Impact of pharmacists providing immunizations on adolescent influenza immunization. *J Am Pharm Assoc* [Internet]; 2016 Jul [cited 2019 Jul 16]; 56(4):446-9. Available from:

<https://www.sciencedirect.com/science/article/abs/pii/S1544319116300279> DOI: 10.1016/j.japh.2016.03.012

2.3.15 A national examination of pharmacy-based immunisation statutes and their association with influenza vaccinations and preventive health

Date of publication: June 2016

Study location: United States of America

Objectives:

To estimate the effects of pharmacy-based immunisation statutes changes on per capita influenza vaccine prescriptions, adult vaccination rates, and the utilisation of other preventive health services.

Method:

A quasi-experimental study that compares vaccination outcomes over time before and after states allowed pharmacy-based immunisation. Measures of per capita pharmacy prescriptions for influenza vaccines in each state came from a proprietary pharmacy prescription database. Data on adult vaccination rates and preventive health utilisation were studied using multiple waves of the Behavioural Risk Factor Surveillance System. The primary outcomes were changes in per capita influenza vaccine pharmacy prescriptions, adult vaccination rates, and preventive health interventions following changes.

Results:

Between 2007 and 2013, the number of influenza vaccinations dispensed in community pharmacies increased from 3.2 to 20.9 million. After one year, adopting pharmacist immunisation statutes increased per capita influenza vaccine prescriptions by an absolute difference (AD) of 2.6% (95% CI: 1.1–4.2). Adopting statutes did not lead to a significant absolute increase in adult vaccination rates (AD 0.9%, 95% CI: –0.3–2.2). There also was no observed difference in adult vaccination rates among adults at high-risk of influenza complications (AD 0.8%, 95% CI: –0.2–1.8) or among standard demographic subgroups. There also was no observed difference in the receipt of preventive health services, including routine physician office visits (AD –1.9%, 95% CI: –4.9–1.1).

Conclusions:

Pharmacists are providing millions of influenza vaccines as a consequence of immunisation statutes, but no significant differences in adult influenza vaccination rates are observed. The main gains from pharmacy-based immunisation may be in providing a more convenient way to obtain an important health service.

Bibliographical reference:

McConeghy KW, Wing C. A national examination of pharmacy-based immunisation statutes and their association with influenza vaccinations and preventive health. *Vaccine* [Internet]. 2016 Jun [cited 2019 Jul 22];34(30):3463-8 Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27219340>

2.3.16 National community pharmacy NHS influenza vaccination service in Wales: a primary care mixed methods study

Date of publication: March 2016

Study location: Wales

Objectives:

To explore and verify the factors that influence the relative performance of pharmacies providing NHS influenza vaccinations.

Method:

Interviews were conducted with 16 pharmacists who participated in the Welsh national pharmacy influenza service in 2013–14. A purposive sampling strategy was used. Qualitative findings were analysed using framework analysis. Potential predictors of vaccination numbers were identified from interviews and a literature review, and included in a multivariable regression model.

Results:

The contribution of community pharmacies towards vaccination in Wales is small. Findings suggest that community pharmacies reach younger at-risk individuals, in whom vaccine uptake is low, in greater proportion than influenza vaccination programmes as a whole. Extended opening hours and urban locations were positively associated with the number of vaccinations given, although pharmacists reported that workload, vaccine costs, unforeseen delays, lack of public awareness, and GPs' views of the service limited their contribution. Pharmacists, aware of the potential for conflict with GPs, moderated their behaviour to mitigate such risk.

Conclusions:

Before community pharmacies take greater responsibility for delivering healthcare services, obstacles including increasing pharmacist capacity, vaccine procurement, health service delays, managing GP–pharmacy relationships, and improving public awareness must be overcome.

Bibliographical reference:

Evans AM, Wood FC, Carter B. National community pharmacy NHS influenza vaccination service in Wales: a primary care mixed methods study. *Br J Gen Practice* [Internet]. 2016 Apr [cited 2019 Jul 22];66(645):e248-57. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4809708/>

2.3.17 Influenza vaccination: A cross-sectional survey of knowledge, attitudes and practices among the Lebanese adult population

Date of publication: December 2015

Study location: Lebanon

Objectives:

To evaluate the 2014–15 seasonal influenza vaccination rate as well as assess the knowledge, attitudes and beliefs among a select Lebanese population towards the seasonal influenza vaccine.

Method:

A cross-sectional survey was performed in 30 pharmacies randomly selected across Lebanon. A 19-item questionnaire was used to record influenza vaccination status, knowledge and attitudes towards the influenza vaccine among the Lebanese general population.

Results:

The survey response rate was 93%. Among the 640 study participants, the overall 2014–15 seasonal influenza vaccination rate was 27.6%. The majority of participants (72.4%) reported irregular uptake of the vaccine. Results of the multivariate analysis revealed that elderly people (odds ratio [OR] 2.25, CI 1.08–4.71), with higher education (OR 1.42, CI 1.09–1.84), higher physical activity (OR significantly higher than 1 for all categories), and chronic respiratory disease (OR 3.24, CI 1.58–6.62) were more regularly vaccinated, while those who visit the doctor “only when needed” (OR 0.55, CI 0.34–0.88) and those who consume more than seven drinks/week (OR 0.24, CI 0.09–0.65) were less regularly vaccinated. When introducing knowledge and attitude variables to the model, “thinking that the vaccine was not needed” was the only correlate that demonstrated a significant inverse association with regular influenza vaccination (OR 0.15; P=0.017).

Conclusions:

Suboptimal vaccination rates exist among the Lebanese ambulatory adult population. Clear misinformation on the importance of regular influenza immunisation is highlighted. This evidence underscores a compelling need to raise public awareness regarding the efficacy of the influenza vaccine.

Bibliographical reference:

El Khoury G, Salameh P. Influenza vaccination: a cross-sectional survey of knowledge, attitude and practices among the Lebanese adult population. *Int J Environ Res Public Health* [Internet]. 2015 Dec [cited 2019 Jul 16];12(12):15486-97. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/26690189>

2.3.18 Seven Seasons of Influenza immunisation campaigns in Portuguese pharmacies

Date of publication: 2015

Study location: Portugal

Objectives:

To provide an overview of the percentage of vaccines administered in pharmacies and other indicators over the years.

Method:

A cross-sectional study was performed at each influenza season (October to March) based on data recorded in pharmacies from 2008–09 to 2014–15. Data were first recorded on paper records and spreadsheet, and from 2012 on they were recorded directly in the pharmacy’s specific software (SIFARMA). All records are anonymously (regarding patients and pharmacy individual data) and automatically transmitted for evaluation purposes by the Portuguese National Association of Pharmacies (ANF). Vaccination records include patient name, age and sex, vaccine and batch used, route of administration, date and pharmacist name.

Results:

The estimated percentage of vaccines administered (on total vaccines dispensed) was 36.4% (2008–09), 49.7% (2009–10), 44.2% (2010–11) and 49% (2011–12). In 2012–13, the percentage was the lowest ever (38%) but increasing (40.9% in 2012–13, 49.2% as preliminary estimate for 2014–15). The preference for pharmacies was established. Until 2011–12, flu vaccines were administered almost solely in pharmacies.

Conclusions:

The first four seasons demonstrate an increase in major indicators. Since 2012–13, flu vaccines are administered free of charge in health centres to individuals aged 65 and over with no need for a prescription. By contrast, the NHS financing of vaccines and service does not occur for pharmacies. The last Government's Report (2013–14) reports influenza coverage of 49.9% in the 65 and over subgroup, lower than in 2008–09. In 2014, the Ministry of Health and ANF signed an agreement which foresees possible incentives for pharmacies' collaboration in public health objectives, including immunisation services. This could be an opportunity to integrate pharmacies in a national influenza immunisation campaign.

Bibliographical reference:

Horta R, Jacinto I, Guerreiro JP, Torre C, Costa Z. 7 seasons of influenza immunisation campaigns in Portuguese pharmacies. National Association of Pharmacies (ANF); 2015.

2.3.19 National seasonal influenza vaccination in Europe, overview of surveys conducted by the Vaccine European New Integrated Collaboration Effort (VENICE) Project

Date of publication: 2015

Study location: 28 EU countries, Norway, Iceland, Liechtenstein

Objectives:

- To collect country-specific recommendations for age, risk and targeted groups.
- To obtain vaccination coverage data.
- To update country-specific vaccination recommendations for targeted and risk groups.
- To obtain latest data on vaccination coverage.
- To identify changes and compliance with EC and WHO recommendations among the EU/EEA countries during different influenza seasons.

Method:

- Annual collaborative studies between EU/EEA countries/ECDC/VENICE Project.
- Surveys with the same methodology each year.

Results:

- All countries recommended vaccinating older age groups in the 2014–15 influenza season.
- 23 countries recommended vaccine for individuals ≥ 65 years.
- 10 countries reported a lower age cut-off (ranging from ≥ 50 to ≥ 60 years of age).
- Seven countries recommended vaccination of healthy children.

Conclusions:

- Recommendations for seasonal influenza vaccination are standard in most of the countries and comply with EC and WHO recommendations.
- Vaccination of children is still uncommon.

- The gap between vaccination recommendations and actual vaccination coverage exists for clinical risk groups, pregnant women and healthcare workers (HCWs), and some countries do not monitor vaccination coverage for older age groups.
- Vaccination coverage for the elderly is lagging in most of the countries except the Netherlands and UK. It did not increase in five influenza seasons and did not meet EU target.
- Vaccination coverage for HCWs and those with chronic medical conditions was moderate or low for these groups of individuals, and did not increase in five influenza seasons.
- Vaccination coverage for pregnant women was monitored by one third of countries, was moderate in the UK, but low in the remaining countries.

Bibliographical reference:

Mereckiene J, Cotter S, Johansen K, Tsoлова S, Penttinen P, Lopalco P, et al. National seasonal influenza vaccination in Europe, overview of surveys conducted by Vaccine European New Integrated Collaboration Effort (VENICE) Project. VENICE Project Gatekeepers Group; 2015

2.3.20 Increasing the uptake of herpes zoster vaccinations via community pharmacies

Date of publication: August 2014

Study location: USA (Massachusetts, Florida and New York)

Objectives:

To investigate the uptake of herpes zoster vaccinations in community pharmacies and the influence of state authorised pharmacist immunisation privileges on vaccination uptake rates.

Method:

- This cross-sectional study analysed herpes zoster vaccination records from 2012 administered at the Walgreens pharmacy chain.
- Vaccination uptake rates were calculated as the number of patients aged ≥ 60 years who received a herpes zoster vaccine per 1,000 pharmacy patients ≥ 60 years filling a prescription for any medicine at Walgreens during the study period.
- Rates of vaccination were examined three months before and after implementation of pharmacist immunisation privilege for herpes zoster in Massachusetts (May 2012), Florida (July 2012), and New York (October 2012).

Results:

- In Massachusetts, the rate of herpes zoster vaccinations per 1,000 pharmacy patients increased from 3.3 to 28.1 after pharmacists were authorised to administer vaccinations under a protocol, a 745% increase ($P < 0.001$)
- In Florida, the vaccination rate increased from 3.4 to 16.2, a 377% increase ($P < 0.001$)
- In New York, vaccination rate increased 803% from 1.3 to 11.6 ($P < 0.001$).
- These states authorised pharmacists to administer vaccinations with a patient-specific prescription.

Conclusions:

- After the legislation, study pharmacies had a significantly higher rate of herpes zoster vaccinations than that before the legislation. Uptake rate was highest in Massachusetts, which granted pharmacists full authorisation to administer the vaccines.
- Results suggest that community pharmacists provided additional access and convenience to herpes zoster vaccines for high-risk populations, resulting in increased uptake.
- Given the suboptimal vaccination rate of herpes zoster, states with limited or no immunisation authorisation for pharmacists should consider expanding pharmacist privileges.

Bibliographical reference:

L. Fensterheim, M. Taitel, A. Cannon, H. Leider. Increasing the uptake of Herpes Zoster vaccinations via community pharmacies. *Journal of the American Academy of Dermatology*, May 2014, Vol.70(5), pp. AB81-AB81.

2.3.21 Pharmacists as providers: targeting pneumococcal vaccinations to high risk populations

Date of publication: October 2011

Study location: United States of America

Objectives:

To evaluate the impact of pharmacists educating at-risk patients on the importance of receiving a pneumococcal vaccination.

Method:

Using anonymised claims from a large, national pharmacy chain, all patients who had received an influenza vaccination between 1 August and 14 November 2010 and who were eligible for pneumococcal polysaccharide vaccine (PPSV) were identified for the analysis. Based on the Advisory Committee on Immunisation Practices recommendations, at-risk patients were identified as being aged over 65 years or as aged two to 64 with comorbid conditions. A benchmark medical and pharmacy claims database of commercial and Medicare health plan members was used to derive a PPSV vaccination rate typical of traditional care delivery to compare with pharmacy-based vaccination. Period incidence of PPSV was calculated and compared.

Results:

Among the 1.3 million at-risk patients who were vaccinated by a pharmacist during the study period, 65,598 (4.88%) also received a pneumococcal vaccine. This vaccination rate was significantly higher than the benchmark rate of 2.90% (34,917/1,204,104; $P < 0.001$) representing traditional care. Patients aged 60–70 years had the highest vaccination rate (6.60%; 26,430/400,454) of any age group.

Conclusions:

Pharmacists were successful at identifying at-risk patients and providing additional immunisation services. Concurrent immunisation of PPSV with influenza vaccination by pharmacists has potential to improve PPSV coverage. These results support the expanding role of community pharmacists in the provision of wellness and prevention services.

Bibliographical reference:

Taitel M, Cohen E, Duncan I, Pegus C. Pharmacists as providers: targeting pneumococcal vaccinations to high risk populations. *Vaccine* [Internet]. 2011 Oct [cited 2019 Jul 22]; 29(45):8073-6. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/21864625>

2.4 References

1. World Health Organization. Equitable access to essential medicines: a framework for collective action [Internet]. WHO policy perspectives on medicines, Geneva, Switzerland; 2004 [cited 2019 Aug 16] Available from: <http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf>
2. International Pharmaceutical Federation (FIP). An overview of current pharmacy impact on immunisation – A global report 2016. The Hague: International Pharmaceutical Federation; 2016. Available from: <https://www.fip.org/file/162> [cited 2019 Aug 16].
3. International Pharmaceutical Federation (FIP). Pharmacy: a global overview — Workforce, medicines distribution, practice, regulation and remuneration 2015–2017. The Hague: International Pharmaceutical Federation [cited 2019 Aug 16].

4. Goad J, Taitel M, Fensterheim L, Cannon A. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. *Ann Fam Med* [Internet]. 2013 Sep [cited 2019 Aug 16];11(5):429-36. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24019274>

3 Developing an advocacy strategy: a stepwise approach

3.1 Situational analysis tool

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Improving vaccination access and coverage is a global imperative and pharmacists can contribute to this goal through a multitude of roles. However, any advocacy strategy aiming to achieve an expanded role for pharmacists in this area at country level needs to be grounded in an in-depth understanding of the needs at country level with regard to vaccination services, as well as the requirements, resources (workforce, infrastructure, financial, etc), support systems, stakeholders and various other elements that need to be considered in order to design a successful and meaningful strategy.

This chapter offers guidance for carrying out a situational analysis at country level with regard to the vaccination landscape and to establish a baseline overview of the situation.

The **objectives** of the situational analysis are:

1. To develop an in-depth understanding of the provision of vaccination and vaccine-related services in the country
2. To assess the need to improve vaccination coverage
3. To assess the existing regulatory framework and the available resources (workforce, infrastructure, financial, etc) for the provision of vaccination service
4. To identify all relevant stakeholders in the vaccination landscape
5. To identify gaps and opportunities for pharmacists to contribute to improved vaccination rates at country

This tool is primarily addressed at pharmacy professional organisations, advocacy bodies, regulators and policy-makers to support them in developing advocacy strategies or enabling regulatory frameworks in countries where pharmacists have a limited role in the vaccination system. It may also be useful a review tool in countries where pharmacists already play vaccine-related roles but can further expand or consolidate such roles.

The information and evidence collected through the situational analysis can be used to inform decision-making in terms of policy development, workforce planning and development, service development and at all relevant levels to achieve better vaccination coverage through pharmacists.

The situational analysis tool is basically a questionnaire that can guide a fact-finding process. Information for completing the situational analysis tool can be gathered through desk-based research, interviews with relevant stakeholders and through an analysis of collected data and documents.

Although the situational analysis should be the starting point of the advocacy process, we recommend that the following chapters are read prior to completing the questionnaire, as they will inform the way you gather the necessary elements.

3.1.1 Situational analysis tool questionnaire

A. EPIDEMIOLOGICAL LANDSCAPE

1. **What are the incidence rates for vaccine-preventable diseases and how have they evolved in the last five years in your country?**

Respond using the table below.

A list of currently available vaccines can be obtained by visiting the World Health Organization website at <https://www.who.int/immunization/diseases/en/>. For each disease or pathogen, information is provided on internationally available vaccines and WHO policy recommendations, together with other key resources.

2. What are the priority diseases in your country (including communicable and non-communicable diseases whose incidence, morbidity or mortality may be influenced by certain vaccines)?

Priority diseases are those with a particularly high incidence or clinical relevance, or with a high social and/or economic impact for the country. They may also have been formally designated as priority diseases by the government, with a special strategy put in place to address them. Your organisation may want to consider how pharmacists may contribute to national strategies around priority diseases, including pharmacy-based vaccination campaigns and other initiatives.

B. ACCESS TO VACCINES AND VACCINATION SERVICES

1. What are the vaccination coverage rates for all relevant vaccine-preventable diseases in your country and how have they evolved in the last five years in your country?

Respond using the table below.

You may find valuable information on the evolution of vaccination coverage rates per country and disease at the following webpages:

- WHO immunisation monitoring data: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tscoveragebcq.html
- WHO Global Health Observatory: <https://www.who.int/gho/immunization/en/>
- Global Vaccine Action Plan indicator portal: <http://apps.who.int/gho/cabinet/gvap.jsp>

2. How do the current vaccination coverage rates compare with the recommendations and goals set by the World Health Organization and other relevant organisations, such as centres for disease control?

Respond using the table below.

The WHO Global Vaccine Action Plan, which was endorsed by the World Health Assembly in 2012, aimed to prevent millions of deaths through more equitable access to vaccines. The plan set a target of 90% coverage for all vaccines by the year 2020.¹

For influenza (flu), in 2003, the World Health Assembly adopted Resolution WHA56.19 urging member states to increase influenza vaccination coverage of all people at high risk and to attain coverage of 75% among the elderly by 2010.²

3. How would you describe the accessibility of vaccination services (geographical distribution, opening times, etc.)

4. How many vaccination points are currently available in your country? And how many community pharmacies exist that could have a role in increasing accessibility to vaccination services?

	Number (A)	Average opening hours per week (B)	Total number of opening hours per week (A x B)
Vaccination points (including primary health centres, vaccination clinics, etc)			
Community pharmacies supervised by a pharmacist			

5. How would you describe access to vaccines and vaccination services per age group (including adults and older adults)?

Please refer to the WHO recommended vaccines per age group (or risk group) at the WHO immunisation policy webpage https://www.who.int/immunization/policy/immunization_tables/en/. These recommendations may be updated with the publication of the new WHO Immunization Strategy 2021–2030 in 2020, so do check for updates. You may also wish to consider access to vaccines not covered by national vaccination programmes (should there be one) or beyond the minimum set of WHO recommendations, and particularly vaccines such as influenza and herpes zoster (shingles) in older adults, travel vaccines or HPV vaccination in adolescents (both sexes). Community pharmacies are playing an increasing role in improving coverage and access to these vaccines in several countries either in collaboration with national vaccination programmes or as a complement to their coverage.

C. WORKFORCE CAPACITY (PHARMACY AND OTHER HEALTH PROFESSIONS)

1. What professions have roles in the vaccination system, including advice on vaccines, scheduling of vaccinations, storage and dispensing of vaccines, administration of vaccines and updating vaccination records)?

	Advice/counselling on vaccination	Scheduling vaccination appointments	Storing and dispensing vaccines	Administering vaccines	Updating vaccination records
Medical doctors					
Nurses					
Pharmacists					
Other					

2. What is the workforce capacity (density of professionals per 10,000 population) for the different vaccination service providers?

Workforce density per 10,000 population
Medical doctors
Nurses
Pharmacists

Other

- 3. How would you describe the level of competence of pharmacists with regard to vaccines and vaccination? Is such competence developed through undergraduate education and training?**

- 4. How would you describe the capacity in your country for the education and training of pharmacists for the delivery of vaccination services? (schools of pharmacy, continuing professional development providers, organisations that offer and/or certify training and competence development)**

Situational analysis per vaccine-preventable disease (responses to questions A1, B1, and B2)

Disease	Incidence rate (%)	Variation in incidence rate in relation to five years ago (+/-%)	Vaccination coverage rate (%)	Variation in coverage rate in relation to five years ago (+/-%)	Difference to the WHO or other recommended coverage rates or goals (+/- %)
Human papillomavirus (HPV)					
Cholera					
Dengue					
Diphtheria					
<i>Haemophilus influenzae</i> type b (Hib)					
Hepatitis A					
Hepatitis B					
Hepatitis E					
Influenza (flu)					
Japanese encephalitis (JE)					
Lyme disease					
Malaria					
Measles					
Meningococcal meningitis					
Mumps					
Pertussis (whooping cough)					
Pneumococcal disease					
Poliomyelitis					
Rabies					
Rotavirus gastroenteritis					
Rubella					
Shingles (herpes zoster)					
Smallpox					
Tetanus					
Tick-born encephalitis					
Typhoid fever					
Tuberculosis (TB)					
Varicella (chickenpox)					
Yellow fever					

D. FINANCING OF HEALTH CARE, VACCINES AND VACCINATION SERVICES

1. What are the current funding priorities for the government of your country, including health- and non-health-related competitive investment?

According to a study by Ozawa et al³ cited by the WHO, an assessment of return on investment (ROI) has found that every dollar invested in vaccines over a decade is estimated to result in a return of 16 times the costs, taking into account treatment costs and productivity losses. Estimates were derived by looking not only at vaccine costs, but also supply chain and service delivery costs. When considering broader economic and social benefits, the ROI for immunisation was 44 times the vaccination costs.³ However, when developing an advocacy strategy for expanded vaccination through pharmacists, it is important to understand that multiple valuable investments compete for limited resources (including, for example, education, infrastructure, public transport, but also other healthcare interventions such as hospital care or life-saving medicines).

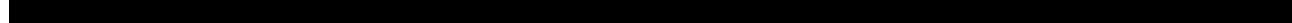
2. What funding mechanisms are available in your country to cover the cost of vaccines and vaccination services? Are people required to pay for these costs out of pocket (which groups and for what vaccines and from which providers)?

3. Is there evidence of the socio-economic impact of vaccination in your country?

There is a wealth of evidence related to the socio-economic impact of vaccines around the world and in many individual countries. You may visit the World Health Organization webpage on immunisation financing at https://www.who.int/immunization/programmes_systems/financing/analyses/en/ and access a number of studies that may be useful to support your advocacy strategy. If you are considering developing a pilot vaccination service in community pharmacies, you may wish to consider developing a model for assessing the economic impact of increased vaccination coverage through pharmacies for the country (including increased productivity, reduced work and school absenteeism, reduced health care costs to treat vaccine-preventable diseases and others).

E. REGULATORY FRAMEWORK AND VACCINATION POLICIES

1. Is there a National Immunisation Technical Advisory Group (NITAG) in your country to advise policy makers and vaccination programme managers on vaccination policies?



2. Is there a national vaccination programme in your country? What population groups and vaccines does it cover? And which groups and vaccines are not covered [e.g., older adults, flu vaccines, etc.]?

3. What are the legal professional requirements for administering vaccines? Do pharmacists comply with such requirements?

4. What are the infrastructural and equipment requirements for the provision of vaccination services? Are community pharmacies adequately prepared and equipped to provide vaccination services in a private and suitable room?

F. STAKEHOLDERS MAPPING AND ANALYSIS

In order to develop a successful advocacy strategy, it is crucial to understand the various stakeholders that make up the vaccines and vaccination system in your country. This will enable you to develop this strategy and the ensuing vaccination services in a collaborative way, gather the necessary supports and become aware of any challenges you may be faced with.

The list of stakeholders may vary for each country, but it may include:

- The Ministry of Health: identify the departments and focal points involved in communicable diseases, non-communicable diseases, primary health care, vaccines and vaccination services, elderly care, (community) pharmacy services
- The WHO country office
- The National Immunisation Technical Advisory Group (NITAG)
- Professional regulatory bodies for health professions such as medical doctors, nurses and pharmacists
- The leadership and relevant technical officers of health professionals’ advocacy organisations and societies (medical doctors — especially primary care physicians/general practitioners, nurses, other pharmacy organisations)
- Relevant consumer and patient organisations, including older adults groups
- Representatives of academic institutions and CPD providers for educating and training pharmacists
- Local and/or international NGOs working in the field of vaccination
- Relevant industry and vaccine supply chain organisations

For each stakeholder, identify their objectives and scope of activity, their role in the vaccination system, the names and contact details of relevant individuals and the key points you will need to address in your interaction with them (reasons to support or object to pharmacists vaccinating, for example).

Organisation	Department	Lead contact person (name and title)	Address	Email address	Telephone number
1					
2					

3
4
5
6
...

G. SUMMARY: MAIN BARRIERS AND OPPORTUNITIES FOR AN EXPANDED ROLE FOR PHARMACISTS IN THE VACCINATION ECOSYSTEM

1. Based on the information gathered through this situational analysis, what are the main opportunities that pharmacists may harness in the vaccination landscape in your country and how can you use them?

2. Based on the information gathered through this situational analysis, what are the main challenges you will need to address and how do you plan to address them?

3.1.2 References

1. World Health Organization. Immunization coverage reaches 84%, still short of 90% goal [Internet]. Geneva: WHO; 2014 [cited 2019 Aug 19]. Available from: https://www.who.int/immunization/newsroom/press/immunization_coverage_july2014/en/
2. World Health Organization Regional Office for Europe. Seasonal vaccination policies and coverage in the European Region [Internet]. Copenhagen: WHO EURO; 2014 [cited 2019 Aug 19]. Available from: <http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/vaccination/seasonal-vaccination-policies-and-coverage-in-the-european-region>
3. Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker DG.. Return on investment from childhood immunization in low- and middle-income countries, 2011–20. Health Aff [Internet]. 2016 [cited 2019 Aug

19];35(2):199-207. Available from: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1086> DOI: 10.1377/hlthaff.2015.1086.

3.2 Bringing stakeholders on board

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Claiming a role in vaccination and earning fair remuneration for the service requires a solid advocacy strategy that needs to be adapted to each country's regulatory framework and to its political, professional and social environment.

The political process is complex, with a multiplicity of factors and actors that are involved in the decision-making process. For a successful plan advocating for vaccination at community pharmacies, it is imperative to understand the context, the stakeholders and their power, interests, and beliefs as well as the existing barriers and opportunities to change, set goals, develop action plans, and permanently evaluate and monitor outcomes.

Preparing the landscape before initiating the advocacy process is of utmost importance. It is essential to dispel myths, anticipate challenges, plan for the training and certification of pharmacists, assess public acceptance, compile evidence and solid arguments, take representative action among policymakers and political parties, and engage pharmacists.

In summary, the advocacy plan must be adapted to the national situation through a deep understanding of the political and professional environment which answers the following universal questions:¹

What do you want?

It is important to identify the problem, set clear objectives, and propose a solution. In the case of vaccination, it is important to identify what the needs are: Is there a problem of access or affordability? Is the vaccination coverage lower than what is targeted? In which areas would vaccination in pharmacies be more effective to increase vaccination rates?

What does the political map look like?

Which level of government represents the authority to influence the decision or has the power to decide? What are the positions and beliefs of each of the stakeholders and influencers? How can the strategic priorities and messages be adapted to the actors' mapping? Reflecting on these issues enables advocates for vaccination at community pharmacies to identify which stakeholders may be opposed to the expanded scope of pharmacists in immunisation as well as identify those who may offer assistance, spread the message positively and promote public support.

What is your plan of action to win?

How you will pass on the message to promote ideas and gather support? What activities and actions are needed? What is needed to ensure the success of your strategy? It is important to understand that decision-makers need a favourable and supportive environment to be willing to make a decision. This means that the change must be viable at both the political and economic levels and that there is sufficient public support or pressure and robust evidence supporting the change.

In this context, engaging with key decision-makers and opinion leaders is of the highest importance to promote policy change. It is also important to map stakeholders and identify their priorities as well as potential partnerships and coalitions that may influence the policy process. The following analyses will facilitate the understanding of the interests of different stakeholders as well as their position to support or oppose vaccination services at community pharmacies.

3.2.1 Key decision-makers and stakeholders

3.2.1.1 Governmental and regulatory institutions

The first step in identifying key decision-makers is to understand the policy and legislative processes at the national level. These processes and potential levels of influence differ from country to country. They vary according to the

political system, namely, whether it is a system based on federal, national and/or regional governments. It is also important to understand who holds legislative and executive power as well as the dynamics of government, parliament, senates and other relevant political institutions.

Moreover, mapping all the relevant decision-makers and the methods through which different groups, legislators and government institutions share responsibility in the policy-making process facilitates the identification of specific stakeholders who hold the power to implement vaccination services at community pharmacies.

At the political level, it is also relevant to identify not only the stakeholders in the current governmental and regulatory bodies, but also those in political parties as well as other governmental areas that may play significant roles in the decision-making and technical process in the field of vaccination. These may include, but are not limited to:

- The Ministry of Health and key staff within it
- Sub-national, regional or local government or departments with a role in vaccination, such as municipalities and regional administrations for health
- The Ministry of Finance, regarding funding decisions
- Community pharmacy regulators
- Chief Pharmaceutical Officers or their equivalent
- Governmental health administration bodies, such as the High Authority for Health, the Health Department, or the General Directorate for Health)
- The National Immunisation Technical Advisory Group (NITAG — https://www.who.int/immunization/sage/national_advisory_committees/en/)
- Health committees in relevant legislative bodies, such as the Senate and Parliament
- Party leaders and committees responsible for the health programme

3.2.1.2 Pharmacists

When defining and implementing plans for advocacy, it is important to assess the acceptance of potential measures and proposals directly in the field. In the case of vaccination services, it is critical to understand the perspective of community pharmacists to engage them in the advocacy plan and address their concerns.

Engaging community pharmacists is a key factor in promoting policy change. Engaging them promotes a smooth implementation of the service, as it reduces the opposition of the professionals who will implement such services themselves in their current practice. Successful outcomes are naturally more likely to be achieved if community pharmacists positively perceive their new service. Furthermore, engaging community pharmacists in the advocacy plan contributes to their commitment in advocating for the service. They will be actively engaged in promoting the service and its benefits to political representatives, stakeholders in the health field, and among the population.

In addition to individual practitioners, it is important that all pharmacy professional organisations (regulators, advocacy bodies, unions, academic and scientific societies, student organisations and others) coalesce around a shared goal and align their agendas. This has been crucial for achieving vaccination rights for pharmacists, as the case studies from Brazil (see Section 6.3) and France (see Section 6.7) illustrate.

3.2.1.3 Other healthcare professionals

To identify the healthcare professionals that may oppose or support vaccination services in pharmacies, it is important to understand the organisation of the healthcare system as well as the healthcare payment system.

Depending on the characteristics of the national healthcare provision system, vaccines are generally administered by general practitioners or by nurses. The funding scheme of healthcare services and payment model for healthcare professionals are important elements to comprehend and analyse, especially if they represent opportunities for opposition to the implementation of pharmacist-led vaccination services in community pharmacies, primarily due to professional and economic reasons.

The professional dynamics, responsibilities and financing schemes are factors that may influence physicians' and nurses' positions on vaccination in community pharmacies. They should be considered of high importance when drafting the advocacy plan so it may be adapted to address these challenges.

3.2.1.4 The public

In many countries, access to healthcare facilities is an intricate process due to several factors, such as distance, opening hours, waiting times and waiting lists, loss of hours of productivity, and high costs. For these reasons, the public generally values proximity and convenience with regards to healthcare services, which constitutes an opportunity for community pharmacies to increasingly play the role of a primary healthcare provider, namely in terms of vaccination services.

In addition, pharmacies and community pharmacists are among the health professionals most trusted by their patients. In different assessments, pharmacists have consistently received high levels of satisfaction by patients with regard to the quality of their services. Many patients have also expressed an expansion of the role of community pharmacists in providing different health services.

In light of these results, the public represents a potential ally in expanding the role of pharmacists to include vaccination. Engaging the public and society through the media as well as having patient organisations and community leaders involved in the discussion therefore represents a route to success through their effectively advocating for pharmacist-led vaccination services.

3.2.1.5 Other stakeholders

Academics and researchers may play an important role in assessing and evaluating both the needs and results of community pharmacy vaccination services as well as in gathering and publishing data and novel evidence. Their involvement is critical in adequately informing politicians and decision-makers with strong and accurate arguments, which ultimately contribute to evidence-based vaccination policies.

Moreover, supply chain stakeholders, such as manufacturers, marketing authorisation holders and wholesalers may have common interests with regard to promoting access to vaccines and vaccination services. Discussions with these stakeholders may lead to partnerships and coalitions based on a common approach to addressing national gaps and needs as well as gather support for the expansion of the pharmacy role in vaccination.

3.2.2 Myths and challenges

As with any process requiring regulatory changes, the implementation of vaccination in community pharmacies and the expansion of pharmacists' scope of practice to include vaccination is complex and challenging. Several pressing challenges have been previously identified and require further information and clarification to better prepare organisations in advocating for pharmacist-led vaccination services.

One of the main difficulties was the limited acceptance or opposition by other healthcare professionals, by the population or even by pharmacists themselves. As vaccination represents a trained skill that is usually performed by nurses or physicians, several concerns were raised over the competence of pharmacists to deliver the service and manage adverse events, such as anaphylaxis.

Concerns regarding logistics were also voiced, as there would be a possible lack of confidentiality and privacy for patients if vaccines were to be administered in the community pharmacy. Logistically, offering vaccine services would supposedly not be adequate considering poor or unintegrated access to and management of patient data and quality of products, such as the cold chain, which may be challenging to ensure.

Financial and economic factors may also constitute a barrier to the implementation of vaccination services in pharmacies. From pharmacists' perspective, if the service is not fairly remunerated, vaccination may be viewed as a time- and resource-consuming service without recognised added value. Furthermore, other healthcare professionals, according to the national remuneration scheme, may perceive the intervention of pharmacists in vaccination as an

increase in competition. Patients may also incur extra costs when opting for vaccination in pharmacies if the service is not reimbursed.

Even after achieving vaccination authority, new challenges will need to be addressed. For example, several countries lack a homogeneous regulatory framework and need to adapt and change proposals according to the legislative setting. Inequality with other vaccination providers is also an important challenge, mostly with regard to the financial costs of the service, the requirement of a prescription to administer vaccines, and the demand and supply for vaccines.

In summary, barriers to implementing vaccination services by pharmacists include:

- Limited acceptance (or overt opposition) by other health care professions, the public or even pharmacists themselves
- Lack of confidence in the qualification and training of pharmacists to provide a safe and quality service
- Lack of confidentiality and privacy of patients
- Concerns over quality assurance in the vaccine supply chain, including the management of the cold chain
- Poor or unintegrated access and management of patient data
- Lack of financial support
- Legislative and regulatory barriers

Nevertheless, while it is important to identify potential challenges, it is just as critical to exchange and learn about the strategies needed to overcome them, ultimately transforming challenges into opportunities and learned lessons. The sharing of best practices and approaches to advocacy may potentiate efforts to advocate for pharmacist-led vaccination in accordance with each national context.

3.2.3 Pillars for a strong advocacy strategy and solid implementation

3.2.3.1 Evidence-based arguments

There are many global organisations committed to gathering and sharing evidence that supports pharmacists as part of the immunisation team as well as describing the unquestionable benefits brought to the public and society as a whole. The experience provided by countries that have already implemented pharmacist-led vaccination services has only reinforced how these services lead to positive financial and health outcomes, all the while contributing to the sustainability of health systems.

Considering their widespread presence, community pharmacies are ideal locations to deliver vaccine services and other injectable medicines. In other words, it would be convenient and practical for patients to receive their vaccines in community pharmacies, not only increasing their ease of access and satisfaction, but also improving vaccination coverage, even in cases where the patient will have to pay for the service. Of note, it has been demonstrated that several patients who choose to receive the influenza vaccine at a community pharmacy had never received such a vaccine before.

In addition to the significant gains in health, vaccination services in community pharmacies have also proven to reduce the financial burden of disease care and to alleviate patient inflow to emergency care units. This service has also shown to contribute to a decline in work absenteeism and in loss of productivity.

The evidence for the need, value and effectiveness of vaccines delivered by pharmacists is not speculative: it has social value, and a broad range of evidence of its benefits has been published. These results should be presented to all concerned stakeholders, together with regulatory bodies and policymakers, to raise awareness on the importance of including this issue in the political agenda. Moreover, to foster a collaborative and positive atmosphere for such policy changes, it is essential that the government acknowledges the safety and added value of pharmacist-led vaccination services as well as understands its purpose in the best interests of patients.

It is, however, recommended to start small. The first steps may include implementing and independently assessing pilot practice-based research projects. These projects will produce tangible quality evidence that can be utilised to inform regulatory bodies and contribute to the widespread implementation of vaccination by pharmacists.

3.2.3.2 Interprofessional collaboration

Optimal healthcare should be both multidisciplinary and interdisciplinary with acting in patients' best interests at its core.

Community pharmacies are very well distributed, even providing health services in rural areas where there is no other health facility or health professional. It is imperative that more isolated populations are not segregated and that they are provided with the same opportunities of access to care and disease prevention, such as vaccination.

To avoid miscommunication or disagreeable circumstances, physicians and nurses should be invited to participate and, if they accept, become involved in the planning process from its beginning. The more transparent the brainstorming, discussion and implementation processes, the easier it will be to reach an agreement and avoid competition or tension. This can be achieved by, for example, establishing collaborative protocols to strengthen interprofessional bonds.

Healthcare professionals should embrace pharmacist-led vaccination services as a factual benefit for the population and for the sustainability of health systems as well as understand that the successful implementation of this service requires communication and cooperation. Pharmacist-delivered vaccination and administration of medicines is complementary to the practice of other healthcare professionals, such as reducing visits to the general practitioner or to the emergency room, which, in sum, decreases the burden on other healthcare services and professionals.

3.2.3.3 Sustainable health systems

The role and scope of practice of community pharmacists has expanded to include several health promotion, disease prevention and disease state management services, aside from dispensing medicines and ensuring their responsible use. Community pharmacies act as a gateway and are an integral part of healthcare systems. Their services contribute to improving the efficiency and sustainability of health systems, namely by preventing the crowding of other parts of the system, such as in general practitioner offices and emergency services. Where necessary, pharmacists refer patients to other healthcare professionals or facilities.

Extending vaccination rights to pharmacists contributes to a country's preparedness for pandemics and emergencies, natural or man-made, that may require mass vaccination or administration of injectable medicines.

Furthermore, this service generates savings and reduces work absenteeism as well as loss of productivity, while it being appropriate, fair and cost-effective that community pharmacies are remunerated for delivering vaccination.

3.2.4 Key messages

In the light of developing an advocacy strategy for expanding the scope of pharmacists to include vaccination, there are several key messages to consider when approaching stakeholders in garnering support for this initiative.

- Preparing the environment before initiating the advocacy process is of utmost importance: planning education and certification of pharmacists, assessing public acceptance, compiling evidence and solid arguments, lobbying policymakers and political parties, and engaging pharmacists are important processes to consider
- Understanding the national political and legislative process as well as the organisation and financing scheme of the healthcare system is also fundamental in identifying key decision-makers, relevant stakeholders, potential opponents, supporters and influencers of pharmacy-based vaccination services
- Advocacy plans must identify the needs and address the challenges associated with implementing pharmacist-led vaccination services through strategies adapted to the national situation and based on strong evidence and clear objectives

- Greater advocacy of the known benefits in public health associated with increased vaccination coverage and ease of access through community pharmacies represents a compelling and essential argument
- Perceived competition and tension with other healthcare professionals providing immunisation services is decreasing, yet remains a challenge in several countries
- The integration of different levels of care (community, primary, secondary and tertiary care) is a key factor to improving access, efficiency, and quality of care in addition to integrating information systems and sharing knowledge between all healthcare professionals, which is essential in ensuring continuity of care
- Pharmacies are connected via electronic network systems that allow them instantly to receive and access information about vaccines, notifications of quality problems or recalls, shortages of vaccines, and other information relevant to the public and other healthcare professionals
- Pharmacies are healthcare services in close proximity to communities, with pharmacists having remarkable confidence from patients. Pharmacists also represent the first and the last point of contact within the health system and are thus in a privileged position to function as a gateway and an integral part of healthcare systems.

3.2.5 References

1. The Democracy Center [Internet]. The Art of Advocacy: Three Essential Questions for Planning Strategy. San Francisco: The Democracy Center, 2017. Available from: https://democracyctr.org/dc_2017/wp-content/uploads/2017/04/art_of_advocacy_rev18Apr.pdf [Cited 2019 Aug 19]

3.2.6 Other useful tools:

- <https://www.pharmacist.com/guidelines-pharmacy-based-immunization-advocacy>
- <http://advocacy.vaccineswork.org/>
- https://www.unicef.org/evaluation/files/Advocacy_Toolkit.pdf
- <https://democracyctr.org/build-real-democracy/>

3.2.7 Summary table

	Government	Pharmacists	Other healthcare professionals	The public
Opportunities	<ul style="list-style-type: none"> Lack of other healthcare professionals/providers in some regions Centralisation of governmental healthcare services with impact on access Need of improving efficiency and reducing waste in healthcare 	<ul style="list-style-type: none"> Contribute to expand the role of community pharmacies in the provision of healthcare systems Promote the integration of pharmacies within the healthcare system namely through the integration of information systems and access to patient health records Increase the number of services available to citizens contributing to an increase in the confidence and loyalty of patients as well as the sustainability of community pharmacies through fair remuneration of the service 	<ul style="list-style-type: none"> Reduces the burden on GPs, primary care services and emergency services allowing other healthcare professionals to have more time and resources for other activities The integration of pharmacy information systems with other healthcare services improves the information about the patient, promoting an effective integration of care Pharmacies can collect data (e.g., patient outcomes and real-world data on effectiveness, safety and pharmacovigilance) that can be shared with other healthcare professionals, improving patient care. 	<ul style="list-style-type: none"> Public trust and are highly satisfied with the quality of services provided by pharmacies Lack of and difficulties in access to other healthcare professionals and services Citizens value convenience, accessibility and affordability of healthcare services
Barriers	<ul style="list-style-type: none"> Need for a favourable political, economic and social environment Budget constraints 	<ul style="list-style-type: none"> Belief that vaccination services are outside scope of practice Lack of confidence in their own qualifications Economically unsustainable since it implies initial investment and is time consuming without perceived return of investment 	<ul style="list-style-type: none"> Lack of confidence in the qualifications and training of pharmacists Perceived as a professional and economic competition Concerns about possible fragmentation of care due to poor medical records, loss of power/ responsibility in the care of patients Inappropriate facilities, logistic and professional procedures that may hinder privacy, quality and safety of the service 	<ul style="list-style-type: none"> Lack of confidence on vaccines Concerns about the influence of the pharmaceutical industry on access to healthcare services Unfamiliarity and lack of information on the availability of services in pharmacies
Strategies	<ul style="list-style-type: none"> Identify key opinion leaders and key decision-makers and influencers and design a target advocacy plan supported by strong evidence Demonstrate that community pharmacies can contribute to increased access and efficiency of healthcare systems while improving quality of life and health outcomes Build coalitions and partnerships with different stakeholders, involving other healthcare professionals, patients and the media to promote a public environment that supports and accepts an increasing role of pharmacies in vaccination 	<ul style="list-style-type: none"> Engage community pharmacies in the advocacy process since the beginning sharing objectives, strategy and outcomes and giving them a voice to address their challenges and concerns; Provide adequate training, support and tools to implement the service. 	<ul style="list-style-type: none"> Invite healthcare professionals' organisations to the advocacy process, working with them in finding ways to address their concerns, find mutual interests and define a collaborative model, for example, through collaboration protocols or agreements Invite other healthcare professionals to be part of the design of the service through their participation in the definition of professional guidelines and training Use evidence to show that the intervention of pharmacies in vaccination is complementary to their own: many patients are vaccinated for the first time in pharmacies, which means that there is no shift in the patients' preferences; decreases the pressure and the burden on the activities of doctors and nurses 	<ul style="list-style-type: none"> Engagement with patients' organisations to share information and evidence on the added value of pharmacies and inviting them to advocate for vaccination in pharmacies Public awareness campaigns on the availability of the service in pharmacies and the benefits of vaccination Proximity, availability and opening hours of pharmacies address lack of healthcare professionals in certain areas, reduce waiting times and meet the expectations of the public Pharmacies provide advice and information in lay language, promoting health literacy, and empowering and engaging patients

3.3 Strategic plan for the implementation of vaccination services by community pharmacies

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This plan proposes a strategy in six phases, each with a set of recommended actions, to guide the implementation of vaccination services in community pharmacies at country level. For each phase, a list of relevant stakeholders and special considerations is provided.

implementing these services could be done gradually, starting with basic activities related to the promotion of vaccination and later moving towards more advanced services, including the administration of vaccines by community pharmacists. Most importantly, introducing these services must be done in line with the actual needs, resources and regulatory framework of each country.

General objective:

To contribute to the improvement of public health through a strategic plan directed to improve/increase vaccination coverage by means of immunisation services by community pharmacy.

Strategic phases:

- Carrying out a diagnostic research of vaccination coverage in the country to set up the real and potential contribution of community pharmacies to this process.
- Developing advocacy activities to implement/expand vaccination services that can be offered by community pharmacies to improve access to vaccines.
- Providing knowledge, skills, and abilities to pharmacists that will enable them to develop activities related to vaccination by community pharmacists.
- Providing resources to community pharmacists to enable them to supply safe and efficient vaccination services to the public.
- Developing/participating in vaccination promotion activities from the community pharmacy to communicate and educate patients on the benefits of immunisation.
- Setting up dispensing services, recommendation/pharmaceutical indication and administration of vaccines in community pharmacies, to expand vaccination coverage.

Phase 1: Carrying out a diagnostic research of vaccination coverage in the country to set up the real and potential contribution of community pharmacies to this process.		
Tactics	Stakeholders	Considerations
1.1 Identification of the official national vaccination schemes and the age/risk groups to which they are directed.	a) Pharmaceutical professional organisations b) Health authorities	It is necessary to define if each vaccine/vaccination scheme is aimed at the whole population (universal application) or if it is directed at patients with certain conditions (vaccination scheme by at-risk groups).
1.2 Identification of vaccination objectives for each of the official national schemes as well as updated vaccination coverage targets, both nationally and locally.	a) Pharmaceutical professional organisations b) Health authorities	It is important to obtain national vaccination coverage data per geographical area and identify the gaps in which there should be an intervention.
1.3 Understanding how national vaccination programmes function and how they are organised to target each age group.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies d) Non-governmental organisations	It is necessary to identify all stakeholders involved in national vaccination programmes, as well as their relation with governing bodies in order to provide vaccination services in community pharmacies.

1.4 Identification of providers and funders of vaccines included in the official national vaccination schemes, per target age group.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies d) Non-governmental organisations e) International and local donors	It is recommended to identify, for all vaccination schemes (universal or targeting at-risk groups), financial groups that can provide the acquisition of vaccines and their administration to analyse the coverage rates of the service.
1.5 Identification of the total number of community pharmacies, their distribution according to the geographic population areas (for example, departments, provinces, municipalities, health regions, health areas, health districts) and the total population that could be covered, per age group.	a) Pharmaceutical professional organisations	It is necessary to analyse the capability of community pharmacies in order to reduce the existing gap between the actual vaccination coverage rate and the vaccination targets in the country. This analysis requires stratification per age group and national vaccination schemes (universal, by at-risk groups).

Phase 2: Developing advocacy activities to implement/expand vaccination services that can be offered by community pharmacies to improve access to vaccines.		
Tactics	Stakeholders	Considerations
2.1 Identification and definition of vaccination activities that can be supplied by pharmacists from community pharmacies to patients and the public in general.	a) Pharmaceutical professional organisations	It is necessary to identify all vaccine-related activities that pharmacists can perform in community pharmacies in accordance with current regulations.
2.2 Development of a proposal for the implementation or expansion of vaccination services in community pharmacies to patients and the public in general.	a) Pharmaceutical professional organisations	a) According to data obtained in strategy 1, estimate the potential impact on vaccination access and coverage if pharmacy-based vaccination services are implemented/expanded. b) The proposal could be supported by studies and experiences from other countries to indicate the impact of vaccination activities performed by pharmacists on the country's vaccination coverage.
2.3 Incorporation and active participation of pharmacists in national or local immunisation committees/groups that define vaccination policies and programmes.	a) Pharmaceutical professional organisations	Pharmacists should collaborate as advisers in making decisions related to vaccination policies and programmes. Thus, the impact of pharmaceutical services in vaccination may be taken into account to achieve the objectives defined by the country.
2.4 Definition of competencies and requirements that pharmacists and community pharmacies must meet to provide vaccination services to the public.	a) Pharmaceutical professional organisations b) Health authorities	The competencies and minimum requirements that pharmacists and pharmacies must have should be defined in accordance with the pharmaceutical vaccination services that will be provided to patients and the public.
2.5 Establishment of alliances with other health professionals who provide vaccination services to patients and the public.	a) Pharmaceutical professional organisations b) Health authorities c) Other organisations of health professionals	Pharmacists must participate in interdisciplinary working groups and develop cooperative partnerships that allow for the implementation or expansion of vaccination services provided by community pharmacies.

Phase 3: Providing knowledge, skills, and abilities to pharmacists that will enable them to develop activities related to vaccination by community pharmacists		
Tactics	Stakeholders	Considerations
3.1 Introduction at undergraduate education level of contents on immunisations, vaccines, vaccine-preventable diseases, official national vaccination schemes and application of injectables.	a) Faculties/schools of pharmacy b) Pharmaceutical professional organisations c) Health authorities	Starting from undergraduate education and training, pharmacists must develop theoretical knowledge and practical skills that enable them to provide vaccination services at community pharmacies.
3.2 Development and implementation of continuing professional development	a) Faculties/schools of pharmacy	The programmes of continuing professional development courses in vaccination should be evaluated and updated

programmes aimed at providing vaccination services by pharmacies and participating in vaccination programs.	b) Pharmaceutical professional organisations c) Health authorities	periodically so that they can cater to the needs of the country.
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Phase 4: Providing resources to community pharmacists to enable them to supply safe and efficient vaccination services to the public		
Tactics	Stakeholders	Considerations
4.1 Development of pharmaceutical practice guidelines for each of the vaccination activities that can be performed in pharmacies in accordance with the country's regulations.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies	It is desirable that these guidelines define indicators of control and evaluation for each of the vaccination activities from the pharmacy.
4.2 Development of standard operating procedures (SOPs) and technical standards that pharmacies must comply with for providing vaccination services. Such SOPs should include: human resources, infrastructure, equipment, materials, vaccine management, safety and hygiene related to the administration of vaccines and elimination of waste products, vaccine registration and continuing education. See list in Section 3.3.3.1	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies	These SOPs must define the minimum quality standards for each one of the elements as well as their control and evaluation indicators.
4.3 Identification of objective and updated sources of information on immunisations, vaccines, clinical guidelines for managing vaccine-preventable infectious diseases and official national vaccination schemes.	a) Pharmaceutical professional organisations b) Health authorities c) Medicines information centres or services	It is necessary that pharmacists have timely and easy access to official sources of information on medicines and pharmacotherapy.

Phase 5: Developing/participating in vaccination promotion activities from the community pharmacy to communicate and educate patients on the benefits of immunisation		
Tactics	Stakeholders	Considerations
5.1 Identification, preparation and distribution of information materials on vaccines and vaccination schemes for patients and the public in general.	a) Pharmaceutical professional organisations b) Health authorities c) Medicines information centres or services d) Insurance companies e) Pharmaceutical companies f) Non-governmental organisations g) Community pharmacists	It is necessary to provide simple and updated information on vaccine-preventable diseases, the advantages of vaccination, and the official vaccination schemes in the country. Consider using printed materials such as pamphlets or brochures, posters and information boards, audio-visual material such as videos, television and radio clips, and social media.
5.2 Design of, implementation of and/or participation in activities related to vaccination information and education for families, the community, schools and work spaces, either pharmacist-led or in coordination with other health professionals or health authorities.	a) Pharmaceutical professional organisations b) Health authorities c) Medicines information centres or services d) Insurance companies e) Pharmaceutical companies f) Non-governmental organisations g) Faculties/schools of pharmacy h) Community pharmacists	It is important to develop specific information and education activities according to age and target groups (family, community, school, work)
5.3 Design of, implementation of and/or participation in vaccination campaigns in accordance with schedules established by national and international health authorities.	a) Pharmaceutical professional organisations b) Health authorities c) Medicines information centres or services d) Insurance companies	Vaccination campaigns should be in agreement with vaccination priorities established by the country. For example, these may include vaccination against measles or against seasonal influenza, and also those defined by the WHO such as World Tuberculosis Day or other relevant World Health Days (for vaccine-preventable

	e) Pharmaceutical companies f) Non-governmental organisations g) Faculties/schools of pharmacy h) Community pharmacists	diseases), World Immunisation Week, and World Hepatitis Day.
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Phase 6: Setting up dispensing services, recommendation/pharmaceutical indication and administration of vaccines in community pharmacies, to expand vaccination coverage		
Tactics	Stakeholders	Considerations
6.1 Design and implementation of counselling services, dispensing, recommendation/pharmaceutical indication and administration of vaccines, in accordance with the procedures related to the supply of vaccines and the available regulations in the country.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies d) Community pharmacists	a) The advocacy, counselling, and dispensing services can be provided first, followed by the pharmaceutical recommendation/indication service and expanding to the administration of vaccines with its corresponding registry and access to vaccination records. b) Design and implementation of these services should consider their economic sustainability, by including a remuneration model. For example: i) vaccines are provided by the public health system and the pharmacy supplies them according to the vaccination schemes established, receiving a payment for the service rendered, whether public or private; ii) vaccines are acquired and supplied by the pharmacy, receiving a public or private reimbursement for the service provided; iii) vaccines are acquired and supplied by the pharmacy, receiving an out-of-pocket payment from the patient.
6.2 Design and implementation of compliance systems to control the vaccination schemes and services provided (counselling, dispensing, recommendation/pharmaceutical indication and administration of vaccines) according to the characteristics of every patient.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies d) Community pharmacists	Pharmacists must individualise the reminder and monitoring systems in order to remind vaccination needs to the patient; they should use all available means for that purpose: appointment allocation, written reminders or electronic media.
6.3 Design and implementation of procedures that allow pharmacists to access the vaccination record of the patient, as well as being able to record or report the administration of the vaccine in the community pharmacy, as appropriate.	a) Pharmaceutical professional organisations b) Health authorities c) Insurance companies d) Community pharmacists	Pharmacists must at least have access to the vaccination card (physical or electronic) of each patient to provide them with important information to make decisions regarding the dispensing or recommendation/indication and administration of vaccines. Access to this information will also assist pharmacists in managing reminders and monitoring systems adapted to each patient.

3.4 Roles and technical requirements for pharmacy-based vaccine-related services

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3.4.1 Introduction

Pharmaceutical services play an important role in public health, contributing to the improvement of the quality of life of patients and communities. Community pharmacies stand as a reference point for patients and represent, in many cases, the first point of contact with the health system.

Pharmacists' functions and responsibilities have evolved in recent years, with pharmacists nowadays playing the role of health promoters, advocates of responsible use of medicines, and pharmaceutical care providers among other important roles. Vaccination services are a part of this dynamic shift of the role of the pharmacist beyond dispensing, with pharmacists having the potential to be involved in all stages of the development, promotion, supply, administration and monitoring of vaccines. However, their participation in such a process is quite heterogeneous, mainly depending on the country of practice.

Many of the points described below are applicable to any country, irrespective of its income level. However, in every nation, it is paramount to consider the existing scenario, the regulatory framework, the available resources (including workforce and infrastructure, among others) and the country's needs in terms of vaccination services.

3.4.2 Vaccine-related roles of community pharmacists

Vaccination services in community pharmacies, whether intra- or extramural, are made up of a set of activities that pharmacists deliver to meet the health needs related to immunisation and the vaccination status of individuals. The purpose of these services is to improve public health by optimising access and vaccination coverage. In this regard, six working areas were identified in which the pharmacist should participate to ensure timely, safe, accessible and efficient services for the patient.

3.4.2.1 Advocacy for vaccination

Advocacy for health 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, advocacy is focused on vaccination services by community pharmacy and it can be achieved through the following actions:

- Participating in and/or advising national or local immunisation committees and groups
- Actively participating in educational processes and providing updated and timely information to patients and the population regarding vaccination
- Distributing printed or electronic information addressed to patients and the community
- Conducting and/or participating in national vaccination campaigns

3.4.2.2 Management of the vaccine supply chain

Management of the vaccine supply chain includes information, acquisition, programming, storage, distribution, control, and evaluation stages. In each of these phases, pharmacists must be involved as medicines experts, both nationally and locally. Actions include the following:

- Participating in the definition of the vaccines that will be supplied
- Participating in the needs analysis about provision and assignment of financial resources, according to vaccination objectives and priorities
- Participating in the acquisition processes of vaccines, ensuring that they come from reliable and recognised quality sources
- Establishing and complying with the technical conditions related to conservation and safekeeping of vaccines
- Ensuring the compliance with technical requirements related to vaccines conservation at all stages of their distribution and transfer, all the way from manufacturers to the administration to an individual
- Ensuring compliance with the quality, safety and efficacy of vaccines
- Participating in the administrative control of the supply process
- Performing studies to determine the consumption, costs and impact of vaccines (for example, increased coverage)

- Obtaining, analysing and interpreting data corresponding to the vaccines supply process

3.4.2.3 Counselling on vaccination status

Pharmacists are experts in medicines and thus possess the knowledge and skills to offer information, advice and assistance in immunisation and vaccination. Their role as a counsellor with regard to medicines and vaccines includes the following actions:

- Reviewing patients' vaccination status according to vaccination schemes established in the country
- Developing vaccination reminder systems for the patient to keep their vaccination schedule up to date
- Evaluating special health situations and contraindications related to vaccination and, if appropriate, refer the patient to a physician for evaluation
- Identifying and providing guidance to risk groups, especially those that are not covered by national and/or mandatory vaccination schemes
- Detecting, reporting and following up on events that have been reported to be attributable to vaccinations (in other words, suspected adverse reactions to vaccines) to the national and/or regional pharmacovigilance unit
- Detecting, reporting and monitoring medication errors (prescription, indication, dispensing, administration) related to vaccines

3.4.2.4 Dispensing vaccines

It is important to note that dispensing vaccines is subject to regulation in each country, depending on whether there is a need for a medical prescription or not. In any case, dispensing involves the delivery of information to the patient, including the essential conditions for the adequate conservation of the vaccine until its administration. It is necessary to keep a record of all vaccines dispensed at the pharmacy, either with or without a prescription.

3.4.2.5 Pharmaceutical recommendation (indication) of vaccines

Pharmaceutical recommendation/indication of vaccines is carried out according to national vaccination programmes and/or guidelines about the prevention of infectious diseases. It is important to highlight the importance of registering the vaccines recommended by the pharmacists.

3.4.2.6 Administration of vaccines to patients

The administration of a vaccine in a community pharmacy corresponds to the procedure by which patients receive a vaccine administered by the pharmacist or another authorised member of the pharmacy team, either orally or parenterally (intramuscular, intradermal or subcutaneous), to produce the specific immunity induced by the product. Actions related to the administration of vaccines include:

- Registering and documenting all administered vaccines: registration in the patient's vaccination record (electronic record or vaccination card) and in the pharmacy records
- Reporting the vaccines administered to the official national immunisation record
- Managing waste products related to the administration of the vaccine
- Following up on patients to promote compliance with vaccination schemes

3.4.3 Essential requirements

To ensure pharmacists can perform activities related to vaccination services in the community pharmacy, it is necessary to have the following elements in place:

3.4.3.1 Legal and technical framework

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

- National regulation that identifies and defines 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: promotion of vaccination, management of the supply chain of vaccines, counselling on the vaccination status of the patient, dispensing of vaccines, pharmaceutical indication/ recommendation of vaccines, and administration/application of vaccines, either intra- or extramurally
- 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 and/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 and/or administered
- Registration and reporting of administered vaccines
- Reporting suspected adverse reactions or medication errors related to vaccines
- Elimination of 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
- Managing emergencies arising from the administration of vaccines in the pharmacy

3.4.3.2 Requirements of pharmaceutical professionals

The requirements of pharmaceutical professionals include:

- Knowledge about infectious diseases preventable by vaccination, immunisations, type of vaccines available in the country, management of the supply chain of vaccines, 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
- Technical skills for the administration of injectable medicines by the intramuscular, intradermal and subcutaneous routes
- Participation in a continuous education programme in the vaccination area, according to vaccination activities authorised to be carried out in the pharmacy

For more in-depth information about the required competencies for vaccine-related roles by pharmacists, see Chapter 5, Developing a competent pharmacist workforce for vaccine-related roles.

3.4.3.3 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.¹ In the context of vaccination, GPP requirements serve to ensure safe, timely and effective immunisation. The following requirements regard the logistics and operational conditions for offering optimal vaccination services.

The requirements regarding infrastructure include:

- Pharmacies should include 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.
- As 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.

3.4.3.4 Orders and procurement

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 redacted and reviewed to ensure substandard, adulterated, unlicensed and spurious, falsely labelled, falsified or counterfeit vaccines are neither procured nor allowed into the system.

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

3.4.3.5 Storage conditions and storage equipment

Vaccines are sensitive medical products that require particular attention with regard to their storage. Vaccines should be stored in their 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).²

For refrigerated vaccines, measures should be taken to ensure the integrity of the cold chain.² 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.²

3.4.3.6 Dispensing and patient records

It is important to safely archive documentation regarding prescriptions for vaccines, immunisation records, and other relevant information. Utilising an organised archive system or ensuring sufficient electronic resources to keep record of this information is necessary.

3.4.3.7 Equipment for vaccine administration and disposal

The necessary supplies for vaccine administration should be readily available at all times. These supplies include syringes, needles, alcohol wipes, sticking plasters, sterile gauze pads and medical gloves.³

The necessary supplies to ensure safe disposal of vaccines and other supplies should be readily available at all times. These include disposal containers specifically designed for sharp objects. Policies and procedures should be developed and reviewed to ensure the adequate disposal of these products.

3.4.3.8 Equipment and medicines for anaphylaxis management

The necessary supplies and medicines for anaphylaxis management should be readily available at all times. These supplies include tongue depressors, light sources, stethoscope, sphygmomanometer and pocket masks.^{3,4} Oxygen, IV lines and fluids may also be included.^{3,4} Necessary medicines include epinephrine for anaphylactic reactions, and H1 antihistamines, such as diphenhydramine, for hives or pruritus.^{3,4}

Policies and procedures regarding anaphylaxis management should be developed and reviewed.

3.4.3.9 Information, policies, and procedures

Documents regarding vaccination, including the benefits and common concerns about vaccination as well as vaccine-specific information, should be readily available to distribute to patients.

Policies and procedures should be readily available for consultation by the pharmacy workforce.

3.4.3.10 Materials and supplies

The requirements regarding materials and supplies include:

- Access to objective and updated sources of information on immunisations, vaccines, clinical guidelines for managing infectious diseases preventable by vaccination, and official national vaccination schemes
- Printed or electronic materials designed to be used in informative, educational processes, and vaccination campaigns according to the target population
- Access to the patient's vaccination history, either physical (for example, vaccination card) or electronic (patient's medical history, centralised national immunisation record)
- Medicines and medical materials for the administration of vaccines and those used in case of an emergency secondary to the administration of a vaccine
- Materials for the proper disposal of infectious-contagious materials (waste materials and products from the administration of vaccines)

3.4.3.11 Economic sustainability of vaccination services in the pharmacy

The requirements regarding the economic sustainability of vaccination services in the pharmacy include:

- Definition of the types of vaccines that will be supplied by the pharmacy
- Definition of the providers of vaccines that will be supplied by the pharmacy (public and/or private)
- Definition of payment fees for the provision of the vaccination service by the pharmacy (public fee, payment for private health insurance, payment for reimbursement, direct payment, or other)

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3.5 Monitoring implementation and progress

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Evidence supporting pharmacy-based vaccination is essential for the success of the advocacy plan for pharmacist-led vaccination services. It provides legitimacy to advocates and supports different levels of policy and decision-making processes.

As such, this contributes to a political and public environment that is more open to support an expanded role for pharmacists and to address the barriers and challenges related to the acceptance and implementation of pharmacy-based vaccination services.

The increasing number of countries implementing pharmacy-based vaccination services is leading to more evidence and robust data, which are key to promote the diffusion of policies and knowledge at an international level.

A standard approach to monitoring and evaluating pharmacy-based vaccination programmes is needed to generate evidence of the impact of pharmacy interventions, which allows the comparison of data at the international level and the application and adaptation of these interventions at the national level.

The aim of this chapter is to propose a standard approach of methods to monitor and evaluate the implementation of a country-level pharmacy-based vaccination programme.

3.5.1 Introduction

There are many factors that can contribute to low immunisation rates, such as the distance to immunisation centres and their inconvenient opening hours. The role of community pharmacists providing immunisations in alternative community settings may improve patient access and immunisation uptake.

Community pharmacies are highly accessible and may improve convenience for receiving vaccinations. Their typically long opening hours and easy accessibility make pharmacies an attractive, practical immunisation option. In addition, pharmacies are present throughout areas often devoid of easily accessible health establishments, such as rural communities.

Changes in infection incidence and prevalence of certain diseases are strongly associated with immunisation rates and coverage. Consequently, these parameters are also the most likely primary indicators of success in the implementation of national and global vaccination programmes. It is likely that the impact of these programmes extends beyond the national health system. Therefore, it is important to evaluate patient level outcomes, such as access and satisfaction.

To measure the impact of a vaccination programme, it is recommended to start with a small set of indicators that can be adapted to different circumstances and that are feasible to monitor as well as allowing the tracking of progress over time.

Overall, it is suggested that frequent communication with pharmacies participating in the first immunisation season or pilot phase is established to guarantee that crucial needs are met.

Pharmacies participating in immunisation programmes should be advised to keep adequate and appropriate records, preferably using their computer system. The records should keep track of administrations and manage pharmacy stock and other data. A proper monitoring system, built upon a proper record system, should allow issues to be identified and corrected in a timely manner. It is advised that data gathered by community pharmacies be centralised by a third-party entity that can analyse, synthesise and disseminate global and per pharmacy indicators, while maintaining patient confidentiality.

Each time a vaccine is administered to a patient, it is recommended that the following information is registered:

1. Patient's name
2. Age
3. Type of vaccine
4. Name of the vaccine and marketing authorisation's holder name
5. Dose
6. Site and route of administration
7. Vaccine administration date
8. Lot or batch number
9. Anaphylactic reaction, if observed
10. Date that the next dose is due

Community pharmacists' read-and-write access to electronic patient records is important to ensure the integration of information in a centralised patient's vaccination electronic record.¹ Record keeping should preferably be mandatory, and vaccinations should also be recorded in a specific vaccination card given to each patient.²

A record of the vaccine inventory should be maintained using the same method. It is also recommended that the pharmacy keeps additional records, such as pharmacist and staff training records, informed consent records and other relevant patient records.

3.5.2 Possible indicators or methods of measurement

To measure the success of the implementation of a vaccination programme, it is crucial to identify several key indicators. By using these indicators, it is possible to track if the programme is being implemented as expected and achieving its outcomes.

3.5.2.1 Process indicators

Process indicators are those that measure programme activities and outputs. The measurement of both activities and outputs indicate whether the programme is being implemented as planned.

An example of process indicator related to pharmacist-led vaccination is the number of pharmacies participating in immunisation, the absolute and the percentage of the total number of pharmacies of a country or region, combined with the number of pharmacists that complete specific immunisation training.

Studies have shown that pharmacists who had received immunisation-related educational training are more prepared to vaccinate than those who had not and found common barriers to be less problematic. Furthermore, community pharmacies that had a greater number of certified pharmacists were more likely to offer immunisation services.^{3,4}

The implementation and expansion of immunisation programmes in community pharmacies generally increases the number of vaccines administered, therefore indicators such as the number of vaccines administered, percentage of people that have never been vaccinated before or percentage of high-risk vaccinated patients should also be monitored.

3.5.2.2 Outcome indicators

Outcome indicators are valuable tools to indicate if the programme is achieving the expected effects in the short and long term. If outcome indicators are designed to measure the changes over time, these should be measured at more than one point, for instance, before and after the implementation of the programme. Long-term outcomes are often difficult to measure and attribute to a single programme. However, that does not mean a programme should not try to determine what was its impact on the outcome of interest (e.g., decrease in morbidity related to a specific health issue).

Pharmacists, through responsible practice in community pharmacies, can also markedly improve healthcare outcomes as well as patients' quality of life. There are two straightforward outcome indicators commonly used to assess vaccination programmes, either routine vaccination in clinics and community pharmacies or vaccination campaigns:⁵

- **Vaccination coverage** The vaccination coverage is calculated by dividing the number of vaccine doses administered by the size of the target population. To highlight community pharmacies' participation, this outcome should be assessed before and after their participation and stratified by high-risk groups.

Vaccination coverage can be measured at administration level by counting the number of doses of vaccines given and dividing by the number of eligible individuals in the population. Alternatively, coverage can be measured by determining the vaccination status of eligible individuals selected for a population-based survey.

- **Incidence of vaccine-preventable diseases** The result of increased immunisation rates should be a decrease in the incidence of the disease the vaccine is meant to prevent. Adequate population coverage with a vaccine should decrease the incidence of this disease. To assess this indicator, central disease data from the Ministry of Health or equivalent should be used.

There are several factors contributing to the success (or failure) of an immunisation programme and customer satisfaction is one of them. Evaluation of patient satisfaction can determine the needs, expectations and attitudes of patients to pharmaceutical care delivery in community pharmacies.⁶

Studying patient satisfaction results can improve the quality of current services, assess the need for new services and enhance communication and expectations between the pharmacist and patient.

It has been observed in many cases that patients who are satisfied with healthcare services will most probably continue with the services provided, maintain their connection with providers, adhere to their treatment and, as a result, benefit from better health. Furthermore, by utilising patient assessments, healthcare providers can more appropriately assess patients' needs, interests and perceptions. As a result, pharmacists as providers should be encouraged to be more responsible for the quality of the services they provide.⁶

Several issues in the measurement process are important and need to be considered and controlled wherever possible. These include selection bias: for example, in most studies, patients selected to test satisfaction were drawn from a convenience sample, usually "handpicked" by the pharmacist. Such patients tend to tailor their responses to match what they believe the provider hopes to hear. Response rates should also be evaluated and non-responders should be compared with responders in terms of sociodemographic characteristics. Finally, the length of time between experience of service and evaluation should be sufficiently short to avoid potential recall bias.⁷

3.5.2.3 Summary

As a summary, key indicators include:

- Number of pharmacies providing the service (national/ regional)
- Percentage of pharmacies providing the service in the total of pharmacies (national/ regional)
- Number pharmacists qualified to administrate vaccines
- Number of pharmacies certified to provide vaccination services
- Number of vaccines administered in community pharmacies
- Percentage of people vaccinated for the first time
- Percentage of people from high-risk groups vaccinated
- Vaccination coverage (number of vaccine doses administrated/size target population) particularly before and after the participation of community pharmacies in the immunisation programme
- Vaccine-preventable diseases incidence (decrease in the incidence of the target disease)
- Satisfaction indicators

3.5.3 Key messages

Generating evidence is key for a successful advocacy plan since it can be used at different levels of the policy cycle to identify challenges and solutions, to address barriers and challenges, and to contribute to the acceptance of pharmacy-based vaccination programmes.

A standard approach of methods to monitor and evaluate the implementation of a country level pharmacy-based vaccination programme enables replication and comparability of data.

It is recommended to start with a small set of indicators that can be adapted to different circumstances, that are feasible to monitor and that allow for adequate progress tracking over time.

It is also recommended to keep electronic records of all vaccines administered in pharmacies, based on a set of predefined data, promoting its integration in electronic patient records. This is of the utmost importance to monitor and evaluate implementation of pharmacy-based services and to share information among other healthcare professionals for a more effective integration of healthcare services.

Finally, to measure the success of the implementation of a vaccination programme, it is crucial to identify key indicators to understand if the programme is being properly implemented and if it is achieving the expected health outcomes.

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3.6 Expanding pharmacists' authority beyond flu vaccination

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When the American Pharmacists Association (APhA) identified pharmacists being immunisation providers as a strategic focus, it also identified an ultimate vision that guided its work over the past 25 years. That vision was that “pharmacists are an accessible, valued and recognised member of the immunisation team who are authorised and compensated for providing immunisation service related to Advisory Committee on Immunisation Practices (ACIP)/government entity recommended vaccinations that improve public health”.

Achievement of this vision typically takes time, development of strategic partnerships and a demonstration of the value of pharmacists' engagement in this area. The APhA's approach to its certificate training programme supported progress towards this vision as the training programme was designed to educate pharmacists across a person's lifespan to position them as knowledgeable and capable providers ready to assume expanded roles to meet the immunisation needs of their communities. As pharmacists' authority expanded, they already had the necessary training and knowledge to administer the newly authorised vaccines.

Most efforts begin with pharmacists gaining authority to administer influenza vaccines, typically to adult patients. Pharmacists should embrace this authority and commit to effectively and efficiently providing the service and demonstrating their value to public health and team-based care. Successfully accomplishing this will support expansion of authority and will attract non-pharmacist advocates for pharmacists' expanded role. Pharmacists providing immunisations facilitates a mind-shift among the public and decision-makers from pharmacists being solely a purveyor of a product to being a patient-care provider.

Again, pharmacists must look beyond administering only influenza vaccine to administering vaccines across a person's lifespan. Technological advancement in influenza vaccination will eventually provide patch or other non-injection delivery methods that do not need a healthcare professional to administer. Therefore, pharmacists should continue to seek authority to administer all recommended vaccines as valued members of the healthcare team and to position themselves as knowledgeable healthcare providers working to improve public health and access.

As you seek expansion of pharmacists' immunisation authority, consider the immunisation needs of your community and other members of the healthcare team. How can pharmacists increase public knowledge and improve access to vaccinations against vaccine-preventable illnesses? How can pharmacists ensure that patients complete vaccination series in accordance with established vaccine schedules and have those immunisations reported to the patient's medical record and existing immunisation registries?

Create a plan for your practice and community that addresses these factors and solicit support from other healthcare providers and public decision-makers for the expansion of pharmacists' authority. A key fact you should attempt to gather is the current vaccination rates for the vaccines you are wishing to gain authority to administer. What harm would it cause to add an accessible healthcare provider to improving vaccination rates? Seek the support of medical specialists (i.e., cardiologists, obstetrician-gynaecologists, endocrinologists, etc) who typically do not administer vaccines but whose patients benefit from the vaccinations. They can be great sources of referral to immunising pharmacists.

The transition to expanded authority can begin by simply assessing patients' immunisation histories and recommendations for needed vaccines based upon their age, medical history, employment, etc. When identifying needed immunisations, inform the patient, talk about the value of getting vaccinated and, if the patient agrees, vaccinate the patient or refer them to a provider who can. When making a referral provide the patient with a document, or inform the provider whom you are referring the patient to, that the patient is coming to them because you are making the referral. This will help others see you as a team member focused on improving public health.

There are numerous approaches to obtaining expanded immunisation authority, ranging from authority coming from a law or regulation to the authority being delegated from a prescriber via a protocol or prescription. Clearly identify expectations of each member of the immunisation team regarding public messaging, vaccine administration, referrals and documentation of administered vaccines.

Attempts will be made to place greater requirements on pharmacists than on other team members — do not allow this to occur and be consistent in bringing the discussion back to the standards required of other healthcare providers. Numerous requirements have been placed on US pharmacists over the years, and pharmacists have risen to each one of them.

Receptivity to expanded authority is typically greater for adult vaccines such as pneumococcal, zoster/shingles, Tdap/Td, HPV, and Hepatitis A and B. From there, based upon the needs of your community and existing vaccination rates, pharmacists can impact adolescent and childhood immunisation rates, or improve access to travel health services. Look for challenges that communities are dealing with from a public health perspective and how pharmacists/pharmacies can increase public education and access to immunisations. Consider these examples:

- Many communities are combatting the opioid crisis in the US. It is estimated that approximately one in three people will develop herpes zoster (HZ, shingles) during their lifetime, resulting in an estimated one million episodes in the US annually. The risk for post-herpetic neuralgia (PHN) in patients with zoster is 10%–18%. PHN is a debilitating complication of HZ. The risk of PHN after HZ increases with age and opioids are a part of the armament practitioners utilise to manage PHN pain. Zoster vaccine reduces the risk of developing shingles and PHN. Public decision makers are encouraged to consider zoster vaccination as one of the tools to reducing the need for opioid medication. Increased access to the vaccine through pharmacist administration is one of the many tools communities can utilise to reduce the need for opioids.
- The importance of vaccine series completion can be addressed through collaboration with immunising pharmacists, reducing the workload stress on medical practices so that they can focus on the care of complex patients. For example, the medical practitioner can conduct the initial patient assessment and administer the first dose of a multi-dose series, with the pharmacist administering the remaining doses and documenting the vaccine administrations into the medical record and/or immunisation registry. Examples of this include HPV and hepatitis A & B vaccinations.
- Pharmacists are educated regarding the recommended pneumococcal vaccinations and the importance of Tdap vaccination to specific patient populations, such as pregnant patients and family members. Incorporating immunisation assessment within the pharmacists' patient care process provides opportunities for increased public education and improved access to these important vaccines, thereby benefiting public health.

Critical to pharmacists' achievement of expanded immunisation authority is a commitment to documenting administered vaccines in the patient's medical record and/or immunisation registry. For medical providers who are remunerated on meeting established immunisation quality measures, obtaining this documentation helps them to achieve the measures and positions pharmacists as a collaborating team member versus competition.

Immunisations are a year-round patient care activity and the knowledge/skills, public trust and accessibility of pharmacists are unique attributes that should not be overlooked by public decision makers. Keep the needs of patients and communities as your guiding light.

3.7 Developing and achieving a remuneration model for the service

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Across the globe, a large number of deaths are still caused by diseases which could be prevented by vaccination. This is particularly the case in low-income countries. The economic position which leads to these health inequalities will only be worsened by not making vaccination available to more of the world's population. While the impact of infectious diseases on the people they infect is widely recognised, the wider-economic burden is often more difficult to quantify. However, governments and policy makers are becoming increasingly aware that vaccines not only reduce mortality and morbidity, but also have a positive impact on the economy and society at large. Improved levels of vaccination will only be possible with adequate levels of investment, which will only happen if decision makers realise the full value.

This chapter will:

- Describe the global benefits of vaccination, including the wider socio-economic improvements resulting from successful vaccination programmes
- Make the case for the inclusion of pharmacies as an accessible, safe and cost-effective provider of vaccination services
- Provide a model for costing a pharmacy vaccination service

3.7.1 Return on investment

Vaccination is one of the most successful and cost-effective health interventions of all time, second only to clean water, according to the WHO.^{1,2} Infectious diseases which once killed hundreds of millions of people have been all but wiped out. In the 20th century smallpox killed 300 million people; thanks to vaccination, smallpox is eradicated and people are now safe from its impact. This is a remarkable achievement in global public health. However, the benefit of smallpox vaccination does not stop at saving millions of lives. The eradication of this infection alone had a significant impact on the world's economy. The benefit/cost ratio for the whole globe was in the region of a staggering 159:1. In other words, every US\$1 spent on eradicating smallpox through vaccination produced an economic return of \$159.³

In the WHO Decade of Vaccines (2011–2020) plan, it is estimated that, if the coverage targets for introduction and/or sustained use of 10 vaccines alone (those against hepatitis B, *Haemophilus influenzae* type b, human papillomavirus, Japanese encephalitis, measles, meningococcus A, pneumococcus, rotavirus, rubella and yellow fever) in 94 countries during the decade are met, between 24 and 26 million future deaths could be averted compared with a hypothetical scenario under which these vaccines have zero coverage.⁴ Hitting the coverage targets for these vaccines would also deliver hundreds of billions of dollars of economic benefit over the decade.⁴

It is a widely held belief that vaccination is only important early in people's lives and many vaccination programmes have been designed around childhood immunisation.⁵ Development of vaccines since their inception was mostly focused on preventing the infectious diseases that cause childhood mortality.¹ Nevertheless, it is becoming increasingly accepted that, to gain the full health and economic benefits from vaccination, a life-course approach must be taken. Including the populations that utilise higher proportions of healthcare expenditure, such as the elderly, extends the benefit of existing vaccinations and encourages the development of new ones. A typical example of vaccination through the life-cycle is vaccination with the seasonal inactivated influenza vaccine for people aged ≥65 years, which the WHO recommends should be administered annually.⁶ One of the key levers for increasing vaccination rates across people's life-course is to increase convenience of access⁵ and it is not difficult to see the significant role pharmacy could play in this.

3.7.2 The socio-economic value of vaccines

Traditional approaches of economic evaluations of health interventions have taken a narrow view of the benefits they confer. They have focused on the cost effectiveness of treatments (and prevention) in terms of cost per number of lives

saved or other treatments averted.⁷ As the positive impact of good population health on economic growth has become widely accepted, the case for vaccination has become stronger.

Vaccination not only protects against illness but also reduces the burden that illness would have placed on society and individuals for the rest of their lives. For example, vaccinated children will grow up into healthier adults who are more economically active. Vaccinated adults will take less time off work and be more able to contribute positively to society.

There are a number of ways vaccines can help improve economic growth.

3.7.2.1 Productivity

A healthy population is essential for the growth of economies and vaccinations should form the foundations of public health programmes if countries are to reach their full potential. The economic benefits of vaccinations against 10 diseases in 73 low and middle-income countries between 2011 and 2020 through an increase in productivity is estimated at US\$251.4bn.⁸

Vaccinations improve productivity by:

- Increasing healthy life expectancy — this expands the population available to be economically active
- Reducing long-term disability — this increases the average productivity of each member of the workforce and helps people keep working for longer during their life

This combination, of more people working and each of those individuals being more productive, gives a positive boost to the economy. There will be increased tax returns, and the increasing wealth of the population will further increase economic growth. However, an increase in people undertaking paid work is not the only beneficial outcome. More people will be able to take on unpaid work (such as caring for children or the elderly) providing further socio-economic benefit.

3.7.2.2 Education

Improving the education of the population should be an important consideration for any country looking to improve its economic fortunes. Ensuring that children are not prevented from accessing education due to ill health or disability is key to this. Vaccination helps to improve access to education in the following ways:

- A reduction in school days lost due to self-limiting illness
- Fewer children with long-term disability leading to a reduced ability to learn or dropping out of education completely
- Families spending less on health care due to illness will be able to invest more of their income in their children's education and development

The combination of these improvements at a population level will have a positive impact on the future economic growth of countries that invest in comprehensive vaccination programmes.

3.7.2.3 Consumption and investment

As populations become vaccinated, people are able to work for longer and have higher expectations for their lifetime earnings. They will also not need to spend as much on associated health care. As this combines with living in an increasingly prosperous country for the reasons detailed earlier, people will have more money to spend or save. This will encourage higher levels of consumer-led demand, further fuelling growth. Increased longevity also provides an incentive to save for the future and provides capital for investment with the associated economic benefits this brings.

3.7.2.4 Demographic changes

Vaccination reduces infant and child mortality. This has a corresponding beneficial effect on fertility rates, reducing them as families realise the increased likelihood that their children will survive into adulthood.⁹

Life expectancy is increased by vaccines, and retirement due to ill health is more likely to be delayed. This could help to mitigate against the demographic challenges posed in some areas of the world of an ageing population. As the number of older people continues to grow and as they have increasing levels of frailty, morbidity and weakened immune

systems, they are more likely to suffer the ill effects of infectious diseases. The impact of not protecting adults from vaccine-preventable-diseases throughout their lives is likely to increase their need to access health care, which is provided at a cost likely to reduce their economic input providing a concomitant downward drag on growth.¹⁰

3.7.2.5 Antimicrobial resistance

Antimicrobial resistance (AMR) is an increasingly serious threat to global public health that requires action across all government sectors and society. It is projected that, without action, AMR could lead to 10 million deaths each year and cost US\$ 100 trillion by 2050.¹¹ There is no single solution to fight AMR, and there will need to be progress across a whole range of strategies if we are not to see these predictions come true.

Vaccination is a key pillar of the fight against AMR, but has not always had the same focus as some of the other areas (i.e., developing new antimicrobials).¹² While there is no getting away from the need for new antibiotics, each time one is developed it is only a matter of time before resistance develops to it. A continual flow of new antibiotics will be needed. Vaccines, however, have been used for years with little significant impact on resistance.

Vaccines help slow AMR progression by reducing the circulation of sensitive and resistant pathogens and, as a result, by reducing the use of antimicrobials.^{12, 13} While quantifying the economic benefit of vaccination on reducing the progress of AMR is still being explored, the impact on reducing AMR is well documented.¹⁴ Multi-antibiotic-resistant strains of pneumococcal infection more than halved following the introduction of a conjugate pneumococcal vaccine in the United States in 2000.¹⁵

3.7.2.6 Summary

Vaccination is one of the cornerstones of any equitable and cost-effective health system across the globe.¹⁶

The WHO makes the case for access to vaccinations to be considered a basic human right by countries and individuals, such is their importance in the prevention of disease and ill health. As outlined in this section, the benefits of vaccination spread far further than keeping a vaccinated individual healthy. The impact of a successful vaccination programme can improve the health of the whole population through both direct and indirect impacts. Vaccination can help reduce healthcare costs, allow health budgets to be spent in other areas, and promote the economic success of countries by having a healthier population who are more economically productive.

Vaccination offers excellent return for investment for countries, health systems and individuals. It reduces spend on direct disease care, reduces antimicrobial resistance, reduces absenteeism, improves productivity, etc. It is sound economic policy to invest in improved vaccination coverage and uptake. However, despite the growing consensus in the economics community about the role of vaccines and improved health as an important strategy for improving economic growth, it too often remains difficult to make the case for expanded vaccination programmes.

3.7.3 Gaining the attention of decision makers

The economic information described earlier in this chapter will provide you with an outline of the arguments you could use to influence policymakers in your country to start, continue or expand investment in a comprehensive vaccination programme. This will require local adaptation using data available about the circumstances particular to the challenges in your country or region.

If there is an existing vaccination programme, you should try to access data on how successful it is. If current services are already providing an effective programme, it will be more challenging to make the case for provision through pharmacy to be funded. However, recent evidence from Ireland¹⁷ shows that the introduction of a pharmacy vaccination service can support increased vaccination through a range of providers supporting multidisciplinary collaboration.

If you can demonstrate gaps in provision or poor coverage, then a pharmacy-run service would be an ideal addition to the vaccination programme to help increase vaccination rates and ensure the health and economic benefits of vaccination are more widely realised.

3.7.4 Pharmacy remuneration

The provision of health services requires investment if they are to be delivered effectively and with high quality and sustainably over time. When calculating the funding required to deliver a pharmacy-based service such as vaccinations, there are a number of factors which must be considered if the service is to be successfully incentivised for the desired outcomes (in this case improved vaccination coverage). Several aspects should be considered.

Set up or annual costs

These will be the costs associated with planning for service delivery and regularly reviewing and improving the quality of provision, such as:

- Training costs for all staff involved, not only the person administering the vaccine but all of those involved in helping make the service a success
- Development of processes or action plans — delivery of a clinical service such as vaccination should be based on a standard procedure (a standard operating procedure, SOP); planning this will help to make sure that the service is as safe and effective as possible
- Suitable professional indemnity insurance should be in place — it is important to check with insurance providers before starting any new service
- There should be a regular review of the service to improve quality and identify any areas of risk
- Waste management — vaccination services produce clinical waste, including contaminated sharps/needles; these will require specialist disposal
- Capital expenditure — new equipment may need to be purchased, such as chairs or IT systems to allow for recording

Service delivery costs

These are the direct costs of delivering the vaccination service, such as:

- Staff time — this should include the person administering the vaccine and those involved in service delivery, e.g., those helping to explain the service to patients and staff who are recording information about the vaccination; travel costs should also be considered if vaccination will be happening at different locations
- Consumables — items such as gloves, needles and syringes, dependent on the local requirements
- Cost of the vaccine — this will sometimes be accounted for separately from the vaccination service due to the fluctuations of vaccine costs; doing this will help reduced the risk that price rises make the service cost prohibitive
- Stock holding costs — costs associated with holding stock such as storage space, refrigeration and finance costs
- Administration time — good record keeping is essential to allow for reporting, claiming from healthcare payers and quality improvement

Premises costs

Vaccination should be undertaken in a suitable environment and the cost of premises and suitable workspace must be taken into account.

These considerations will help you estimate the cost of service delivery. To provide an incentive for pharmacies to invest in a vaccination service, it is also important to provide a return on investment. An acceptable level of return will be specific to each area but it must also take into account the increased level of risk for those pharmacies entering a new market or providing a new service.

3.7.5 Third party remuneration of vaccine programmes in pharmacy

There are still too few countries which allow pharmacists to administer vaccines to the public, and this needs to improve to obtain adequate vaccination coverage. However, gaining regulatory/legislative approvals represents only one barrier to ensuring the pharmaceutical profession plays its full role in delivering a successful vaccination programme. One of the key barriers preventing pharmacies playing a greater part in vaccination programmes is remuneration and

reimbursement, specifically how pharmacies are paid for the vaccine and for the costs associated with delivering it (which can be extensive and have been detailed earlier).¹⁹

In countries without third party remuneration models for pharmacies, members of the public need to privately pay for both the vaccine and the administration if they wish to use their pharmacy. Evidence from both Portugal and the United Kingdom show that when third party remuneration of pharmacy vaccination is introduced, rates of coverage increase.^{17,20}

However, with healthcare budgets under strain and the lack of support for vaccination from policymakers in some countries, it is often a challenge to build a case for funding provision from a third party. It is therefore essential to gather a number of evidence-based reasons to help build the case for support. Consider the following:

1. Before looking for funding, first think about what you wish to achieve and where funding will be needed. It is important to consider all the costs. These will not only represent the remuneration and reimbursement for the pharmacy, but will also represent costs in the system (such as processing claims at the payer). Identifying and addressing these early on means that they are less likely to be used as barriers later.
2. Is this the right time? Provide evidence of discussions and consultations with relevant organisations, colleagues (pharmacists and other healthcare professionals), patients and the public, decision makers, etc.
3. What is the rationale? Provide clear evidence for the need/demand for a pharmacy vaccination service, for example:
 - The vaccination service will support the global effort to tackle infectious diseases and antimicrobial resistance — for some vaccinations, uptake is below the European/global goal, highlighting the need for an increase; utilising every pharmacy-patient encounter as an opportunity to educate and improve vaccination uptake as well as providing a vaccination administration service will contribute to national and global vaccination uptake
 - Health equality and equity — everyone has the right to the highest standard of health; providing access to vaccination to improve public health
 - Return on investment — vaccination is cost-effective; implementation of other cost-effective measures such as train-the trainer education models for pharmacists or integrating vaccination in undergraduate curricula
4. Do you have what it takes to implement vaccine services successfully (staff, facilities, processes, etc.)? It is essential to plan for the launch of any new service. Many efforts prior to the establishment of vaccination services will need to be made to ensure staff are competent and confident and that patient acceptability has been explored.
5. With regard to outcomes, long-term impact and future work, include details of what you envision your service will help achieve in the longer term. A small pilot using a fresh approach is often a great way to test a concept that, if successful, can be rolled out more widely. Robust evaluation should be planned to help encourage future roll out.

3.7.6 References

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4 Implementing a vaccination service at the pharmacy level

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The time and resources required to set up and implement a vaccination service should not be underestimated. There are a number of factors that need to be considered and addressed in advance of setting up and implementing a successful vaccination service in your pharmacy, and it is important that you fully understand the requirements and potential pitfalls. To ensure that you are able to roll out a successful service it is good practice to:

1. Start small by developing and delivering a small and structured pilot service
2. Evaluate your pilot service, identifying successes and challenges
3. Use the data from your evaluation to make recommendations for continuous service improvement
4. Use the above learning to improve and expand your service

The purpose of this chapter is to provide you with a series of practical checklists to assist you with your planning, set up and coordination of the essential tasks and activities involved at each stage of the process, including guidance on how best to develop, deliver and evaluate your service.

4.1 What type of vaccination service will you be offering?

The type of vaccination service you will be offering will depend on the priority and demands in a particular geographical area (e.g., does demand exceed supply?), the service users and the feasibility of implementing a particular vaccination service in a pharmacy. In advance of choosing and setting up a vaccination service, it may be helpful to consider the following points:

- What are the regulatory requirements in your country/jurisdiction?
- Are there any professional guidelines and/or standards that you will need to adhere to, to ensure best practice?
- Which stakeholders (e.g., department of health, relevant regulatory bodies and other vaccination providers) are likely to be able to help you develop and implement your vaccination service? You should aim to collaborate/coordinate with other healthcare providers where possible.
- Are there any existing vaccination campaigns (local, regional or national) that could help you with the development, implementation and evaluation of your vaccination service?
- Who is legally authorised and competent to provide vaccination services in your pharmacy?
- Who can be vaccinated in your pharmacy and which vaccines can be administered?
- Does the service user need a prescription and, if so, what impact would this have on the delivery of your service?
- Is consent from the service user required?
- What procedures need to be followed if there is an adverse event following vaccination (reporting to vaccination registers, reporting adverse events, monitoring and auditing of vaccination services)?
- What documentation and records (mandatory and non-mandatory) need to be kept?
- Will you be audited to ensure compliance with standards and regulatory requirements?
- Are the pharmacy's insurance policies adequate for the delivery of vaccination services you wish to offer?

For the development and delivery of a small pilot that can then be expanded we suggest the following approach:

1. Choose one area for service delivery, e.g., a small number of pharmacies in a particular region of the country where you think you could generate encouraging results
2. Choose one type of vaccination, e.g., influenza (flu)
3. Choose one target population, e.g., adults over 65 years old

4.2 Plan and organise your team

To deliver a successful service you will need a supportive and effective team working with you. Take the time to ensure that everyone in your pharmacy, even those not directly involved, are informed and comfortable with this new service and the associated change. Staff should also be fully vaccinated to protect their health and the health of your service users. Other considerations include:

- Assign a lead or coordinator (and a co-lead backup) for your vaccination service to ensure the service runs as smoothly as possible
- Determine who (legally) can and will be responsible for:
 - Informing and advising service users about their vaccination
 - Arranging appointments and handling or referral of service user queries or complaints
 - Managing the inventory and ordering supplies
 - Monitoring the temperature in the vaccines' storage units (at least twice a day)
 - Administering vaccines
 - Dealing with adverse events and emergencies
 - Dealing with all related administrative tasks (vaccination records, invoices, reimbursements, etc.).
- Determine who will be legally accountable for the service provided:
 - The pharmacy owner
 - The superintendent
 - The manager
 - The professional administering the vaccine
- Determine who needs to be present when a vaccine is administered; in some countries, in addition to the pharmacist administering influenza vaccine, a second (appropriately trained) pharmacy staff member must also be present

4.2.1 Ensure your team is appropriately trained

All healthcare professionals providing vaccination services must possess relevant knowledge and be appropriately trained to administer vaccines and injectable medicines. It is also important to consider whether training requirements will vary for different staff involved in the service, e.g., for students, registered pharmacists, pharmacy technicians and assistants.

The content of the training courses may vary. However, they generally include the following topics:

- General immunisation concepts, vaccine preventable diseases
- Roles and responsibilities of the staff involved in the vaccination service
- Communicating with patients and the public about vaccination
- Strategies for improving vaccination rates
- National Vaccination Schedule and vaccines provided under the vaccination service
- Policies and procedures, legislation and good practices
- Safe handling, storage and disposal of vaccines and vaccination material
- Administration of vaccines and injectable medicines
- Safety procedures, warnings and precautions
- Infection prevention and control
- Waste management
- Contraindications, adverse events that may occur from a vaccination, allergic reactions, anaphylaxis and counter-measures
- Roles and responsibilities during an emergency situation arising from a vaccination
- First aid, basic life support (may include automated external defibrillation), cardiac pulmonary resuscitation (CPR)
- Monitoring requirements for the vaccination service

- Documentation, record keeping and reporting, including policies and procedures for collecting patient information
- Privacy and confidentiality
- Relevant resources — legislation, standards, guidelines, and references

Other factors to consider when organising staff training include:

- Does the training have to be recognised, approved, accredited or certified?
- What level will the training be delivered at, e.g., undergraduate, postgraduate?
- How will the training be delivered, and by whom?
- What will the duration of the training be?
- What is the cost? Will it be paid by the employer or by the employee?
- Will there be a final assessment?
- Will a certificate of completion be issued? If so, for how long will it be valid?
- Will there be a mandatory refresher? If so, how frequently?

4.2.2 Ensure you have sufficient human resources

The type of service you offer will impact on your staffing levels so it is important to coordinate this with your staffing plan. You will need to make decisions on the following:

- Will you be offering your vaccination service every day or only on specified days/times?
- Will the service be offered by appointment or on a walk-in basis, or a combination of both? If so, a vaccination booking and reminding service will need to be developed.
- The actual time required to administer the vaccine will need to be taken into account. In addition, the time required to provide a vaccination service will vary depending on the number of staff members involved. You may need to consider whether additional staff, including pharmacists, will need to be recruited.

4.3 Logistical considerations

4.3.1 Plan your vaccination area and workspace

Your workspace should be well planned to enable the delivery of an effective vaccination service:

- Aim to have a private (or semi-private) consultation area
- The area should be large enough to:
 - Accommodate the service user and their carer, if required
 - Accommodate the equipment needed to store, prepare, administer and dispose of vaccines and supplies
 - Allow surface, space and equipment required to respond to any adverse events and medical emergencies
 - Allow space for a computer if required to record vaccination data
- Good lighting, ventilation and hand washing facilities should be made available

4.3.2 Managing your vaccination supplies

You will need to ensure you have the following supplies in place before you offer your vaccination service:

- Vaccine administration supplies, including syringes, needles, alcohol wipes and medical gloves
- Appropriate equipment for safe disposal of biohazardous materials, sharps and other medical waste, e.g., a sharps container; you will also need to set up a waste disposal service if you do not already have one in place
- Emergency response supplies — materials required to treat an anaphylactic event and other emergencies, e.g., anaphylaxis response kit

- Consider where you will order your vaccination supplies from:
 - Directly from pharmaceutical manufacturer(s)
 - Directly from pharmaceutical wholesaler(s)
 - Provision through your health department
- Ensure you gather and file all the necessary documentation pre- and post-ordering your vaccines
- Ensure you have adequate vaccination supplies to meet service demands

4.3.3 Ordering your vaccines

Influenza (flu) is the vaccination most commonly administered in pharmacies around the world¹. Other frequently administered vaccinations include pneumococcal and travel vaccines and, in some countries, pharmacies are permitted to provide vaccinations which are part of the national vaccination schedule.

There are currently over 26 infectious diseases that can be effectively prevented by a vaccine²:

Human papillomavirus (HPV)	Lyme disease	Rubella
Cholera	Malaria	Shingles
Dengue	Measles	Smallpox
Diphtheria	Meningococcal meningitis	Tetanus
<i>Haemophilus influenzae</i> type b (Hib)	Mumps	Tick-borne encephalitis
Hepatitis A	Pertussis (whooping cough)	Typhoid fever
Hepatitis B	Pneumococcal disease	Tuberculosis (TB)
Hepatitis E	Poliomyelitis	Varicella (chickenpox)
Influenza (flu)	Rabies	Yellow fever
Japanese encephalitis (JE)	Rotavirus gastroenteritis	+ Combined vaccines

Ordering the vaccines should be the last step before service delivery. Vaccines are expensive and have a limited shelf-life so careful planning and effective stock management systems are essential.

4.3.4 Ensure you have effective vaccine storage systems

It is important that correct storage procedures for vaccines are adhered to, including:

- Appropriate vaccine storage equipment to ensure cold-chain maintenance:
 - It is recommended that you have separate fridge and freezer units (rather than one combined fridge/freezer unit) with capacity to ensure the safe storage of vaccine products
- Temperature monitoring equipment:
 - Before ordering the vaccines, ensure your storage equipment is working properly, i.e., ensure the fridge/freezer temperatures have been stable within the recommended range for at least one week prior to ordering your vaccines

Continuously develop, improve and adhere to the relevant protocols for safe and effective storage of vaccines and vaccination supplies.

4.4 Costing, service payment and reimbursement

It is important that you develop a project plan, including timelines, for service implementation, budgeting and costing to patients. You will need to determine the following:

- How much will it cost to setup and run your vaccination service?
- Do reimbursement schemes apply (e.g., through national government schemes)? See Chapter 3.7
- Will the vaccination service be paid for by the service user (including the cost of the vaccine and/or administration service)? If so, ensure that the costs are clearly visible in your pharmacy (e.g., on a poster).

4.5 Providing care to service users

It is essential that you implement a system that ensures you are offering an equitable vaccination service, i.e., that all your service users are offered appropriate vaccination information and/or vaccine administration. Specific considerations when providing care to your service users include:

- Ensuring the patient's history is reviewed
- Ensuring you consider service users' age (child, adolescent or adult), special populations, health status and high-risk patient groups (e.g., patients with long-term conditions or multi-morbidity, immunocompromised patients, pregnant patients and patients under specific treatments)
- Ensuring pre-immunisation checklists are used to identify contraindications or precautions to the vaccines to be administered
- Ensuring you are compliant with regulatory prescription requirements
- Ensuring you have robust processes in place for vaccine administration, to identify and manage adverse events following vaccination and to ensure adequate provision of aftercare to service users
- Ensuring patient confidentiality

4.5.1 Providing vaccination information and advice to service users

Pharmacies have an essential role in public health and can make a significant contribution to vaccination uptake by informing and educating service users about their vaccines. To help raise awareness, it may be useful to integrate promotional activities into your vaccination service; these could include developing and distributing leaflets, letters and chart stickers, or displaying posters and other resources in public spaces. It may also be useful to coordinate your promotional activities with other existing (multidisciplinary) campaigns. You could, for example, consider setting up a partnership with a physician to establish a local vaccination protocol.

The type of information you provide will depend on your service users and the type of vaccination services you provide. Ensure you have considered the following points:

- Information and advice should be provided to service users, including information about the pros and cons of vaccinations; your staff must also be mindful of different cultural and religious beliefs and prepared to address any misconceptions about vaccination
- Ensure that the services provided are clearly visible in the pharmacy, including information about schedules, cost or other important considerations
- Emergency response protocols should also be clearly displayed.

4.5.2 Vaccination records

Effective and systematic vaccination records are essential for service delivery as they can help identify patients and target groups for vaccination, ensure vaccination schedules are met and, as a result, contribute to an increase in vaccine uptake. The information recorded can also be used for service evaluation and improvement and to ensure integration of local vaccination services (e.g., physician-pharmacy-school) through information sharing. Ensure you are compliant with regulatory requirements (national/jurisdiction) — check with your health department or regulatory body if there is a systematic vaccination record system or registry that you should adhere to. Other considerations include:

- Consent — is a patient-signed consent form required before administration of the vaccine?
- Record format — will records be paper or digital/electronic; will there be a patient's vaccination card? Consider whether you will need new software
- Record storage — where will vaccination records be kept? How will they be organised? How long will you keep them for?
- Details that should be recorded:
 - Individual details: identification number, name, age, gender, contact details, medication, allergies
 - Product details: name/type, name of manufacturer, brand, marketing authorisation number, batch number and expiry date of the vaccine

- Administration service details: route and site of administration, dose, date/time, funding source, details of the professional who prescribed the vaccine, details of the professional who administered the vaccine, adverse events
- Storage and use and sharing of recorded information:
 - Healthcare centres, community pharmacies, hospitals, schools, private sector; be aware that there may be significant differences in procedures and systems between the public and private sector
 - Consider patient confidentiality, data ownership and management.
- It is important to ensure you also record enough information to assist you with monitoring and auditing of vaccination services; you may also need to collect additional information to help with the service evaluation

4.6 Evaluating your vaccination service

In most cases, evaluation is used to assess the extent to which a service has achieved its objectives. The findings from a robust evaluation can not only inform you whether your vaccination service was successful, but also why it was successful, and how you can improve and/or expand your service. If your service has not achieved its objective, the findings from the evaluation can help explain why, and identify areas for improvement.

The most well-known distinction in evaluation types is between formative and summative evaluation. The formative evaluation examines the delivery and the quality of the implementation of a service in order to suggest areas for improvement. It is used to feed into a continuous development of a project/service, through ongoing learning and development in response to interim findings. Some examples of formative evaluation questions might include:

- What are the strengths and weaknesses?
- What works and what doesn't work?
- What is the feedback from service users about what should or could be improved?
- How can you make it more cost-effective?

In contrast, the summative evaluation looks at the effects or outcomes of a project/service, for example, what has happened subsequent to delivery of your service, and assessing whether you can confidently infer that your service caused a particular outcome. Some example of summative evaluation questions might include:

- Does your vaccination service meet your service users' needs effectively and efficiently?
- What difference is your vaccination service making? To whom and why?
- To what extent can the outcomes be attributed to your vaccination service, e.g., increased uptake of vaccinations in the area due to increased service hours/convenience?
- How do outcomes and costs compare with those of other options available? Is your service cost-effective?
- Should your service continue to be delivered?
- Is your vaccination service ready for a roll-out or expansion?

It may not be possible to formulate evaluation questions without using a comparator (baseline) — your service led to improved outcomes compared with what? Ultimately, the comparison made will depend on the evaluation questions that need to be addressed, as well as practical issues such as budget and expertise.

4.6.1 Formulating questions

Important points to consider when developing evaluation questions:

- What are the aims and objectives of your vaccination service?
- Why are you conducting an evaluation?
- What are your intended outcomes and how will you use the information collected?

Ensure your evaluation questions are developed with stakeholders' involvement (including service users), or that you at least obtain feedback from stakeholders as part of the process.

When drafting questions, ensure they are:

- Clear and easy to understand
- Coherent, relevant, measurable and time-bound

Ensure, also, that it is possible to identify what information is required to answer and how the information can be collected.

4.6.2 Choosing your method

The approach you take for your evaluation will be determined by its aims and objectives and therefore the methods and tool used will need to be appropriate for your questions and desired outcomes. Generally, an evaluation involves a combination of quantitative (numbers) and qualitative (words) methods but this will depend on a number of factors: the purpose, scale, time and resources available. It is recommended that you explore further resources and seek expert assistance as and when required.

4.6.3 Collecting and analysing data

Where possible, data that is routinely available (e.g., collected as part of your vaccination records) should be utilised for the evaluation. However, additional information may be required, such as understanding the public opinion about your service. It is vital that a practical approach to collecting data is developed and integrated into your service so that it does not impact on the day-to-day workflow.

A simple method of collecting feedback from your service users could be in the form of a survey (example in [Appendix 1](#)). Your survey will need to be tailored to your service and what you are trying to find out:

- Keep it clear and simple; use closed questions as much as possible (i.e., yes/no, good/bad, etc.) and provide response categories for respondents to select — this will make the survey easier for your service users to complete and for you to analyse
- Keep it short (ideally, no longer than one page and taking less than five minutes to complete)
- Be careful not to include any sensitive questions
- Do not use jargon, abbreviations or vague terms
- Make sure you can keep all the information confidential and, if possible, anonymous
- Explain the purpose of the survey and what will you be doing with the information collected
- Avoid small fonts and limit number of different fonts used
- Make sure you proof read, review and user test to improve both the format and content prior to pilot

Data analysis can be a complex process and the approach taken will depend on the design of the evaluation. There is a plethora of resources available which provide useful guidance on how to analyse data. It is recommended that you explore further resources and seek expert assistance when required.

Examples of service impact/success measures may include:

- Total number of vaccinations provided and impact on vaccine update/rate, e.g., patients vaccinated in your pharmacy have not previously been vaccinated, the pharmacy increased accessibility to vaccines due to the service provided (no appointment required, location the pharmacy, etc.)
- Total number of responses/questionnaires received and service users' feedback

4.6.4 Top tips for service evaluation

Perfect evaluations are often not possible, and compromises will sometimes need to be made as a result of constraints on time, expertise and resources available. However, being aware of this from the outset should ensure you collect the most reliable and objective information possible. Some useful tips with the development of your evaluation are summarised below:

- Start planning your evaluation from the beginning so you can learn from it — ensure you have a comparator (baseline) and collate data/feedback continuously
- Be prepared for the likelihood of change when designing an evaluation — balance flexibility and robustness

- Explore whether similar evaluations have been conducted; others who have developed a similar service may be happy to share their learning and evaluation tools

Once your vaccination service is developed and established, you will need to ensure the service is continuously monitored to identify areas for improvement, such as improving documentation, procedures and cost-effectiveness. A robust evaluation can inform best practice and significantly influence decision-making so make sure you allocate time for careful planning and effective execution.

4.7 Service expansion and wider implementation

If service expansion is something you are considering, then this should be built into your evaluation. Findings from your evaluation will be able to tell you whether your service is meeting your users' needs, help you understand the public perception of your service, strengths and weaknesses, and whether roll out/expansion is feasible. If designed properly, the information collected as part of your evaluation will also be able to advise you on how best to expand your service. These may include:

- Improving your communication methods in order to increase vaccine uptake by your service users, or specific patient groups
- Increasing access to vaccine information by creating robust distribution systems that effectively reach service users, or particular hard-to-reach groups
- Improving access to your vaccination services — location and times offered
- Improving the efficiency and cost-effectiveness of your service
- Improving your systems, processes and procedures (including vaccination record systems)

It is important to stress that the information collected, including the robustness of the data, will be dependent on your evaluation design.

4.8 Additional practical tools and resources

Additional practical tools and resources can be found in [Appendix 2](#).

4.9 References

1. International Pharmaceutical Federation (FIP). An overview of current pharmacy impact on immunisation – A global report 2016. The Hague: International Pharmaceutical Federation; 2016. Available from: <https://www.fip.org/file/162> [cited 2019 Aug 16].
2. Immunization, Vaccines and Biologicals – Vaccines and Diseases. World Health Organization. Available online at <https://www.who.int/immunization/diseases/en> [Accessed 4 July 2019].

5 Developing a competent pharmacist workforce for vaccine-related roles

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Pharmacists play a key role in immunisation, including the safe supply and dispensing of vaccines. The accessibility and expertise of pharmacists also contribute to educating their patients and advocating for vaccination as part of health promotion initiatives and activities. Nonetheless, expanding pharmacists' scope of activity to administer vaccines themselves — as they are already authorised to do in several countries — will assuredly contribute to increasing vaccine coverage and ultimately improving the health of their communities. This opportunity thus sheds light on the need for the pharmacy workforce to develop and maintain the necessary competencies to safely and effectively deliver vaccination services.

The suggested set of competencies encompasses the knowledge, skills, and abilities to provide optimal services related to vaccines and should be considered according to the relevant framework and to the distinctive features of pharmacy practice of each respective country or territory. The competencies outlined in the American Pharmacists Association Pharmacy-Based Immunisation Delivery activity describe key information in determining the following competencies.¹

Competency 1: Integrate public health knowledge in advocating for vaccines

Knowledge regarding the legal, ethical and health implications of vaccinations is required by the pharmacy workforce because they interact directly with patients. The pharmacy workforce should be equipped to promote the benefits of vaccines for patients, communities and health systems, and to address any questions or concerns.

In countries where pharmacists can administer vaccines, the legal framework surrounding their authorisation to vaccinate is foundational and is thus required to be known, understood and applied by the pharmacy workforce. Educating patients regarding this legal framework also reinforces the breadth of potential ways in which pharmacists are invaluable partners in helping manage and improve their patients' health.

The potential health benefits of vaccines, at both individual and societal levels, are also important for the pharmacy workforce to comprehend and communicate to patients. The development of vaccines has led to the reduction in rates of diseases, even to the point of eradicating certain diseases that were once severe and even deadly.² Healthcare-associated costs to manage these diseases are also avoided through vaccination.²

Competency 2: Utilise principles of immunology, vaccine development and vaccine-preventable diseases to optimise vaccine services

The pharmacy workforce's knowledge of vaccine services is not only limited to the framework that surrounds it, but should also integrate immunological principles, adequate comprehension of the developmental process of vaccines and information on the specific diseases that are prevented by vaccination.

Grasping principles of immunology will essentially allow the pharmacy workforce to explain in appropriate, clear terms how vaccines work from a physiological perspective. The knowledge of passive and active types of immunity, the mechanism of action of vaccines, and the principles of herd immunity are among some of the essential topics to not only understand and integrate, but also to educate patients.^{1,3}

Furthermore, understanding how vaccines are developed is equally important, and knowing how to access information regarding doses, methods of administration as well as the characteristics of different vaccines are necessary to individualise vaccine administration.

The understanding of vaccine-preventable diseases is also an essential component in educating patients.^{1,3} The clinical features of these diseases that are prevented by vaccination, as discussed from a public health perspective, make up a

significant portion of reinforcing the benefits of vaccines. Information regarding vaccination regimens as well as the immunisation schedule are also important matters to discuss.

Competency 3: Utilise clinical judgement to screen patients as well as individualise and monitor vaccine therapy

The pharmacy workforce is required to put into practice their public health and theoretical knowledge of vaccines along with their clinical analysis to provide effective and safe vaccine services. Appropriate leaflets and informational resources should be provided to patients to furnish them with useful information regarding the vaccine.

The development of this competency is necessary to screen patients for vaccine eligibility, identify contraindications and precautions to administration of vaccines and individualise immunisation, as well as monitor for and manage potential adverse effects, among other measures.^{1,3}

Screening patients for vaccine eligibility as well as identifying contraindications and precautions to vaccine administration requires a proper analysis of the patient's health record and medication profile among other clinically relevant information. Pharmacy support personnel can also assist pharmacists in screening patients based on pre-determined algorithms and procedures.

The individualisation of vaccine therapy primarily consists of the analysis of the patient's characteristics, past medical history and medication profile, but also resonates with the principle of patient-centred care. For example, selecting the appropriate vaccine according to the immunisation schedule or the timing of other vaccines, as well as the preferred route of administration, are all part of the practical competency of pharmacists.⁴ Pharmacy support personnel can also assist pharmacists in individualising vaccination therapy by administering standardised questionnaires to patients to better understand their preferences.

The monitoring of adverse effects as well as their management is pivotal to the pharmacists' role in vaccination. With the authorisation to administer vaccines comes the responsibility of providing appropriate follow up, particularly for adverse events. Pharmacists should possess knowledge on the potential of adverse events, their incidence, their risk for harm, and their methods of management, including basic life support and management of anaphylactic reactions.⁵ Pharmacy support staff may also assist pharmacists by monitoring for any signs or symptoms that may be attributed to occurrence of any adverse effects that would require the attention of the pharmacist.

Competency 4: Ensure the safe administration of vaccines

Knowing how to safely administer vaccines is an important competency to be developed as well as be periodically reassessed. The knowledge of different sites of administration as well as methods of administration of intramuscular, subcutaneous, intradermal or intranasal vaccines are essential to ensure the safe administration of vaccines.

Having access to the necessary equipment to ensure secure administration of vaccines and proper disposal is equally important.

Competency 5: Optimise vaccination services in the pharmacy setting

The logistical requirements for offering optimal vaccine services, including the necessary infrastructure and equipment, must not be overlooked. The knowledge of these requirements and the capacity to set them in place in an organised manner remains a foundational competency to ensuring optimal vaccination services in the pharmacy setting.

Ensuring efficient pharmacist-led vaccination services begins with integrating knowledge on the current vaccine market, supply chain and local health services as well as utilising the necessary resources for construction, disposal and waste management, and information technology. Knowledge of the operational requirements of vaccination services to ensure the appropriate ordering, reception, storage and disposal of vaccines is an important competency to be acquired. Integrating these requirements is necessary to ensuring there are adequate physical spaces and informational resources to deliver optimal vaccination services.

Optimising vaccination services also includes developing and reviewing policies and procedures to address optimal workflow practices as well as utilising promotional strategies to advocate for pharmacist-led vaccination services.

By integrating public health knowledge, theoretical principles on immunology and vaccination, clinical analysis, and safe administration techniques with knowledge on the logistical needs of vaccination services, the pharmacy workforce will be well equipped to safely and effectively deliver services related to vaccines.

5.1 References

1. American Pharmacists Association. Pharmacy-based immunization delivery [Internet]. American Pharmacists Association; c2019 [cited 2019 Aug 2]. Available from: <https://www.pharmacist.com/pharmacy-based-immunization-delivery>
2. Andre FE, Booy R, Bock HL, Clemens J, Datta SK, John TJ, et al. Vaccination greatly reduces disease, disability, death and inequality worldwide. *Bull World Health Organ*. 2008 [cited 2019 Aug 2];86(2):81-160.
3. National Association of Pharmacy Regulatory Authorities. Supplemental competencies on injection for Canadian pharmacists [Internet]. National Association of Pharmacy Regulatory Authorities; 2017 [cited 2019 Aug 2]. Available from: [https://napra.ca/sites/default/files/2017-09/Supplemental Competencies on Injection for Canadian Pharmacists2012.pdf](https://napra.ca/sites/default/files/2017-09/Supplemental%20Competencies%20on%20Injection%20for%20Canadian%20Pharmacists2012.pdf)
4. McKesson. Building a patient-centered pharmacy immunization service [Internet]. McKesson; 2017 Oct [cited 2019 Aug 2]. Available from: <https://www.mckesson.com/blog/building-a-patient-centered-pharmacy-immunization-service/>
5. Advisory Committee on Immunization Practices. Preventing and managing adverse reactions [Internet]. Centers for Disease Control and Prevention; 2017 [cited 2019 Aug 2]. Available from: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html>

6 Learning from others: country case studies

For this toolkit, FIP invited its member organisations from countries where pharmacists have achieved vaccination authority or are currently advocating towards that goal to share their experience and key elements from their advocacy strategy with their peers from around the world, to establish a corpus of best practices and examples that can be extrapolated, adopted and adapted in other countries. These case studies follow (with a couple of exceptions) the structure below:

Point	Description
Key factors	Key factors to consider when advocating for pharmacist/pharmacy-based vaccination services — why was/is this a priority area? Top arguments for the introduction or expansion of vaccination authority for pharmacists or at community pharmacies.
Timeline	Summary timeline of the process towards achieving and/or expanding vaccination authority for pharmacists or at community pharmacies (key milestones: date and event).
Main challenges	Main challenges and obstacles that the organisation encountered.
Partnerships and support	How the organisation built partnerships and achieved support towards this goal: <ol style="list-style-type: none"> With/from other health professions With/from policy makers With/from the public
Mobilisation	How the organisation engaged and mobilised pharmacists/pharmacies in general and addressed resistance to change
Training and certification	How the training and certification for pharmacists to provide vaccination services works in the country
Professional standards and requirements	Existence and description of professional standards and requirements for pharmacy-based vaccination services, with internet links when available. <ol style="list-style-type: none"> For the service itself For providers (if pharmacists and/or pharmacy technicians) For premises and equipment
Vaccination records	The role of pharmacists/pharmacies in managing vaccination records, and namely if this is integrated with health systems and other providers
Assessment of pharmacist-led vaccination	Evidence of the impact of vaccination by pharmacists/pharmacies generated by the organisation or in the country (from pilot projects or post-implementation assessments, including links to studies when available).
Advice to other organisations	“Been there, done that” — tips and advice for other organisations

6.1 Argentina

Organisation:	Argentinian Pharmaceutical Confederation
Case study authors:	María Isabel Reinoso and Alicia Merlo
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6.1.1 Key factors

1. In Argentina, holders of a pharmacy degree are authorised to administer vaccines, although there are several differences between the 24 provinces. Due to their autonomy, each province may or may not adhere to the laws and resolutions issued by the National Executive Power, the Ministry of Health and the Argentine National Food, Drug and Medical Technology Administration.
2. Thanks to their accessibility, geographical distribution and extended business hours, pharmacies can conveniently provide vaccine services to patients. As Argentina has a large surface area, there are even pharmacies present in places where there are few or no hospitals and/or other healthcare facilities, which clearly shows their importance in providing health services within their communities.

6.1.2 Timeline

Date	Event
November 1958	Resolution 1732/58 of La Plata, province of Buenos Aires, initially authorised pharmacists to administer intramuscular or subcutaneous injections under medical indication. This regulation was extended by resolution 1460/1411 later in May 2011 to incorporate intradermal injections with the specific intention to enable vaccination by this route.
September 1983	Law 22.909 stated that vaccination was authorised in pharmacies under a prescription requirement as well as other specifications, such as recording of the vaccination procedure. Through the years, pharmacies across different jurisdictions in Argentina have implemented vaccination services that are required to comply with the minimum conditions for vaccination centres.
May 1995	The requirements were set out in resolution MSP 67/95 of the National Law for Pharmacy Practice 17565/67 and in specific standards for each jurisdiction. The various legal documents include detailed specifications on the premises, equipment, materials and waste.
February 2004	The Argentinian Pharmaceutical Confederation (CoFA) Standard No. 4/04 defined the standards and provides guidelines and recommendations for the administration of vaccines and injectable medicines in pharmacies.
2018	Law 27491 was enacted to describe public policy regarding the control of vaccine-preventable diseases. ¹

6.1.3 Main challenges

- Raising awareness and achieving the commitment of pharmacists for the administration of vaccines
- Allowing for the administration of vaccines included in the official vaccination schedule to be provided free of charge by law when administered in hospitals and healthcare facilities
- Achieving public-private partnerships to support this activity; for the time being, partnerships have been established for the influenza vaccine and the anti-pneumococcal vaccine

6.1.4 Partnerships and support

- a. With/from other health professions

None described.

- b. With/from policy makers

Partnerships were established through amendments of laws and resolutions. CoFA negotiations took place with different sponsors who recognise pharmacies as healthcare facilities and as integral parts of communities, playing an important role in health prevention and promotion.

- c. With/from the public

The public advocated for the administration of vaccines in pharmacies due to the proximity of pharmacies to their homes as well as their extended business hours and walk-in basis. In addition, the trust that patients have in their pharmacist is an important asset, reaffirming the importance attributed to pharmacy services by the community.

6.1.5 Mobilisation

Thanks to the creation of a cascade immunisation course in 2000, approximately 4,000 pharmacists across the country were trained and updated on matters regarding vaccination and immunisation.

6.1.6 Training and certification

Pharmacists who wish to administer vaccines in their pharmacy premises must obtain the required certification as well as successfully complete refresher courses on immunisation, approved by the competent authorities, including CoFA and other various organisations. Of note, the pharmaceutical organisations in Argentina are regional associations and are all members of CoFA.

All healthcare professionals providing vaccination services must possess the required knowledge and apply the current vaccination standards for the administration of vaccines, as well as ensuring the cold chain and biosafety of vaccines. There is a range of different training courses available across the 24 jurisdictions whose contents may vary significantly. For example, a standard training course may include 60 hours of face-to-face and/or distance learning on vaccine preservation and elimination, measures to take in case of a power outage, vaccine administration techniques, novel vaccines and strains, warnings and precautions, surveillance of adverse events potentially attributable to vaccination or immunisation and anaphylaxis. Although review requirements are not defined, annual updates on the training contents are provided.

A guide describing vaccination as part of pharmaceutical services in primary health care was developed in 2018.²

6.1.7 Professional standards and requirements

- a. For the service itself

CoFA Standard No. 4/04 of February 26, 2004 describes the standards and provides guidelines and recommendations for the administration of vaccines and injectable medicines in pharmacies.

- b. For providers

As above.

- c. For premises and equipment

An operating guide was developed by the Ministry of Health which outlines basic principles for safe vaccination.³ http://www.msal.gov.ar/images/stories/bes/graficos/0000001461cnt-2019_guia-operativa-vacunacion-segura.pdf

There are also standards and requirements regarding premises and equipment outlined in official documents. For example, particularly for the province of Buenos Aires, there are requirements regarding premises and equipment set forth in decree 3521/00 — Pharmacy Authorisation Requirements, article 12.⁴

In addition, for the province of Entre Ríos, there is legislation endorsing the administration of injectable medicines, including the requirement from the provincial Ministry of Public Health to have installed a cabinet for the administration of vaccines in pharmacies.

Law 3818: <http://www.entrierios.gov.ar/msalud/wp-content/uploads/2017/02/ley3818.pdf>

Law 9817: <https://www.cofaer.org.ar/mvc/5/index.php?action=Noticia::main&id=996>

6.1.8 Vaccination records

For vaccination campaigns carried out for beneficiaries of the social security system, vaccines should be validated through a computer system, including information regarding the member as well as the type of vaccine administered. Vaccines administered outside the social security system are entered in the vaccination record.

One of the main limitations for a greater development of pharmacy-led vaccination in Argentina is the limited acceptance and support from the government and the health system. Currently, pharmacies do not possess adequate vaccine stock for the national immunisation programme. For the time being, the community pays for pharmacy-based vaccination services, and reimbursement programmes only apply in certain situations.

Vaccination records are mandatory in the public sector in Argentina; however, currently there is no systematic recording of vaccine administration in the private sector, including pharmacies. Nevertheless, as defined in CoFA Standard no. 4/04 of 8 October 2012, pharmacies are required to maintain a registry of vaccines and injectable medicines administered. This registry is required to be organised by month of administration as well as utilise specific identification numbers. It is also required to maintain information regarding the age and gender of the patient as well as the type and dose of the vaccine administered.

Vaccinations are also required to be recorded in a specific vaccination card that should be given to each patient. Individual certificates of immunisation for children, adolescents and adults are available from the website of the Ministry of Health, and there is also an international certificate of vaccination or prophylaxis. At the present time, recorded vaccination information is not shared across pharmacies, and there is no interaction between the private and public sectors. Official data published by the Ministry of Health only relates to the public sector as data from pharmacy-based vaccinations is not officially used or analysed.

6.1.9 Assessment of pharmacist-led vaccination

A table from 2010 to 2018 summarising the number of pharmacies that have adhered to influenza vaccine and anti-pneumococcal vaccine campaigns for pensioners covered by the national social security system as well as types of vaccines administered can be found below. The vaccination period has not ended in 2019.

	Number of pharmacies offering vaccination	Influenza (number of vaccinations)	Pneumococcal 13 (number of vaccinations)
2010	3,431	323,047	
2011	3,800	697,631	
2012	3,712	547,816	
2013	3,801	503,585	
2014	3,269	377,596	
2015	3,571	329,305	
2016	3,710	630,074	
2017	3,716	529,555	96,278

2018	3,831	532,919	208,100
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Source: CoFA

6.1.10 Advice to other organisations

- Expand pharmacists' responsibilities in vaccination services
- Maintain continuous training on vaccination and immunisation

6.1.11 References

1. Argentinian Government. Law 27491 [Internet]. Argentinian Government; 2018 [cited 2019 Jul 21]. Available from: <https://www.boletinoficial.gob.ar/detalleAviso/primera/199515/20190104>
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6.2 Australia

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6.2.1 Key factors

1. Public attention has typically focused on improving vaccination rates in children; however, the largest unvaccinated group of people recommended for immunisations are adults. Of 4.1 million unvaccinated Australians, 92% (3.8 million) are adults and only a small fraction are children.
2. Access to vaccination has unnecessary barriers. Increasing access to vaccination increases immunisation coverage. In the state of New South Wales (NSW), pharmacist-led vaccinations were restricted to influenza in adults 18 years and over. It was proposed this be expanded to include measles-mumps-rubella (MMR) and diphtheria-tetanus-pertussis (dTpa) vaccines and the age of administration be lowered in order to maximise access.
3. Pharmacists are skilled and a highly accessible workforce with appropriate levels of training that could be mobilised quickly in times of emergency (e.g., pandemic). Trained pharmacists already deliver influenza vaccinations intramuscularly or subcutaneously so are well placed to offer other vaccination services to build herd immunity.

4. Evidence suggests that a significant proportion of patients accessing vaccination services through community pharmacies would not have otherwise been vaccinated. A proportion of these patients are also willing to pay for the administration.
5. Clinical need:
 - Recent outbreaks of MMR (in 2018) and subsequent measles alerts issued by the health department highlighted the need for greater awareness, access and coverage. With measles being highly contagious and with travellers representing a potential target, community pharmacists are well placed to intercept and administer MMR.
 - Pertussis is also highly contagious. Pertussis epidemics typically occur every three to four years, and it is expected that cases will continue to increase into 2019. The last major outbreak was in 2015/16, when almost 7,000 people became ill between October and December 2015. Parents and grandparents in contact with newborns are encouraged to be vaccinated, and community pharmacy creates the opportunity for better vaccination coverage.

6.2.2 Timeline

Date	Event
January 2018	Health department engagement
March 2018	Development of policy and detailed description
March–August 2018	More than 80 stakeholder meetings with members of parliament, other organisations, health department representatives
July 2018	Announcement of election promise by opposition to expand vaccination services by pharmacists in NSW
August 2018	Meeting with NSW Health Minister and proposed expansion of MMR and DTPa accepted with a decrease in age to 16 years for all vaccines (based on age of consent at a state level)
23 November 2018	Regulation change announced on expansion of vaccination services by pharmacists https://www.legislation.nsw.gov.au/regulations/2018-656.pdf
1 December 2018	Online transition module available to pharmacists who have already undertaken the training in preparation for 1 January 2019 implementation date
1 January 2019	NSW Regulation change active
June 2019	Estimated 2,000 pharmacists with new qualification Flu vaccinations hit record numbers (with another 400,000 ordered for the private market) highlighting greater awareness and uptake of pharmacist administered vaccines

6.2.3 Main challenges

- Resistance by the Department of Health to expand vaccination — vaccination was seen as a “tool” to facilitate patients seeing a doctor
- Medical groups opposed to vaccination and the potential to “fragment care”
- Lack of public health awareness around the availability of vaccinations through community pharmacy

- Supply of specific vaccines to the private market and government-funded programmes confusing pharmacists, GPs and patients
- Time required to review evidence and develop policies (in conjunction with other key initiatives)

6.2.4 Partnerships and support

a. With/from other health professions

- Working with the Pharmacy Guild of Australia in NSW to develop a joint immunisation policy paper specific to state needs, joint briefing that highlighted key messages, and the call to action for an expansion of vaccinations through community pharmacy
- Engaging with nurse immunisers in delivering the practical components of the workshop as well as assessing pharmacist competence in the administration of vaccines according to recognised standards
- Communicating with medical groups in consultation with the department — e.g., establishment of a vaccination working group targeting a coordinated approach to the flu season and an established toolkit for all providers (GPs nurses and pharmacists)
- Federal engagement — with medical groups and consumer groups

b. With/from policy makers

- Working with researchers to support gathering evidence for expansion of vaccination services — e.g., the NSW PSA president published a paper on the success of influenza vaccination in community pharmacy highlighting that a significant proportion of people being vaccinated by pharmacists for influenza would not have otherwise have been vaccinated
- Conducting meetings with all political parties at a state and federal level utilising a joint policy document by PSA and the Pharmacy Guild of Australia, as well as a summary briefing with key messages was effective in reinforcing commitment being sought by government and the positive impacts for the community
- Ensuring NSW department communication and collaboration across various units and stakeholders including the chief medical officer, chief pharmacist, legal team, regulatory unit and infectious diseases team

c. With/from the public

- The PSA commissioned a Galaxy Poll survey (consumer survey) to be conducted that showed almost two-in-three Australians believe pharmacists should be able to administer common vaccinations that are currently only administered by doctors; the nationwide poll also found that 64% of Australians support pharmacists administering common vaccines, with greater convenience cited as a benefit by 62% of respondents
- Several articles in the press were written, outlining the impracticalities of current legislation and access to vaccination (e.g., parents being unable to vaccinate their teenagers in the same place they received their vaccinations)

6.2.5 Mobilisation

With a significant proportion of pharmacists in NSW trained in influenza vaccinations, the PSA ensured online training was made available within a month of the announcement of vaccination expansion and was easily accessible to pharmacists in regional and remote locations.

The PSA implemented a communications plan around pharmacists' expansion in NSW so that training could occur prior to the effective date of change in state regulation on 1 January 2019. Pharmacists who had undertaken previous training were targeted in the first instance to enrol in the online transition module.

The second wave targeted pharmacists who had not undergone any prior training and were seeking to undertake the required training to become accredited vaccinators.

A number of bulletins and articles were utilised during this time to reinforce the regulation change, benefits to the community and opportunity for pharmacists.

Since 1 January 2019, in NSW over 30 workshops have been delivered (with more scheduled) and over 1,000 pharmacists have completed the required training to vaccinate patients 16 years and over against influenza, dTpa and MMR through the PSA alone. Overall, it is estimated 2,000 pharmacists have completed the training in NSW.

6.2.6 Training and certification

Pharmacists must complete an accredited training course that complies with the Australian Pharmacy Council “Standards for the accreditation of programmes to support pharmacist administration of vaccines”.

The accredited training provider issues a certificate confirming competency to vaccinate following completion of the accredited training programme (for all authorised vaccines that the pharmacist intends to administer).

Pharmacists must ensure that they have completed training for all authorised vaccines that they intend to administer. Pharmacists must also have current certification in anaphylaxis, first aid and CPR (CPR certification must be completed annually).

Previously in NSW, enrolment in the programme was limited to registered pharmacists and provisionally registered pharmacists (interns). In NSW trained pharmacy interns can administer vaccinations under supervision by a registered pharmacist who is a certified vaccinator. The training has now been expanded to include pharmacy students enrolled in Australian accredited pharmacy degree programmes.

6.2.7 Professional standards and requirements

a. For the service itself

There are the NSW Vaccination Standards, with each state health department setting the standards of delivery according to jurisdiction. These standards outline the scope of vaccination services permitted, requirements for pharmacist training, practice standards pertaining to recording vaccinations, pharmacy premises and equipment, patient consent and availability, management of adverse events and post-vaccination care.² The NSW Influenza Vaccination Provider Toolkit was developed in 2019 to assist with the implementation of pharmacist-led vaccination.³

b. For providers (if pharmacists and/or pharmacy technicians)

For providers, the NSW Vaccination Standards and the Influenza Vaccination Provider Toolkit provide useful information.^{2,3} Information on pharmacist initiation and administration of vaccines by NSW Health as well as the PSA Immunisation Resource Hub are also readily available.^{4,5}

c. For premises and equipment

Standards and regulations for premises and equipment are outlined in the NSW Vaccination Guidelines.² The PSA Immunisation Guidelines, as well as the Pharmacy Guild Guidelines entitled “Pharmacy Guild of Australia guidelines for conducting pharmacist initiated and administered vaccination services within a NSW community pharmacy environment”, provide useful information.⁶

6.2.8 Vaccination records

Pharmacists are required to record vaccinations. This is typically done through the dispensing software in community pharmacy or through clinical services platforms such as GuildLink, which is integrated directly to the Australian Immunisation Register (AIR), the national register that records vaccines given to people of all ages across Australia. All

vaccines administered by the pharmacist must be reported in the AIR. Recently Australia has also implemented electronic health records (MyHealthRecord) which is also integrated with AIR (not all Australians have a MyHealthRecord, and patients can control what medicines are recorded).

6.2.9 Assessment of pharmacist-led vaccination

In NSW, there was no pilot project that led to expansion. The evidence from international and Australian studies along with clinical need were sufficient to lead to a regulation change.

A post-implementation assessment of influenza vaccinations administered by pharmacists was conducted and used in the policy document development.⁷ Several other studies have also been conducted.^{8,9}

6.2.10 Advice to other organisations

- Resilience and persistence are key — every interaction with key stakeholders is an opportunity to bring them with you on a journey
- Keep the message simple — develop a story starting with the need, the opportunity and the benefits
- Focus on the patient and community health benefits vs. benefits to pharmacists
- Utilise real-life examples in your discussions with key stakeholders — patients who have had trouble accessing vaccines, recent outbreaks etc.
- Work with others — you cannot achieve it alone
- Challenge thinking within the health department and with members of parliament — if you believe it is important, then it is
- Empower your members (or other pharmacists) to spread the word and meet with key influencers and local members

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6.3 Brazil

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6.3.1 Key factors

1. Pharmacist-led immunisation, in addition to the consolidation of clinical practice and the establishment of pharmacies as health care facilities, highlights the importance of pharmaceutical professionals in Brazil's pharmacies and in the public, free, and universal National Immunisation Programme.
2. For vaccines that are not part of the public National Immunisation Programme, patients can access them in different locations, such as pharmacies, which are convenient given their close proximity to patients' homes and their extended opening hours.
3. When vaccines were initially offered in pharmacies, there was a reduction in their price provided by private hospitals and health clinics. The Institute for the Defence of the Consumer (IDEC) conducted a study on the prices of vaccines offered in the private sector, and the results showed that patients were able to find cheaper vaccines in pharmacies.¹
4. As immunisation hesitancy is large in Brazil and in other parts of the world, patients can rely on pharmacists and pharmacies to engage in educational health campaigns, to dispel myths and to educate the population about vaccine-preventable diseases.
5. Data from the Ministry of Health in Brazil show that rates for immunisation coverage have drastically decreased among adults and elderly. This represents an opportunity for pharmacists and pharmacies to educate patients about the importance of immunisation for those age groups.
6. In Brazil, pharmacists have had, for many years, the legal right and technical competence to provide injectable medicines (contraceptives, vitamins, anti-inflammatory medicines, hormones, anticoagulants, insulin, etc). Such previous experience was important in the process of expanding the scope of pharmacists, such as in providing immunisation services.

6.3.2 Timeline

Date	Event
1973	Law 5991 regulated the administration of injectable medicines in pharmacies. ²
2009	Resolution 44 of the National Agency of Health Surveillance (Anvisa) regulated the administration of medicines in pharmacies in the context of pharmacotherapy. ³
2010	A group of pharmacists claimed, through the "Letter of Itapema", that the Brazilian Federal Council of Pharmacy regulate the professional practice of pharmacists in immunisation, and advocated for the regulation of vaccine administration in pharmacies by Anvisa.
2013	The Brazilian Federal Council of Pharmacy (CFF) issued Resolution 574, which regulated the dispensing and administration of vaccines by pharmacists in pharmacies. ⁴
2013	The CFF issued Resolution 585, which regulates clinical roles of pharmacists. ⁵
2014	Pharmacies, with the issuing of Law 13021, started to offer vaccines and serums for commercialisation. However, Ordinance 1/2000 (Anvisa/Funasa), allowed only for medical doctors to be responsible for health care facilities that administered vaccines (pharmacists were not authorised). ⁶

<p>2014–17</p>	<p>Several laws and resolutions were issued regulating the administration of vaccines by pharmacists in pharmacies in different Brazilian cities and states:</p> <ul style="list-style-type: none"> • Law 16473/2014 in the state of Santa Catarina⁷ • Technical Note 03/2016 regarding health surveillance in the state of Paraná⁸ • Ordinance SES 445/2017 in the state of Rio Grande do Sul⁹ • Law 4527/2017 in the state of Amazonas¹⁰ • Law 5884/2016 in the city of Sumaré, state of São Paulo¹¹ • Complementary Law 381/2016 in the city of Piracicaba, state of São Paulo¹²
<p>2017</p>	<p>Anvisa issued Resolution 197, which regulated the minimum requirements for human immunisation services. That health legislation was a turning point for pharmacists, as it did not limit the technical responsibility of immunisation services to medical doctors; rather, it offered pharmacists the opportunity to be professionally responsible for healthcare facilities where vaccination services are provided, in addition to administering vaccines themselves.¹³ This resolution applies to all types of vaccination centres: public, private, charity-led, civil, and military. Anvisa also issued Technical Note 01/2018 (GRECS-GGTES) to assist professionals in understanding several points of Resolution 197.¹⁴</p>
<p>2018</p>	<p>The CFF issued Resolution 654, which regulates the necessary requirements for immunisation services provided by pharmacists. This resolution could finally be fully implemented because the health legislation issued in 2017 allowed pharmacists to be technically responsible for healthcare facilities that offered vaccination services (including pharmacies).¹⁵</p>

6.3.3 Main challenges

The main challenge was to overcome the resistance of other professionals who conceived pharmacist-led immunisation as a threat, especially in the labour market. The biggest opposition was from medical doctors and nurses. The obstacles started to arise when lawsuits were filed by both professions against the role of pharmacists in immunisation.

Another challenge is the impossibility of following the first response protocol in cases of anaphylaxis, as pharmacies are not allowed to stock adrenaline. It is necessary to change this health regulation, as this medicine can only be dispensed with a medical prescription and is exclusively used in hospitals. Therefore, pharmacies are unable to acquire adrenaline to use in case of emergencies. The 10ml flask of physiological saline is also restricted to hospitals in Brazil. Also, in Brazil, the EpiPen is not registered by Anvisa.

Increasing the number of pharmacists licensed to offer immunisation services also represents a challenge. In the initial phase of implementation of pharmacist-led vaccination. The following states and pharmacy chains were identified as offering the implemented service:

- Rio Grande do Sul: Panvel, Tchê, Farmácia Associadas, Agafarma
- Santa Catarina: Catarinense, Panvel and Raia
- Paraná: Vale Verde, Nissei, Panvel
- Mato Grosso: Multidrogas Network, Unifarma in the city of Ivinhema
- Minas Gerais: Araújo and Farmácia Indiana
- São Paulo: Onofre, Raia, Drogasil, Panvel, Drogaria São Paulo
- Rio de Janeiro: Venâncio, A Nossa Drogaria, Drogaria Moderna, Retiro
- Ceará: Fortaleza

Another challenge is increasing the number of courses providing training in basic life support, which will have an impact in the education of immunising pharmacists. The health legislation does not currently require compulsory training on basic life support, but CFF Resolution 654 recommends it. There is increasing advocacy by the Regional Councils of

Pharmacy and the Brazilian Society of Community Pharmacists and Pharmacies for training in basic life support for immunising pharmacists.

6.3.4 Partnerships and support

a. With/from other health professions

Rather than support, several challenges were encountered when trying to establish partnerships with other health professions.

b. With/from policy makers

Partnerships with policy makers were achieved through:

- Advocacy for the support of projects of federal and state laws
- Joint work with the parliamentary front of pharmaceutical care
- Advocacy among all the organisations representing the profession through a forum created to define strategies for the pharmaceutical profession
- Working with a consultancy firm on parliamentary matters in addition to creating a working group dedicated to these matters and to the follow-up of law bills related to the profession
- Meeting with the Ministry of Health and the president of Anvisa to claim health regulation reforms after Law 13021
- Approaching the Regional Councils of Pharmacy with the local health surveillance agencies to align strategies of professional and health inspection

c. With/from the public

- The Brazilian Society of Immunisation started to receive pharmacists as possible professionals to join the association, which historically had only included medical doctors and nurses
- The role of the pharmacist in immunisation was promoted to the population through media advertisement, clarifying and marketing the role of the pharmacist as a provider of immunisation services
- Leaflets were made available to promote immunisation offered by pharmacists; these leaflets were produced by the Regional Councils of Pharmacy¹⁵
- Private pharmacies also undertook their own marketing strategies to promote the implementation of the immunisation services

d. Organisations related to the profession

Efforts were made to garner support from organisations such as the Brazilian Society of Community Pharmacists and Pharmacies, the Brazilian Association of Pharmacies and Drugstores (Abrafarma), the Regional Councils of Pharmacy and other organisations related to the profession and pharmacies.

6.3.5 Mobilisation

The Brazilian Federal Council of Pharmacy coordinated the creation of the National Advocacy Forum for the Recognition of the Value of the Pharmacy Profession, a political movement which acted upon the approval of Law 13021/2014. This law recognised Brazilian pharmacies as healthcare facilities, enabling the administration of vaccines in pharmacies, Article 7.¹⁶

Anvisa participated in political and technical work to ensure the implementation of the new health regulation for the provision of immunisation services in pharmacies and that the pharmacist could be professionally responsible for those services. This action resulted in the publication of the Resolution 197/2017 (Anvisa).

Through a specific working group, consisting of experienced immunisation pharmacists, a professional resolution was produced aiming to define the necessary requirements for the pharmacist to work with vaccines (Resolution CFF 654/2018).

The professional regulations were based on the standards and requirements defined in the documents of the governmental National Immunisation Programme.

6.3.6 Training and certification

The training and licensing for pharmacists working with vaccines are carried out by complementary continuing education courses accredited by the Brazilian Federal Council of Pharmacy. The council elaborated the minimum requirements for the provision of immunisation services by pharmacists through Resolution 654/2018.

Another method for the accreditation of pharmacists working in immunisation is a postgraduate course in a university recognised by the Ministry of Education that meets the requirements of Resolution 654/2018 (CFF). A pharmacist may also attend a course offered by the public National Immunisation Programme.

According to Resolution 654/2018 (CFF), pharmacists must demonstrate to Regional Councils of Pharmacy that they possess a minimum of 12 months of professional experience and that they are able to act in the area of immunisation.

Resolution 654/2018 (CFF) recommends that pharmacists attend a course on basic life support to work in immunisation.

Many Brazilian organisations offer courses to encourage the provision of immunisation services by pharmacists, and all those courses are accredited by the Brazilian Federal Council of Pharmacy, such as: Society of Community Pharmacies, universities, Abrafarma, and Regional Councils of Pharmacy. Some of these courses are available online on the following links:

- <https://crfrs.org.br/portal/pagina/eventos-detahes.php?ide=981>
- <http://ibras.com.br/cursos/servico-de-vacinacao-em-farmacias-da-implantacao-seguranca-na-pratica-da-aplicacao/>
- <http://crfms.org.br/noticias/cursos/4404-inscricoes-abertas-para-curso-sobre-vacinacao-humana-undefined-habilidade-em-imunizacao-para-farmaceuticos>
- <https://sincofarma.org.br/cursos/imunizacao-e-administracao-de-vacinas/>

6.3.7 Professional standards and requirements

- a. For the service itself

The minimum requirements for the immunisation services are described in the health legislation of Anvisa (Resolution 197/2017).⁷ Some of these requirements are:

- The need for the management of technologies and processes of the service, which include appropriate infrastructure for the conservation and use of vaccines that are registered or authorised by Anvisa
- Immunisation services must adopt procedures to ensure the quality of the vaccines during transportation
- Immunisation services must ensure the immediate management of potential problems related to vaccines
- The administration of vaccines that are not listed in the National Immunisation Programme will be carried out only with a medical prescription
- Information regarding the administration of vaccines must be registered in the immunisation card of the patient and in the digital system defined by the Ministry of Health
- Records on each patient concerning administered vaccines must be kept
- Records on the origin of the vaccines must be kept available
- Adverse effects after vaccines must be notified as determined by the Ministry of Health
- Immunisation errors must be notified in the Anvisa system

- Accidents and failures that may have contributed to immunisation errors must be investigated
- b. For providers

For providers, the requirements are defined in Resolution 654/2018 (CFF) and in the health legislation of Anvisa, Resolution 197/2017.^{7,14} Some of these requirements are:

- Requirements for the pharmacist according to Resolution 654/2018 (CFF): Successfully completing a continuing education course (complementary) that meets the minimum requirements established in the Appendix of Resolution 654/2017. The course must be accredited by the Brazilian Federal Council of Pharmacy or recognised by the Ministry of Education, or be offered by the National Immunisation Programme. It is recommended that the pharmacist attends a review course annually regarding the theoretical contents related to the immunisation service and the National Immunisation Programme. It is also recommended that the pharmacist attends a course of basic life support.
 - Requirements for the pharmacist according to Resolution 197/2017 (Anvisa): Professionals who work in immunisation must be periodically trained for the service regarding the following topics: waste management, registration related to vaccines, investigation and notification of adverse effects after vaccine administration, knowledge of the vaccine calendar proposed by the National Immunisation Programme and procedures in case of potential problems.
- c. For premises and equipment

For premises and equipment, the requirements are defined in the health legislation of Anvisa (Resolution 197/2017). Some of those requirements are that the healthcare facility must:

- Have a specific health licence to provide immunisation services
- Be registered in the National Registry of Health Care Facilities (CNES)
- Have appropriate infrastructure for the immunisation service

6.3.8 Vaccination records

Issues regarding registration of vaccines are described in Articles 5 and 6 of Resolution 654/2018 (CFF) and in Section V of Resolution 197/2017 (Anvisa).^{7,14} The notification system for adverse effects by Anvisa and the Information System by the National Immunisation Programme are not yet integrated within pharmacy systems, but professionals are required to notify adverse effects in the Anvisa system. After the publication of these regulations, the Anvisa Management of Pharmacovigilance system joined the Uppsala Monitoring Centre (UMC) and set up VigiMed, a new system of registration, processing and sharing of adverse effects of medicines and vaccines.

On the management of registration of vaccines according to Resolution 654/2018 (CFF):

- Vaccines administered in pharmacies must be notified by the pharmacist on the Anvisa system, in case of incidents, adverse effects or technical complaints
- Information on dosages of administered vaccines must be registered by the pharmacist in the patient's immunisation card, in the information system defined by the Ministry of Health and in the medical records of the patient
- Every month, the secretaries of health from each city must receive information on the dosages administered, following the standard model of the Information System of the National Immunisation Programme
- Pharmacists must provide a declaration of the service to the patient

On the management of the registration of vaccines, according to Resolution 197/2017 (Anvisa):

- Information regarding the administration of vaccines must be registered in the patient's immunisation card of and in the information system defined by the Ministry of Health
- A medical file must be kept for each patient regarding the administered vaccines
- Registers on the vaccines origin must be kept
- Adverse effects after vaccine administration must be notified as determined by the Ministry of Health
- Immunisation errors must be notified in the Anvisa system
- Accidents and failures that may have contributed to immunisation errors must be investigated

6.3.9 Assessment of pharmacist-led vaccination

There is an ongoing pilot project for post-implementation assessment, evaluating whether immunisation pharmacists and the offer of immunisation services have influenced the country's immunisation coverage.

6.3.10 Advice to other organisations

- Brazil's case presents not only a great opportunity for pharmacists, but also a portrait of previously encountered challenges. There is a large number of vaccines defined by the National Immunisation Programme which allows pharmacists to play an important role in immunisation. However, vaccines that are not listed in this programme may only be administered with a medical prescription.
- The expansion of immunisation services to pharmacies has contributed to the increase of accessibility to vaccination, as pharmacies have flexible hours, and have also contributed to decreasing the price of these medical products.
- Implementing this pharmacist-led service has required much effort to tackle several challenges, ultimately to reaffirm the role of pharmacists as health professionals who contribute to health promotion and prevention of diseases.
- This movement also contributes to enhancing the visibility of the profession. Adequately advocating for our profession requires strong leaders with political skills to align organisations with shared goals and the academic sector.

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6.3.12 Other resources

Links to other publications by the Ministry of Health (in Portuguese):

1. Vaccination procedure guidelines
http://bvsmms.saude.gov.br/bvs/publicacoes/manual_procedimentos_vacinacao.pdf
2. Guidelines for the epidemiological surveillance of vaccination adverse events
http://bvsmms.saude.gov.br/bvs/publicacoes/manual_vigilancia_epidemiologica_eventos_adversos_pos_vacinacao.pdf
3. Cold chain management
http://www.saude.pr.gov.br/arquivos/File/rede_frio_2017_web_VF.pdf
4. Handbook for Reference Centres for Special Immunobiologicals
http://www.saude.pr.gov.br/arquivos/File/-01VACINA/manual_crie_.pdf

6.4 Canada

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6.4.1 Key factors

1. Immunisation rates

- Each year, the flu causes more than 12,000 hospitalisations and 3,500 deaths in Canada.¹
- Canada's 2025 vaccination coverage goals are to achieve 80% vaccination coverage (one dose) of a pneumococcal vaccine among adults 65 years of age and older and 80% vaccination coverage (one dose per season) of an influenza vaccine among adults aged 65 years of age and older and among adults 18–64 years of age with high risk conditions.
- Canada's actual influenza vaccination rate for those over 65 years of age lags behind other developed countries such as New Zealand, the United States and the United Kingdom.² In the 2016–17 season, influenza coverage was 69% among adults aged 65 years of age and older, 37% among adults aged 18–64 years with medical conditions, and 36% among adults 18 years and older.³
- In 2016, the vaccination rate for pneumococcal infection in Canada for people 65 years and older was estimated at 42%.⁴
- Governments are eager for low-cost options to increase immunisation rates to mitigate the health and economic consequences of the flu.

2. Pharmacists can reduce barriers to immunisation

- Vaccine hesitancy: Pharmacists are well-positioned to provide vaccine education, dispel myths, discourage complacency and encourage patients to get vaccinated.
- Barriers to access: Lack of access to family physicians, local clinics or limited opening hours of available clinics mean that many patients may face considerable barriers to obtaining vaccines, especially those in rural areas or those who otherwise have difficulty accessing the health care system (e.g., language barriers, socioeconomic status).

3. Accessibility of pharmacists

- Pharmacists are the most accessible health care provider. They can be seen without an appointment and most pharmacies are open late and at weekends. Patients see their pharmacist up to 10 times more often than they see their family doctor.
- A 2018 [national poll](#) conducted by Abacus Data found that 78% of Canadians would visit a pharmacist for the flu shot and 67% would visit a pharmacist for other vaccinations.⁵

4. Health care system efficiencies

- Given the scarcity of healthcare resources and backlogs seen in all areas of the system, pharmacist-delivered immunisations can help offload patients from community clinics and allow physicians and nurses to focus scarce resources on patients in need of more specific care that only a family physician or nurse can provide.

6.4.2 Timeline

Date	Event
2007	Alberta <ul style="list-style-type: none"> Pharmacists authorised to administer flu and all other vaccines/injections Only pharmacists with advanced prescribing authority can also prescribe publicly funded vaccines beyond the flu shot and other injectable drugs CA\$13 publicly funded fee for service (reduced from \$20 on 17 May 2018)
2008	New Brunswick <ul style="list-style-type: none"> Pharmacists authorised to administer flu and other vaccines \$12 publicly funded fee for service for flu vaccines only, and only to individuals at high risk of influenza complications as well as for members of their households
2009	British Columbia <ul style="list-style-type: none"> Pharmacists authorised to administer flu and other vaccines/injections \$10 fee for service for publicly funded vaccines
2012	Ontario <ul style="list-style-type: none"> Pharmacists authorised to administer flu and other vaccines \$7.50 fee for influenza vaccination only under publicly funded programme (\$5 for nasal spray).
2013	Nova Scotia <ul style="list-style-type: none"> Pharmacists authorised to administer flu and other vaccines \$12 publicly funded fee for service for flu vaccine only
2014	Manitoba <ul style="list-style-type: none"> Pharmacists authorised to administer flu and all other vaccines/injections \$7 fee for service only for publicly-funded vaccines Prince Edward Island <ul style="list-style-type: none"> Pharmacists authorised to administer flu and all other vaccines/injections Dispensing fee for flu vaccine only (\$12.36) Newfoundland and Labrador <ul style="list-style-type: none"> Pharmacists authorised to administer flu and all other vaccines/injections \$13 publicly funded fee for service for flu vaccine only
2015	Saskatchewan <ul style="list-style-type: none"> Pharmacists authorised to administer flu and all other vaccines/injections \$13 publicly funded fee for service for flu vaccine only
2020	Quebec <ul style="list-style-type: none"> Quebec is the last jurisdiction in North America that does not allow pharmacists to administer vaccines Legislation has been tabled to amend regulations to allow pharmacists to administer vaccines

6.4.3 Main challenges

- Pushback from physicians/nurses:
 - Lack of awareness and confidence from other healthcare professionals about pharmacists' education and training to ensure patient safety
 - Concerns about own lost revenue and scope creep from pharmacists
- Immunisation authority required support from pharmacy regulatory bodies:
 - Regulators act on behalf of patient safety and interest are the key players working with government to make changes to pharmacy legislation and regulations

- Until recently, the Quebec College of Pharmacists has been reluctant to make immunisations a priority; therefore, Quebec is the last jurisdiction (outside the Canadian territories of Northwest Territories, Nunavut and Yukon) in North America to enable pharmacists to provide vaccinations
- Pharmacists' reluctance to provide service:
 - Initial reluctance to provide immunisation services could be attributed to the need for physical contact with patients and the lack of perceived value from offering these services
 - This was more of a challenge when the move toward pharmacist immunisations was first gaining ground
 - Most employers now require that pharmacists are certified in injections as a condition of employment
- Pharmacy workflow and staffing:
 - Pharmacists and managers worried about workflow interruptions with vaccination services
 - Pharmacies with only one pharmacist on staff may have to make some patients wait while they offer vaccines to others
- General apathy among the public about obtaining vaccines
- Lack of awareness of pharmacists as immunisers among the public
- Inadequate vaccine allocation to pharmacies
- Inadequate payment for services:
 - In some provinces, pharmacists do not receive any public payment for immunisation services and must request that patients pay out of pocket
 - In provinces where pharmacists do receive publicly funded fees for immunisation services, many pharmacists and managers do not believe the funding is sufficient to make vaccinations a sustainable service in pharmacy
- Lack of integrated immunisation registry/Duplication of service:
 - Pharmacists in most provinces do not have access to the immunisation registry or they can access patient vaccination records but cannot contribute to the registry; this can lead to challenges for accurate record keeping and concern from government about duplication of services as well as public-funding, which has caused governments to impose age limits on pharmacist-administered vaccines and deny reimbursement for vaccines beyond the flu shot
- While age of the patient differs across jurisdictions, pharmacists are generally restricted from providing injections to children under a certain age (ranging from 5 to 9 years of age).

6.4.4 Partnerships and support

- a. With/from other health professions

Partnerships with and support from other health professions include the following:

- Assurances that pharmacists will obtain the appropriate training and certification regarding immunisation services
- Advocating for the shared goal of improved patient health
- Demonstrating evidence that pharmacist immunisation services increase immunisation rates
- New regulations have been introduced in Canada that make providing vaccinations less attractive to other health care providers, e.g., stricter vaccine storage and cold chain requirements that increase the risk of shipping vaccines from a pharmacy to a physician's office
- The government of Newfoundland and Labrador has enacted changes that physicians cannot bill for immunisations on top of the physicians' visit

- b. With/from policy makers

Partnerships with and support from policy makers were achieved through:

- Pharmacist immunisation campaigns

- Working with policy makers to lay a framework for the appropriate training and certification for pharmacists to deliver immunisation services
 - Meetings to educate policy makers about the benefits of pharmacist immunisation services, including increased immunisation rates
- c. With/from the public

Partnerships with and support from the public were mainly achieved through public education campaigns about what services pharmacists should be providing.

6.4.5 Mobilisation

To engage and mobilise pharmacists, several actions were undertaken:

- National and provincial pharmacy associations developed education (in person and online learning) and showcased the work of pharmacy practice leaders and researchers in immunisation services.
- Some jurisdictions offered fully funded training programmes (e.g., the Pharmacy Association of Saskatchewan offered fully funded training [approximately CA\$500] over 1½ years, which resulted in 80% of pharmacists in Saskatchewan being trained.)
- With ongoing pressures on governments to cut drug costs, associations and pharmacy business leaders communicated to the profession that immunisations should be seen as an opportunity to expand funding for services and improve public awareness of pharmacists as providers of direct patient care.
- Associations and pharmacy leaders across Canada have communicated the importance and instilled the values of embracing expanded scopes of practice within the profession of pharmacy. This has been both a top down and grassroots movement to embrace pharmacy practice change and improve patient care. It is now clear that advanced practice is here to stay and if pharmacists are not offering patient services such as immunisations, then they are being left behind.
- With the understanding that a purely dispensing model is no longer viable for pharmacy, pharmacists now see vaccinations as a way to increase traffic to their pharmacies, build better relationships with their patients and to discuss other pharmacy services.
- Another reason pharmacists have embraced vaccines is because of the ease of service delivery. Immunisations are quick to administer, they require very little documentation compared with other services, and there is immediate patient satisfaction.

6.4.6 Training and certification

Regarding training and certification for vaccine administration for pharmacists in Canada:

- All pharmacy schools in Canada now provide injection training to pharmacy students.
- Pharmacy schools, colleges, associations and other institutions provide injection training courses to licensed pharmacists. Most training involves an online component and an in-person practical component. If not provided in a university faculty of pharmacy, courses must be approved by the Canadian Council on Continuing Education in Pharmacy.
- Pharmacists must have valid certification in first aid and CPR from a recognised provider.
- Each jurisdiction in Canada has unique training and certification requirements for the administration of injections and immunisations by pharmacists.
- Pharmacists may be required to complete a re-certification declaration for injections and immunisations at the time of licence renewal, in which pharmacists must declare that they administer drugs via injection in their practice or that they have successfully completed the appropriate education programme.
- Associations have gone to great lengths to address concerns from public health around pharmacist education, and they offer additional education on reporting adverse events, cold chain breaks, etc.

6.4.7 Professional standards and requirements

a. For the service itself

Immunisation manuals, policies, programmes and regulations in each of the different provinces can be found on their respective websites:

- [British Columbia immunization manual](#)
- [Alberta immunisation policy](#)
- Alberta [Immunisation regulations](#)
- [Saskatchewan immunisation manual](#)
- [Manitoba immunisation manual](#)
- [New Brunswick immunisation program](#)
- [Nova Scotia immunisation manual](#)
- [NFLD immunisation manual](#)

b. For providers

Immunisation guidelines, policies, standards of practice, regulations, toolkits and manuals for providers in each of the different provinces can be found on their respective websites. In addition, a document developed by the National Association of Pharmacy Regulatory Authorities outlines competencies for injection.⁶

- National Association of Pharmacy Regulatory Authorities (NAPRA)
[Supplemental Competencies on Injection for Canadian Pharmacists](#)
- British Columbia: [Pharmacist regulations](#)
[Standards](#)
[Pharmacists and Publicly Funded Vaccines in B.C.](#)
- Alberta [Administering drugs by injection](#)
- Saskatchewan [Guidelines for pharmacists](#)
- Manitoba [Practice direction](#)
- Ontario [Regulations](#)
[Administering a Substance by Injection or Inhalation](#)
- New Brunswick [Injection policy](#)
- Nova Scotia [Standards of Practice – Drug administration](#)
[Extended practice regulations](#)
[Toolkit for immunization providers](#)
[Immunization manual](#)
- Prince Edward Island [Practice Directives](#)
- Newfoundland and Labrador [Standards for the Safe and Effective Administration of Drug Therapy by Inhalation or Injection](#)

c. For premises and equipment:

Regarding premises and equipment, national vaccine storage and handling guidelines were developed in 2015.⁷ Provinces have also developed their own guidelines, such as the Guidelines for Medication and Vaccine Injection Safety by the Alberta College of Pharmacy as well as resources developed by the College of Pharmacists of Manitoba.^{8,9}

6.4.8 Vaccination records

Jurisdictions across Canada and health authorities within some jurisdictions have different requirements for managing vaccination records. These may also vary by vaccine administered.

Pharmacists are generally required to keep a record of the patient history, assessment, signed patient consent form and details of each vaccination they provide. Pharmacists must also provide a written record of immunisation to each patient.

Where provincial drug information systems are in use and available to pharmacists, pharmacists may be required to input records of vaccination into these systems. If access to an electronic registry is not available within the jurisdiction, pharmacists may be required to provide aggregated data to the provincial health department as per the province's immunisation policies (e.g., Alberta).

Other provinces may use billing systems to obtain pharmacy records for publicly funded vaccines. For example, in order to receive funding for the immunisation service, the pharmacist would have to make a claim through the provincial drug benefit system. That system would then communicate the details of the vaccination on behalf of pharmacists to the Population Health Branch upon receipt of billing information submitted (e.g., Saskatchewan).

6.4.9 Assessment of pharmacist-led vaccination

Independent research has been conducted to assess the impact of pharmacists as immunisers in Canada.¹⁰⁻¹⁴

6.4.10 Advice to other organisations

Change does not come easy but with persistence and patience, pharmacists, patients, other healthcare practitioners and decision-makers have slowly become more accepting of this authority, and the required systemic changes to help pharmacists excel at this service are slowly being introduced.

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6.5 Costa Rica

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6.5.1 Key factors

In many cases, private community pharmacies represent the first point of access for patients into the healthcare system. Private community pharmacies provide services that have a significant impact on the public health of the country. However, it is necessary to keep record of these actions in order to ultimately recognise their role in the development of public policies.

There is a portion of the population that does not have access to the social security system for immunisation. For these groups, immunisation in private community pharmacies has represented a suitable option for many years.

It is important to note that authorities must consider the contribution of the private sector in national immunisation coverage. It is also necessary to have stakeholders actively participate in the elaboration of a nominal vaccination system to take into account the professional practice and technical requirements.

6.5.2 Timeline

Date	Event
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2001	Law No. 8111. The National Vaccination Law points out that health personnel, both in the public and private sectors, should collaborate in all matters related to the prophylaxis of contagious diseases, including statistical epidemiological analysis, case control, epidemiological surveillance, bacteriological diagnosis, treatment and remaining health measures. ¹
2005	Executive Decree No. 32722 develops regulations for the National Vaccination Law. The decree states that the registration of vaccines applied, manual or digital, and report of adverse reactions is mandatory, in both the public and private sectors. ²
2008	Executive Decree No. 31969-S. The minimum requirements regarding human resources, infrastructure, equipment and documentation for the storage, conservation and application of vaccines in a pharmacy are described in the Manual of Norms for the Enabling of Pharmacies. ³
2009	Legal opinion C-232-2009. The pronouncement of the Attorney General's Office of the Republic of Costa Rica determined that the application of injectables is a customary and usual service of private community pharmacies. Likewise, it was concluded that the dispensing, delivery or application of injectable medications, including vaccines, should always be performed by a pharmacist. ⁴
2012	The National Commission of Vaccination and Epidemiology of the Ministry of Health of Costa Rica, in accordance with the reports submitted by the Costa Rican Social Security Fund (public sector) detected reports of low immunisation rates and low vaccination coverage in some cantons of the country, which were characterised by high economic incomes in households. A study was therefore conducted in two pre-specified health areas possessing the aforementioned characteristics. The results of this study concluded that patients went to private establishments, especially community pharmacies, to receive vaccines. In addition, there was an underreporting of these applications (M. Morera, personal communication, 13 June 2019).
2013	Executive Decree No. 37808-S. The National Vaccination Norm was established as an obligatory observance for public and private centres. With its publication, a transition was promoted from manual to automated notification, through the nominal vaccination system (SINOVAC). It denotes that all users must use the system and, in the case of adverse reactions, they must be notified to the National Pharmacovigilance Centre. Moreover, the decree updated the technical requirements (infrastructure, equipment, procedures and documentation) regarding the management and conservation of immunobiological agents in establishments that manage the supply chain and administer vaccines. ⁵
2017	SINOVAC was introduced. This was the first initiative in having a digital, nominal system of vaccination. In the first stage of the project, the Ministry of Health took into consideration the private sector, including private community pharmacies.
2017	F-744-2017. The circular of the Department of Public Prosecutions of the College of Pharmacists of Costa Rica was established and related to the sale of vaccines in pharmacies that do not have an injectable application service. By order of the Ministry of Health, pharmacists were informed that the sale to the public of vaccines that are not administered in the pharmacy in which they are purchased is not allowed. ⁶

6.5.3 Main challenges

Several challenges were encountered in implementing pharmacist-led vaccination services:

- Vaccines were not considered as medicines, both in the public and private sectors; even some prescriptive definitions make a distinction between the two concepts

- Strong opposition of nurses about the participation of pharmacists in the entire supply management of vaccines, especially in private community pharmacies
- Full compliance with the technical standards for the storage, distribution and conservation of vaccines (cold chain) in private community pharmacies
- Lack of knowledge of pharmacists in immunisations and vaccination regimens
- The change from manual system to computerised system for recording and reporting administered vaccines brought technological gaps for some professionals; in addition, the system is not entirely compatible with the dynamics of private community pharmacies, and pharmacists do not have access to the records of other establishments.

6.5.4 Partnerships and support

- a. With/from other health professions

Efforts were made to achieve interdisciplinary work between nursing and pharmacy at operational level and at the National Commission of Vaccination and Epidemiology of the Ministry of Health of Costa Rica.

- b. With/from policy makers

It was important to have a pharmacist in the formulation of public policies, norms and procedures related to immunisations at the national level.

- c. With/from the public

Traditionally, private community pharmacies have been the point of access to the health system of the population. In general, private community pharmacies are accessible in terms of services, schedules, and distances. The convenience and accessibility of private community pharmacies allowed for facilitated exchange with the public regarding information and education on immunisations. Some pharmacies have periodically developed vaccination campaigns aimed at the population.

6.5.5 Mobilisation

The College of Pharmacists of Costa Rica has an obligation to supervise pharmaceutical establishments and to ensure proper professional pharmacy practice, including assessing if pharmacies meet current regulations related to vaccines. As a result of these actions, in 2018, a virtual self-learning course on good pharmacy practices related to the cold chain was implemented.

Despite these initiatives, more actions are needed to ensure that all establishments and professionals involved in immunisation services comply with all provisions on vaccines. In addition, the organisation should encourage more pharmacists to offer vaccination services from private community pharmacies.

6.5.6 Training and certification

For the application of vaccines in the private community pharmacy, the College of Pharmacists of Costa Rica and the Ministry of Health require that pharmacists comply with current regulations. However, there is no specific certification that accredits the pharmacist as a health professional trained in immunisation.

There are private initiatives aimed to train professionals in the application of injectables which are recognised by the professional recertification system of the College of Pharmacists of Costa Rica. Enrolment in this programme is voluntary.

The College of Pharmacists of Costa Rica coordinates the Deans' Commission, an organisation that has been concerned about the harmonisation of the curricular contents of the five faculties of pharmacy in the country. In consultation with this commission, it was highlighted that all universities comply, at least, with the theoretical contents related to the storage, distribution, conservation and application of vaccines (B. Baltodano, personal communication, 14 June 2019).

6.5.7 Professional standards and requirements

a. For the service itself

Until now, there has been no professional action guide for vaccine administration in private community pharmacies. However, all pharmacists are required to know and abide by the guidelines related to the management of vaccines supply, reporting of the vaccines administered, reporting of adverse reactions, handling of biohazardous waste, and management of expired medicines.

b. For providers

All suppliers of vaccines to private community pharmacies are required to be registered with the Ministry of Health as wholesale medicines distributors and are required to comply with storage and distribution regulations as well as the management of vaccine supply.

c. For premises and equipment

All pharmacists are required to know and abide to the guidelines regarding infrastructure, equipment and documentation in order to comply with the storage, and conservation and application of vaccines in a private community pharmacy.

6.5.8 Vaccination records

The Directorate of Health Surveillance of the Ministry of Health is the entity that regulates and controls the nominal vaccination system (SINOVAC). All immunisation service providers, both public and private, must register and report the application of vaccines. According to the reports received, the Ministry of Health officially establishes the national vaccination coverage plan.

Any pharmacist who is responsible for a private community pharmacy must request access to SINOVAC from the Ministry of Health in order to register and report the immunisations administered in his or her own establishment. The system currently allows for observing, in a nominal manner, all the immunisations made in their own establishment.

Because data from the public health service provider (the Costa Rican Social Security Fund) have not been incorporated in this system, the amount of information available is limited. In addition, the previous registration was not nominal, but a consolidation of the immunisations was sent. At the moment, the Ministry of Health is the only user with access to data from all establishments.

6.5.9 Assessment of pharmacist-led vaccination

Traditionally, vaccine administration in the private sector has been offered in community pharmacies, empowering the professional to analyse the patient's medical history and determine, from a professional criterion, the clinical relevance and safety of administering a vaccine. Before 2017, this professional act was registered in written form and sent to the Ministry of Health, which prepared a consolidated coverage report. As of July 2017, a Nominal Vaccination System (SINOVAC) was implemented with collaboration with the Pan American Health Organization.

SINOVAC was implemented as of July 2017. In the first stage, the records of private community pharmacies and private health centres were included. Historically, these immunisations account for 7% of those made in the country; the remaining 93% is for social security. The system allows the pharmacist to enter information related to the patient's vaccination history. From July 2017 to July 2018, 835 pharmacists registered in the system. Community pharmacists have notified 48,517 immunisations, which represent approximately one-third of the vaccinations carried out in the country's private sector.^{7,8}

6.5.10 Advice to other organisations

- The active participation of the pharmaceutical organisation and pharmacists themselves in the development of public policies related to immunisations is essential.

- The professional organisation should encourage campaigns in community pharmacies that are harmonised with the national public vaccination campaigns.
- Specific training programmes related to professional immunisation services should be proposed.
- It is important that professional organisations perform impact studies regarding pharmacists' interventions in the vaccination systems of their countries.

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6.6 Finland

Organisation:	Association of Finnish Pharmacies
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In Finland, pharmacists are not yet authorised to administer vaccines. However, a few community pharmacies (21 out of approximately 800 country-wide) have introduced a health point in their facilities, where a nurse can provide certain services to customers, including vaccinations. The impact of this service and the level of patient satisfaction were assessed in autumn 2016, and this case study is a report of this pilot project led by pharmacists Saija Kinnunen.

The Association of Finnish Pharmacies is actively advocating for an expanded role by pharmacists in the vaccination landscape.

6.6.1 Key factors

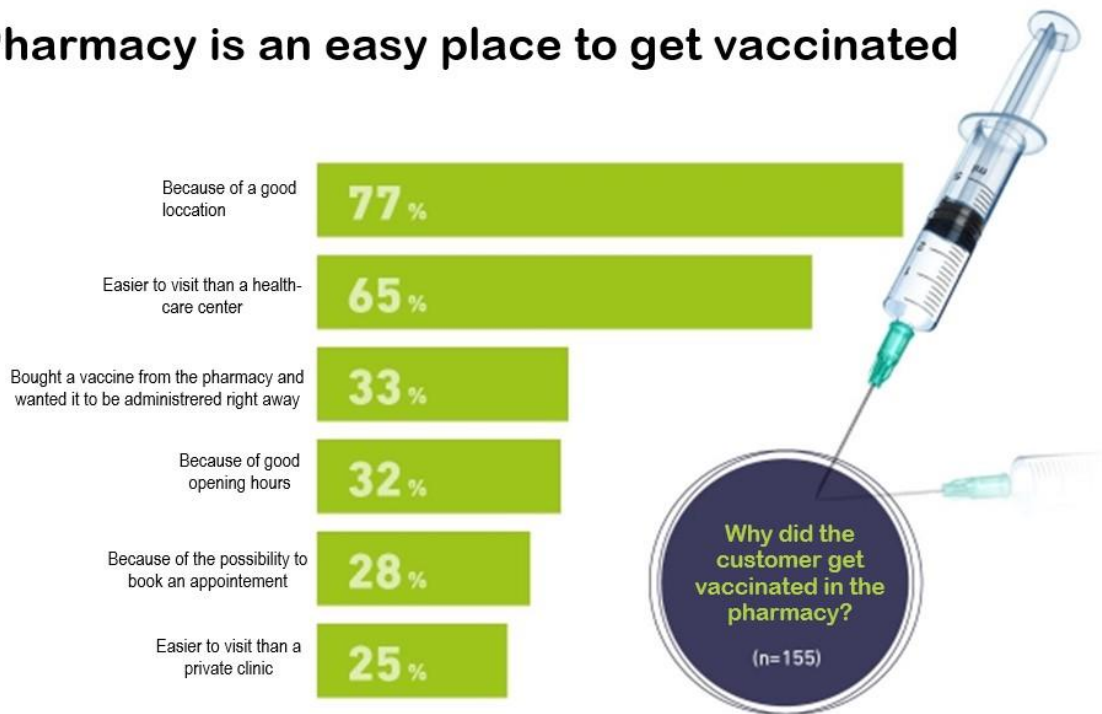
To increase seasonal influenza vaccination coverage, there are two important benefits associated with pharmacies that should be considered: location of sites offering vaccination services as well as the convenience and accessibility of these services.

6.6.2 Assessment of pharmacist-led vaccination

A questionnaire on pharmacist-led influenza vaccine services was conducted in autumn 2016. A total of 155 patients who had been vaccinated in a pharmacy answered the survey.

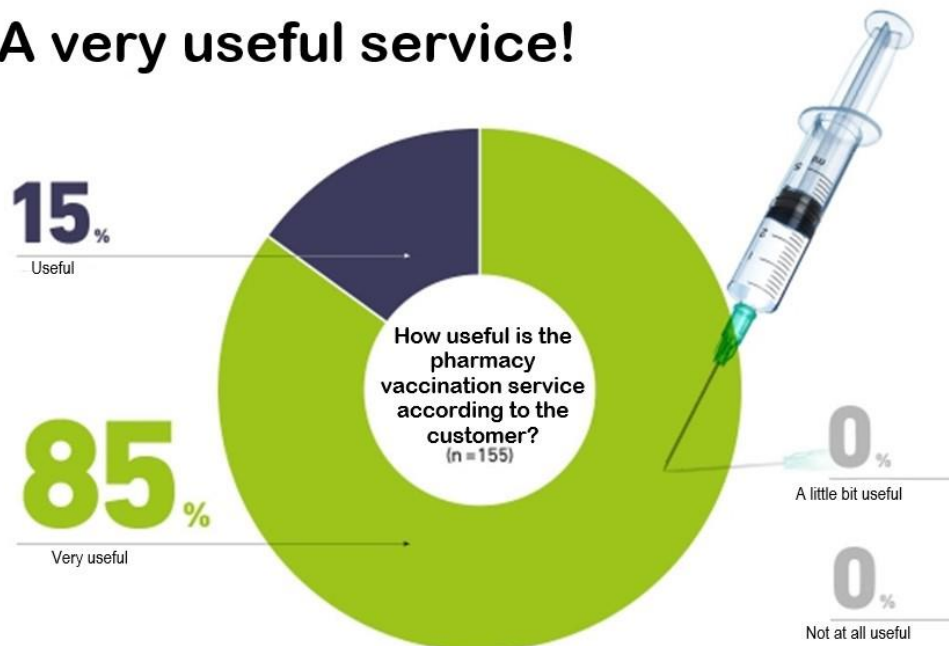
An overwhelming majority of respondents said they had chosen a pharmacy as a vaccination site because of its good location as well as its ease of business when compared with a health care centre. In addition, more than a third of respondents knew that they belonged to an at-risk group for seasonal influenza. While they would have received the vaccine free of charge from the nearest healthcare centre, they preferred receiving the vaccine in the pharmacy.

Pharmacy is an easy place to get vaccinated



The majority of respondents were of working age or pensioners. All respondents found the vaccination service useful, with the majority of them (85%) considering the service very helpful. The results of the survey confirm the evidence brought forward around the world that pharmacy vaccination contributes to increasing national vaccination coverage.

A very useful service!



In fact, for the municipality of Hattula, in the influenza season of 2015–16, only 16% of children under the age of two years received the influenza vaccine in comparison with the national average of 32%. In the case of patients over the age of 65 years, only 38% of patients received the vaccine, nearly 10% less than the national average.

Those who had previously received a vaccine in the pharmacy were more likely to receive the flu vaccine regularly, highlighting how pharmacist-led vaccination services can increase compliance with yearly influenza vaccine schedules. Furthermore, up to nine out of 10 respondents even answered that they were willing to pay between EUR 5 and EUR 10 for the service in addition to the price of the vaccine (EUR 15).

A previous study by the Health and Welfare Institute also suggested similar promising results. For example, the majority of parents of young infants and children agree to vaccinations and make time to ensure their children are vaccinated. However, more often than desired, flu vaccines are left out due to the absence of convenient opening hours in the evening or during weekends. Offering the influenza vaccine in the pharmacy thus represents a solution.

Vaccine services in a pharmacy also opens doors for the promotion of other health services, such as the review of inhalation use and medication review.

6.7 France

Organisation:	French Chamber of Pharmacists
Case study authors:	Carine Wolf-Thal
Email address:	international@ordre.pharmacien.fr

6.7.1 Key factors

Key factors that were considered when advocating for pharmacist-led vaccination services include:

1. Insufficient vaccination coverage in France: 46% of the at-risk population was vaccinated while the public health targets are fixed at 75%.
2. Vision to simplify patient access to healthcare services considering the lack of general practitioners (GPs) and the homogeneous geographical distribution of pharmacies.
3. Proposal to establish a pilot project with services limited to the flu vaccine at a regional level with a limited scope, that is adults 18 years of age and older, targeted by current vaccine recommendations, with the exception of pregnant women and those who have never been vaccinated against flu, and with pre-specified conditions (there should be specific training for pharmacists and an appropriate layout of the community pharmacy premises, including a confidential area to allow for patient interviews prior to administration of the vaccine; the patient's consent must be systematically obtained and a vaccination certificate issued to the patient; the GP should also be informed).
4. Referral to experiences from abroad, as advice was requested from bodies in the United States of America, the United Kingdom, Australia, Portugal, Ireland and Switzerland.

6.7.2 Timeline

Date	Event
December 2016	Authorisation by law for the pilot project for flu vaccination by pharmacists to take place.
2017–18	First season of the pilot project for flu vaccination by community pharmacists in two regions, which was successful and allowed for geographical and demographical expansion.
2018–19	Second season for the pilot for flu vaccination extended to four regions, which was also successful.
December 2018	Vaccination becomes part of the permanent duties of pharmacists.
April 2019	Publication of the Ministerial Order authorising all regions to vaccinate against flu in authorised community pharmacies.
2019/2020	National roll-out of pharmacist-led flu vaccination services in community pharmacies.

6.7.3 Main challenges

The main challenges to implementing pharmacist-led vaccination services include:

- Opposition from physicians and nurses
- Authorisation process during the first year
- Roll-out of training

6.7.4 Partnerships and support

- a. With/from other health professions

No partnerships were established with other health professions. In fact, physicians and nurses were strongly opposed to vaccination by pharmacists. As such, no discussion was possible, and implementing pharmacist-led vaccination had to be promoted without reaching a consensus. There was, however, a strong support from all stakeholders from the pharmacy sector, including unions, students, academia, etc.

- b. With/from policy makers

The strong will of the Minister of Health was a significant determinant in the establishment of vaccination by pharmacists in France. She had proposed the measure (as a pilot project) in a previous draft of the Health Law, but had to step back due to a strong opposition on behalf of physicians in parliament. However, we were supported by another influential member of parliament who was also a physician and who was committed to advocating for the cause.

In addition, one-to-one meetings were conducted with MPs. During these discussions, international examples, studies, and results of a positive public opinion survey which was positive (concluding that six out of 10 French people were in favour of allowing pharmacists to vaccinate against flu) were brought forward.

c. With/from the public

Communication and press campaigns were put forward to shed light on international experiences with pharmacist-led immunisation. A public opinion survey was also commissioned.

6.7.5 Mobilisation

To engage and mobilise pharmacists and address resistance to change, several measures were taken.

A programme was created with all stakeholders from the beginning thanks to many meetings organised collaboratively at national and local levels. Communication with pharmacists as well as the development of a platform to assist pharmacists and retrieve data were also undertaken.

Surprisingly, there was not much resistance to expanding the scope of pharmacists to include vaccinating against flu. Over the two-year pilot project, 12,851 community pharmacists were authorised to vaccinate in 6,685 community pharmacies. This represents 60% of community pharmacists and 76% of community pharmacies in the four experimental regions.

6.7.6 Training and certification

Pharmacists must follow and pass a continuing professional development (CPD) training course of six hours, in accordance with the pedagogical objectives defined by the French Chamber of Pharmacists, including:

- A three-hour theoretical training, with the possibility of e-learning
- A three-hour practical training course on the vaccination act

The certificate given to the pharmacist by the training organisation after successful completion of the training programme must include the training organisation's registration number with the national agency for CPD as well as the registration number specific to the training course provided.

Pharmacists who have already completed vaccination training based on the educational objectives of the pilot project are exempt from this requirement. The same applies to pharmacists who have received training for vaccination in their undergraduate training.

6.7.7 Professional standards and requirements

a. For the service itself

Pharmacists may only vaccinate against seasonal flu. Patients who are eligible to receive the vaccine are adults targeted by current immunisation recommendations, with the exception of those with a history of severe allergic reaction to ovalbumin or to a previous vaccination.

b. For providers

Community pharmacy owners or employed community pharmacists and cooperative or mine rescue pharmacists registered with the Chamber may practise vaccination. Pharmacy students may not currently vaccinate in a pharmacy even if they have been trained.

c. For premises and equipment

Professional standards and requirements include:¹

- Possessing suitable premises for vaccination, including a closed private area for the preliminary interview, accessible from the client area and with medicines out of reach

- Possessing suitable equipment, including a table or desk, chairs and/or an armchair to set up the patient comfortably for injection, water access for handwashing or hydro-alcoholic solutions, and a refrigerated chamber for storing vaccines
- Possessing the necessary equipment for the injection of the vaccine and a first aid kit
- Disposing of healthcare waste at risk of infection in accordance with regulations (article R. 1335-1 et seq. of the Public Health Code)

6.7.8 Vaccination records

Traceability of the vaccination act in the pharmacy

The vaccinating pharmacist is required to register the administered vaccine in the computerised poisonous substances order form, detailing the date of administration of the vaccine and its lot number. The dispensing software does not currently allow for this recording to be performed; however, a decree will set the date of application of this provision, which will take place no later than 1 March 2020.

In the absence of a computer record, the pharmacist transcribes the information into a register in ink, without correction fluid or overprinting. The information transcribed is the information provided in article R. 5132-10 of the Public Health Code, to which are added the date of administration of the vaccine and the batch number of the vaccine.

Transmission of information to the patient and to the general practitioner

The pharmacist is required to register the vaccination in the patient's health record, vaccination record or shared medical record. The pharmacist registers the patient's personal information, the name of the vaccine administered, the date of administration, and the lot number of the vaccine. If the information could not be registered using one of these tools, the pharmacist issues a vaccination certificate to the patient.

In the absence of a shared medical record, and subject to the consent of the vaccinated patient, the pharmacist transmits this information to his or her general practitioner through a secured health messaging system.

6.7.9 Assessment of pharmacist-led vaccination

A pilot project was performed prior to the nationwide implementation of vaccination by pharmacists. To begin, the French Ministry of Health selected two regions for the first pharmacy-based vaccination campaign in 2017–18. For this first season, the target population was restricted to adults over 18 years old who were targeted by current vaccination recommendations, with the exception of pregnant women and individuals who had never been vaccinated against flu before. Patients presenting potential risks to vaccination that were identified by the pharmacist, such as immunocompromised patients, patients with a history of allergic reaction to previous vaccination, or patients with bleeding disorders or on anticoagulant therapy, were referred to their attending general practitioner .

Following the success of the first season, the French Ministry of Health decided to extend the pilot to two additional regions for the second season of the pilot in 2018–19 as well as expand the target population to adults over 18 years old targeted by current vaccination recommendations, with the exception of individuals presenting a history of allergic reaction to previous vaccination.

During the two-year pilot project, 12,851 pharmacists vaccinated 902,699 patients against flu.

6.7.10 Advice to other organisations

- Start with a pilot project
- Ensure adequate training for pharmacists
- Regarding advocacy strategies, utilise public opinion to ensure they already possess strong adherence to the idea and utilise experiences from abroad as models

- Flu vaccination carries virtually no health risks, which limits the risk of adverse events and is reassuring for authorities, the public and other health professionals
- Emphasise that vaccination by the pharmacist is complementary to vaccination by other health professionals, and not in competition with them; the goal is ultimately to increase vaccination coverage rather than observing a shift from one vaccinator to another

6.7.11 References

1. French Chamber of Pharmacists. Vaccination in the community pharmacy [Internet]. French Chamber of Pharmacists; [cited 21 Jul 2019]. Available from: <http://www.ordre.pharmacien.fr/Les-pharmaciens/Champs-d-activites/Vaccination-a-l-officine>

6.8 Ireland

Organisation:	Irish Pharmacy Union
Case study author:	Pamela Logan
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6.8.1 Key factors

Key factors that were considered when advocating for pharmacist-led vaccination in Ireland included:

1. Ireland not achieving the European Commission target for 75% flu vaccination in the elderly
2. The Minister for Health's desire to move more services from secondary to primary care; general practitioners also cited a lack of time
3. Health services wanted to increase flu vaccination rates and were supportive of pharmacists administering vaccines
4. Pharmacy regulators included vaccination in their 2020 strategy
5. Public opinion research showed that public wanted access to more healthcare services from pharmacists

6.8.2 Timeline

Date	Event
2009	During the H1N1 pandemic, there were not enough healthcare professionals to vaccinate the whole population. As a result, pharmacists were trained but not needed as the virus was not as virulent as feared.
14 Oct 2011	Minister for Health signed legislation allowing pharmacists to supply the flu vaccine without prescription and to administer to patients in the pharmacy
Nov 2011	Pharmacists began flu vaccination services

2015

Vaccination services were expanded to include the pneumococcal and shingles vaccines

6.8.3 Main challenges

The main challenges encountered included opposition from some (but not all) doctors who believed that they should be the ones vaccinating and that pharmacist-led vaccination posed a great risk for anaphylaxis.

In addition, some pharmacists were uncomfortable about vaccinating and were uncertain how they would incorporate it into daily practice. Setting up a vaccination service is also expensive when considering costs related to training, adrenaline pens, sharps bins, etc.

The public was also not familiar with the concept of pharmacy vaccination.

6.8.4 Partnerships and support

- a. With/from other health profession

The pharmacy profession constantly reassured other health professions that pharmacists had the competence and skills to provide a vaccination service.

- b. With/from policy makers

The Department of Health and National Immunisation Office were very supportive of pharmacist vaccination.

- c. c. With/from the public

Radio advertisements, posters and informational leaflets for pharmacies were produced. Some public research was also conducted after the first season, which showed high patient acceptability and satisfaction.

6.8.5 Mobilisation

Pharmacy vaccination services were widely promoted in media discussions, debates and interviews as well as by advertising. Detailed information was also developed for pharmacists to demystify the new service and provided support materials (pharmacy standard operating procedures, patient consent forms, etc.) to assist pharmacists in setting up vaccination services. Vaccination promotion materials (posters, leaflets, etc.) were sent to pharmacies to increase public and patient awareness of the service.

6.8.6 Training and certification

- Pharmacists must attend a face-to-face, one-day course which covers injection technique, anaphylaxis and cardiopulmonary resuscitation (CPR)
- Pharmacists must complete an online module on flu vaccination and a refresher online module each year (pneumococcal and shingles modules to be repeated every two years)
- The CPR certificate only lasts for two years so the face-to-face CPR training must be repeated every two years

6.8.7 Professional standards and requirements

- a. For the service itself

The pharmacy regulator (Pharmaceutical Society of Ireland) produced guidance on the provision of vaccination services by pharmacists¹ and guidance on training for vaccination.²

- b. b. For providers

The Irish Institute of Pharmacy provides online vaccination training courses.³

c. c. For premises and equipment

The Irish Pharmacy Union provides template standard operating procedures, answers to frequently asked questions, and promotional materials for pharmacies to assist in delivering a pharmacy vaccination service.

6.8.8 Vaccination records

Legislation requires pharmacists to input a record of all vaccinations (both private and reimbursed) into an online portal hosted by the Health Service Executive. GPs are only required to input reimbursed vaccinations. Both the GP and the pharmacist can see if a patient whose vaccination is reimbursed has already been vaccinated.

6.8.9 Assessment of pharmacist-led vaccination

The Pharmaceutical Society of Ireland carried out an evaluation of the pharmacy flu vaccination service in 2015. It showed a 95% satisfaction rate, with 99% of patients saying they would return to a pharmacy for a flu vaccination.⁴

Since Irish pharmacists first started vaccinating in 2011, flu vaccine deliveries have increased overall by 48%, with increases seen through all channels, including GP flu vaccine deliveries, which increased by 23%.

6.8.10 Advice to other organisations

Advice to other organisations include not worrying about the attitude of other healthcare providers, who will eventually understand, accept and encourage pharmacist-led vaccination. It is also important to ask for help from other countries with previous experiences as they can assist with training, developing procedures, etc.

6.8.11 References

1. Pharmaceutical Society of Ireland. Guidance on the provision of vaccination services by pharmacists in retail pharmacy businesses [Internet]. Pharmaceutical Society of Ireland; 2019 Apr [cited 2019 Jul 21]. Available from: <https://www.thepsi.ie/Libraries/Folder Pharmacy Practice Guidance/PPGF 02 8 Guidance on the Provision of Vaccination Services by Pharmacists in a Retail Pharmacy Businesses.sflb.ashx>
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3. Irish Institute of Pharmacy. All courses [Internet]. Irish Institute of Pharmacy; c2019 [cited 2019 Jul 21]. Available from: <https://iiop.ie/cbs/selector>
4. Pharmaceutical Society of Ireland. Evaluation of the Seasonal Influenza Vaccination Service [Internet]. Pharmaceutical Society of Ireland; c2019 [cited 2019 Jul 21]. Available from: https://www.thepsi.ie/gns/Pharmacy Practice/practice-guidance/PharmacyServices/Vaccination_Service/Evaluation_of_the_Seasonal_Influenza_Vaccine.aspx

6.9 Israel

Organisation:	Pharmaceutical Association of Israel
Case study author:	Howard Rice
Email address:	howard@inter.net.il

6.9.1 Key factors

1. Reducing the workload at managed-care operations (MCOs) during critical vaccination times.

2. Making vaccination more readily available to people who could not get to the MCO.

6.9.2 Timeline

Israel regulated pharmacists' authority to vaccinate in 2017.

6.9.3 Main challenges

- Requiring pharmacists to leave their pharmacies to attend a 28-hour course, often during regular working hours
- No agreed price for the act of administering the vaccine, while MCOs administer the vaccines for free

6.9.4 Partnerships and support

- a. With/from other health professions

Vaccination by pharmacists was advertised in pharmacies and through local flyers.

- b. With/from policy makers

Partnerships with policy makers have been problematic as they have been demanding licensing requirements. Efforts are also being made to have training done in the evening and more locally. Moreover, as mentioned, there is no consensus regarding the fee associated with pharmacist-led vaccination, and there is a competitive environment with MCOs.

- c. With/from the public

Pharmacist-led vaccination has been well accepted by those who received the service and, through word-of-mouth, demand will increase.

6.9.5 Mobilisation

Letters are sent out by internal mail advertising courses.

6.9.6 Training and certification

Each pharmacist must undergo a training course in a designated hospital, pharmacy school or nursing school. It includes the recording of each patient vaccinated as well as method and dealing with emergency reactions.

6.9.7 Professional standards and requirements

For the service itself and for providers, several professional standards and requirements must be met, with pharmacists being required to undergo training courses.

For premises and equipment, pharmacies must either have a consulting room or partitioned area as well as possess the necessary equipment for unexpected reactions.

6.9.8 Vaccination records

Vaccination records are required to be kept for seven years, only for Ministry inspection, and not for MCOs.

6.9.9 Assessment of pharmacist-led vaccination

The pilot project is ongoing. Once the aforementioned challenges are resolved, pharmacist-led vaccination will become more widespread. Discussion and consensus with MCOs will also be required to offer optimal vaccine services to the community.

No milestones for increasing the number of vaccines were defined. This presumably will depend on the success of the current authority.

6.9.10 Advice to other organisations

The main piece of advice is to solve all problems with regulators before starting to implement vaccination by pharmacists.

6.10 Jordan

Organisation:	Jordanian Pharmacists' Association/Immunization Advocacy Programme
Case study author:	Samira Shammass, Laila Jarrar and Maram Alhaj Ahmed
Email address:	Farabirx680@gmail.com

6.10.1 Key factors

1. Emphasising that pharmacists are well trained and accredited professionals as medicines experts and are integral parts of primary healthcare teams
2. The accessibility and widespread distribution of pharmacies
3. Pharmacies' capacity to provide adequate storage and supply conditions

6.10.2 Timeline

The Jordanian Pharmacists' Association (JPA) is currently going through an active advocacy process to achieve vaccination authority for pharmacists. For that reason, this case study is in fact a progress report that may be valuable to other organisations for its timeliness and relevance as a "frontline" account.

Date	Event
Days 1–120	Efforts were made to map the health and vaccination system, including: <ul style="list-style-type: none"> • The laws governing the implementation of vaccination in pharmacies • Current vaccination implementation and the availability of vaccines in the healthcare system • Data collecting • Stakeholder identification
Days 120–180	Situational analysis
Days 180–330	Attitudes and acceptance of both pharmacists and the public towards the implementation of vaccination services in pharmacies were evaluated through a market survey and data collection. A national guideline for immunisation implementation by pharmacists was developed.
Day 330	Modules and training for accreditation were presented to immunising pharmacists.
Days 330–390	The idea was marketed to stakeholders and efforts were made to increase public awareness.

6.10.3 Main challenges

Main challenges to the implementation of pharmacist-led vaccination included:

- A lack of pharmacist training on immunisation at under- and post-graduate levels
- A general resistance towards immunisation
- A lack of specific laws covering implementation of immunisation by pharmacists in pharmacies
- Hesitancy of medical doctors

6.10.4 Partnerships and support

- a. With/from other health professions

Partnerships were achieved with other health professions by sharing the idea and engaging in dialogues with medical doctors through medical conferences and non-official meetings.

- b. With/from policy makers

With policy makers, partnerships were established through being under the umbrella of the JPA. In addition, official approval was received from the Minister of Health for pharmacists to immunise the elderly in a campaign directed at care homes across Amman.

- c. With/from the public

Surveys and awareness campaigns were conducted.

6.10.5 Mobilisation

Mobilising pharmacists falls within our action plan, which also includes publishing the survey results and submitting recommendations to the JPA. One main recommendation is to create a new department within the JPA structure called the “Pharmaceutical Care Department” to follow up on the immunisation project as well as maintain and update relevant processes, which include, but are not limited to, the following:

- Introducing and amending the relevant laws to certify community pharmacies as centres for immunisation as well as defining pharmaceutical care and listing the guidelines and standards of pharmaceutical care in line the previously endorsed Good Pharmacy Practice document of 2010
- Expanding vaccination services offered by community pharmacists nationally to include travel vaccines
- Recommending vaccination for insurance beneficiaries
- Arranging to implement an electronic national immunisation record
- Ensuring that the receipt of vaccination is documented in the patient’s medical record and immunisation registry with the Ministry of Health and Department of Vaccination
- Raising awareness of immunisation needs as an important safe, preventive measure through mass media and social media and as a method to counter misconceptions about vaccines
- Providing immunisation education and training to community pharmacists
- Including immunisation and its application in the pharmacy school curriculum to enable graduates to undertake vaccination.
- Attracting corporate sponsors to train community pharmacists on immunisation and to assist them in qualifying their vaccination premises

6.10.6 Training and certification

The need for training and certification was included in the Jordan Community Pharmacist Immunisation Guidelines.

After surveying and approaching different accrediting training centres internationally and locally, the decision was taken to establish a partnership with the Jordanian University of Science and Technology Pharmaceutical Research Centre to provide the required training for pharmacists on immunisation and cardiopulmonary resuscitation.

6.10.7 Professional standards and requirements

a. For the service itself

According to the Jordan Community Pharmacist Immunisation Guidelines, professional standards and requirements must be met and cover the following topics:

- Registration and training
- Quality of practice and continuing professional development
- Premises qualification
- Staff training
- Practice and compliance with relevant guidelines and protocols
- List of vaccines that pharmacists are authorised to administer and the circumstances in which they are authorised to do so
- Conditions for qualification and related requirements for pharmacists are described as part of these guidelines; under all circumstances, the immunising pharmacist should provide vaccination services in accordance with health regulations

b. For providers

According to the Jordan Community Pharmacist Immunisation Guidelines, professional standards and requirements for providers include:

- Possessing a valid registration with the JPA and a licence to practise the pharmacy profession in Jordan
- Having satisfactorily completed the proper vaccination training by one of the JPA accredited immunising qualification training programmes and which is required to be renewed every three years
- Holding a current first aid certificate (to be updated every three years)
- Holding a current cardiopulmonary resuscitation certificate (to be updated every two years); immunising pharmacists should be able to provide evidence of completed training if required

c. For premises and equipment

According to the Jordan Community Pharmacist Immunisation Guidelines, professional standards and requirements for premises and equipment include:

- The dispensary area is not to be used for immunisation services
- A suitable room or area should be dedicated to the purpose of vaccination; an existing consulting room may be used
- This room should be stocked with adequate levels of the equipment required to deliver vaccines and manage waste
- This area is not to be used as a dispensary, storage room, staff room or retail area

It is also recommended that the vaccination area should:

- Not permit the vaccination process to be visible or audible to other persons in the pharmacy
- Have adequate lighting
- Be maintained at a comfortable ambient temperature
- Have a hand sanitisation facility
- Have ready access to a hand washing facility
- Have sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the vaccine and an accompanying person, and to allow the pharmacist adequate space to manoeuvre
- Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar)

A dispensary refrigerator may be used to store vaccines. However, the immunising pharmacist is also required to comply with the National Vaccine Storage Guidelines, which recommend that the refrigerator should be a temperature-monitored refrigerator, manufactured exclusively for the purpose of storage of vaccines. The refrigerator is also recommended to possess a temperature data logger in order to comply with the Jordanian Good Storage Practice Guidelines.

A copy of the certificate of training completion should be displayed in the vaccination area to assure the public that the immunising pharmacist has successfully completed a JPA-recognised immunising qualification training.

6.10.8 Vaccination records

According to the Jordan Community Pharmacist Immunisation Guidelines, when a vaccine is used in a pharmacy, the record must be retained for three years from the date of vaccination. Capture of the recording electronically in the dispensing software is acceptable, or a specific recording software may be used. However, it is important to note that a copy of the patient-signed consent form must be retained by the pharmacy and stored in a secure place, regardless of whether other vaccination information is stored electronically.

6.10.9 Assessment of pharmacist-led vaccination

Pharmacist-led vaccination has not yet started in Jordan.

6.10.10 Advice to other organisations

Adequately plan a road map, select stakeholders, and monitor, evaluate and run a pilot study before implementing large-scale services.

6.11 Lebanon

Organisation:	Lebanese Order of Pharmacists
Case study author:	Ghassan El Amin and Marwan Akel
Email address:	Not disclosed

6.11.1 Key factors

Key factors in implementing pharmacist-led vaccination services include the experience of the pharmacist, their availability, optimising vaccination coverage and limiting expenses.

6.11.2 Timeline

Elements of the timeline include advocating for vaccinating against flu at all professional events (congresses, etc) as well as advocating for dispensing other vaccines that are not stocked at physician clinics.

6.11.3 Main challenges

Challenges and obstacles to implementing pharmacist-led vaccination services include:

- Not all pharmacists are qualified for vaccination
- The law does not currently allow vaccination by pharmacists
- Conflicts with other vaccination providers

6.11.4 Partnerships and support

Communication with other health professions and with policy makers is important in establishing partnerships with them. With the public, posters in pharmacies may be used to promote the flu vaccine.

6.12 Netherlands

Organisation:	Royal Dutch Pharmacists' Association
Case study author:	Jeltje Luinenburg
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6.12.1 Key factors

Key factors in implementing pharmacist-led vaccination services include:

1. Expanding the role of the pharmacist in health care
2. Providing a service to the patient/consumer
3. Promoting vaccination
4. Outlining a business case for the pharmacist
5. Unburdening general practitioners (GPs)

6.12.2 Timeline

For the time being, pharmacists are not allowed to vaccinate. This may become possible in 2019 or 2020. We are also working towards making vaccination possible for pharmacy technicians under the supervision of a pharmacist.

However, there are local initiatives where pharmacists and GPs work together for travel vaccination. For example, the pharmacist provides advice and orders the necessary vaccines, while the GP provides the prescription and administers the vaccine.

6.12.3 Main challenges

Challenges or obstacles to implementing pharmacist-led vaccination services include:

- The requirement for legislative challenges to expand pharmacists' scope of practice to include vaccination
- Opposition from GPs
- Opposition from vaccination clinics
- Not all pharmacists are eager to vaccinate

6.12.4 Partnerships and support

- a. With/from other health professions

Partnerships have been established with health professions for now at the local level, for example, regarding travel vaccination. Authorisation for pharmacists to vaccinate is being conceived as a back-up for missed vaccinations and for elective vaccinations so as to not impose on other healthcare providers' territory.

- b. With/from policy makers

Regarding policy makers, there is currently a call from the Ministry of Health on how pharmacists can assist in encouraging parents to have their children vaccinated. One of the options is for pharmacists to vaccinate as a back-up

plan for missed vaccinations. This matter will be discussed with the Ministry of Health to make vaccination authority for pharmacists possible.

c. With/from the public

When vaccination authority for pharmacists is achieved, campaigns will likely be undertaken to inform the public about this new role. The Royal Dutch Pharmacists' Association website will also be updated to include information about pharmacist-led vaccination services.

6.12.5 Mobilisation

A plan is currently under way to mobilise pharmacists. It is expected that a financial model for vaccination by pharmacists will be an important aspect to develop.

6.12.6 Training and certification

When vaccination authority for pharmacists is achieved, training for intramuscular and subcutaneous injection and for basic life support will be developed and, ideally, included in future pharmacy curricula. The University of Utrecht already teaches basic life support as part of the pharmacy curriculum.

6.12.7 Professional standards and requirements

a. For the service itself

It is expected that a protocol will need to be followed.

b. For providers

It is expected that providers will require training for intramuscular and subcutaneous injection and for basic life support.

c. For premises and equipment

It is expected that pharmacies will need to possess an epinephrine injection pen readily available in case of anaphylaxis, stored in an approved refrigerator, among other requirements.

6.12.8 Vaccination records

Vaccination records will be an important issue to develop when establishing vaccination authority for pharmacists. Currently, vaccination records are not commonly shared among healthcare providers.

6.12.9 Assessment of pharmacist-led vaccination

Once work towards pharmacist-led vaccination has been achieved, there will possibly be a pilot project, organised by healthcare providers and insurers.

6.12.10 Advice to other organisations

It is premature for us to provide advice at this stage.

6.13 New Zealand

Organisation:	Pharmaceutical Society New Zealand
Case study author:	Richard Townley
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6.13.1 Key factors

When implementing pharmacist-led vaccination services, several key factors are important to consider:

1. Immunisation rates are not reaching World Health Organization and government target levels using the current system of general practice and vaccination at schools.
2. Outbreaks of measles, meningitis and whooping cough are occurring in some regions, requiring emergency reactions from government agencies; individuals are being admitted to hospital and some are dying.
3. Vulnerable populations find it difficult to get to a general practice surgery and to afford the costs of vaccinating
4. Pharmacy offers better access and equity for communities with no appointments, and offer a service that is affordable for private clients or funded.
5. Specific “at risk” population groups, such as those with mental health conditions, addiction disorders or HIV, may immediately benefit from the service.

6.13.2 Timeline

Date	Event
2009	Local pilot pharmacy flu vaccination services are set up. Pilot project becomes the mainstream service for local pharmacies.
2011	Corporate pharmacy group sets strategy and applies for a number of pharmacists to become vaccinators. The government reviewed standards and stated trained pharmacists could vaccinate against flu, but only for private paying clients.
2012	The pharmacy vaccination programme was evaluated, and government and stakeholders held meetings together. The government set new pharmacist guidelines for the national flu immunisation programme. There was a successful application concerning the immunisation guidelines by corporate pharmacy and specialist consultants to reclassify influenza vaccines as deliverable to adults by pharmacists.
2015–16	Regional Health Authority bodies pilot pharmacy providing funded influenza vaccines to patients aged 65 years old and over. Government electronic national immunisation registers are able to receive pharmacy notifications of patient details of vaccinations.
2017	The government allows pharmacists to provide funded flu vaccines to patients older than 65 years and pregnant women.

6.13.3 Main challenges

- Government recognition of pharmacists as vaccinators
- Enrolling pharmacists in vaccinator training for all health professionals
- Gathering volume of support from pharmacy/pharmacists and pharmacy investment in submissions to change regulations
- General practice resistance
- Pharmacy access to government public health immunisation registers to record pharmacy patients

6.13.4 Partnerships and support

- a. With/from other health professions

Support from general practice was not forthcoming.

b. With/from policy makers

To achieve partnerships with policy makers, pharmacy can be added to the equation to achieve desired immunisation rates. In addition, public access and equity are important concepts.

A pilot project can be conducted to generate evidence for presentation in applications for reclassification. Pharmacy is now part of Government strategy for all immunisation programmes for the future.

c. With/from the public

Uptake by the public rapidly increased, due to access and then funding for targeted population segments. Promotion and media advertising from large pharmacy groups, based on research, presenting pharmacists as trained vaccinators also contributed to achieving public support.

6.13.5 Mobilisation

A corporate pharmacy group led the mobilisation of its pharmacies and pharmacists and invested in strategy.

6.13.6 Training and certification

Pharmacists undergo the same vaccinator training as all health professional vaccinators which is provided by the same authorised and recognised organisation.

6.13.7 Professional standards and requirements

Professional standards and requirements for the service itself, for providers, and for premises and equipment can be found online.¹

6.13.8 Vaccination records

Currently, integrated electronic national immunisation records are used. Each pharmacy has its own portal to input patient details, which is a Government imperative, and allows general practice to identify and prevent vaccines being administered more than once.

6.13.9 Assessment of pharmacist-led vaccination

An initial local pilot project was conducted by an innovator pharmacy. Several second larger pilots were conducted for submission for reclassification from corporate pharmacy groups.

6.13.10 References

1. New Zealand Government. Pharmacist vaccinators [Internet]. New Zealand Government; 2018 [cited 2019 Jul 21]. Available from: <https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-programme-decisions/pharmacist-vaccinators>

6.14 Philippines

Organisation:	Philippine Pharmacists Association
Case study author:	Yolanda R. Robles
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6.14.1 Key factors

Several priority ideas that were considered when advocating for pharmacist-led vaccination services include:

1. Two top causes of mortality are vaccine-preventable (pneumonia and influenza)
2. The vaccination rate among adults is poor, and the government only supports immunisation for children
3. Pharmacies are strategically located all over the country
4. Indication of trust in the capacity of pharmacists to vaccinate adults by the Philippines Food and Drug Administration
5. The implementation of universal health care provides an opportunity for pharmacists to be involved in health promotion and disease prevention

6.14.2 Timeline

Date	Event
June 2014	The Philippine Pharmacists Association (PPhA) presented a concept paper to the Food and Drug Administration and the Professional Regulation Commission on the potential role of pharmacists in adult immunisation.
October 2014	An Immunisation Stakeholders' Group was created.
December 2014	An Immunisation Training Group was created at the University of the Philippines College of Pharmacy
January 2015	Six training modules were developed by the Immunisation Training Group.
July 2015	The draft training modules were submitted to the Department of Health, FDA, Professional Regulation Commission and PPhA for review.
January 2016	The training modules were reviewed based on recommendations.
January 2017	The core group of pharmacists using the training modules was identified.
July 2017	The core group was trained using the training modules in the Preparation of the Trainers Manual on Adult Immunisation.
October 2017	Guidelines for implementation of adult immunisation services were developed.
April 2018	Soft launch of the PPhA Immunisation Advocacy Presentation of the Trainers Manual on Adult Immunisation and Proposed Guidelines.
April 2018– November 2018	Regional training of immunisation trainers in Luzon, Visayas and Mindanao in cooperation with the schools and colleges of pharmacy.
January–March 2019	A series of dialogues with the Professional Regulation Commission Board of Pharmacy regarding the accreditation of the PPhA as a training arm in pharmacists' immunisation and certification of pharmacists as immunising pharmacists took place.

6.14.3 Main challenges

Main challenges included:

- Delays in approval of guidelines by the regulatory bodies
- Limited resources for the cascade of the training of community pharmacists nationwide/ sustainability of the training programme
- Non-acceptance of/non-familiarity with immunisation practice by certain groups: policy makers, other health professionals, government officials
- Lack of mechanisms for the certification of pharmacists as immunisers by regulatory agencies
- Distrust of the general public on the vaccination programmes of the government due to the recent fiasco on a controversial dengue vaccine (2018)

6.14.4 Partnerships and support

- a. With/from other health professions

Partnerships with/from other health professions were achieved by:

- Including various health professionals in the Vaccination Stakeholders' Group organised by the PPhA
- Joining the activities of the National Foundation on Vaccination — public education, dissemination of leaflets about vaccination
- Incorporating vaccination in the PPhA's continuing professional development programme for pharmacists
- Representing pharmacists in the Department of Health Disease Prevention and Control Bureau

- b. With/from policy makers

To establish partnerships with policy makers, official visits to the Food and Drug Administration, Professional Regulation Commission (PRC) Board of Pharmacy, Philippines Senate, Department of Health, and local government units were organised to discuss the potential benefits of having pharmacists as adult immunisers.

- c. With/from the public

The vaccination module was included in the PPhA's public education campaign during 2018 World Pharmacists Day activities implemented nationwide. Information, education and communication materials were also produced entitled "Myths and facts about vaccination".

6.14.5 Mobilisation

The PPhA established the Advocacy Group on Immunisation in 2017 and this was launched publicly at the national convention in April 2018. A core group is responsible for leading the implementation of adult vaccination by pharmacists from training and guideline development.

The Pharma Roadshow public education programme held during the 2018 World Pharmacists Day mobilised pharmacists in different provinces of the Philippines to educate village residents on vaccination and antimicrobial stewardship. The technical facts and health benefits, including adverse effects of vaccines, were discussed and the public were encouraged to ask questions. With this programme, pharmacists were likewise educated to deal with health promotion activities for the public.

6.14.6 Training and certification

The process of developing the mechanism for certification was undertaken by the PRC Board of Pharmacy in the first quarter of 2019 in coordination with PPhA Immunisation Advocacy Group.

6.14.7 Professional standards and requirements

- a. For the service itself

The Pharmacy Act of 2016 (Republic Act 10918) describes vaccination by pharmacists under the scope of pharmacy practice.

b. For providers

Professional standards and requirements for providers are to be included in the Philippine Practice Standards for Pharmacy which was due for revision in the second half of 2019.

c. For premises and equipment

The proposed guidelines were submitted to the FDA and its decision is awaited by the PPhA.

6.14.8 Vaccination records

The Pharmacy Act of 2016 requires pharmacies to maintain patient medication records. Pharmacists are required to gather and store patients' vaccination data in electronic or manual form as part of the guidelines proposed to the FDA, and data should be maintained confidentially for a specified number of years. Pharmacists are also required to be able to report aggregate vaccination data to the Department of Health on an annual basis to reflect pharmacists' contribution to its immunisation programme.

Currently, there is no existing national health record system yet, but the law on e-health has been recently approved. This development represents an opportunity for data on vaccination to be incorporated in the system. At the moment, the PPhA participates in the preparation of the implementing rules and regulations and the potential inclusion of e-health in the undergraduate pharmacy curriculum.

6.14.9 Assessment of pharmacist-led vaccination

The stage of assessing pharmacist-led vaccination has not yet been reached.

6.14.10 Advice to other organisations

The first step in introducing a new service is to study the relevance and social value of that service, i.e., vaccination by pharmacists. Pharmacy organisations need to work to facilitate the legal and policy framework that will support pharmacist-led vaccination services. There is a need to identify stakeholders and organise a meeting to guide and convince these sectors of the value of vaccination by pharmacists. This includes "physician champions" who have trust in pharmacists.

Potential dissenters/opposers should be addressed early on and misconceptions should be answered so as not to hamper progress of implementation. Vaccination and the required skills to administer vaccines should be included in the pharmacy curriculum.

6.15 Portugal

Organisation:	National Association of Pharmacies and Portuguese Pharmaceutical Society
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6.15.1 Key factors

1. Vaccines are the most effective and safe resource for protection against certain infectious diseases, such as seasonal flu. However, there is a growing trend of misinformation about vaccines, potentiating any potential fear of adverse reactions. Pharmacists, as qualified healthcare professionals, are important to dispel myths and doubts in this matter among the population.
2. Due to their wide geographic distribution, pharmacies represent a valuable healthcare network, working closely to the population and having remarkable relationships of confidence with patients. Pharmacies are

- establishments of great convenience, efficiency and affordability, offering the public extended working hours with no need for appointments.
3. The ageing of the population and the increase of chronic diseases contribute to a higher awareness of the importance of public health and prevention. One of the most effective ways to increase health prevention is through vaccination, where pharmacies can play a significant role, especially in infectious diseases, such as seasonal flu.
 4. Thanks to their proximity and the confidence with which the population relies on pharmacies, pharmacists can identify high-risk patients and specific target groups for vaccination and provide the necessary advice. Pharmacists can also actively participate in health follow-ups, with reminders and recall systems to ensure that vaccination schedules are met, and regional/global targets are achieved.
 5. The flu season is one of the busiest times of the year in hospital emergency rooms and general practices. By receiving the flu vaccine at a pharmacy, patients contribute to promoting a more sustainable health system and to avoiding the overburdening of healthcare units.
 6. The added-value of pharmacy vaccination services through an increasing access to the public and uptake of vaccines promotes evidence-based policies and leverages pharmacies to advocate for a fair remuneration of the vaccination service.
 7. In a world where misconceptions about vaccines are rising, it is imperative to establish a healthcare workforce that is able to support the public's needs and concerns on immunisation and, thus, increasing interprofessional collaboration.

6.15.2 Timeline

Date	Event
2007	New legislation allowed pharmacies to expand their scope of activity into new areas such as immunisation (delivering vaccines that are not covered by the National Vaccination Plan).
2008	The National Association of Pharmacies developed a complete training programme based on the American Pharmacists' Association Certificate Training Programme. A specific intervention model and recommendations to support pharmacies and pharmacists in the provision of this new service during first National Flu Vaccination Campaign was developed. Of note, in the 2019–20 flu season, the National Flu Vaccination Campaign will be in its 12 th edition.
2009	The first vaccination campaign against human papillomavirus was developed.
2010 - 2012	Vaccination campaigns against influenza and pneumococcal diseases were developed.
2013	Certification of the Training Programme for Pharmacists as a Pharmaceutical Competency on Vaccination and Administration of Injectable Medicines was developed.
2016	The National Association of Pharmacies signed an agreement with the Ministries of Health and Finance, in which it is stated that pharmacies can carry out public health interventions, such as vaccination against influenza.
Since 2017	Pharmacy-based influenza vaccination records were integrated into the electronic vaccination bulletin of the national health system.
2018–19	A pilot project for influenza vaccination without the need for a prescription and charges for vaccine and administration was established in the municipality of Loures, in the district of Lisbon.

6.15.3 Main challenges

- The initial limitations to the development of pharmacists' role in immunisation were associated with constraints in the legislation, as well as acceptance, support and recognition by other healthcare professionals, particularly by nurses
- When this service was launched, the population was not used to having pharmacists vaccinate, an act which was previously performed by other healthcare professionals (e.g., nurses); it was necessary to gain the population's confidence and satisfaction
- Initially, pharmacists showed some discomfort in providing the service, mainly due to technical aspects; that barrier was overcome through practical training in the administration of vaccines and injectable medicines

6.15.4 Partnerships and support

a. With/from other health professions

The presentation of vaccination results in Portuguese pharmacies were several times presented at conferences promoted by health entities and healthcare professionals. An example of this is the European Science Working Group on Influenza, at which Portuguese pharmacies were repeatedly requested to share their successful results.

b. With/from policy makers

Regarding partnerships with policy makers, Portuguese pharmacies have always shown their complete willingness to participate in meetings promoted by the General Directorate of Health, which brings together several Portuguese health entities. The production of evidence regarding the added value for payers was decisive.

c. With/from the public

With regard to gaining the support of the public, a satisfaction survey was sent to persons vaccinated in the first national campaign against Influenza. The results showed that 94% of the respondents were satisfied or very satisfied with the service. Since 2008, an annual immunisation campaign has been developed nationally.

6.15.5 Mobilisation

In Portugal, pharmacists are required to be registered by the Portuguese Pharmaceutical Society, which is directly responsible for accrediting the vaccination training and issuing the pharmaceutical competency certificate. The National Association of Pharmacies, which represents 94% of pharmacies, developed efforts of informing pharmacists about the added-value of delivering vaccination and administering injectable medicines in their own pharmacies. The support provided to pharmacies and pharmacists by the national organisations on training, regulatory information and guidelines was key to successful implementation of the vaccination service.

There is an annual vaccination campaign, airing on national television, to raise awareness on the importance of vaccination and reminding the public of the proximity and competence of pharmacies and pharmacists. All in all, it was a gradual process since 2007 and all the concerned parties were consistently informed and invited to participate.

6.15.6 Training and certification

To be able to vaccinate, pharmacists are required to be certified by the Portuguese Pharmaceutical Society (PPS) and to hold a pharmaceutical competency accreditation (PCA) on vaccination and administration of injectable medicines.

The PPS developed a common training framework for the minimum training requirements in order to certify training programmes with PCA.¹

The minimum requirements lay out a number of modules and contents that are required to be included in any training programme certified by the PPS.

Apart from the training programme, pharmacists are required to hold a training in basic life support (cardiopulmonary resuscitation and automated external defibrillation) for the PCA to be valid. The PCA (includes both the vaccination training and the basic life support training) is valid for five years. After this time, pharmacists are required to enrol in an online recertification training (which is also subject to PPS certification) and attend a basic life support training course for the PCA to be renewed for another five years.

6.15.7 Professional standards and requirements

- a. For the service itself

No information.

- b. For providers

Only pharmacists who have received specific training recognised by the Portuguese Pharmaceutical Society and nurses who were hired to vaccinate can provide the service in Portuguese pharmacies.

- c. For premises and equipment

To provide this service, pharmacies must have the following premises and equipment:

- Adequate facilities for providing the service
- Chair or couch
- Hand/surfaces sanitiser
- Disposable gloves
- Alcohol
- Compresses
- Syringes and needles
- Sticking plasters
- Container for collection of hospital waste
- Sphygmomanometer
- Stethoscope
- Equipment and medicinal products to treat an anaphylactic event (epinephrine, oxygen kit)

6.15.8 Vaccination records

Vaccination record data are registered on the pharmacy information system and have been automatically integrated on the electronic vaccination bulletin of the national health system Patient Health Data Platform since 2018.

Vaccination records are mandatory. More than 90% of Portuguese pharmacies register on SIFARMA (the informatics system) information about the patient's name, age, sex and national health system number, trade name of the vaccine, lot number, route of administration, date of administration and the name of the pharmacist who administered the vaccine.

6.15.9 Assessment of pharmacist-led vaccination

Under an agreement with the Ministry of Health to further integrate vaccination in the public national health system, the Directorate-General for Health invited a group of 39 community pharmacies to collaborate as vaccination points against influenza. The pilot took place in Loures, District of Lisbon, between 15 October and 31 December 2018. The goal was to increase flu vaccination coverage in people aged 65 years or over by improving access to the vaccination through the contribution of pharmacies. The results were very positive when compared with those of the previous year. The collaboration between Loures pharmacies and national health system health centres resulted in a 31.8% increase in vaccination coverage in this municipality.²

6.15.10 Advice to other organisations

- Contact policy makers — Pharmacies have a significant role in public health due to their high distribution and proximity. When evidence shows that the service generates financial benefits and positive results on healthcare, it is easier to be granted political support.
- Ensure appropriate training — Pharmacists are healthcare professionals with appropriate skills and can reinforce their competencies with qualified training to administer vaccines.
- Optimise the use of technology — New technologies can leverage closer cooperation between healthcare professionals, namely the existent connection between the information technology system of the pharmacies and the Patient Health Data Platform.
- Inform patients about vaccination benefits — Vaccination against influenza among people aged 65 years or over has fallen in many countries, and pharmacists have an important role to counter this trend. It is essential to communicate effectively with the population about the existence and importance of the service. The need for investment on the creation of institutional advertisements and publicity should be considered.
- Conduct pilot projects — Recognising the most fragile locations with motivated and experienced pharmacies could represent a good opportunity to build a small pilot.
- Share your experience — When pharmacists realise the impact the service can have in the population, with improvement of quality of life, the promotion of a more sustainable health system and, of course, the possibility to have the service reimbursed, there is a higher motivation to succeed.

6.15.11 References

1. National Direction of the Order of Pharmacists. Administration of vaccines and injectable medications in community pharmacy [Internet]. National Direction of the Order of Pharmacists; 2018 [cited 2019 Jul 21]. Available from: https://www.ordemfarmaceuticos.pt/fotos/documentos/adminstracao_de_vacinas_e_medicamentos_injetaveis_em_farmacia_comunitaria_1320614745c59b0bf7c757.pdf
2. Finnegan G. Pharmacy pilot project increases flu vaccination by 32% [Internet]. Vaccines Today; 2019 [cited 2019 Jul 21]. Available from: <https://www.vaccinestoday.eu/stories/pharmacy-pilot-project-increases-flu-vaccination-by-32/>

6.16 Switzerland

Organisation:	pharmaSuisse
Case study author:	Danielle Stegmann, Luc Besançon
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6.16.1 Key factors

1. Switzerland has low vaccination coverage rates, especially for measles.
2. Public demand, trust in the role of the pharmacist, and willingness to be immunised in community pharmacies.
3. Convenience through high accessibility to pharmacies given their longer operating hours.
4. In an effort to strengthen preventive measures, the Swiss Government supported an increased role of pharmacists in primary care in its national vaccination strategy (which was further reflected in its non-communicable diseases strategy and revision of the Medical Professions Act).
5. Pharmacists are important players able to support the national vaccination strategy to increase the overall vaccination rate. Pharmacists are not only involved in vaccination counselling, but also in vaccinating adults in the majority of the cantons.¹

6.16.2 Timeline

Date	Event
2008	Vaccination by pharmacists was discussed at the 2008 FIP congress in Basel. pharmaSuisse also organised a vaccination symposium for Swiss pharmacists to raise their awareness on this topic.
2009	A campaign to support pharmacists in vaccination counselling and promote the use of the electronic vaccination record (viavac) was organised. Discussions with the Swiss Ministry of Health began.
2010–12	Development of a dedicated education programme leading to certification for pharmacists.
2015	Change of legislation with the introduction of vaccination services by pharmacists in five cantons (out of 26), with one canton allowing a pilot with only three pharmacies.
2018	Official study analysing vaccination rates of 2016–17 and 2017–18. The University of Basel was the first university to integrate vaccination in the undergraduate curriculum.
2019	The University of Zurich integrated vaccination in its undergraduate curriculum for pharmacists. Nowadays, almost all cantons have granted vaccination rights to pharmacists (with the exception of four cantons and an additional canton where vaccination may only be done with a medical prescription). The number of vaccinations performed in community pharmacies continues to grow: 20,500 flu vaccinations were recorded on a voluntary basis in the 2018–19 season; 21,600 tick-borne encephalitis vaccinations have been administered in the 2018–19 season up until 4 June 2019.

6.16.3 Main challenges

Switzerland is a federal state, where pharmacy practice is defined at canton level: there are 26 different regulations and scopes of practices. The implementation required advocacy work in 26 different parliaments.

Other challenges include:

- Limited acceptance/support by other healthcare professionals
- No financial support by government/health system
- No business case for community pharmacies
- Lower density of pharmacies in some German-speaking cantons (where dispensing doctors are allowed)

6.16.4 Partnerships and support

- With/from other health professionals
 - Establishment of high-quality postgraduate education for pharmacists, with involvement of other healthcare professionals
 - Education approved by medical specialists and members of the governmental commission of vaccination
 - Some education modules, such as vaccination techniques and resuscitation techniques, were delivered by medical specialists
 - Support of the implementation of vaccination in community pharmacy through appropriate documentation (e.g., algorithms and questionnaires to be filled with the patient to assess potential risk factors associated with vaccination) which benefited from the review of medical experts

- b. With/from policy makers
 - Federalism: discussions started with one canton (Zurich) and later expanded to other cantons
 - Discussions with and regular information to the Swiss Ministry of Health
 - Efficient information and advocacy toward the parliament by pharmaSuisse
 - Inclusion of pharmacists in the governmental national vaccination strategy

- c. With/from the public
 - High confidence in and acceptance of the pharmacist in public vaccination was instrumental in strengthening the role of pharmacists and their relationships with their patient; it was welcome by the public and contributed to upholding pharmacists' reputation
 - Promotion of the services through local community pharmacies (specific communication tools were developed by pharmaSuisse and shared with its members)

6.16.5 Mobilisation

To engage pharmacists in vaccination services, it was imperative to motivate pharmacists to embrace their new role as a healthcare professional, including in preventive health care.

To motivate pharmacists to participate in increasing vaccination coverage, pharmaSuisse worked towards the inclusion of pharmacists in the governmental national vaccination strategy. They also responded to pharmacists' questions on vaccination as well as interacted with canton health authorities involved in the implementation of vaccination.

Tools to empower pharmacists included:

- Partnership with viavac (the Swiss electronic vaccination record) to facilitate vaccination counselling by pharmacists
- Development and provision of high-quality education programmes leading to certification
- Development and provision of vaccination service material as well as important documents (e.g., triage questionnaires) to support pharmacists in the promotion and provision of vaccination services
- Development and implementation of an easy-to-use reporting system which also supports the annual evaluation of the impact of pharmacy vaccination services

6.16.6 Training and certification

The training is a five-day programme, covering:

- A theoretical component: the governmental national vaccination plan, epidemiology, theory about vaccinations and illnesses, electronic tools
- A practical component: injection techniques and resuscitation courses

A refresher course (consisting of two half-day courses), including a resuscitation refresher, is required every two years.

This education is now integrated in the undergraduate curricula of two universities in Basel and in Zurich and will be integrated in Geneva university's curriculum in 2020.

The standards for the education of pharmacists can be accessed here:

- In [German](#)
- In [French](#)

6.16.7 Professional standards and requirements

- a. For the service itself

Service standards have been defined by pharmaSuisse. They are available to pharmaSuisse members.

- b. For providers

Each pharmacist must hold the certificate “Vaccination and blood sampling”, which needs to be renewed every two years.

- c. For premises and equipment

Each canton has set a list of specifications for the provision of vaccination services in a pharmacy (premises, equipment, hygiene, etc.)

6.16.8 Vaccination records

There is no national electronic health record in Switzerland. pharmaSuisse has partnered with the main electronic vaccination record in Switzerland, called viavac (www.viavac.ch), which can be accessed by healthcare professionals.

In addition, there is also a vaccination record (online tool) sponsored by the Swiss Ministry of Health for use by healthcare professionals as well as by the public.² pharmaSuisse promotes the use of viavac among its members, but it is not a requirement for any healthcare professional to use this record.

6.16.9 Assessment of pharmacist-led vaccination

pharmaSuisse performs an annual assessment of the impact of pharmacies on immunisation using the self-developed online platform for its members.

Moreover, an independent study was performed by the firm BSS on vaccination services in pharmacies regarding the number of vaccines as well as pharmacists’ satisfaction with this service.³

6.16.10 Advice to other organisations

- Motivating pharmacists to undertake additional education to strengthen their role as healthcare professionals
- High quality and credible education
- Collaboration with vaccination specialists and local physicians
- Good communication and repeating transparent information with healthcare authorities and main stakeholders
- Long-term advocacy work with Parliament, policy makers and relevant stakeholders
- Understanding the barriers, concerns and needs of pharmacists to implement this new service and responding to these through appropriate support by national association such as standard operating procedures, communication materials, professional tools and other forms of support

6.16.11 References

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2. MyVaccines Foundation. The Swiss electronic vaccination record [Internet]. MyVaccines Foundation; c2019 [cited 2019 Jul 21]. Available from: <https://www.mesvaccins.ch/>
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<https://www.pharmasuisse.org/de/1987/Cleveren-L%C3%B6sungen-Impfen-in-der-Apotheke.htm?Article=1598463>

6.17 United States of America

Organisation:	American Pharmacists Association
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6.17.1 Key factors

1. Community need — What are the current vaccination rates and public health needs of the community that pharmacists could have an impact on? If access is an issue, pharmacists can help address it
2. Needs of other healthcare professionals — Identify gaps and challenges that pharmacists could assist in addressing
3. Support of patients — What are the challenges patients experience in obtaining desired vaccinations that pharmacists could address? How comfortable are patients with getting vaccinated by trained pharmacists?
4. Pharmacists' knowledge and ability — Consider training a group of pharmacist before seeking authority on a broad scale and have these pharmacists engage with coalitions and other providers around immunisation efforts in the community
5. Engage in local immunisation activities — demonstrate pharmacists' commitment to improving public health

6.17.2 Timeline

Date	Event
Since 1996	<p>The American Pharmacists Association (APhA) House of Delegates adopts policy calling on pharmacists to assume at least one of three roles: educator, facilitator or administrator of vaccines.</p> <p>APhA developed and adopted guidelines for pharmacy-based immunisations.</p> <p>APhA developed and delivered a pharmacy-based immunisation delivery certificate training programme. Over the years utilised, with partners, a train-the-trainer model to train more than 340,000 pharmacists. Along with this, developed process and commitment for keeping information current and providing continuous education to pharmacists.</p> <p>APhA has worked with state affiliates to expand scope of authority for pharmacists related to immunisation activities — types of antigens pharmacists can administer, age of patients to whom pharmacists can administer vaccines and procedures pharmacists must follow. The ultimate goal is to attain authority for pharmacists to administer all Centers for Disease Control Advisory Committee on Immunization Practices (ACIP) recommended vaccines across a person's lifespan.</p>
Since the early 2000s	<p>Pharmacists took up leadership roles within immunisation coalitions and were appointed to National Immunization Advisory Committees (APhA was given a liaison seat on the ACIP, Steering Committee on the National Adult and Influenza Immunization Summit, pharmacist became voting member on the HHS National Vaccine Advisory Committee (NVAC) and APhA provided a liaison seat on NVAC.</p>
2007	<p>APhA calls on all pharmacy personnel to receive all ACIP recommended vaccines for healthcare providers. In addition, the policy called on pharmacist recognition as "first responders" in disaster and pandemic situations.</p>

2012

APhA coined the term “immunisation neighbourhood”, which has now been embraced by stakeholders throughout the medical and public health community,

6.17.3 Main challenges

- Support of the medical community; concern with disruption of the medical home
- Gaining legislative/regulatory authority
- Payer recognition and inclusion as in-network providers
- Support of pharmacy management and critical mass of pharmacists, giving pharmacists a comfort level with providing the service on top of their other activities
- Access to vaccination history and documentation

6.17.4 Partnerships and support

a. With/from other health professions

APhA identified what the challenges and needs of other health professionals were and how pharmacists could help address them. We also showed them the education pharmacists received (which was more than most healthcare providers received) and affirmed that we were not trying to disrupt the medical home but instead help them (and even refer patients back to them as about 40% of patients did not have an identified primary care provider). We encouraged pharmacists to ask physicians how they would like to be informed and the parameters of the protocol agreement. In some cases, where there was resistance, we obtained agreement to do a pilot. That demonstrated what pharmacists could do and led to support for broader authority.

b. With/from policy makers

Regarding partnerships with/from policy makers, we identified the gap in vaccination rates and established national goals under the current/traditional system. What harm would it do if we added pharmacists as authorised immunisers? In some cases, we had to start with authority for influenza and pneumococcal vaccinations for patients aged 18 years and over, and then demonstrated what pharmacists could do — with no problems documented. That led to expansion of authority (more antigens and a wider age range of patients who could be vaccinated). We demonstrated the education and training pharmacists and student pharmacists receive in this area.

c. With/from the public

Regarding support from the public, we educated the public about the importance of vaccinations, the education and knowledge of pharmacists, and the convenience of getting vaccinated by pharmacists. We demonstrated to the public that pharmacists can and do follow established procedures that other health professionals follow. Pharmacies utilised their marketing/advertising mechanisms to promote vaccinations and the role of pharmacists. Our goal was to move pharmacists from patient education that said “ask your physician and other healthcare professionals” to “ask your physician, pharmacist or other healthcare professionals” (with the aim of removing pharmacists from the “other” category, which we were successful in achieving).

6.17.5 Mobilisation

APhA incorporated immunisations as a critical component of the organisation’s strategic plan that resulted in its inclusion across all aspects of our work (education, publications, advocacy, etc). We published success stories, addressed potential barriers with solutions and worked with state affiliates, providing access to our subject matter experts. In addition, we provided tools to pharmacists to assist in implementation of immunisation services and worked with our government’s largest payer (Medicare) to have pharmacists recognised and compensated as immunisation providers, like other immunisation providers. We utilised immunisations to paint the picture for the future patient care direction of pharmacists and its importance in gaining recognition for pharmacists providing other patient care services. We established a national awards programme to highlight best practices and drive pharmacists to seek expanded authority.

We also engaged student pharmacists early in their careers to understand the importance of immunisations and carry that with them as they entered into practice.

6.17.6 Training and certification

When APhA developed its training programme 23 years ago, the vision was to train pharmacists to be knowledgeable and accessible resources for vaccines across a person's lifespan. Even though pharmacists may not be able to administer all vaccines in every US state, APhA wanted to make sure that they were knowledgeable to serve as a resource to help patients and caregivers to understand the vaccine recommendations and how to read the schedule, to be a knowledgeable resource for patients and the public to ask questions, and to be valued providers within the immunisation neighbourhood.

Today, more than 340,000 pharmacists have been trained through APhA's gold standard training programme, recognised by the US Center for Disease Control and Prevention for its quality and content. To achieve these training numbers we utilised partnerships and a train-the-trainer approach. The 20-hour training programme has been reviewed by physicians, nurses and public health professionals who acknowledged that the programme met or exceeded the immunisation training most other health professionals receive.

APhA made a commitment to keep the programme updated, as recommendations can change throughout the year. In addition to the initial training, keeping pharmacists up to date on the newest immunisation recommendations is critical, and our immunisation training and information portfolio fulfils this need. Pharmacists are continually building their skillsets to support their ability to meet community needs like their expansion into the provision of travel health services (for which APhA has developed a specific training programme).

6.17.7 Professional standards and requirements

a. For the service itself

APhA created guidelines for pharmacy-based immunisations.¹

APhA also developed a resource for incorporating immunisation services within the Pharmacists' Patient Care Process.²

b. For providers

Pharmacists are expected to follow national standards and state-based requirements, in the same way as other immunisation providers.

Of note is that state boards of pharmacy and/or public health departments may issue requirements for immunisation providers.

c. For premises and equipment

Standards for premises and equipment are influenced by the requirements imposed by state legislators and regulators (board of pharmacy and/or public health). Pharmacists are able to administer vaccines within their practice setting as well as in their communities.

6.17.8 Vaccination records

One major concern raised by medical providers is receiving documentation when vaccines are administered by pharmacists. Pharmacists still have limited access to electronic health records, but in most states they have access to immunisation information systems (IIS, also known as immunisation registries) to report vaccinations to. In addition, pharmacists are encouraged to inform patients' primary care providers (if known) of the vaccinations and to provide patients with documentation of the vaccinations provided. The US vision is to have the IIS serve as the portal for all immunisation providers to report to and to access patients' immunisation history for forecasting patient immunisation needs.

6.17.9 Assessment of pharmacist-led vaccination

There have been many studies, articles and awards programmes conducted over the past 25 years that have demonstrated the value and impact of pharmacists as immunisation providers.

Some of the resources and studies can be found online.^{3,4}

6.17.10 Advice to other organisations

- Learn from organisations like APhA, which have dealt with the challenges and have created a sustainable model
- If political pressure against the authority is strong, it can be foreseeable to request for a pilot project or to start slow to demonstrate what pharmacists can do; some of our best advocates for expanded pharmacist authority are non-pharmacists
- Meet or exceed existing standards and inform pharmacists that engagement in immunisations requires continuous education as vaccine recommendations change; in addition, have representatives from pharmacy participate in immunisation coalitions and other activities to demonstrate the profession's commitment to improving public health
- Encourage practices to identify immunisation champions who could coach other pharmacists and serve as leaders in your country to assist in advocacy and relationship building
- Seek ways practices can make immunisation a “team sport” through engagement of all their practices' staff and develop collaboration with other providers in the community

6.17.11 References

1. American Pharmacists Association. Guidelines for pharmacy-based immunization advocacy and administration [Internet]. American Pharmacists Association; 2019 [cited 2019 Jul 21]. Available from: https://pharmacist.com/sites/default/files/files/Guidelines_for_Pharmacy_Based_IMZ_Advocacy_Approved_Jan_26_2019.pdf
2. American Pharmacists Association. Resource guide for immunization services [Internet]. American Pharmacists Association; c2019 [cited 2019 Jul 21]. Available from: https://pharmacist.com/resource-guide-immunization-services?is_sso_called=1
3. American Pharmacists Association. Immunization center [Internet]. American Pharmacists Association; c2019 [cited 2019 Jul 21]. Available from: https://pharmacist.com/immunization-center?is_sso_called=1
4. American Pharmacists Association Foundation. Project impact immunizations [Internet]. American Pharmacists Association; [cited 2019 Jul 21]. Available from: <https://www.aphafoundation.org/project-impact-immunizations>

6.18 Wales (United Kingdom)

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6.18.1 Key factors

1. The previous model of flu vaccination led by general practitioner practices was not sufficient to meet national vaccination targets.
2. A new service model was needed to support further progress towards achieving the World Health Organization's recommendation of achieving 75% uptake in flu vaccination rates for all those in at-risk groups.

3. The pharmacy model was considered to offer potential advantages regarding accessibility, especially for patients unable or unwilling to access GP practices during standard working hours.
4. The continued growth in pharmacy vaccination numbers suggests that patients value the service.

6.18.2 Timeline

Date	Event
0–12 months	The first national flu vaccination enhanced pharmacy service was planned and implemented in a number of pilot sites in Wales, with a particular focus on rural communities. Uptake was evaluated in terms of total numbers of people vaccinated and with regard to specific target groups — 65 year olds and over, and 0–64 year olds.
13–24 months	All pharmacies were invited by commissioners to participate in future flu vaccination campaigns. Eighty-one pharmacies in Wales provided the service between 1 October 2012 and 31 January 2013, representing 11% of pharmacies in Wales.
25–60 months	Continued development and national evaluation of community pharmacy flu vaccination service demonstrate year on year increases in vaccination uptake via community pharmacy. By 2017–18, 60% of all community pharmacies in Wales were responsible for delivering 4.5% (36,130) of all flu vaccinations in Wales.

6.18.3 Main challenges

Training

Implementing a robust national training and accreditation programme has been challenging. Providing face-to-face training across large geographical areas, especially rural areas, managing cross-border pharmacist accreditation and varying content delivered by private training providers were just some of the key challenges to implementing a community pharmacy flu vaccination service.

Timescales

Providing community pharmacies with finalised service documentation and patient group directions^a well in advance of the service start date represented one of the main challenges. Adoption of national flu vaccination template, developed by public health authorities, helped to move the service forward at a quicker pace. Public Health Wales adopted the Public Health England template for this purpose.

Private versus public services

There was some confusion with patients and GP practices regarding the difference between and responsibilities associated with varying service models.

Capacity

Offering the service can be time-intensive for pharmacies with limited capacity, especially during October and November. Vaccination services may limit the delivery of other pharmacy services.

Finance

Pharmacies may be averse to financial exposure associated with vaccine purchase. There may also be a perception that pharmacy and GP practice services are “competing” for same cohort, with associated financial implications and tensions between the community pharmacy sector and GP.

^a Patient Group Directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber). Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.¹

6.18.4 Partnerships and support

a. With/from other health professions

Initial concerns were raised by GPs regarding the safety of vaccination within pharmacies, including potential for double vaccination at GP practice and pharmacy. In addition, there was also a concern regarding the potential for financial impact on GP sustainability if the number of patients accessing vaccination at GP practices were to decrease significantly. Commissioning bodies audited the quality of information provided to patients by vaccinating pharmacies and were able to manage individual concerns.

b. With/from policy makers

National steer regarding pharmacy flu vaccination was vital in securing commitment to the service and bolstering confidence in pharmacy flu vaccination services among commissioners. Managing objections to the service was straightforward in terms of the aims to increase access to services and increase uptake in flu vaccinations, particularly in target/at risk groups.

c. With/from the public

National and publicly funded promotion of the service is limited. However, several pharmacies are highly proactive in raising awareness directly with patients. Vaccination numbers have grown considerably in recent years, suggesting the service has public support.

6.18.5 Mobilisation

There were limited efforts to engage pharmacists initially. Once financial potential was realised, community pharmacies with the capacity needed to effectively deliver vaccination services were engaged. Challenges remain in encouraging some community pharmacies to consider achieving accreditation and delivering the community pharmacy flu vaccination service.

6.18.6 Training and certification

Consensus on a national process was achieved and originally developed by the national training and education provider using NHS trainers. A national steer on training continues through this route, but pharmacists access training via approved private providers. There is some variation between geographical/ commissioning areas, i.e., anaphylaxis training, and there is some variation in content in the training provided by different private providers.

6.18.7 Professional standards and requirements

a. For the service itself

Professional standards and requirements regarding the seasonal influenza vaccination exist.² The Royal Pharmaceutical Society also provides member-specific advice on setting up an influenza vaccination service.³

b. For providers

There are national minimum standards and a core curriculum for immunisation training for registered healthcare practitioners.⁴

c. For premises and equipment

There are standards for the delivery of pharmacy services.⁵

6.18.8 Vaccination records

Initially, the pharmacist-led vaccination service was introduced as a paper-based service. An electronic flu module has since been introduced to support effective electronic records and improved communication. Further development will support electronic communication regarding vaccination.

6.18.9 Assessment of pharmacist-led vaccination

The implementation of the community pharmacy influenza service was evaluated at a national level, and the results have been published.⁶

6.18.10 Advice to other organisations

- Formalise training and accreditation requirements well in advance
- Target “new” cohorts of patients rather than compete for existing patients
- Allow community pharmacy to promote services within agreed limitations
- Publicise success, and support and reward community pharmacies providing robust and accessible services

6.18.11 References

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2. Season influenza vaccination service [Internet]. Community Pharmacy Wales; [cited 2019 Aug 19]. Available from: <http://www.cpwales.org.uk/Contract-support-and-IT/Enhanced-Services/Seasonal-Influenza-Vaccination-Service.aspx>
3. Setting up a flu vaccination service [Internet]. Royal Pharmaceutical Society; c2019 [cited 2019 Aug 19]. Available from: <https://www.rpharms.com/resources/quick-reference-guides/setting-up-a-flu-vaccination-service>
4. National minimum standards and core curriculum for immunisation training for Registered healthcare practitioners [Internet]. Public Health England; 2018 Feb [cited 2019 Aug 19]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679824/Training_standards_and_core_curriculum_immunisation.pdf
5. Standards for registered pharmacists [Internet]. General Pharmaceutical Council; c2019 [cited 2019 Aug 19]. Available from: <https://www.pharmacyregulation.org/standards/standards-registered-pharmacies>
6. Community pharmacy influenza vaccination 2012-13 [Internet]. Welsh Government; 2013 [cited 2019 Aug 19]. Available from: <https://gweddill.gov.wales/docs/dhss/publications/131009pharmacyflureporten.pdf>

7 Conclusions

FIP has prioritised and supported an expanded role for pharmacists in improving vaccination coverage rates around the world through a variety of roles — from raising awareness and trust in vaccines to providing evidence-based advice on vaccinations, to administering vaccines and updating vaccination records. This commitment is driven by the evidence of the impact that pharmacists already have in the vaccination landscape in several countries and by our profession's alignment with the global health agenda and priorities of the World Health Organization.

Over the years, FIP has conducted surveys, published reports, organised seminars and congress sessions and advocated on behalf of our member organisations about the contribution of pharmacists to reducing the burden of communicable diseases through an expanded use of vaccines.

With this toolkit, we aim to support pharmacists' organisations worldwide in claiming or expanding their role in vaccination systems. This publication not only offers a set of practical tools and contents to assist our member organisations in developing their own advocacy strategy, but it also compiles evidence and best practice from around the world that can inspire others to move forward.

Some of the key final messages we can extract include:

- It is a global imperative to consolidate primary health care and disease prevention strategies to reduce the burden of disease and make health systems more efficient and resilient. Vaccines are among the safest and most effective tools to prevent and eradicate communicable diseases, and it remains a global priority to improve access to vaccines and vaccination coverage rates among all age groups.
- It is paramount to adopt a life-course approach to vaccination in all countries. From new-born infants to older adults, each age-group has particular needs in terms of disease prevention and deserves the highest possible standards of quality of life and disease-free well-being.
- Vaccines are second only to clean water in terms of their impact on public health. But they are also a sound investment from an economic point of view, with up to US\$ 44 returns on investment for every \$1 spent on immunisations.
- There is established evidence of the advantages of pharmacists' roles in immunisation in terms of improved accessibility and supply, vaccination rates and coverage; and public acceptance and trust in vaccines.
- There is a growing trend for an active involvement of pharmacists with vaccination-related services, with a rapid development in the past decade.
- Access to education and training is key in progressing development of vaccination and vaccine-related services.
- Balanced reimbursement systems would contribute to growth of vaccination services, both in terms of widespread implementation and sustainability over time.
- Perceived competition threats to other healthcare professionals providing immunisation services are diminishing but remain a challenge in some countries. An expanded role for pharmacists in vaccination is aimed at increasing vaccination coverage rates, not shifting demand from one provider to another.
- Greater advocacy of the known public health gain of increased vaccination coverage and ease of access through community pharmacies is essential.
- Leadership bodies should consider targeted campaigns to promote the established societal benefits of pharmacy-based vaccination.
- Preparing the environment before initiating the advocacy process is of utmost importance: planning education and certification of pharmacists, assessing public acceptance, compiling evidence and solid arguments, gaining the support of policy makers and political parties, and engaging pharmacists.

Be sure to count on the support of FIP's team and our network of volunteers and member organisations throughout your advocacy journey.

#FIP4vaccination / #VaccinesWork / #pharmacists

Appendix 1. Pharmacy vaccination service — Patient satisfaction questionnaire

Please note that the survey questions and response categories should be tailored to the purpose of your evaluation, your vaccination service(s) and how these are promoted.

Your opinion counts and can make a difference. We use feedback from patients to improve our service.

We would be grateful if you could complete this questionnaire — it should take less than five minutes. All responses are anonymised and all information will be kept confidential. If you have any questions please ask a member of our staff who will be happy to assist you.

Your gender

- Male Female Other

Your age

- Under 18 18–24 25–34 35–44
 45–54 55–64 65 or over

Did you have a flu vaccination last year/winter?

- Yes, in this pharmacy Yes, in another pharmacy Yes, in my healthcare centre
 No, I wasn't able to No, I chose not to Other, please specify _____

How did you hear about our pharmacy's flu vaccination service? (Select all that apply)

- I have used this service before From the pharmacy staff Poster in this pharmacy
 From my doctor/nurse Poster in the healthcare centre Word of mouth
 An advert (newspaper, TV or radio) Other, please specify _____

What did you like most about our vaccination service? (Select all that apply)

- Not having to book an appointment
 This is the pharmacy I regularly use
 Difficulty getting an appointment at my healthcare centre
 Convenient location (i.e., easier for me to get to the pharmacy)
 Convenient opening hours
 Treated well by staff
 I was given the right amount of information
 Quick and easy
 Other, please specify _____

What is your level of satisfaction with the following?

a) How soon you were able to book an appointment

- Very satisfied Fairly satisfied Not very satisfied Not at all satisfied

b) Information provided by pharmacy staff about your vaccination and/or the pharmacy vaccination service

- Very satisfied Fairly satisfied Not very satisfied Not at all satisfied

c) Waiting time before getting your vaccination administered

- Very satisfied Fairly satisfied Not very satisfied Not at all satisfied

d) The consultation room where you had your vaccine administered

- Very satisfied Fairly satisfied Not very satisfied Not at all satisfied

Overall, how satisfied are you with the vaccination service you received today?

- Very satisfied Fairly satisfied Not very satisfied Not at all satisfied

Would you recommend our vaccination service to your family and friends?

- Yes Maybe/Not sure No

How can we improve our service?

Thank you for your time

Appendix 2. Pharmacy vaccination service — Additional practical tools and resources

Resources to support the development of a vaccination service

- ACT pharmacist vaccination standards [Internet]. Australian Capital Territory Government, Health Directorate. Available from: <https://www.legislation.act.gov.au/View/di/2019-42/current/PDF/2019-42.PDF>
- Guidance on the provision of vaccination services by pharmacists in retail pharmacy businesses [Internet]. The Pharmaceutical Society of Ireland; 2019. Available from: https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/PharmacyServices/Vaccination_Service.aspx
- Guidelines for conducting pharmacist initiated and administered vaccination service within a New South Wales community pharmacy environment [Internet]. The Pharmacy Guild of Australia; 2016. Available from: https://www.guild.org.au/_data/assets/pdf_file/0022/49405/NVCP-Guidelines.pdf
- Vaccinating adults: a step-by-step guide [Internet]. Immunisation Action Coalition. Available from: <http://www.immunize.org/guide/>
- Vaccination en pharmacie [Internet]. pharmaSuisse. Available from: <https://vaccinationenpharmacie.ch>
- Vaccine storage and handling toolkit [Internet]. Centers for Disease Control and Prevention.. Available from: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- Vaccines [Internet]. Geneva: World Health Organization. Available from: <https://www.who.int/topics/vaccines/en>.

Resources to support staff education and training

- Plácido GM, Guerreiro MP. Administração de vacinas e medicamentos injetáveis por farmacêuticos - uma abordagem prática [Internet]. Lisbon: Ordem dos Farmacêuticos, 2015. Available from: <https://www.ordemfarmaceuticos.pt/pt/publicacoes/manuais/administracao-de-vacinas-e-medicamentos-injetaveis-por-farmacuticos-uma-abordagem-pratica>
- The Australian immunisation handbook [Internet]. Australian Government, Department of Health. Available from: <https://immunisationhandbook.health.gov.au>
- The pink book: course textbook 13e [Internet]. Centers for Disease Control and Prevention; 2015 . Available from: <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
- The green book - immunisation against infectious disease [Internet]. Public Health England. Available from: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
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- Pharmacist initiation and administration of vaccines [Internet]. New South Wales Government, Department of Health. Available from: <https://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/pharmacist-vaccinations.aspx>
- Standards for the accreditation of programs to support pharmacist administration of vaccines [Internet]. Australian Pharmacy Council. Available from: <https://www.pharmacycouncil.org.au/policies-procedures/standards/>
- Fondation mesvaccins - Le carnet de vaccination électronique suisse [Internet]. Available from: www.myvaccines.ch

Resources to support service evaluation

- Flu vaccination – patient questionnaire [Internet]. Pharmaceutical Services Negotiating Committee. Available from: <https://psnc.org.uk/services-commissioning/advanced-services/flu-vaccination-service/flu-vaccination-patient-questionnaire>
- Evaluation of the seasonal influenza vaccination service [Internet]. The Pharmaceutical Society of Ireland. Available from: https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/PharmacyServices/Vaccination_Service/Evaluation_of_the_Seasonal_Influenza_Vaccine.aspx
- Quality improvement projects targeting immunization [Internet]. Centers for Disease Control and Prevention.. Available from: <https://www.cdc.gov/vaccines/ed/quality-improvement-proj.html>

Resources to support patients and the public with their vaccinations

- The adult vaccine assessment tool [Internet]. Centers for Disease Control and Prevention. Available from: <https://www2.cdc.gov/nip/adultimmsched>
- Chickenpox vaccination service toolkit [Internet]. Merck Sharp & Dohme Ltd. Available from: <https://www.msconnect.co.uk/therapy-areas/vaccines/chickenpox-toolkit.xhtml>
- Communication toolkit on immunisation: how to increase immunisation uptake [Internet]. European Centre for Disease Prevention and Control. Available from: <https://ecdc.europa.eu/en/publications-data/communication-toolkit-immunisation-how-increase-immunisation-uptake>
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- Vacinação [Internet]. Brazilian Government, Ministry of Health. Available from: <http://www.saude.gov.br/saude-de-a-z/vacinacao>
- Vacinação [Internet]. Portuguese Government, Ministry of Health. Available from: <https://www.dgs.pt/saude-publica1/vacinacao.aspx>
- Vacunas e inmunización [Internet]. Government of Buenos Aires. Available from: <https://www.buenosaires.gob.ar/salud/programasdesalud/vacunaseinmunizacion>

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