

Establishing an Education Framework for Pharmacist-Led Vaccination Services

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of the requirements of the

Degree of Master of Pharmacy

Tamara Attard

Department of Pharmacy

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Dedicated to my parents, brother, fiancé and cat Romeo, for their constant support throughout this journey

Abstract

Pharmacist-led vaccination services implemented in several countries are proving to be a paradigm shift in improving vaccination rates across the globe. The aims of this study were to identify pharmacy students', pharmacists' and patients' perspectives of pharmacist-led vaccination services and to compile and validate an education framework aimed at pharmacy schools in Europe, for the advancement of pharmacist-led vaccination services. Three self-administered questionnaires were compiled, validated and distributed to pharmacy students, pharmacists and patients, respectively. An education framework was compiled and this proposed framework was validated through a Delphi Method amongst a sample of European pharmacy educators. The perception of pharmacy students, pharmacists and patients on pharmacist-led vaccination services and a validated education framework applicable for European countries were the outcomes of this study. Fourteen students (N=16) feel confident to provide vaccination services after completing a training programme, 48 pharmacists (N=62) are willing to administer vaccines given that they attend a vaccination training programme, and 146 (N=163) patients trust the pharmacist to administer the influenza vaccine, given that pharmacists are trained within this field. An education framework was compiled, outlining the following aspects of pharmacist-led vaccination services; regulatory aspects, national guidelines, responding to patient needs, vaccine handling and storage, preparation and reconstitution of vaccines, administration of vaccines and documentation practices. Six participants who filled in the validation document gave an overall positive opinion on the Education framework proposed with a few suggestions which were taken on as amendments, leading to a finalized education framework. The validated education framework can be used by pharmacy schools to include vaccination preparation and administration training in their curricula, serving as a basis to implement pharmacist-led vaccination services.

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Chapter 1

Introduction

1.1 Background

The concept of immunization and vaccines dates back to 1796, when Edward Jenner inoculated a young boy with a sample of a lesion of small pox from a milkmaid (Hogue *et al.*, 2006; Artenstein, 2010). The young boy was then exposed to small pox and he showed that he was immune to it. This was the first known instance in scientific history of immunization. It took almost a hundred years before stabilizing the concept of immunization as a practice (Artenstein, 2010). In a 10-year vaccination campaign by the World Health Organization, small pox was eradicated by 1977 (Berche, 2022).

Vaccination plays a very important role, since through vaccination, 3.5-5 million deaths per year are prevented.¹ There are diseases for which vaccines are available, however, due to lack of vaccination, complications which may eventually lead to death may occur. This results in additional workload and use of healthcare system resources, which could be prevented or controlled.² Authorities, worldwide, embark on routine and supplementary vaccination covering the majority of the population, as a strategy to eradicate diseases. In this respect, such eradication programmes have targeted polio and measles (Omer *et al.*, 2013). There are several reasons for which people decide not to get vaccinated. Such reasons include general indifference of the public, myths related to safety, quality and efficacy of vaccines, cost of vaccines, inconvenient hours and location, waiting times and waiting at a clinic with sick patients alluding to an increased risk of disease (Kamal *et al.*, 2003). Consequently, this may lead to low vaccination rates.

¹ World Health Organisation (WHO). Vaccines and Immunization [Internet]. Geneva (Switzerland): WHO; 2024 [cited 2024 Jul 28]. Available from: https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1

² World Health Organisation (WHO). Myths and facts about immunization [Online]. Europe: WHO; 2015 [cited 2024 Jul 28]. Available from: <https://iris.who.int/bitstream/handle/10665/346012/WHO-EURO-2015-3374-43133-60386-eng.pdf>

Pharmacists play an essential role in the daily lives of patients. They are generally the first healthcare professionals in the community, patients seek since they are the most accessible (Motulsky *et al.*, 2021). Pharmacists have been involved in the vaccination process since the mid-1800s, where although they did not administer vaccines, they took care of the storage, preparation and delivery of the small pox vaccine, so that it was available for the physician to administer (Hogue *et al.*, 2006; Rhodes *et al.*, 2017). Nowadays, pharmacists act as educators and facilitators for medicinal products including vaccines. This has shifted the role of the pharmacist from the traditional compounding role to a more patient-oriented role (AlGhurair *et al.*, 2012). In general, pharmacists provide the patient with the necessary medicine as prescribed by the physician, provide patient advice tailored to that specific patient, and advise the patient on how to use a product and possible side effects, amongst other information. In some countries, pharmacists are vaccine administrators as well (Hogue *et al.*, 2006) in line with the legislation of that country. Such countries include Argentina, Brazil, Paraguay, Venezuela; Canada, Costa Rica, USA; Denmark, France, Greece, Ireland, Malta, Norway, Portugal, Switzerland, UK; Chad, Kenya, Sierra Leone, South Africa; Israel, Lebanon; Hong Kong, Philippines; Australia and New Zealand³ (Tannenbaum & Tsuyuki, 2013; Chiu *et al.*, 2022). Pharmacists contribute to increasing vaccination rates, by direct administration or by educating society (Isenor *et al.*, 2016). Vaccination is indeed a goal that several countries try to achieve (Omer *et al.*, 2013).

1.2 Vaccine Strategies

Different countries have different vaccination strategies. In some countries and even different states within such countries, the administration of vaccines by pharmacists

³ International Pharmaceutical Federation (FIP). An overview of pharmacy's impact on immunization coverage [Online]. The Hague (Netherlands): FIP; 2020 [cited 2024 Jul 28]. Available from: <https://www.fip.org/file/4751>

depends on a number of factors, mainly age group (Table 1.1) and type of vaccine (Table 1.2). There are exceptions and conditions depending on the country. In legislation, the type of vaccine which can be administered by pharmacists to the particular age group is also specified. Other factors for the administration of vaccines by pharmacists include legislation and the need for a physician's prescription. In the USA, legislation differs between states. In some states, pharmacists can administer vaccines as long as a prescription from a physician is presented, whilst in other states, a prescription is not required (Bach & Goad, 2015).

'Vaccine Strategies' involves training of pharmacists, storage, administration and documentation, which are governed by legislation. Different pharmacies have different procedures in place. A patient can go for the vaccine either by appointment or walk-in without any appointment necessary or a combination of both (Hattingh *et al.*, 2016; Tak *et al.*, 2020). It is important to have the appropriate storage equipment and that such equipment is calibrated and checked regularly.

Additionally, it is important to have an adequate area or consultation room to administer the vaccine. It is essential that pharmacists are prepared in an event of an adverse reaction, which may occur and hence have adrenaline, parenteral antihistamines and a blood pressure monitor available (Bach & Goad, 2015).

Table 1.1. Administration of vaccines by pharmacists to particular age groups in different countries

Age group		
Age (years)	Country	Comments
5	Canada	
6+	USA	Patient age varies between states
17+	Australia	Study based on Western Australia
All ages	New Zealand ⁴	Depending on type of vaccine

Table 1.2. Type of vaccines administered by pharmacists in different countries

Type of Vaccine ^{3,4,5}	
Type of Vaccine	Country
Hepatitis A and B	USA
Herpes Zoster	Ireland, New Zealand, USA
Human papilloma virus	New Zealand, UK and USA
Influenza	Australia, Canada, Ireland, New Zealand, UK and USA
Meningococcus	Iceland, Jordan, Lebanon, New Zealand, USA
Pneumococcus	Ireland and USA
Diphtheria Tetanus and acellular Pertussis	Australia, France, Greece, Iceland, Israel, Jordan, Lebanon, New Zealand, Philippines, USA
Travel vaccines (in general)	UK and USA

Data compiled from Bach & Goad, 2015; Hattingh *et al.*, 2016; ISB, 2015; Isenor *et al.*, 2016; Omecene *et al.*, 2019; Tak *et al.*, 2019.

1.3 Training

Training of pharmacists, during the undergraduate course or else via continued education programmes, is essential when participating in the process of vaccination, as this

⁴ Ministry of Health NZ. Immunization Handbook 2020 [Online]. New Zealand; 2020 [cited 2024 Jul 28]. Available from: <https://www.tewhaturora.govt.nz/for-health-professionals/clinical-guidance/immunization-handbook#pdf>

⁵ International Pharmaceutical Federation (FIP). Advocating expansion of the pharmacist's role in immunization [Online]. The Hague (Netherlands): FIP; 2022 [cited 2024 Jul 28]. Available from <https://www.fip.org/file/5137>

encourages and empowers pharmacists to provide better immunization services (Merks *et al.*, 2021).

Training does not only entail how to administer the vaccine, but also training on, assessing the need for vaccination, the storage of the vaccine, how to recognize adverse reactions, both those that occur immediately and those that occur a few days later, knowing how to handle these adverse reactions and filling in the right documentation, amongst others (Poudel *et al.*, 2019). In the United States of America, pharmacy students may be involved in programmes such as the pharmacist-driven immunization programme, such as the one organized in North Carolina. In such programmes, students are given the opportunity to research the guidelines regarding vaccination, fill in the paperwork required, use the aseptic technique, and also administer the vaccine themselves (Stilwell *et al.*, 2017). Hence, the students gain experience and training on the whole process of vaccination. Additionally, they may be given the opportunity to administer vaccines to actual patients outside of the classroom setting, whilst still being supervised (Stilwell *et al.*, 2017). This is advantageous as this is in preparation for their vaccination duties once they graduate. In the USA, training of pharmacy students to administer vaccines is part of the Doctor of Pharmacy (Pharm.D.) curriculum (Bach & Goad, 2015).

According to the FIP 2020 Global Survey³ for example, the FIP is also offering training to its members (Ecarnot *et al.*, 2019) as this is perceived as a contribution to pharmacist confidence and practical knowledge on vaccine administration (Akala *et al.*, 2005). Also, peripheral training programmes give this opportunity to existing practitioners who were not trained during their studies or did not study at a post graduate level (Romanelli & Freeman, 2012).

According to FIP³, 39% of the countries involved in the survey, stated that this training is obligatory. Additionally, only 34% of countries allow pharmacists to apply for the necessary training for vaccine administration. In 2022, FIP published a reference guide as part of the FIP Global Competency Framework presenting a list of knowledge, skills and techniques which should be included as part of undergraduate pharmacy training programmes for immunization services.⁶ This list can also serve as a checklist for pharmacists who never received training or require further training as part of their continuous professional development.

1.4 Documentation

Documentation is an important aspect when considering the immunization process. It is proof of what activities were carried out, and if done properly and fully, it can be also very informative. Patients would have the complete information regarding their vaccination history, including the date when the vaccines were administered, the type of vaccines and any booster doses and side effects experienced, amongst others. Hence the patient would have a complete immunization profile. Patients would not remember their vaccination history hence documentation is important for traceability (Ecarnot *et al.*, 2019). From this information, pharmacists can advise accordingly. According to Lutz and colleagues (2018), in a survey conducted in the USA, 93.3% of pharmacists administered vaccines with only 53.2% documenting administered vaccines in an immunization information system. One possible explanation is that documentation may be time consuming and elaborate (Stilwell *et al.*, 2017), especially if this happens in a busy pharmacy. Documentation helps improve assessment of the need for vaccination and the coordination between pharmacists and physicians, who also administer vaccines. This

⁶ International Pharmaceutical Federation (FIP). The FIP Vaccination Reference Guide [Online]. The Hague (Netherlands): FIP; 2022 [cited 2024 Jul 28]. Available from <https://www.fip.org/file/5158>

would alert the practitioners if the patient received complete immunization or not (Bach & Goad, 2015). Hence, immunization information systems make this process seamless if carried out correctly. Australia has a system called “My Health Record” where health records may be shared (Spinks *et al.*, 2020). So, if a pharmacist has access to the patient’s profile, the pharmacist can add the necessary information regarding the vaccination and this would appear in the patient’s history. This depends on whether a pharmacist has access, how much access, and if they can amend it or not.³ Another example of a platform, also based in Australia, is GuildCare (Hattingh *et al.*, 2016). However, 67% of the FIP³ participants report that pharmacists do not have access to patient records. There is also the option of paper-based documentation, however this has several disadvantages, including lost papers, incorrect disposal of papers and patient data breach, amongst others. Within such systems, patients are given a receipt (NVAC, 2014) or a vaccine information statement, and others uploaded information to a registry and others had their own registry (Stilwell *et al.*, 2017; Westrick *et al.*, 2018). From the study by Westrick *et al.* (2018), there were also instances where practitioners did not report immunization records to an immunization registry.

1.5 COVID-19

The sudden and unexpected spread of COVID-19 worldwide led to a rapid response from world health authorities to mitigate its impacts on human health, wellbeing and worldwide economy. Several pharmaceutical companies together with the Food and Drug Administration, European Medicines Agency and other health authorities, sought for a fast track solution through the development and distribution of vaccines (Chakraborty & Maity, 2020). The short duration from research and development to market led to the effective immunization of several populations around the world. Health authorities of several countries devised a vaccination programme, most of which in line with the World

Health Organisation, calling in health care professionals (HCPs) to contribute to this mass immunization. With the ever-changing viral strains, HCPs were also called in to deliver booster doses of the vaccine to the already-vaccinated population. Pharmacists were amongst the HCPs called in to contribute (Shtaynberg *et al.*, 2023). In Australia and in the USA, apart from other countries, healthcare professionals, including pharmacists, had to undergo a training programme to be able to reconstitute and administer the vaccine (Paradissis *et al.*, 2023). This was due to the particular characteristics of the COVID-19 vaccine employing new vaccine technologies. Within some member states of the EU, pharmacists were generally considered as educators and facilitators only (Paudyal *et al.*, 2021). The pandemic has led to initiatives for pharmacists to become vaccinators. In Belgium, the pharmacists were trained to administer the COVID-19 vaccines whereas in Italy, the government also organised a training course leading to the pharmacists being able to administer vaccines (Paudyal *et al.*, 2021). The onset of all this was the COVID-19 pandemic.

1.6 Aims

The aims of this study were to identify pharmacy students', pharmacists' and patients' perspectives on pharmacist-led vaccination services and to compile and validate an education framework aimed at pharmacy schools in Europe, for the advancement of pharmacist-led vaccination services.

Chapter 2

Methodology

2.1 Study Overview

This study was carried out to understand and identify the needs, expectations and challenges for pharmacist-led vaccination services and to compile and validate an education framework for such services. The study was divided into two phases. Phase 1 targeted groups who are involved directly or indirectly in the need and implementation of vaccination services by pharmacists. A follow-up of this phase led to the development of the education framework, designated as phase 2. The structure of this study in terms of phases is illustrated in figure 2.1.

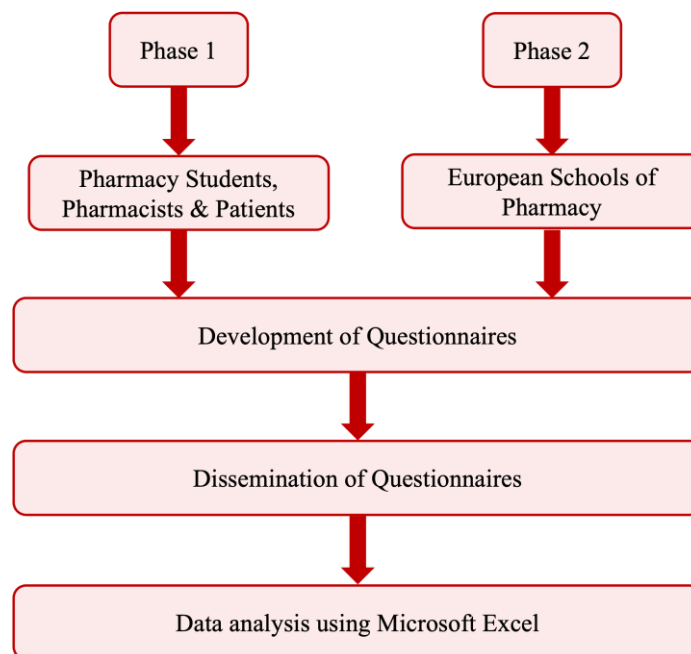


Figure 2.1. Study Overview

2.2 Ethics approval

Ethics approval was sought for both phases of the study, by submitting an online application to the Faculty Research Ethics Committee.

For phase 1, ethics approval was sought for the three different groups targeted during this phase of the study. A dissertation proposal, protocol, and pharmacy student, pharmacist and patient' questionnaires were also submitted. Ethics approval was acquired with the application ID of MED-2022-00077 (Appendix A.1).

Phase 2 was also submitted for ethics approval. A validation report and the education framework as well as a personal curriculum vitae were also submitted. Ethics approval was acquired with the application ID of MED-2024-00002 (Appendix A.2).

2.3 Phase 1: Perception on pharmacist-led vaccination services

Pharmacy students' questionnaire (Appendix B.1). An educational programme for pharmacy students was set up and the training of second-year pharmacy students in the preparation and administration of vaccines, was carried out. This programme was evaluated via a questionnaire, which was prepared and then validated by two students, where each question was validated according to relevance, specificity and clarity. Reliability test for the questionnaire was also carried out, which involved six students filling in the questionnaire twice, on day 0 and day 15, to confirm or reject reliability of the questionnaire. The responses for each student were compared at day 0 and day 15.

The questionnaire was then disseminated to seventeen second-year pharmacy students who had undergone the training programme, so as to evaluate pharmacy student preparedness involved in the preparation and administration of vaccines. The inclusion criteria for participants considered for this questionnaire were (1) students who were currently enrolled in the B.Sc. (Pharm. Sci.) course; and (2) students who were offered the education programme aimed at vaccinology.

The questionnaire comprised of three sections; participant demographics, knowledge on the preparation and administration of vaccines, and skills.

All fifteen questions were closed-ended, some of which with a Yes/No response, whereas others were based on a Likert-scale (Joshi *et al.*, 2015; Robinson, 2024).

Pharmacists' questionnaire (Appendix B.2). Pharmacists' views on pharmacist-led vaccination services, were studied through the use of a self-administered questionnaire. The questionnaire was prepared and then validated by a panel of two pharmacists and two health care professionals. A reliability test was also carried out where ten pharmacists participated by filling in the questionnaire on day 0 and day 15. The responses at day 0 and day 15 were compared for each participant.

No specific exclusion criteria were applied to this questionnaire. Participants, who were graduates of Bachelor of Pharmacy (Hons.) and more recently graduates of the Bachelor of Science (Hons.) in Pharmaceutical Science and Master of Pharmacy, were considered.

Although a mixed method was used, including both quantitative (close-ended) and qualitative (open-ended) questions, the questions was primarily close-ended. Twenty-three questions were closed-ended, some of which with a Yes/No response, whereas others were based on a Likert-scale. The last question was open-ended, so that participants could include additional comments.

Patients' questionnaire (Appendix B.3). Patients' views on pharmacist-led vaccination services, were studied through the use of a self-administered questionnaire. The questionnaire was prepared and then validated by a panel of two patients. Reliability testing was also carried out where ten patients participated by filling in the questionnaire on day 0 and day 15 and the responses were compared for each participant.

No specific exclusion criteria were applied. Although patients under the age of 18 were excluded from participating, the parents or guardians were asked questions in relation to vaccine administration to their young ones. This criterion takes into account bias by parents and guardians who are deciding for their children.

Although a mixed method was used, including quantitative (close-ended) and qualitative (open-ended), the questionnaire was primarily a closed-ended type. The questionnaire was set in both Maltese and English to ensure that participants understood the questions well and to ensure that participants express themselves freely and comfortably.

Twelve questions were closed-ended, some of which with a Yes/No response, whereas others were based on a Likert scale. The last question was open-ended, so that participants could include additional comments.

2.4 Dissemination of questionnaires and Analysis of Data

Pharmacy students' questionnaire. The questionnaire was converted to an electronic version in Google Forms (docs.google.com/forms). The questionnaire was disseminated to pharmacy students, through the Administration Office of the Department of Pharmacy.

Pharmacists' questionnaire. The questionnaire was converted to an electronic version in Google Forms (docs.google.com/forms). The questionnaire was distributed via the Pharmacy Council and through pharmacist specific social media platforms, such as Facebook, WhatsApp and Signal.

Patients' questionnaire. The questionnaire was converted to an electronic version in Google Forms (docs.google.com/forms). The questionnaire was distributed via the social media platforms, such as Facebook, WhatsApp and Instagram. The questionnaire was

also disseminated through the snowball sampling method (Makwana *et al.*, 2023) as hard copies.

Anonymity was maintained for all three questionnaires. For online questionnaires, email addresses or any form of participant identification details were not gathered. Anonymity was also maintained for the in-person disseminated questionnaires.

For each questionnaire, the qualitative and quantitative data was converged into one spreadsheet in order to obtain a single data set. Once data was collected the information was inputted in Microsoft Excel (version 16.87). The Yes/No responses were converted into the 1/0 binary system. The numeric system for the Likert scale was retained but for the interpretation of the results, the five-number system was converted into a three-numbered system, combining 1 and 2, and 4 and 5, whereas 3 was retained separately. This was performed to obtain an improved representation of the data set.

Statistical analysis was carried out using a Microsoft Excel add-on software, XLStat (Version 2017.4.46756, Addinsoft 1995-2024). Re-test reliability is carried out for a questionnaire so as to test whether the questionnaire produces consistent results when answered by the same group of people at different points in time. If there is a high correlation between the two time points, this indicates that when the questionnaire is disseminated, responses would be consistent and reliable. For reliability testing of questionnaires, the paired sample t-test was used (Gravesande *et al.*, 2019) to compare the means between two time points for the same subjects. For the analysis of the quantitative data for the questionnaires distributed to the different stakeholders, descriptive and quantitative statistical tools were used. Spearman's correlation coefficient (r_s) was used for this study, since the rank scored data for one or more of the variables was not continuous. Pearson's correlation coefficient (r) was not used since the dataset

did not involve any continuous variables (Field, 2013). Statistical significance was considered at $p < 0.05$.

2.5 Phase 2: Education Framework

A thorough literature search was carried out in order to understand the compilation and setting up of an education framework. Digital sources were mainly consulted, using search engines such as Google Scholar, HyDi and PubMed. The following keywords were used: vaccine, education framework, pharmacist, guidelines, legislation and vaccinology. Additionally, documents, reports and publications disseminated by the International Pharmaceutical Federation (FIP) were reviewed.

Based on this information, an education framework incorporating different aspects of vaccinology was compiled (Appendix B.4). The education framework consisted of seven categories representing different aspects of vaccinology. The categories include (1) regulatory aspects, (2) national guidelines, (3) responding to patient needs, (4) vaccine handling and storage, (5) preparation and reconstitution of vaccines, (6) administration of vaccines and (7) documentation practices (figure 2.2).

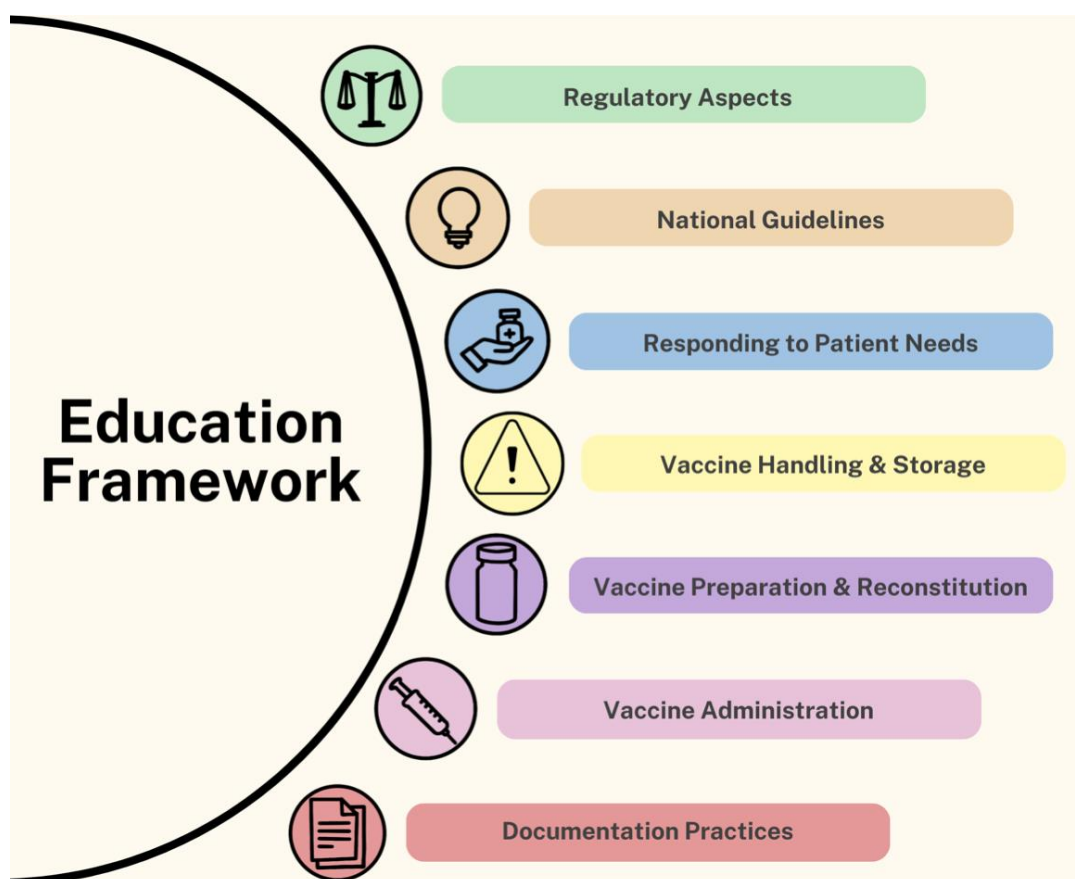


Figure 2.2. Education Framework Outline

The education framework was validated by different European schools of pharmacy with the aim of being implemented as part of vaccination training programmes through the Delphi Method (Massaroli *et al.*, 2018). This was done by disseminating the education framework, together with a validation report developed using Google Forms. The validation report comprised of five close-ended questions based on a Likert scale, where 1 represented a low score and 5 represented a high score (Appendix B.5). The following aspects of the education framework were assessed. The questions were comprehensiveness of education framework document, applicability of education framework document, specificity, relevance and clarity

For each of the last three questions, a Likert scale was set up for the seven categories mentioned within the education framework. The inclusion criteria for participants considered for this validation report were professors and academics: (1) teaching at a European School of Pharmacy, (2) involved in a curriculum leading to a Pharmacist's degree, and (3) involved in a curriculum covering aspects of vaccinology. Taking into account comments from the validation panel, amendments were made to the education framework, which led to a finalised version of the education framework.

2.6 Dissemination of Results

Results obtained from this study were disseminated as poster presentations at two conferences: the European Association of Faculties of Pharmacy Annual Conference 2023 held between 17-19 May 2023 in Valencia, Spain (Appendix C.1), and the European Association of Hospital Pharmacists 28th Annual Congress 2024 held between 20-22 March 2024 in Bordeaux, France (Appendix C.2).

Chapter 3

Results

3.1 Overview

The study was based on three stakeholder questionnaires and validation reports for the education framework (figure 3.1). For Phase 1 of the study, there were 247 participants; 16 pharmacy students, 62 pharmacists and 163 patients. For Phase 2, there were 6 professors and academics who participated in the validation of the education framework.

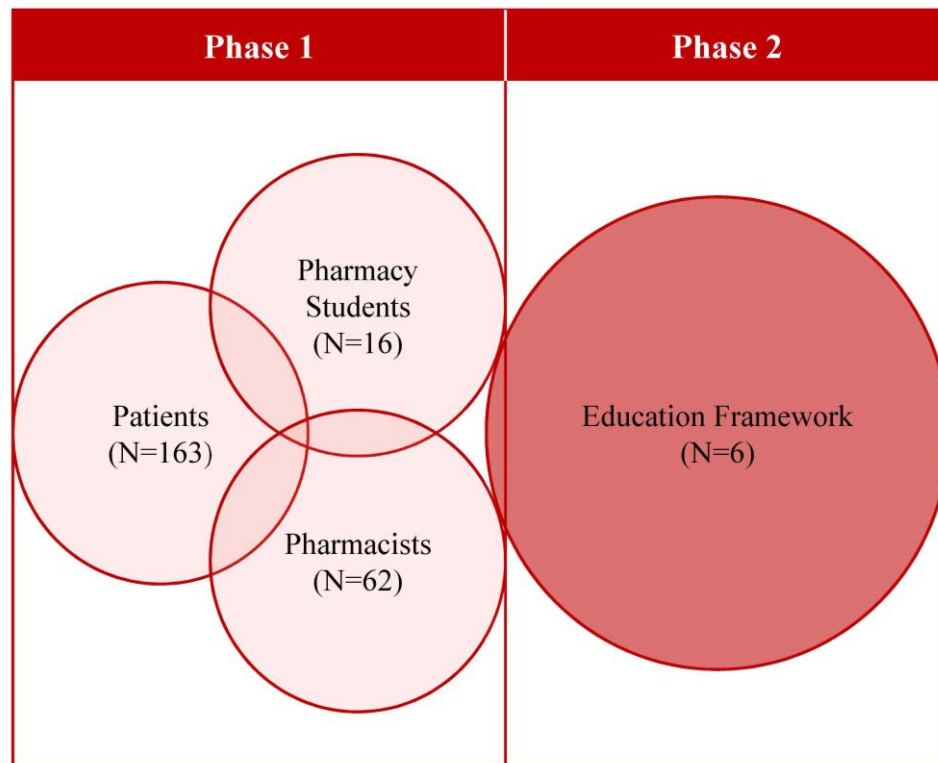


Figure 3.1. Participant numbers of this study

3.2 Phase 1: Stakeholder's perspectives on pharmacist-led vaccination services

The formulation of the three questionnaires was based on a three-step process: validation, reliability testing and dissemination (figure 3.2).

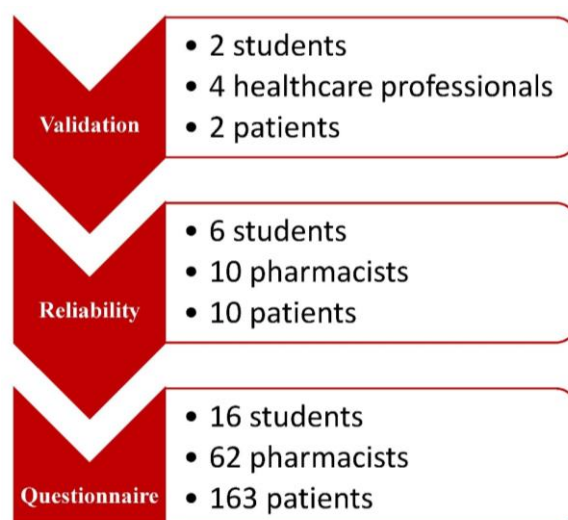


Figure 3.2. The three-step process for the formulation of the questionnaires

3.2.1 Pharmacy Students

For the validation, the questionnaire was evaluated by two second year pharmacy students, for the criteria of relevance, specificity and clarity, who had to indicate using a Likert scale (1 = not relevant/not specific/not clear and 5 = very relevant/very specific/very clear). Both students indicated that overall the questions were relevant to the study, specific and clear, giving a value of either 4 or 5. No comments were provided by these students.

The questionnaire was distributed to six pharmacy students for reliability testing. The questionnaire was answered twice by students at a time interval of fifteen days. Pairwise t-test was applied to all questions to determine reliability of each question over this time span (Appendix D, table D.1). Statistical evaluation for the reliability of the questionnaire indicates that respondents showed consistency for the two time points ($p > 0.05$). The statistical ranking of the reliability testing was further considered. Demographic questions (gender and age) scored a p-value of 1.000, showing a strong correlation between the two time points. Other questions that scored a p-value of 1.000 included the students'

awareness of errors in the preparation of vaccines, knowledge on guidelines, awareness on vaccine waste disposal and preparation of vaccines including reconstitution. Questions that scored a lower p-value (0.076-0.611) included questions on awareness and confidence as shown in Appendix D, table D.1.

The questionnaire was disseminated for data collection to seventeen pharmacy students. Twelve female and four male students (n=16), age ranging between 19 and 29 years, answered the questionnaire. This was the demographic section of the questionnaire.

The second section of the questionnaire evaluated knowledge on the preparation and administration of vaccines. This comprised of seven questions with a “Y/N” response. All respondents (n=16) replied that they are aware of the procedure that should be followed to dispose of waste during handling. One student out of the sixteen was unaware of vaccine administration errors, ways how to prevent them, their contraindications and how these can be identified. Two out of sixteen students were unaware of errors that may occur during vaccine preparation and on the storage conditions and handling of vaccines prior to administration. The question with the highest negative responses, in this section, was the one related to an incident of a needle stick injury, where seven out of sixteen pharmacy students were unaware of what course of action they should pursue.

The third section relates to the skills involved through the whole vaccination process from patient education to practical and administrative aspects of vaccinology. Two questions were based on a “Y/N” response, whereas the other four questions were based on a Likert scale. In the case of question 10, all students declared that they have the skills required for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules.

Question 11 relates to the students' confidence in vaccination skills (figure 3.3). Twelve students out of sixteen were confident with the provision of immunization services in compliance with documentation requirements. Similarly, twelve students were confident with the recognition of post-vaccination reactions. Eleven out of sixteen students were confident in educating patients regarding vaccines. In the management of post-vaccination reactions and describing the relevant first aid procedures, seven and six students, respectively, replied positively for these questions with six and five students feeling less confident in performing these tasks.

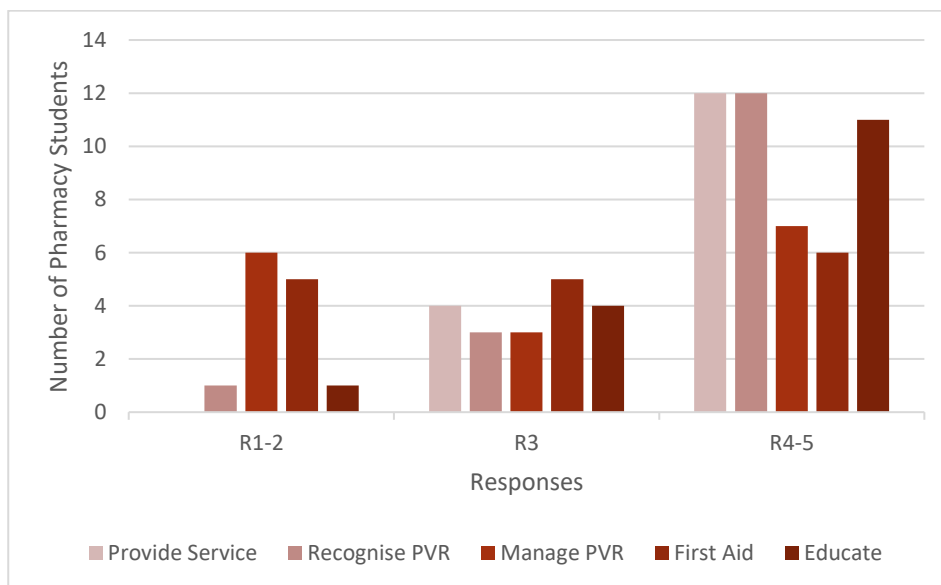


Figure 3.3. Confidence in skills by Pharmacy students (R1-2=least confident; R3=Confident; R4-5=very confident)

Question 12 questions pharmacy students on their confidence in administering a vaccine safely to paediatrics (0-15 years) and adults (16 and over). Figure 3.4 illustrates that fifteen out of sixteen students are very confident in administering a vaccine safely to adults. In the case of paediatric patients, students showed a mixed response to this question, with three replying as very confident, seven as confident and six as less confident.

When asked on their preferred route of administration (question 13), in terms of confidence, pharmacy students seem to be more confident in administering vaccines via the intramuscular route (14/16), than the subcutaneous route, where there was normal distribution in terms of confidence; most confident with 6 students, confident with seven students and six students being less confident (figure 3.5).

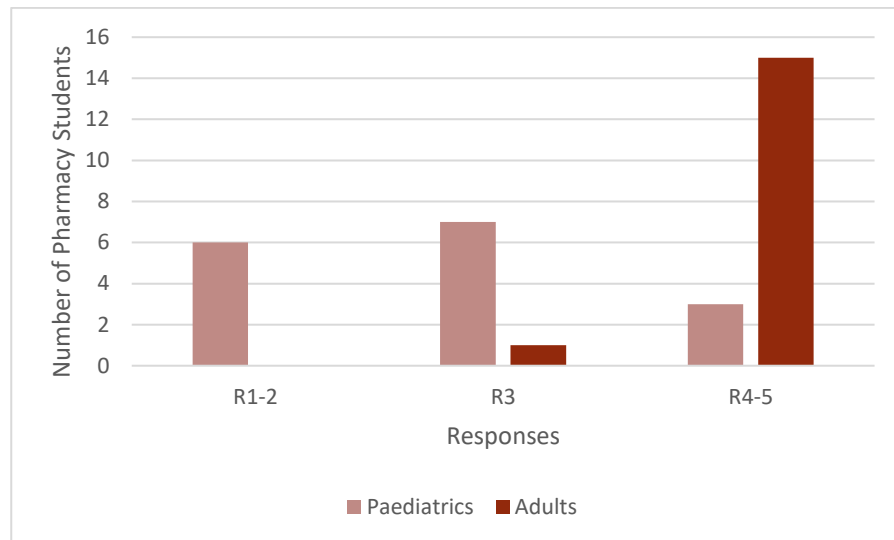


Figure 3.4. Confidence pharmacy students in administering a vaccine safely to different age groups (R1-2=least confident; R3=Confident; R4-5=very confident)

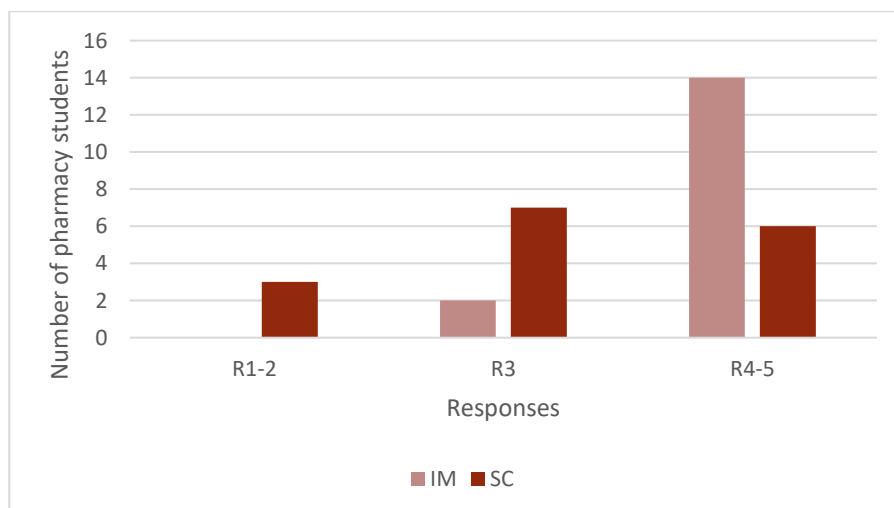


Figure 3.5. Confidence pharmacy students in administering a vaccine via different routes (R1-2=least confident; R3=Confident; R4-5=very confident)

Question 14 relates to the administration of a vaccine at different sites of injection. Figure 3.6 illustrates that fifteen out of sixteen students are confident in administering a vaccine to the deltoid/shoulder area, and thirteen out of sixteen are confident with administering the vaccine to the arm area. A normal distribution was observed for the thigh area administration with four students who are very confident, eight students who are confident but four students who are less confident.

The students were asked questions, as future pharmacists, on how much they feel confident to educate the patient regarding vaccines and any concerns they may have, to prepare/reconstitute vaccines and to administer vaccines (question 15). In general, students seem to be confident though two out of sixteen responded negatively to the first two questions while three responded negatively to the third question, indicating that students are generally confident in the roles of administrators, educators and facilitators (figure 3.7).

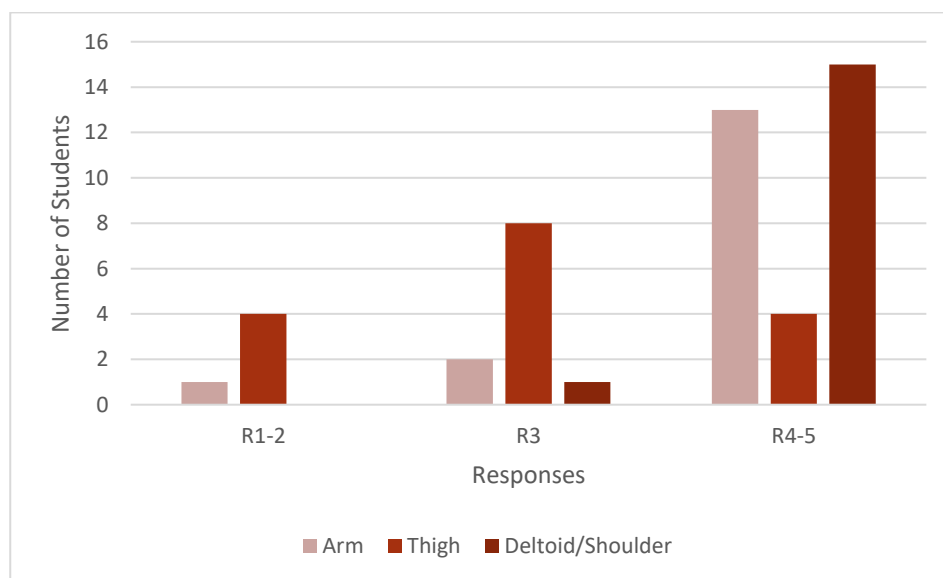


Figure 3.6. Confidence pharmacy students in administering a vaccine via different areas (R1-2=least confident; R3=Confident; R4-5=very confident)

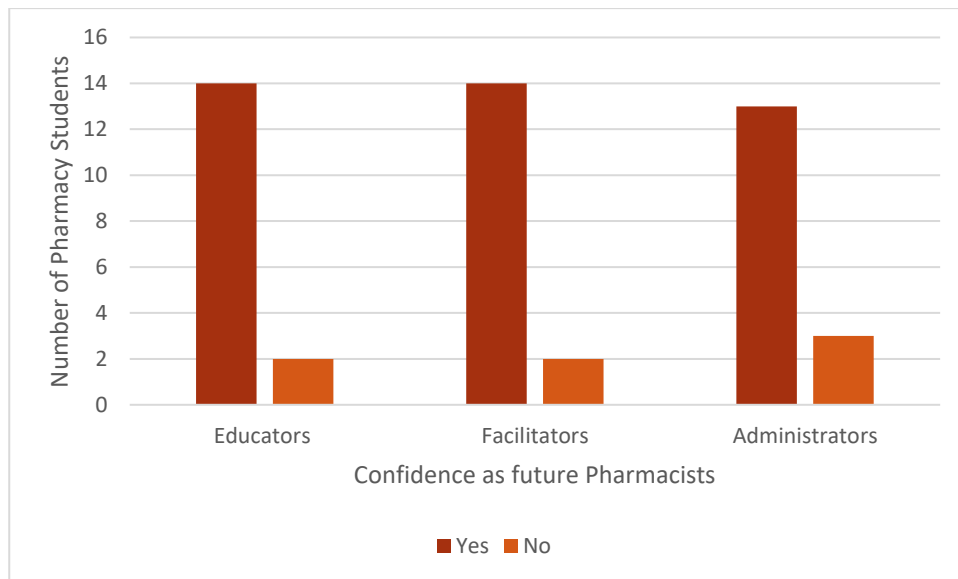


Figure 3.7. Students' responses in relation to their confidence as future pharmacists

Correlation statistics were carried out to determine any particular trends in the responses obtained from the fifteen questions of the questionnaire (Appendix D, table D.2). In the case of the Spearman's correlation the full Likert scale was considered. A good statistical correlation ($r_s > 0.821$) was observed in the number of pharmacy students ($n=12$) who felt confident with the provision of the vaccination service, were able to recognise post-vaccination reactions, and were willing to educate the patient. When asked regarding the management of post-vaccination reactions and first aid procedures, it is unclear how confident they feel, because responses were almost distributed equally across the Likert scale. Additionally, the r_s value obtained for these two parameters was 0.632 showing a weak correlation. Students prefer to administer vaccines to the adult group ($n=13$) over the paediatric group ($n=3$) with a weak negative correlation between the two ($r_s = -0.395$). The preferred route of administration is via the intramuscular route ($n=11$) over the subcutaneous route ($n=5$) with a weak positive correlation between the two ($r_s = 0.344$), whereas the preferred site of injection is at the deltoid/shoulder site ($n=8$), followed by the arm ($n=6$) with the least, the thigh ($n=2$). There was a strong correlation between the

Arm and Deltoid/Shoulder areas ($r_s=0.975$), but weak positive correlation between these two areas and the thigh area ($r_s<0.200$).

3.2.2 Pharmacists

For the validation, the questionnaire was evaluated by two pharmacists and two other healthcare professionals, for the criteria of relevance, specificity and clarity, who had to indicate using a Likert scale (1 = not relevant/not specific/not clear and 5 = very relevant/very specific/very clear). All respondents indicated that overall the questions were relevant to the study, specific and clear. One healthcare professional commented that at the age of 16, a patient is considered to be an adult not a paediatric patient. This was relevant to question 16 of the questionnaire.

The questionnaire was distributed to ten pharmacists for reliability testing. The questionnaire was answered by pharmacists twice at an interval of fifteen days. Pairwise t-test was applied to all questions to determine reliability of each question over this time span (Appendix D, table D.3). Demographic questions (gender, age and age of practice) scored a p-value of 1.000. Other questions that scored a p-value of 1.000 included the pharmacists' awareness on the current guidelines, awareness on vaccine waste disposal, skills to manage side effects of vaccination, administration to paediatrics and attendance to a training course on vaccinology. Questions that scored a lower p-value (0.082-0.676) included questions on awareness and confidence as shown in Appendix D, table D.3. Questions that showed a significant difference between the pharmacists' responses between the two occasions ($p<0.05$) include the recognition of post-vaccination reactions, awareness of the procedure in case of a needle stick injury incident, confidence to educate

patients, the administration of vaccines in the thigh, and awareness of contraindications and how these are identified.

The questionnaire was disseminated for data collection to pharmacists, physically and as a Google Forms link in pharmacists' groups on social media platforms. Sixty-two pharmacists answered the questionnaire, comprising of forty-five females and seventeen males, age ranging between 23 and 69 years. Twenty-eight respondents practise in a community pharmacy, six respondents practise in a clinical setting, eight respondents work in industry, three respondents work in academia and the remaining seventeen respondents practise in other sectors. This was the demographic section of the questionnaire.

The second section of the questionnaire comprised of seven questions, dealing with the knowledge on the preparation and administration of vaccines, with a "Y/N" responses. When the sixty-two respondents were asked regarding their current knowledge on errors (questions 5 and 6), pharmacists answered that they are aware of errors during preparation and administration of vaccines (n=32 and 33, respectively). The majority of pharmacists are aware of contraindications (question 7, n=45), the current national guidelines (question 8, n=42), the procedure of vaccine storage (question 9, n=58) and on how to dispose the waste during handling (question 10, n=56). More than half (n=37) of the respondents are aware of the procedure should they get a needle stick injury (question 11). The majority of the respondents do not have the necessary skills to manage possible side effects (n=44) and 33 respondents have the skills for the preparation and reconstitution of vaccines.

The third section of the questionnaire, related to skills, comprises of six questions; two questions of the "Y/N" type and four with a Likert Scale. When asked about the skills

related to immunization there were no clear trends for most of the responses. When pharmacists were asked on their skills to manage possible side effects of a vaccine, forty-four respondents do not express their ability to carry out this activity (question 12). Half of the pharmacists admit that they have the skills for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules (question 13, n=33). For question 14, the question was designed with a Likert scale challenging pharmacists with their confidence in a number of skills (figure 3.8). Half of the pharmacists (32 out of 62) are not willing to provide immunization services in compliance with documentation requirements. Most pharmacists admit that they are relatively or not confident in recognising post vaccination reactions (16 – less confident, 26 – confident and 20 – very confident). The management of post vaccination reactions and provision of first aid show similar trends with pharmacists' confidence, having half of the pharmacists less confident with these activities (29 and 26 respondents, respectively) and only fifteen pharmacists being very confident. However, it transpires that forty-five pharmacists are confident in providing education to patients regarding vaccination.

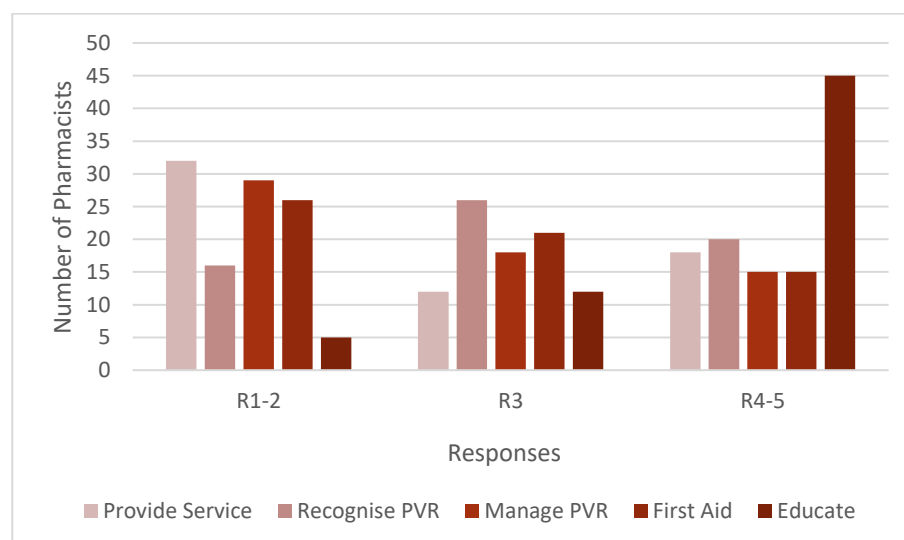


Figure 3.8. Confidence in skills by pharmacists (R1-2=least confident; R3=Confident; R4-5=very confident)

Question 15 relates to the confidence of pharmacist in administering a vaccine safely to different age groups. Figure 3.9 suggests that most pharmacists are not confident with the administration of a vaccine to paediatrics (0-15 years) and adults (16 years and over) with fifty-two and thirty-four pharmacists out of the sixty-two respondents, respectively.

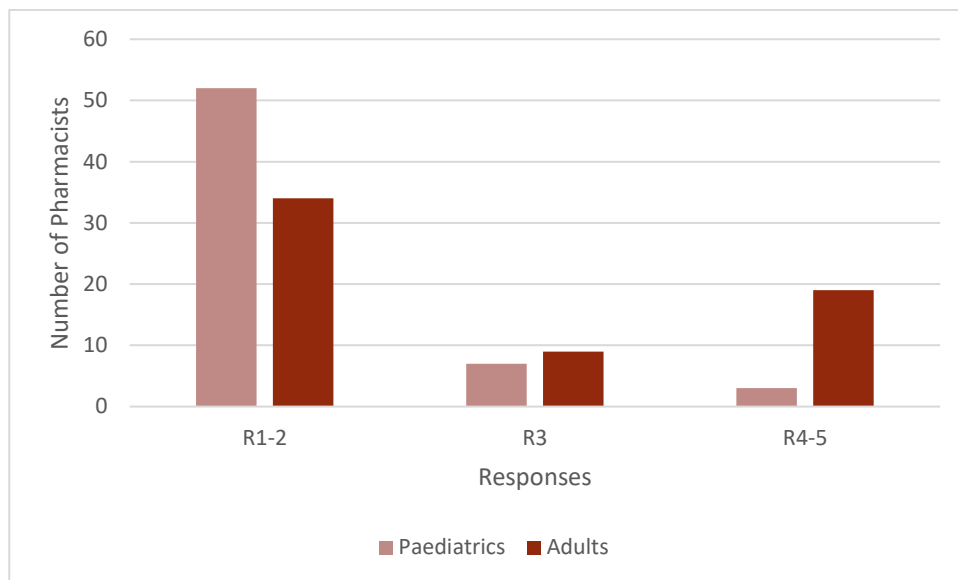


Figure 3.9. Confidence pharmacists in administering a vaccine safely to different age groups (R1-2=least confident; R3=Confident; R4-5=very confident)

When asked on their confidence to administer vaccine by particular routes (question 16), there is a concentration of pharmacists at both ends of the scale (figure 3.10). Although thirty-three and twenty-eight pharmacists are less confident with the administration of vaccines via the intramuscular and subcutaneous routes, respectively, twenty-two pharmacist are very confident to administer vaccines via both routes.

The pharmacists were also asked for their preferred site of administration (question 17, figure 3.11). Most of the pharmacists are not very confident with the administration of vaccines in the arm, thigh and deltoid/shoulder (thirty-one, thirty-six and forty-two

respondents, respectively). Only seventeen, sixteen and eleven pharmacists are very confident to administer a vaccine in these areas, respectively.

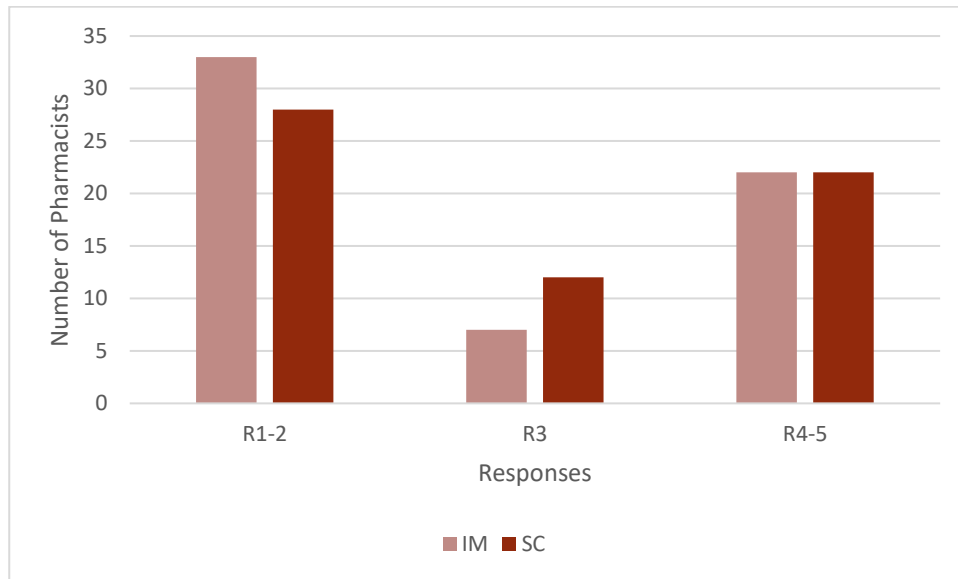


Figure 3.10. Confidence pharmacy students in administering a vaccine via different routes (R1-2=least confident; R3=Confident; R4-5=very confident)

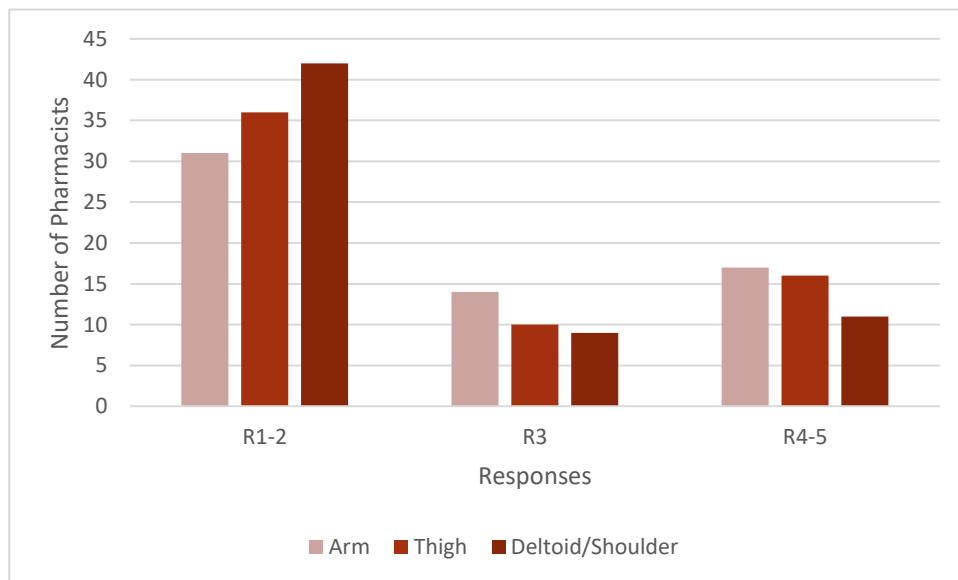


Figure 3.11. Confidence pharmacy students in administering a vaccine at different sites (R1-2=least confident; R3=Confident; R4-5=very confident)

Section 4 relates to service provision with a total of seven questions; six questions of the “Y/N” type and an open ended question. Most of the pharmacists (forty-six out of sixty two) admit that they have not received training to administer vaccines in the past (question 18). However, fifty-five pharmacists are willing to attend a short training programme covering the basic concepts and skills required for immunization. This also complements questions 20 and 21, in which forty-three pharmacists are willing to administer vaccines to patients and forty-seven pharmacists think that it is feasible to carry out immunization services in community pharmacies.

Questions 22 and 23 were dedicated to pharmacists who practise in the community. In fact, 54 out of 62 pharmacists answered these last two questions. When asked, if they think that the premises where they practise, requires modifications to carry out immunization services, twenty-six replied no whereas twenty-eight replied yes. Most of the pharmacists (forty-eight out of fifty-four) believe that they would be open to charge a service fee for preparing and administering the vaccine. Question 24 was open-ended with three pharmacists providing additional comments to the questionnaire.

The responses obtained from four questions of the questionnaire, correlation statistics were carried out to determine any particular trends in the data obtained (Appendix D, table D.4). In the case of the Spearman’s correlation, the full Likert scale was considered. There was a good positive correlation between the provision of first aid with the management and recognition of post-vaccination reactions, and service provision ($r_s > 0.564$) but a negative correlation with education of patients on vaccination ($r_s < -0.564$). There was a weak positive correlation between the administration of vaccines to paediatrics and adults ($r_s = 0.400$) and between the intramuscular and subcutaneous routes of administration ($r_s = 0.359$), due to the high density of participants at both ends of the

scales. There was also a good positive correlation between the three areas of injection ($r_s > 0.667$) with a high correlation between the thigh and deltoid/shoulder areas ($r_s = 0.975$).

3.2.3 Patients

For the validation, the questionnaire was evaluated by two lay persons, for the criteria of relevance, specificity and clarity, who had to indicate using a Likert scale (1 = not relevant/not specific/not clear and 5 = very relevant/very specific/very clear). The validation was carried out for the English version and Maltese version of the questionnaire. All respondents indicated that overall the questions were relevant to the study, specific and clear.

The questionnaire was distributed to ten patients for reliability testing. The questionnaire was answered by patients twice at an interval of fifteen days. Pairwise t-test was applied to all questions to determine reliability of each question over this time span (Appendix D, table D.5). Statistical evaluation for the reliability of the questionnaire indicates that respondents showed consistency for the two time points ($p > 0.05$). Demographic questions (gender, age, nationality and level of education) scored a p-value of 1.000. Other questions that scored a p-value of 1.000 included trust in their pharmacist to give the influenza vaccine to them and to their children, trust in their pharmacist to deliver other vaccines to them and to their children. Questions that scored a lower p-value (0.279-0.494) include the questions related to information requested to their pharmacist, if the replies were satisfactory and whether they are willing to pay a fee for the service.

The questionnaire was disseminated for data collection to patients, physically and as a Google Forms link on social media platforms. One hundred and sixty-three patients, ninety-seven females and sixty-six males, age range between eighteen and seventy years

and over, filled in the questionnaire (figure 3.12). The majority of respondents were Maltese (n=155) with six patients being European Union nationals and two patients being international. The majority also have a tertiary education (n=112), followed by those with post-secondary education (n=30), those with a secondary education (n=19) and two patients having a primary education. These questions comprised the first section of the questionnaire.

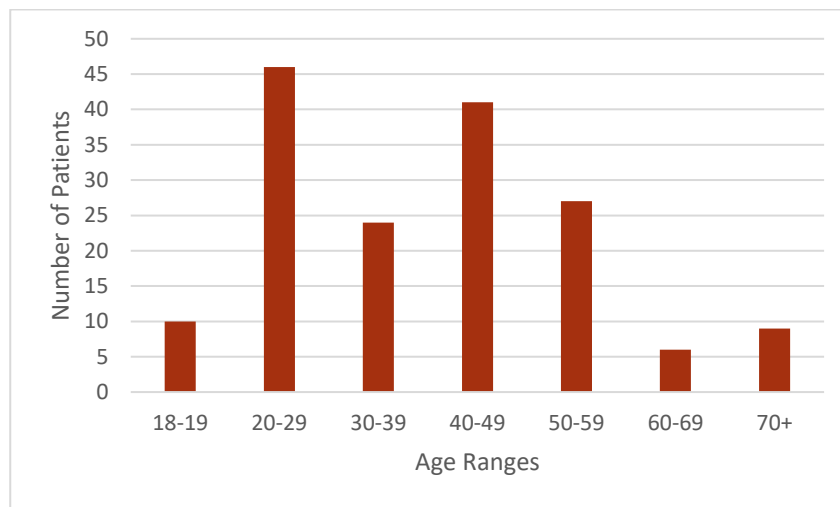


Figure 3.12. Age distribution of respondents

The second part of the questionnaire involved the evaluation of patient perspectives on vaccine education and administration by pharmacists. This section included five “Y/N” questions, three Likert-based questions and one open-ended question at the end for other comments.

One hundred and two patients asked the pharmacist questions regarding vaccines (question 5), namely general information about a particular vaccine (n=38), uses (n=6), concerns (n=13), side effects (n=41) and others (n=4), where patients were free to mention any other type of vaccine information they requested from the pharmacist in question 6 (figure 3.13).

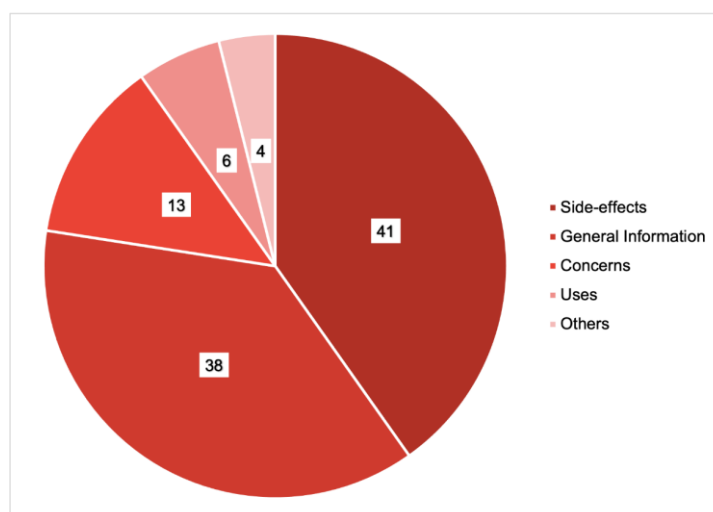


Figure 3.13. Type of information requested from patients to their pharmacist

In question 7, the patients were then asked whether they were satisfied with the pharmacists reply. Seventy-one patients felt very satisfied with the pharmacist's response, twenty-three patients felt satisfied with the pharmacist's reply, whereas eight patients felt not satisfied with the pharmacist's reply.

Patients were then asked whether they would trust their pharmacist to administer the influenza vaccine to them, the influenza vaccine to their child, other vaccines such as tetanus, Hepatitis B, etc to them and other vaccines such as diphtheria and hepatitis B to their child (questions 8-11). One hundred and forty-six patients would trust their pharmacist to administer the influenza vaccine to them and one-hundred and thirty four patients trust their pharmacist to administer other types of vaccines to themselves. The number of patients who responded 'yes', that is, they would trust their pharmacist to administer vaccines to their child was overall lower than trusting their pharmacist to administer vaccines to them. One hundred and twenty-nine patients trust their pharmacist to administer the influenza vaccine to their child, whilst one hundred and twenty-four

patients trust their pharmacist to administer other types of vaccines to their child (figure 3.14).

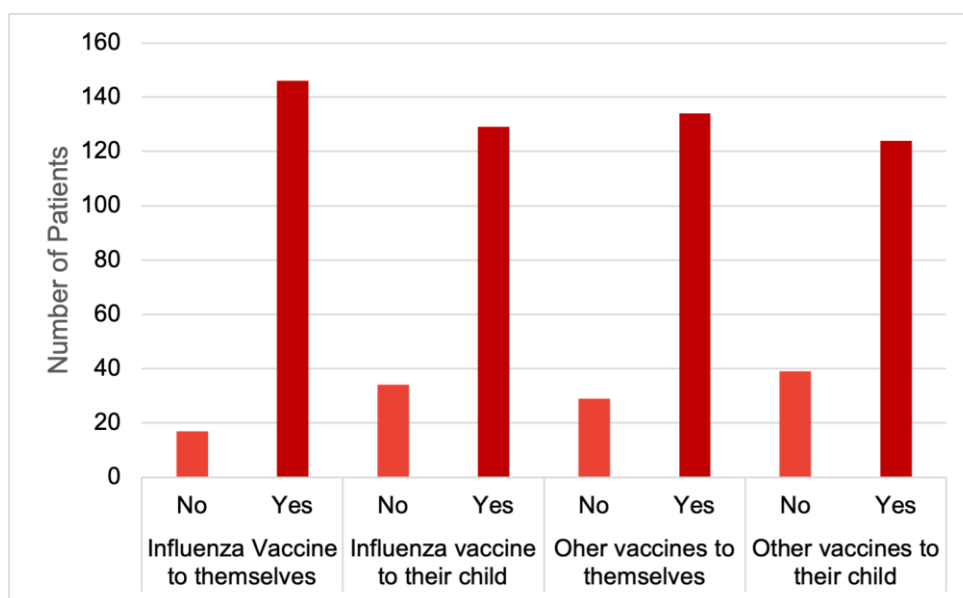


Figure 3.14. Patients' trust in pharmacists administering vaccines

The patients were asked whether they would be open to paying a fee for an immunization service by their pharmacist (question 12). Seventy-five patients were willing to pay €5 for the service, followed by twenty-nine patients willing to pay €3 for the service, followed by twenty-two patients willing to pay €2 for the service and thirty-seven patients not willing to pay anything.

The last question was an open-ended question where patients could leave a comment. Twenty-four patients left a comment.

3.3 Phase 2: Education Framework

3.3.1 Education Framework document evaluation by Validation Panel

The education framework was developed and aimed at pharmacy students and also pharmacists requiring further training. It is divided into 7 categories representing different aspects of vaccinology.

Six participants reviewed the education framework (Appendix B.4) and filled in the Validation Report (Appendix B.5). The participants were professors or pharmacists who work at schools of Pharmacy across Europe. The Validation Report included five Likert scale questions (1=not and 5=very, comprehensive/applicability) and an open-ended question for comments (question 6). Questions 1 and 2 involved assessing comprehensiveness and applicability of the Education Framework as a whole document. Table 3.1 illustrates that the respondents judged the Education Framework document as comprehensive and applicable due the 4/5 scoring for these two questions.

Table 3.1. Overall comprehensiveness and applicability of Education Framework document

	Number of respondents				
Likert Scale*	1	2	3	4	5
Comprehensiveness	0	0	0	3	3
Applicability	0	0	0	1	5

*1=not and 5=very, comprehensive/applicability

Questions 3-5 related to the assessment of specificity, relevance and clarity for each of the seven sections of the education framework, respectively. Figure 3.15 illustrates that the respondents judged the Education Framework document on the three criteria with a high score (mainly 4/5 scoring) for the seven sections.



Figure 3.15. Assessment of specificity, relevance and clarity for each of the seven sections of the education framework by the validation panel

3.3.2 Education Framework Amendments

As part of the education framework, the validation panel members included comments on how the document can be improved. Table 3.2 lists the recommendations provided by the validation panellists. This led to changes to the Education Framework which resulted in the finalised version as in Appendix B.4.

Table 3.2. Recommendations provided by the validation panellists

Panellist No.	Comments: Recommendations
1	A very professional piece of work. Easy to read and follow. Well written.
2	Nice document, very clear
3	In the chapter about regulatory aspects, I feel that the framework should also include not only national laws and regulations regarding pharmacists' role in Immunization, but also National laws and regulations regarding vaccines and vaccines administration practices in general. I feel ethics is also missing - confidentiality included. In the chapter about administration of vaccines, I feel there is too much specific information about the administration itself, but that should not be the focus of this framework, it is part of the education. Also, I believe that this framework does not specify what is part of the theoretical and what is part of a practical/hands-on education module. I also feel not too much is mentioned in regards to vaccine administration safety and pharmacist training to react to anaphylactic reactions. Basic Life Support is usually associated as well. I believe the framework can be improved. Here is another website for your reference: https://www.ordemfarmaceuticos.pt . Within the website the following document is available: Recognition Training of Pharmacists. Vaccine administration and injectable medicines in community pharmacy. ⁷ Also, some consideration must be given to the fact whether this is a pharmacist competence that can only be acquired by registered pharmacists, or if indeed students may already acquire it in undergraduate studies.
4	On page 6 the sentence "Pharmacists' role as vaccine facilitators" could be improved to "Pharmacists' role as vaccination facilitators". The word "correct" or "appropriate" could be used instead of "right" in this sentence on page 11: "Inserting the needle at the right angle of insertion according to the route of administration". Because right angle can mean also 90 degrees angle
5	In my opinion, this educational framework represents an innovative and extremely useful tool, especially for the elderly segment of the population, reducing the risk of hospitalization and therefore substantially reducing healthcare costs.
6	The study entitled Education Framework for Pharmacist-led vaccination Services is a highly useful and valuable material that provides information to pharmacy students and pharmacists how to provide Pharmacist-led vaccination service. The COVID-19 pandemic revealed how important is immunization led by pharmacists in order to support overwhelmed healthcare system and contribute to vaccine acceptance. In that sense, this education framework is highly needed for education of pharmacists as it covers the most important aspects of pharmacist-led vaccination: 1) regulatory aspects, 2) National Guidelines, 3) responding to patients' needs, 4) vaccine handling and storage, 5) vaccine preparation and reconstitution, 6) vaccine administration and 7) documentation practices. To conclude- I recommend this educational material as a guide for student/pharmacist vaccination training programmes

⁷https://www.ordemfarmaceuticos.pt/fotos/documentos/adminstracao_de_vacinas_e_medicamentos_injetaveis_em_farmacia_comunitaria_1320614745c59b0bf7c757.pdf

Chapter 4

Discussion

4.1 Overview

The aims of this study were to identify pharmacy students', pharmacists' and patients' perspectives on pharmacist-led vaccination services and to compile and validate an education framework aimed at pharmacy schools in Europe, for the advancement of pharmacist-led vaccination services.

Generally, education frameworks related to the field of pharmacy require input from the three major stakeholders; pharmacy students, pharmacists and patients (Paradis *et al.*, 2018). This strategy was adapted for the current education framework. Pharmacy students, who are considered as future pharmacists, are an ideal target group considering that students are during their learning process at university before graduating as healthcare professionals. Pharmacists, who are practising within the community and clinical setup, constitute another important target group which would require a structured framework and training programme to practise within this field of medicine. Patients, who are the recipients of vaccination, are another target group whose opinions and perceptions should be considered and evaluated. Other healthcare professionals such as physicians, nurses and paramedics were excluded from this study as the key protagonist is the pharmacist, hence the title of this study "Establishing an Education Framework for Pharmacy-led Vaccination Services".

The need to involve pharmacists in vaccination services was an incident rather than a planned change in legislation or direction from healthcare authorities. Prior to the COVID-19 pandemic, very few countries recognised the role of the pharmacist as vaccine administrators. As mentioned by Paudyal and colleagues (2021), due to the urgency of reaching herd immunity in a short period of time so as to mitigate catastrophic repercussions that the pandemic brought with it, authorities sought the need to involve pharmacists to equip fellow healthcare professionals to achieve this goal. When the

pandemic subsided, this triggered regulatory bodies, governments and working groups in various jurisdictions to affect changes in legislation to permit pharmacists to take up their roles as vaccine educators, facilitators and administrators. As exemplified in the study by Lee and co-workers (2020), in Australia legislation was changed as a consequence of the COVID-19 pandemic, to allow pharmacists to administer vaccines to patients over 10 years of age, in addition to adults who pharmacists were already authorised to vaccinate.

4.2 Stakeholder's perspectives on pharmacist-led vaccination services

The formulation of the questionnaires was based on a three-step process: validation, reliability and finalization of the questionnaire (Aithal & Aithal, 2020). For each stakeholder group, once the questionnaire was formulated, this was reviewed by two to four members of the stakeholder group. Further to validation, the questionnaire was amended accordingly and tested for reliability by six to ten members of each stakeholder group. As previously mentioned, reliability testing consisted of the filling in of the questionnaire by a set number of individuals at two different times, two weeks apart. This was necessary so as to determine whether the questions of the questionnaire were clear and comprehensive to the respondents and whether the respondents were consistent in their responses (Tsang *et al.*, 2017). Consistency in any replies does not mean that the respondents agree with a particular statement or question. For example, consistency can be considered if a respondent replied “No” in both instances, or marked a specific rank on the Likert scale for both instances. It is also worth noting that with a Likert scale question versus a question with a “Yes/No” answer, there are more chances of variability in Likert scale type of questions, as on Day 0 a participant may have listed a Likert rating of 2 but on Day 15, they may have listed a Likert rating of 1. In principle, 1 and 2 Likert scale ratings are very similar and both indicate a low score, however when running the

pairwise t-Test, the difference in the value is noted and result in a statistically significant different outcome. This was taken into consideration when analysing the results. The questionnaire was finally reviewed and disseminated to the respective stakeholders as previously mentioned.

4.2.1 Pharmacy Students

A vaccination training programme was developed and delivered to pharmacy students, at the Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, in the first year of the Bachelor of Science (Hons.) in Pharmaceutical Science course for the first time during academic year 2021-22, as part of the study-unit PHR1301 – Pharmaceutics 1.⁸ This training programme involves:

- 1) Three hands-on laboratory practical sessions using injection simulators to practise preparation and reconstitution of vaccines and administration via the intramuscular, subcutaneous and intradermal routes,
- 2) Three observation sessions within the National Immunization Service-Primary Healthcare, and
- 3) First aid course. Upon successful completion of the training programme, a skills checklist and pharmacy-based vaccination delivery certificate are issued. Skills in documentation post-administration and management of post-vaccination reactions are practised.

A questionnaire consisting of fifteen questions (twenty-five questions in total including sub-questions) was developed and validated. The students were asked to score the

⁸ University of Malta (UM). Study-Unit Description [Online]. Msida (Malta): UM; 2024 [cited 2024 Jul 28]. available from <https://www.um.edu.mt/courses/studyunit/PHR1301>

relevance, specificity and clarity of the questions provided, without actually filling in the questionnaire. The respondents did not provide any additional comments and so the questionnaire was passed on to the next step which was reliability testing. The replies to questions related to demographics were consistent hence scoring a p-value of 1.000. Students also scored a p-value of 1.000 for other assertive responses, particularly questions that were related to the course content and also the hands-on practice achieved via the administration of the Influenza vaccine at health centres around Malta. Such questions included knowledge on the preparation of vaccines and potential errors in their preparation, awareness on vaccine waste disposal and knowledge on guidelines. On the other hand, there were questions that had a lower p-value score. It could be noticed that from the responses as well as p-values obtained from the pairwise t-Test, questions which involved a level of responsibility and maturity had the most inconsistency. For example, question 12a, which asked whether the student would feel confident in administering a vaccine to a paediatric patient (0-15 years), the p-value obtained was 0.465, which indicates that students provided different responses on Day 0 and Day 15. Another typical example is the students' response to the awareness of the procedure should the student get a needle stick injury (question 9). In this situation, responsibility prevails leading to inconsistent replies over the two-week time interval ($p=0.175$). For questions where the respondents had to 'wear the shoes' of a pharmacist, the responses were indecisive as at one point they might have replied in their capacity as a student and in other instances they might have replied in the capacity of a future pharmacist. This explains the low score obtained for questions 15a and 15c related to patient education ($p=0.363$) and 'unsupervised' vaccine administration ($p=0.363$).

After reliability testing was carried out, the questionnaire was then disseminated to the same cohort of students who were promoted to their second year in the Bachelor of

Science (Hons.) in Pharmaceutical Science course. At this stage, the respondents had to fill in the questionnaire only once, and any inconsistencies could not be detected. Sixteen students out of the seventeen students the questionnaire was sent to, filled in the questionnaire. Apart from the uneven gender distribution, being university students, the age range did not vary significantly. The replies, provided for the second section of the questionnaire that relates to knowledge on the preparation and administration of vaccines, were relatively consistent with those provided during the reliability testing. This goes in accordance with the relationship of the reliability of the questionnaire and the credibility of the study as mentioned by Singh (2017). Whereas overall, the students were quite knowledgeable on how to manage and handle vaccines, the main issue relates to the course of action required if a needle stick injury occurs. Needle stick injuries are very common amongst nurses and physicians. In a study by Abdo and colleagues (2024), the prevalence of needle stick injuries by nurses was 95.36%. According to Keicher and co-workers (2024), the prevalence of needle stick injuries in Germany, per year was 31.4%, with physicians being most at risk. It may be pointed out that the procedure of how to prevent and handle needle stick injuries should be clearly explained to students. Additionally, during the training programme marks should be awarded to students who are able to solve such an issue. The third section was based on skills related to the vaccination process, administrative tasks and patient education. Through question 10, the students were confident in their role as facilitators. In fact, it is the role of the pharmacist to prepare and dispense medications. In question 11, students were challenged with their confidence in vaccination skills. In general, respondents were confident with the provision of the vaccination service, recognition of post-vaccination reactions and patient education. This emphasises the role of the pharmacist as an administrator and educator. However, overall the students were less confident with the management of post-

vaccination reactions and first aid. Although first aid is a requirement alongside the vaccination training programme for certification, it might be necessary that some aspects of first aid that are particularly pertinent to vaccination issues, should be emphasised during the vaccination training programme. In a study by Bushell and colleagues (2020), it was reported that students who completed a first aid course, had higher scores with respect to knowledge in post vaccination training assessments. When asked on the administration of vaccines to different age groups, students replied that they were confident in administering vaccines to adults. This might arise from the fact that this cohort of students was already exposed to the administration of the Influenza vaccine during the training programme. On the other hand, students had mixed responses to the administration of vaccines to paediatrics. Considering that most of the students in the cohort were 19 year olds, considering the paediatrics group extending to the age of 15 years, may indicate that the students were dealing with teenagers within their age group. Most probably, if the age range had to be readjusted according to the different stages of intellectual child development, as outlined by Saracho (2023) to the following age groups (such as birth-2, 2-7, 7-11, 12-15 years), a different response might have been obtained. The students who were less confident, might have considered some concerns with the tender age subgroup within the paediatric group. This is understood since paediatrics especially younger paediatrics tend to have more risks and vaccination errors tend to occur more in paediatrics. Paediatrics are given a number of different vaccines, so errors such as wrong dose, wrong vaccine, wrong time or wrong route of administration are common errors (Bundy *et al.*, 2009). Additionally, agitated and restless infants whilst being administered an intramuscular vaccine may lead to incorrect administration, possibly leading to nerve damage or injury which can have serious consequences (Jung & Hyun, 2014). Students were asked on their confidence in administering vaccines via

different routes. They were more confident with the intramuscular rather than the subcutaneous route. Students were also asked on the preferred site of injection. The most preferred is the deltoid/shoulder site, followed by the arm and finally the thigh. Generally vaccines are administered to adults at the deltoid/shoulder site (Nakajima *et al.*, 2017), whereas the anterolateral thigh may be the preferred site for infants and the elderly due to potential for nerve damage, injury, and adverse reactions (Sabharwal & Simon, 2023).

In summary, a vaccination training program was developed for first-year pharmacy students at the University of Malta during the 2021-22 academic year, incorporating practical lab sessions and observation within the National Immunization Service. Students practiced vaccine preparation and administration, and upon completion, received certification. A questionnaire validated by students without comments moved to reliability testing, showing high consistency for demographic and course-related questions but variance in questions involving responsibility and maturity. The final dissemination of the questionnaire to second-year students showed consistent knowledge in vaccine handling but highlighted issues in managing needle stick injuries and administering vaccines to different age groups, particularly paediatrics. Confidence was higher in administering vaccines intramuscularly and to adults, with a preference for the deltoid/shoulder site. From this exercise, it may be highlighted that the vaccination training programme requires updating on a number of aspects on which some students pinpointed a potential lack of information. Additionally, it is ideal that the training programme is repeated at the end of the pharmacy course as suggested by Baldolli and colleagues (2020).

4.2.2 Pharmacists

A questionnaire consisting of twenty-four questions (thirty-two questions in total including sub questions) was developed and validated. For the validation process, four healthcare professionals, two pharmacists and two physicians, were asked to participate. Although, as previously stated, physicians were excluded as stakeholders, the validation of the questionnaire was entrusted to these healthcare professionals given that physicians are generally involved in vaccination services.

The panel was asked to score the relevance, specificity and clarity of the questions provided, without actually filling in the questionnaire. The questionnaire had an overall positive validation. One healthcare professional mentioned that at the age of 16 years, a patient is considered to be an adult. This led to a change to question 16, where before it read whether respondent felt confident to administer vaccine to paediatrics (0-17 years). This was amended to 0-15 years. The questionnaire then underwent reliability testing, involving ten pharmacists who filled in the questionnaire on Day 0 and once again on Day 15. Statistical analysis was carried out using the pairwise t-Test. The opening questions relate to demographics; gender, age and years of practice. Pharmacists showed consistency in their replies between the two time points, scoring a p-value of 1.000. However, the only demographic question that pharmacists were not consistent was the area of practice ($p=0.085$). Pharmacists who practice in the community would definitely show consistency, but those pharmacists who either practice as locum pharmacists or worked in the past as community pharmacists, may reply differently at the two time points. The same pharmacists also showed consistency in other questions such as their awareness of current national guidelines, awareness on how to dispose of vaccine waste, skills related to side effects following vaccination, willingness to follow a vaccination training programme and administration of vaccines to paediatrics. Such consistency

determines the pharmacists' determination in their responses, either positive for most but particularly negative for the last question mentioned above. In other questions, pharmacists showed less consistency indicating that they either carried out a task or think that they are able to carry out a task on one occasion, but changed their mind on the second occasion. Given that pharmacists may handle vaccines, once they are procured and then dispensed to the attending physician or specialist prior to administration, may lead to a certain degree of assertiveness in their role as vaccine facilitators but not as vaccine administrators. Being aware of their potential limitations, and possible errors during the preparation of vaccines, pharmacists showed a similar response to their disposition to provide immunization services ($p=0.676$). Lower p-value scores were obtained for skills related to the administration of vaccination, including age groups, site of injection, route of administration and previous training ($p<0.371$). Though there was some hesitation, past experience may have affected the inconsistency between a pharmacist's response on both occasions. For instance, some pharmacists may recall an instance where they were aware of vaccination administration errors by the attending physician, so this was marked as a "Y". However, then considering their potential role as vaccine administrators, they might feel that they are not up to par and they might not recognize a vaccination administration error in that situation ($p=0.341$). Inconsistency prevailed in a number of questions, showing a statistically different response between the two time points ($p<0.05$). Such inconsistencies were observed for questions related to vaccine contraindications, awareness on a needle stick injury incident, patient education, administration of vaccines at the thigh area and recognition of post-vaccination reactions. It transpires that most of the respondents may show a positive response at one instance but then a negative response at the other instance, or vice versa. This provides uncertainty in the role of pharmacists as educators, facilitators and administrators vis-à-vis

vaccination, according to these ten pharmacists. The extent of the current pharmacist involvement in vaccination practices, could be understood better with the responses of a larger cohort of pharmacists. The participating pharmacists provided also open-ended feedback during the reliability testing step. The aim of this exercise was to determine whether the same pharmacist would mention the same comment at the two time points (day 0 and day 15). Only two out of ten pharmacists mentioned the same comment at the two time points, which may indicate that these two pharmacists wanted to stress their arguments, whereas another two pharmacists mentioned their comments once, thinking that it was enough to mention their comments at the first instance only. The other six pharmacists did not provide any feedback. However, some informative comments mentioned by those four pharmacists included the following:

- One of the pharmacists commented that adequate training and human resources must be highlighted and enforced if immunization had to be available at a community pharmacy level.
- Consistent with this response, another pharmacist commented that if the pharmacist-led vaccination service had to be implemented, administrations would need to be by appointment when two pharmacists are present in the pharmacy. The pharmacist administering the vaccines cannot be distracted on the counter and focused on the patient vaccination. This may lead to increased risk of errors as mentioned by Parajuli and colleagues (2022). According to the study by Goad and co-workers (2013), where the number of vaccinations administered by pharmacists and the hour of the day were compared, the most vaccinations administered were between 11:00 and 16:00. These hours represent the time when pharmacies are either closed or less busy, when compared to the morning or

evening shift. Therefore, vaccinations may be administered to patients during this period of the day.

- Some commented that it does not feel safe to administer vaccines at the pharmacy especially if there is a reaction to the vaccine, the pharmacist cannot handle such situations alone.
- Some pharmacists also commented on past experience, stating that when they used to practise in a pharmacy, the premises were not adequate for vaccination services.
- In addition, some even commented that if vaccination services are expected to be carried out at pharmacies, a pharmacist fee needs to be introduced. A study carried out by Houle and colleagues (2013) identified thirty-four programs where pharmacists administer vaccines, which are publicly funded. So, the pharmacist can claim an amount per vaccine.

Following the reliability testing step, the questionnaire was then disseminated to a greater number of pharmacists. Although there was no particular targeted pharmacist group, in accordance with the reliability test result, the majority of respondents were community pharmacists (n=28) and pharmacists who were practising in other sectors but locum as well (n=27). This would reduce potential bias on responses since the immunization service is foreseen to be carried out in community pharmacies. The questionnaire captured a majority of mature pharmacists (age range: 50-59 years of age, n=28), as compared to the other age groups; 40-49, 30-39 and 18-29 years of age with ten, thirteen and eleven respondents, respectively. When considering age and years of practice, there was a strong positive correlation ($r_s=0.929$) indicating that experience relates to age, hence complementing the unbiased targeting of mature pharmacists as respondents to this questionnaire. Therefore, it was expected that these mature pharmacist might have

experienced situations related to vaccination in their capacity as educators, facilitators and potential administrators which may be reflected in their responses in the questionnaire. This contrasts with the lack of encounters and experience of pharmacists with 1-10 years of experience.

Approximately half of the respondents expressed their knowledge on the preparation and reconstitution of vaccines (n=33) and their awareness of errors during the preparation and administration of vaccines (n=32), and the procedure required in case of a needle stick injury (n=37). Most probably, this is due to the fact that they might have encountered such situations during their practice. On the other hand, the majority of the respondents were knowledgeable on the current national guidelines (n=42) and on the procedure of vaccine storage (n=58) and were aware of contraindications to vaccines (n=45) and vaccine waste handling (n=56). These four tasks are within the remit of the traditional pharmacist as a facilitator, which goes in part, in accordance with Yemeke and co-workers (2021). Pharmacists expressed their concern that they are not skilled to manage possible side effects of a vaccine (n=44), which complements the gaps in their vaccination skill set. In fact, it seems that half of the pharmacists are not willing to provide immunization services (n=32). This arises from a lack in the recognition and management of post vaccination reactions (n=44) and a lack in providing first aid assistance (n=26). When it comes to age groups, most pharmacists were not confident with the administration of vaccines to all age groups. Patients from different age groups react differently to vaccine administration, and it is likely that pharmacists were not aware of all possible scenarios they might encounter in this regard. Although there was a mixed response in relation to the route of administration, most pharmacists were not confident to administer vaccines via the intramuscular (n=33) and subcutaneous routes (n=28). On the other hand, one third of the pharmacists were confident in administering the vaccine

via these routes (n=22, for each route). However, when asked on the site of administration (figure 3.10), it turned out that most of the pharmacists were not confident with vaccine administration holistically.

The last section deals with training on vaccination. Spearman correlation statistics reveal that age and former training do not correlate to each other ($r_s=0.204$). Whereas previous student cohorts (now practising pharmacists) received general training on the administration of medicinals via the parental route, vaccination training is a recent introduction, and therefore the younger pharmacists were still willing to attend a training programme. When considering a possible relationship between pharmacists' former and future involvement in vaccination training programmes, it transpires that there is no correlation between these two ($r_s=0.210$). This lack of correlation is due to two main reasons: (1) those who already received former training were willing to renew their training (n=16), and (2) those who did not receive former training were willing to attend the training programme (n=39). When considering the area of practice with attendance to future vaccination training programmes and vaccine administration, it emerged that area of practice does not correlate with the two parameters ($r_s=-0.023$ and -0.123 , respectively). This indicates that even pharmacists who were not mainly working within the community were willing to attend a training programme (community pharmacists, n=28; willingness to attend, n=55). The same argument holds for the relationship between the area of practice and willingness to administer vaccines (n=43). The additional number may be reflected in a number of locum pharmacists.

Whereas most of the pharmacists had not received vaccination training during their undergraduate studies and throughout their years of practice, they were willing to attend a vaccination training programme. These pharmacists admitted that they would then be ready to offer immunization services at the community pharmacy.

In summary, this questionnaire revealed and confirmed the reluctance of pharmacists to provide vaccination services at this current state. However, most of the pharmacists were confident in providing information to patients with regards to vaccination. This confirms that current status of pharmacists as educators. However, if pharmacists were to be given the opportunity to attend a training programme on vaccination, covering elements that they currently lack, the respondents commented that they would be willing to provide the service.

4.2.3 Patients

A questionnaire consisting of thirteen questions was developed and validated. The patients were asked to score the relevance, specificity and clarity of the questions provided, without actually filling in the questionnaire. The respondents did not provide any additional comments and so the questionnaire was passed on to the next step which was reliability testing. The replies to questions related to demographics, including gender, age, nationality and education level, were consistent hence scoring a p-value of 1.000. Patients also scored a p-value of 1.000 for other assertive responses, for example, whether they trust their pharmacist to administer the influenza or other vaccines to them and/or their children, i.e. question 8 to 11. All respondents were consistent for all four questions at the two time points. For questions related to the patient's queries on vaccination (question 5), satisfaction in the pharmacist's replies (question 6) and queries on other aspects of vaccination (question 7), the respondents were less consistent in their responses between the two time points ($p < 0.494$). Given that patients generally ask pharmacists several queries, even those that are related to other medications, food supplements, toiletries and cosmetics, at the time of filling the questionnaire, the patients may forget or may not include a response, as was the case with questions 5 and 7 ($p = 0.343$, for both

questions). When patients were asked on their willingness to pay for immunization service by their pharmacist, there was inconsistency between the two time points for the respondents ($p=0.279$), with six retaining the same monetary value between the two occasions while the other four changed the value.

Following the reliability testing step, the questionnaire was then disseminated to a wider number of patients. There was no particular targeted patient group, though when considering the age groups (figure 3.11), when the ages were categorised into two major groups (18-39 and 40-70⁺), the numbers tallied to 80 and 83 respectively. These numbers provide a balance in questions responses. For example, when questions are related to adult vaccination, the total number of individuals should provide a realistic response as only adult respondents above the age of 18 were considered in this study. When questions are related to the paediatric population, half of the respondent number tends to reply considering a realistic scenario with their children, whereas the replies of the other respondents would be based on perception, as a 60 year old would either base the reply on their opinion decades earlier or consider their grandchildren as a current scenario.

From this study, it can be It is very common that patients ask their pharmacists questions related to their medications and vaccines ($n=102$). Respondents asked vaccine-related questions to their pharmacist, generally related to side effects, general information, concerns and uses. Some respondents extended their selection to the category “Others” where they had the opportunity to comment on what information they request from their pharmacist. A patient mentioned that they usually speak to their brother who is a physician regarding medical information. Another patient mentioned that they suffer from headaches regularly, so they asked the pharmacist what product they would recommend should the patient experience a headache as a side effect of a vaccine. Another patient mentioned that they are allergic to certain medication so when asking about a particular

vaccine, they ask whether it is safe and if it contains any of the medicinal products/ingredients the patient is allergic to. The fourth patient who left a comment as part of the “Others” said that they had asked the pharmacist questions about all of the mentioned type of information, that is general information about a particular vaccine, uses, concerns and side effects.

Question 5 and Question 12 were compared so as to determine if the advice provided by the pharmacist correlates with the willingness of patients to be provided this service against a fee. The majority of respondents (n=46) ask their pharmacist questions regarding vaccines and are also willing to pay €5 for the immunization service, the highest fee that was presented to the patients in the questionnaire. Eighteen respondents asked their pharmacist questions about vaccines and are willing to pay €3 for the immunization service and fifteen respondents who requested information on vaccines from their pharmacist were willing to pay €2 for the immunization service. Twenty respondents asked their pharmacist questions on vaccines however, were not willing to pay for an immunization service. Two respondents left a comment at the end of the questionnaire stating that they simply said that they were not willing to pay for the immunization service since they receive vaccinations for free from the government. One respondent mentioned that if a particular type of vaccine were not to be provided for free by the government, and they would want to take that vaccine, then they would have no problem with paying the pharmacist for the immunization service. From this, it is good to note that there are vaccines that are provided for free from the government and for this reason patients were not willing to pay for the immunization service. However, should the vaccine be available privately and patients cannot be reimbursed, then they are willing to pay for the immunization service, in this case administered by the pharmacist. This is reflected by

the weak correlation between patients seeking advice by the pharmacist and patient's willingness to pay a fee for the pharmacist's service ($p=0.074$).

The respondents had the opportunity to leave a comment at the end of the questionnaire. This resulted in twenty-one comments. Eight respondents believe that pharmacists are capable of providing immunization services. One respondent mentioned that they prefer going to primary healthcare centres for vaccine administration and another mentioned that they only trust a family physician who proved themselves over time. Some respondents ($n=5$) commented that they would trust their pharmacist to administer vaccines given that they are trained and qualified to do so. The perception obtained from the comments is that patients know that physicians and nurses are trained to administer vaccines, but many are not aware that pharmacists can legally administer vaccines in Malta, though they are not fully trained to provide this service. With regards to pharmacists administering vaccine to paediatrics, respondents were more hesitant. Three respondents mentioned that they would prefer if the paediatrician administered vaccines to paediatrics, as they believe that paediatricians are more qualified to administer vaccines to paediatrics, especially in terms of body anatomy of new borns and infants but also their 'antics'. One respondent mentioned that not all staff at the pharmacy are qualified. In this case, it can be made clearer that only pharmacists who have undergone a vaccination training programme would be administering vaccines. Three respondents mentioned that they believe that their pharmacist provide them with correct information about vaccines, which enables them to make an informed decision. However, they mentioned that it is up to them to decide whether they would take the vaccine or not, as some patients do not agree with the administration of all vaccines available. One respondent mentioned that pharmacists play an important role in encouraging immunization since they are the first healthcare professionals patients seek, especially if there is a good pharmacist-patient

relationship. Four respondents mentioned that they trust their pharmacist and that they find pharmacists to be as helpful as physicians. Patients commented that pharmacists are knowledgeable about vaccines in general but also on information related to storage conditions and ingredients/vaccine components.

In summary, the patient questionnaire was distributed to a broad range of patients, categorized into two major age groups (18-39 and 40-70+), yielding a balanced response. The study showed that patients often seek vaccine-related advice from pharmacists, with many expressing willingness to pay for immunization services. Most respondents (46) would pay €5, while others preferred lower fees or none due to government providing free vaccines and administration. Comments indicated a general trust in pharmacists' ability to administer vaccines, though some preferred physicians or primary healthcare centres, especially for paediatric vaccinations. The overall perception was that pharmacists are knowledgeable and play a crucial role in patient education and in promoting immunization to patients.

4.2.4 Comparisons of perceptions and views of stakeholders

Twenty-one questions were selected from the students' and pharmacists' questionnaire and the data was challenged with unpaired t-test statistic, the Student's t-Test. Seven questions were based on knowledge and awareness whereas fourteen questions were based on confidence (Appendix D, table D.7). The responses provided by the sixteen pharmacy students and sixty-two pharmacists were taken into account. Awareness questions considered the role of the pharmacist as a facilitator and an administrator. Most of the students were aware of errors that may occur during preparation (n=14/16) and administration of vaccines (n=15/16), whereas less pharmacists (n=32 and n=45/62,

respectively) were aware of these errors, resulting in a statistically significant difference for both types of errors between the two groups ($p < 0.05$). In a conventional setup, the pharmacist dispenses the vaccine to the patient just before visiting the physician or specialist at the pharmacy's clinic. So generally pharmacists are not involved in the preparation and in particular the administration of vaccines. On the other hand, students acquired hands on practice during the training programme and the observation and administration of the Influenza vaccines in health centres. Both pharmacy students and pharmacists are aware of contraindications and how these can be identified in a patient. However, students seem to be more knowledgeable than pharmacists on this aspect ($p = 0.075$). Both pharmacy students ($n = 14$ and $n = 16$, respectively) and pharmacists ($n = 58$ and $n = 56$, respectively) were knowledgeable on the storage conditions of vaccines prior to vaccination and were aware of how to dispose of waste during handling ($p > 0.200$). These tasks are also within the remit of a pharmacist, resulting in a high number of positive responses for both students and pharmacists. Half of the pharmacy students ($n = 8$) and two-thirds of the pharmacists ($n = 68$) were aware of the current guidelines of the national immunization scheme and where to find them ($p = 0.192$). It is more likely that pharmacists encountered with these guidelines when asked by patients rather than students who should look up these guidelines just for information. This shows that knowledge on guidelines during practice is very important. Although, it has been already highlighted that needle stick injury are sometimes difficult to manage, approximately half of the students ($n = 9$) and pharmacists ($n = 37$) are aware on the procedure dealing with this incident. Both groups alike, require further knowledge and training on this aspect ($p = 0.807$).

Confidence questions tackled issues related to the role of the pharmacist as an educator, facilitator and administrator of vaccines. It transpires that pharmacy students ($n = 16$) were

more confident in providing immunisation services than pharmacists (n=30 out of 62) ($p<0.05$). This may be due to a lack of training received by pharmacists (n=16) vis-à-vis the student cohort (n=16) ($p<0.001$). However, pharmacists were willing to attend vaccination training programmes leading to an increase in the positive responses of pharmacists to this question (n=43), which seems to narrow the gap with the student responses ($p=0.352$). This was observed also in other countries, such as Poland, where pharmacists were willing to provide immunization services following a training course on vaccination (Merks et al., 2021). Pharmacy students (n=15) and pharmacists (n=57) are confident in educating patients on matters related to vaccines and vaccination. This fulfils the role of pharmacists as vaccine educators (Quigley et al., 2022). When it comes to confidence in more practical aspects of vaccination, pharmacy students tended to score higher than pharmacists, mainly related to the vaccination training students received, as mentioned earlier. One other aspect that merits mentioning is that although some pharmacists might have acquired training in previous years, it is not known when this training was received. From the time of training, students replied to the questionnaire within a few of months. This may explain why students were more confident than pharmacists on the practical aspects. Additionally, Appendix D table D.7 highlights differences between the two groups with respect to vaccination of different age groups ($p<0.001$), route of administration ($p<0.05$) and site of administration ($p<0.001$).

In summary, this comparative analysis involving sixteen pharmacy students and sixty-two pharmacists evaluated twenty-one questions, which relate to knowledge and confidence about vaccination roles. It transpires that students were more aware of errors in vaccine preparation and administration than pharmacists, with a significant difference. Both groups were knowledgeable about vaccine storage and disposal, but students demonstrated greater knowledge of contraindications. Confidence levels in providing

immunization services were higher among students than pharmacists, likely due to recent training. Although pharmacists showed willingness to improve through training, confidence in practical aspects remained higher among students, reflecting recent hands-on training.

4.3 Education Framework

Following positive responses from the three stakeholders during phase 1 of the study, an education framework for pharmacist-led vaccination services was compiled. This involved an extensive literature search for education frameworks set in different countries. However, there was a lack of information on education frameworks, specifically on pharmacist-led vaccination services (Rahma et al., 2021). There were several studies which evaluated training programmes of pharmacist-led vaccination services (Feret et al., 2015; Mills et al., 2021; Yemeke et al., 2021). An education framework is designed in a way that it mentions the main key points, but is generally very broad. It encompasses a wide range of topics and skills. A training programme on the other hand is more detailed and specific, focusing more on certain topics and skills. An education framework is aimed for longer periods and hence updated less frequently whereas a training programme is aimed to be for shorter periods and updated more frequently. An education framework can be used as a basis for a number of training programmes.⁹

⁹ The Australian Health Workforce Institute (AHWI). Competency-based Education and Competency-based Career Frameworks: Informing Australian health workforce development [Online]. Adelaide (Australia): AHWI; 2011 [cited 2024 Jul 28]. Available from: https://researchoutput.csu.edu.au/ws/portalfiles/portal/13364556/12131508_published_report.pdf

The education framework developed in this study is aimed at pharmacy students and also pharmacists requiring further training. It is divided into seven categories representing different aspects of vaccinology.

The first category discusses regulatory aspects. This takes into consideration different regulatory frameworks within different countries, highlighting the roles of pharmacists as vaccine educators, facilitators and administrators.

The national guidelines category focuses on the sources and tools pharmacists can use to be able to guide the patient better. Guidelines are updated regularly depending on the country and disease trends, therefore the aim of this category is to make pharmacists aware of the sources available to look up and to keep up with the latest guidelines.

The responding to patient needs category guides the pharmacist on how to identify in which scenarios the pharmacist can recommend a particular vaccine to a particular patient. For example, for a patient in their 70s, one would recommend the influenza vaccine, or for a patient with fever, vaccine administration would have to be postponed.

This category also discusses patient education, where patients seek advice from the pharmacist and ask questions about vaccines e.g. vaccine safety or side effects.

Vaccine handling and storage focuses on how the vaccine should be stored, whether it needs to be stored at a particular temperature and how temperature should be monitored, the expiration date, as well as other common practices such as (FIFO) first in, first out and keeping child and adult vaccines or vaccines with similar names separate from each other.

The vaccine preparation and reconstitution category discusses the initial steps before administering the vaccine. This involves checking the vial/ampoule, confirming the physical characteristics and packaging in accordance with the specification, good practice of reconstitution, using clean equipment and wearing personal protective equipment.

The vaccine administration category focuses on the administration of vaccines, that is, checking the name, dose, expiration date of the vaccine vial/ampoule, wiping the area with an alcohol swab, using the correct route of administration e.g. subcutaneous versus intramuscular, and the correct angle of insertion for example, 45° or 90°.

The last category discusses documentation practices which would include information related to the date of administration, vaccine name, batch number, and dose. These are to be documented either in a vaccination booklet or an online system where vaccination records are kept.

Each category has a competencies checklist which after training is completed, the pharmacy student/pharmacist would be competent in providing vaccine knowledge and administration.

The validation of the framework involved reviewing of the Education Framework and filling in of a Validation Report, using the Delphi Method (Massaroli *et al.*, 2018). The validation report included five Likert scale questions and an open-ended question at the end. This served as a guide for the respondents to carry out their validation, leaving some room for personal comments, which might not have been covered by the close-ended questions. The validation report questions evaluated the comprehensiveness and applicability of the Education Framework as a whole and specificity, relevance and clarity for each of the seven sections. The validation report was formulated into a Google Form

which was sent, together with the education framework to eleven different European Schools of Pharmacy. Six participants reviewed the education framework, originating from Croatia, Italy, Portugal, Serbia, Slovenia, and Wales.

For comprehensiveness and applicability of the education framework, there was an overall positive response with a rating of 4 or 5 for both parameters. For the other three parameters, specificity, relevance and clarity, although there were some scores of 3, the majority were 4 or 5. The categories of the framework which had a scoring of 3 included clarity and specificity for the regulatory category and the administration of vaccines category.

From the scoring of the close-ended questions there was an overall positive response. For the last question of the validation report, where respondents could leave a comment, all six respondents commented. Three respondents (panellist 1, 2, 5 and 6) commenting on the clarity and usefulness of the framework, whilst the other three respondents (panellists 3 and 4) gave recommendations for improvement on certain categories of the framework.

Panellist three commented that in the regulatory aspects category, national laws and regulations regarding vaccines and vaccine administration could have been included as well, apart from the regulations and laws concerning pharmacists' role in vaccination. This panellist also commented on the lack of ethics, where topics such as confidentiality could be included. The panellist commented that there was too much information on the administration of vaccines in the administration of vaccines category, which can be included in the training programme rather than this education framework. The panellist mentioned that information that the distinction between the theoretical module and hands-on module was not so clear. Vaccine administration safety and pharmacist training in response to anaphylactic reactions were not mentioned in the education framework. The

panellist also mentioned that some consideration must be given to the fact whether this is a pharmacist competence that can only be acquired by registered pharmacists, or if indeed students may already acquire it in undergraduate studies. The panellist also provided a website for additional information.¹⁰

Panellist 4 commented on the term ‘vaccine’ used in a sentence which should be switched to ‘vaccination’, however this amendment was not made since the idea behind the phrase pharmacists’ role as vaccine facilitators’ was that through pharmacists vaccines can be made available to the patient, rather than making the whole vaccination process available to the patient. The panellist mentioned that when explaining that “when one is inserting the needle at a right angle”, the term ‘right’ might not be appropriate in this case, as whereas in the sentence above reference to the correct insertion of the needle, using the term ‘right angle’ can infer a ninety-degree angle. This amendment was made in the education framework so as to avoid and prevent misunderstanding. Table 4.1 lists the original text of the Education Framework and the respective amendments carried out to the text in line with the panellists’ recommendations. Additionally, the Education Framework was reviewed for any possible amendments. Within the ‘Competencies Checklist’ the original term ‘student’ was used to state the competencies which the ‘student’ should acquire after undergoing the training programme. This term was intended to include participants undergoing the training programme, that is, students and pharmacists. So as to avoid confusion the term ‘student’ was replaced with ‘trainee’.

¹⁰ Ordem dos Farmacêuticos (OF). Competência em Administração de Vacinas e Medicamentos Injetáveis [Online]. Lisbon (Portugal): OF; 2024 [cited 2024 Jul 28]. Available from: <https://www.ordemfarmaceuticos.pt/pt/assuntos-profissionais/competencias-farmaceuticas/administracao-de-vacinas-e-medicamentos-injetaveis/a-competencia/>

Table 4.1. Amendments to the Education Framework text in line with the panellists' recommendations

Panellist 3	Before	The recent COVID-19 vaccination strategy led to changes in the regulation related to pharmacists' role in vaccination, such as the reconstitution and of vaccines. (Reise <i>et al.</i> , 2021).
	After	The recent COVID-19 vaccination strategy led to changes in the regulation related to pharmacists' role in vaccination, such as the reconstitution and administration of vaccines. (Reise <i>et al.</i> , 2021). Pharmacists are encouraged to consult and keep updated with national laws and regulations regarding vaccines and vaccine administration.
	Before	Fifteen minutes are allowed to ensure that the patient does not experience immediate side effects, and if patient does, the necessary treatment has to be provided.
	After	Fifteen minutes are allowed to ensure that the patient does not experience immediate side effects and anaphylactic reactions , and if patient does, the necessary treatment has to be provided.
	Before	Given the benefits of documentation, apart from proper training of pharmacists on how to handle vaccines and administer them, pharmacists should have access to vaccination records, so as to provide seamless healthcare together with other healthcare professionals.
	After	Given the benefits of documentation, apart from proper training of pharmacists on how to handle vaccines and administer them, pharmacists should have access to vaccination records, so as to provide seamless healthcare together with other healthcare professionals. Confidentiality is an important consideration to be observed by pharmacists so as to maintain a healthy pharmacist-patient relationship and to be in-line with the code of ethics.
Panellist 4	Before	Inserting the needle at the right angle of insertion according to the route of administration.
	After	Inserting the needle at the correct angle of insertion according to the route of administration.

In summary, following positive feedback from stakeholders, an education framework for pharmacist-led vaccination services was developed. The framework, designed for pharmacy students and pharmacists, includes seven categories covering various

vaccinology aspects and a competencies checklist for each category. Validation involved feedback from six European pharmacy schools, with overall positive responses but some suggestions for improvements, especially regarding regulatory aspects and ethics. The amendments were carried out and the Education Framework was finalised. The Delphi Method suggests that more rounds are carried out so that the panellists could evaluate their previous comments, until a consensus is reached. Given that the suggested amendments were trivial and overall the validation had a positive outcome, only one round was necessary to finalise the framework. Having said that the finalised education framework document was not sent again to the panellists for a second and final round of validation, due to time constraints. The validated and finalised version of the framework may be used as a model by schools of Pharmacy as a basis to set up a training programme aimed at pharmacy students and pharmacists for the provision of pharmacist-led vaccination services.

4.4 Limitations

The limitations of this study included sample size and time restrictions, during both phases of the study. During the first phase, only one cohort of students who had undergone the training took part in this study. The training programme is still being offered to subsequent cohorts of first year pharmacy students, therefore other cohorts could have been included, had it not been for time constraints. With regards to pharmacist and patient responses, the researcher could have gone to different pharmacies across Malta and Gozo and left a few copies of the respective questionnaires to be filled in anonymously at the pharmacy; pharmacists during hours when the pharmacy was not busy and patients whilst in the waiting room waiting for the physician. Due to time

constraints, this was not feasible. During the second phase of the study, the education framework was sent for validation, first to ten European Schools of Pharmacy with reminders sent, yet no responses were collected. The researcher attended a conference where one response was gathered. The education framework was sent to twenty-eight different researchers on ResearchGate after reviewing similar work to this study, however only one response was gathered. The education framework was then sent to another eleven different European Schools of Pharmacy representatives, and then four responses were gathered, bringing it to a total of six responses.

4.5 Future work

Future work can involve planning and implementing a strategy for a vaccination training programme for pharmacists, together with the setting up of a national immunization programme coupled with a health campaign in collaboration with the Department of Health. This would be beneficial even because from the results obtained, not all patients who answered the questionnaire were aware that there are pharmacists who are trained on how to prepare and administer vaccines. Additionally, if the education framework had to be implemented, the infrastructure of the electronic healthcare system has to be updated so as to cater for pharmacists' accessibility to patient vaccination records. This would include the inputting of vaccination records by the pharmacists in the system as part of the documentation process.

Additional research or studies which can be carried out may include more specific patient populations such as paediatrics, vulnerable patients such as elderly, and patients with certain comorbidities for example asthma. Such studies may provide information on the current situation of specific patient groups in relation to vaccination, and specific regulations and rules or guidelines for such patient populations. This research can also be

expanded to America, Canada, Australia and African countries, to get an overview of what is done in such countries and compare such strategies with the European model. This extensive study can then lead to changes in the training programmes offered to pharmacists, improving pharmacist-led vaccination services and improving overall population health.

4.6 Conclusion

The study aimed to understand perspectives on pharmacist-led vaccination services from pharmacy students, pharmacists, and patients, and to develop and validate an educational framework for pharmacy schools in Europe. A vaccination training program for first-year pharmacy students at the University of Malta included practical laboratories and observation, with certification upon completion. The program revealed students' confidence in vaccine handling but highlighted areas needing improvement, such as managing needle stick injuries and paediatric vaccinations. Pharmacists showed reluctance to provide vaccination services but were willing to do so with further training. Patients expressed trust in pharmacists for vaccination information and many were willing to pay for immunization services, though some preferred government-provided free vaccines and vaccination. Following positive stakeholder feedback, an education framework was compiled and validated by various European Schools of Pharmacy, emphasizing the need for comprehensive training in pharmacist-led vaccination services.

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Appendices

Appendix A – Ethics Approval

A.1 Phase 1: Pharmacy student, pharmacist and patient perspectives on pharmacist-led vaccination services

form.urec@um.edu.mt
to me ▾
Tue, 3 May 2022, 11:29 ☆ ↶ ⋮

Dear Tamara Attard,

Please note that the status of your REDP form (MED-2022-00077) has been set to *Acknowledged*.

MED-2022-00077	31/03/2022	Action in the Evolvement of Vaccination in Pharmacy	Faculty of Medicine & Surgery	Acknowledged
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Figure A.1 Confirmation of Ethics Approval via email and UREC platform

A.2 Phase 2: Education Framework

form.urec@um.edu.mt
to me ▾
Fri, 5 Jan, 07:33 ☆ ↶ ⋮

Dear Tamara Attard,

Please note that the status of your REDP form (MED-2024-00002) has been set to *Acknowledged*.

MED-2024-00002	03/01/2024	Establishing an Education Framework for Pharmacist-Led Vaccination Services	Faculty of Medicine & Surgery	Acknowledged
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Figure A.2 Confirmation of Ethics Approval via email and UREC platform

Appendix B – Material Produced

Overview

Three self-administered questionnaires were prepared and disseminated to pharmacy students (Appendix B.2), pharmacists (Appendix B.3) and patients (Appendix B.4) respectively for phase 1 of the study. An education framework (Appendix B.5) and validation report (Appendix B.6) was compiled for phase 2 of the study.

B.1 Pharmacy Students' Questionnaire

Section 1: Participant Demographics

1. Gender

- ☐ Female
- ☐ Male
- ☐ Do not wish to disclose
- ☐ Other

2. Age

- ☐ 17-18
- ☐ 19-29
- ☐ 30+

Section 2: Knowledge on the preparation and administration of vaccines

- | | | |
|--|------------------------------|-----------------------------|
| 3. I am aware of errors during preparation and how to prevent them. | Yes ☐ | No ☐ |
| 4. I am aware of vaccination administration errors which can occur and how to prevent them. | Yes ☐ | No ☐ |
| 5. I am aware of contraindications and how to identify contraindications in a patient. | Yes ☐ | No ☐ |
| 6. I am aware of the current guidelines of the national immunization scheme and where to find them. | Yes ☐ | No ☐ |
| 7. I know the storage procedure involved in refrigeration and handling of the vaccines, prior to administration. | Yes ☐ | No ☐ |
| 8. I am aware of how to dispose of the waste during handling. | Yes ☐ | No ☐ |
| 9. I am aware of the procedure should I get a needle stick injury. | Yes ☐ | No ☐ |

Section 3: Skills

10. I have the skills required for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules Yes ☐ No ☐

11. How confident do you feel from 1-5 (1 = no knowledge and 5 = very confident) that you have the skills:

	Least 1	Confidence			Most 5
		2	3	4	
a. To provide immunization services in compliance with documentation requirements	☐	☐	☐	☐	☐
b. To recognise post-vaccination reactions	☐	☐	☐	☐	☐
c. To manage post-vaccination reactions	☐	☐	☐	☐	☐
d. To describe relevant first aid procedures	☐	☐	☐	☐	☐
e. To educate patients regarding vaccines	☐	☐	☐	☐	☐

12. How confident are you in administering a vaccine safely to the following age groups?

	Least 1	Confidence			Most 5
		2	3	4	
a. Paediatrics (0-15 years)	☐	☐	☐	☐	☐
b. Adults (16 and over)	☐	☐	☐	☐	☐

13. How confident are you in administering a vaccine safely through the following routes?

	Least 1	Confidence			Most 5
		2	3	4	
a. Intramuscular (IM)	☐	☐	☐	☐	☐
b. Subcutaneous (SC)	☐	☐	☐	☐	☐

14. How confident are you in administering a vaccine safely at the following injection sites?

	Least 1	Confidence			Most 5
		2	3	4	
a. Arm	☐	☐	☐	☐	☐
b. Thigh	☐	☐	☐	☐	☐
c. Deltoid/ Shoulder	☐	☐	☐	☐	☐

15. As a future pharmacist, do you think you will feel confident:

- | | | |
|---|------------------------------|-----------------------------|
| a. To educate the patient regarding vaccines and any concerns they may have | Yes ☐ | No ☐ |
| b. To prepare/reconstitute vaccines | Yes ☐ | No ☐ |
| c. To administer vaccines | Yes ☐ | No ☐ |

Thank you!

B.2 Pharmacists' Questionnaire

Section 1: Participant Demographics

1. Gender

- ☐ Female
- ☐ Male
- ☐ Do not wish to disclose
- ☐ Other

2. Age

- ☐ 18-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60-69
- ☐ 70+

3. Years of Practice

- ☐ 1-10
- ☐ 11-20
- ☐ 21-30
- ☐ 31-40
- ☐ 40+

4. Area of Practice

- ☐ Community Pharmacy
- ☐ Clinical Pharmacy
- ☐ Industry

- ☐ Academia
- ☐ Other

Section 2: Knowledge on the preparation and administration of vaccines

5. I am aware of errors during preparation and how to prevent them. Yes ☐ No ☐
6. I am aware of vaccination administration errors which can occur and how to prevent them. Yes ☐ No ☐
7. I am aware of contraindications and how to identify contraindications in a patient. Yes ☐ No ☐
8. I am aware of the current guidelines of the national immunization scheme and where to find them. Yes ☐ No ☐
9. I know the storage procedure involved in refrigeration and handling of the vaccines, prior to administration. Yes ☐ No ☐
10. I am aware of how to dispose of the waste during handling. Yes ☐ No ☐
11. I am aware of the procedure should I get a needle stick injury. Yes ☐ No ☐

Section 3: Skills

12. I have the skills to manage possible side effects of the vaccine (15 minutes after administration). Yes ☐ No ☐
13. I have the skills required for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules. Yes ☐ No ☐
14. How confident do you feel from 1-5 (1 = no knowledge and 5 = very confident) that you have the skills:

a.	To provide immunization services in compliance with documentation requirements	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

b.	To recognise post-vaccination reactions	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

c.	To manage post-vaccination reactions	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

d.	To action relevant first aid procedures	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

e.	To educate patients regarding vaccines	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

15. How confident are you in administering a vaccine safely to the following age groups?

a.	Paediatrics (0-15 years)	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

b.	Adults (16 and over)	Least	Confidence				Most
		1	2	3	4	5	
		☐	☐	☐	☐	☐	

16. How confident are you in administering a vaccine safely through the following routes?

a. Intramuscular (IM)	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐
b. Subcutaneous (SC)	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐

17. How confident are you in administering a vaccine safely at the following injection sites?

a. Arm	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐
b. Thigh	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐
c. Deltoid/ Shoulder	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐

Section 4: Service Provision

18. I have received training to administer vaccines in the past Yes ☐ No ☐
19. Would you attend a short training course covering the basic Yes ☐ No ☐
 concepts and skills required for immunization?
20. Are you willing to administer vaccines to patients? Yes ☐ No ☐

21. Do you think it is feasible to carryout immunization services Yes ☐ No ☐
in community pharmacies?

If you practise in the community (full-time/locum) please answer questions 22 and 23

22. Do you think the premises where you practise, requires Yes ☐ No ☐
modifications to carry out immunization services?

23. Would you be open to a service fee for preparing and Yes ☐ No ☐
administering the vaccine?

24. Other comments

Thank you!

B.3 Patients' Questionnaire

B.3.1 English Version

Section 1: Participant Demographics

1. Gender

- ☐ Female
- ☐ Male
- ☐ Do not wish to disclose
- ☐ Other

2. Age

- ☐ 18-19
- ☐ 20-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60-69
- ☐ 70+

3. Nationality

- ☐ Maltese
- ☐ EU
- ☐ International

4. Education Level

- ☐ Primary
- ☐ Secondary
- ☐ Post-secondary
- ☐ Tertiary

Section 2: Vaccine education and administration by pharmacists

5. Have you ever asked your pharmacist questions regarding vaccines? Yes ☐ No ☐

6. If yes, what type of information did you ask for?

☐ General information about a particular vaccine

☐ Uses

☐ Concerns

☐ Side effects

☐ Others: _____

7. Were you satisfied?	Least	Confidence			Most
	1	2	3	4	5
	☐	☐	☐	☐	☐

8. Would you trust your pharmacist to give you an influenza vaccine? Yes ☐ No ☐

9. Would you trust your pharmacist to give your child an influenza vaccine? Yes ☐ No ☐

10. Would you trust your pharmacist to give you other types of vaccines e.g. Tetanus, Hepatitis B. Yes ☐ No ☐

11. Would you trust your pharmacist to give your child other types of vaccines e.g. Diphtheria, Hepatitis B. Yes ☐ No ☐

12. Would you pay for an immunization service by your pharmacist?

☐ €5

☐ €3

☐ €2

☐ No

13. Other comments

Thank you!

B.3.2 Maltese Version

Taqsim 1 : Demografija tal-Partecipanti

1. Sess

☐ Mara

☐ Raġel

☐ Nippreferi ma ngħidx

☐ Ieħor

2. Età

☐ 18-29

☐ 30-39

☐ 40-49

☐ 50-59

☐ 60-69

☐ 70+

3. Nazzjonalità

☐ Malti/ja

☐ UE

☐ Internazzjonali

4. Livell ta' Edukazzjoni

☐ Primarja

☐ Sekondarja

☐ Post-sekondarja

☐ Terzjarja

Taqsim 2: Edukazzjoni u amministrazzjoni tat-tilqim mill-ispizjara

5. Qatt staqsejt lill-ispizjar tiegħek dwar il-vaċċini?

Iva ☐

Le ☐

6. Jekk iva, x'tip ta' informazzjoni tlabt?

☐ Informazzjoni ġenerali dwar vaċċin partikolari

☐ Użi

☐ Xi ħaġa li nkwetatek

☐ Effetti negattivi

☐ Ohrajn: _____

7. Kont sodisfatt/a?

L-inqas

Sodisfazzjon

L-aktar

1

2

3

4

5

☐

☐

☐

☐

☐

8. Tafda lill-ispizjar tieghek biex jaghtik vaccin tal-influwenza? Yes ☐ No ☐

9. Tafda lill-ispizjar tieghek biex jaghti lit-tifel/tifla tieghek vaccin tal-influwenza? Yes ☐ No ☐

10. Tafda lill-ispizjar tieghek biex jaghtik tipi ohra ta' vaccini, eżempju Tetnu, Epatite B. Yes ☐ No ☐

11. Tafda lill-ispizjar tieghek biex jaghti lil ibnek/bintek tipi ohra ta' vaccini, eżempju Difterite, Epatite B. Yes ☐ No ☐

12. Kemm lest li thallas ghal servizz ta' tilqim mill-ispizjar tieghek?

☐ €5 (2)

☐ €3 (3)

☐ €2 (1)

☐ Xejn

13. Kummenti Ohra

Grazzi!

B.4 Education Framework

EDUCATION FRAMEWORK FOR
PHARMACIST-LED VACCINATION
SERVICES

2024

Tamara Attard
Master of Pharmacy Student

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Abbreviations

COVID-19	Coronavirus Disease 2019
DTaP-Hib-IPV-HepB (6 in 1)	Diphtheria, tetanus, pertussis, polio, <i>Haemophilus influenzae</i> type b (Hib) and hepatitis B vaccine
Men ACWY	Meningococcal bacteria ACWY vaccine
PCV	Pneumococcal conjugate vaccine
Men B	Meningococcal B vaccine
MMR	Measles-Mumps-Rubella vaccine
HPV	Human papillomavirus vaccine
SmPC	Summary of Product Characteristics

1. Introduction

Vaccination plays a very important role in preventing hospitalizations and 4-5 million yearly deaths, globally¹. Advocating for increased immunization rates remains relevant. Pharmacists are the first healthcare professionals, patients seek due to their accessibility (Motulsky *et al.*, 2021). They are viewed as vaccine educators, facilitators, and administrators by patients worldwide. Pharmacists have been involved in vaccination since the mid-1800s with their roles varying from procurement, storage and preparation, to also administering vaccines more recently (Rhodes *et al.*, 2017). Due to the COVID-19 pandemic and all the challenges that came with it, it led countries such as Belgium and Italy, amongst others, to develop and implement a protocol for immunization by pharmacists. This was brought about by the everchanging needs of healthcare systems across the globe, since there was a race against time to immunize as many people as possible to achieve herd immunity (Paudyal *et al.*, 2021). Nowadays, pharmacists in France can administer not only the COVID-19 vaccine but also other vaccines such as influenza, human papillomavirus (HPV), meningitis and measles, mumps and rubella (MMR), amongst others (Poiraud *et al.*, 2023).

By ensuring that pharmacy students and pharmacists receive proper training on the various aspects with respect to vaccination, pharmacist-led vaccination services can be promoted and utilised so as to contribute to the well-being of the patient and also help reduce additional burden on the national healthcare system especially where primary healthcare services are already strained due to resources (Lavenue *et al.*, 2023).

This education framework was designed focusing on empowering pharmacy students and pharmacists, by providing vaccine preparation and administration training. The FIP Vaccination Handbook for pharmacists² was used as a baseline tool to support the elaboration of this framework.

2. Aims

This education framework aims to provide information to equip pharmacy students and pharmacists, who require further training, with the necessary tools to provide pharmacist-led vaccination services.

¹ World Health Organisation (WHO). Vaccines and Immunization [Internet]. Geneva (Switzerland): WHO; 2019 [cited 2024 Jul 28]. Available from: <https://www.who.int/news-room/facts-in-pictures/detail/immunization#:~:text=Immunization%20prevents%20deaths%20every%20year,cost%20effective%20public%20health%20interventions>.

² International Pharmaceutical Federation (FIP). FIP Vaccination Handbook for pharmacists [Internet]. The Hague (Netherlands): FIP; 2021 [cited 2024 Jul 28]. Available from: <https://www.fip.org/file/5009>

3. Description

The education framework is subdivided into seven categories: (1) regulatory aspects, (2) national guidelines, (3) responding to patient needs, (4) vaccine handling and storage, (5) preparation and reconstitution of vaccines, (6) administration of vaccines and (7) documentation practices (Figure 1).

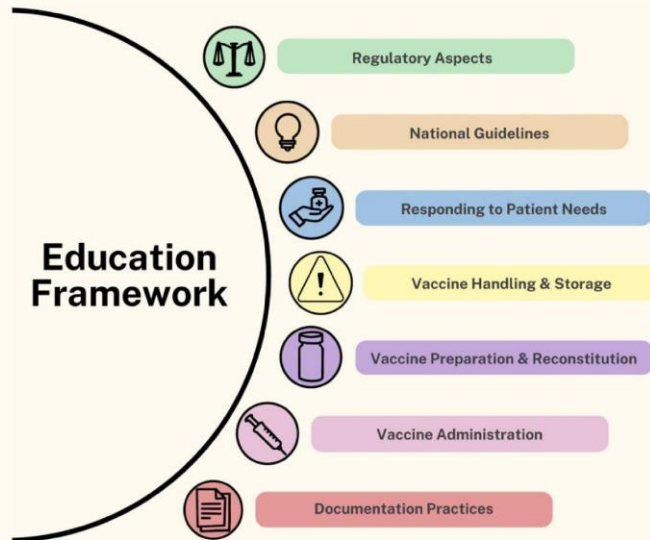


Figure 1. Education Framework Outline

3.1 REGULATORY ASPECTS

Different countries have different regulations on the roles of pharmacists in vaccination. Pharmacists act as educators and facilitators worldwide. They are involved in educating the patient and providing reliable information with regards to vaccines. Pharmacists also act as facilitators since they increase vaccine access to patients by sourcing such vaccines, which patients can have dispensed and then seek administration services. In some countries, pharmacists act as vaccine administrators as well (Isenor *et al.*, 2019). In the European Union, 26 countries have legislation where pharmacists can act as vaccine

administrators³. The age of the patient and type of vaccine that would be administered are factors which also differ between countries whether pharmacists can administer vaccines or not (Poudel *et al.*, 2019).

The recent COVID-19 vaccination strategy led to changes in the regulation related to pharmacists' role in vaccination, such as the reconstitution and administration of vaccines. (Reise *et al.*, 2021). Pharmacists are encouraged to consult and keep updated with national laws and regulations regarding vaccines and vaccine administration.

Competencies Checklist

Trainee shows an understanding and knowledge of:

- Pharmacists' role as vaccine educators ☐
- Pharmacists' role as vaccine facilitators ☐
- Pharmacists' role as vaccine administrators ☐
- National laws and regulations regarding pharmacists' role in immunization ☐

3.2 NATIONAL GUIDELINES

There are different guidelines or schedules which incorporate recommended vaccines to be administered. There are guidelines for special population groups including paediatrics, immunocompromised patients, immigrants, healthcare providers, pregnant and lactating women and also travellers. Travel vaccines such as polio, typhoid, yellow fever and others, are administered before patients travel internationally. The regulations and guidelines for vaccines differ, as it depends on the country, the patient characteristics and also the current disease trends and guidelines are updated regularly⁴ (Kroger *et al.*, 2023).

Some countries may require mandatory vaccination for specific vaccines and certain age groups. To take an example, the tuberculosis vaccine is mandatory in Bulgaria, Croatia, Czech Republic, Hungary,

³ International Pharmaceutical Federation (FIP). An overview of pharmacy's impact on immunisation coverage [Internet]. The Hague (Netherlands): FIP; 2020 [cited 2024 Jul 28]. Available from: <https://www.fip.org/file/4751>

⁴ Centers for Disease Control and Prevention (CDC). General best practice guidelines for immunization: best practices guidance of the Advisory Committee on Immunization Practices (ACIP) [Internet]. United States of America: CDC; 2023 [cited 2024 Jul 28]. Available from: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

Latvia, Poland and Slovenia. It is recommended in other countries when the patient is at a higher risk of contracting the disease for example in Cyprus, Finland, France, Greece, Liechtenstein, Luxembourg, Malta, Netherlands and Portugal. Apart from this, the tuberculosis vaccine is recommended to be administered at birth except for Norway and Sweden where it is recommended to be administered ≥ 6 weeks⁴.

Guidelines vary from time to time due to the constant studies being carried out on the safety and efficacy of vaccines. Guidelines have also changed because of current disease trends and events which occurred. For example the COVID-19 pandemic was a driver for changing guidelines not only on the importance of vaccination of COVID-19 but also for the influenza vaccine. Outbreaks of HPV and tuberculosis have been increasing lately due to lack of proper education and immigration respectively. These events act as driver to change guidelines (Thanasas *et al.*, 2020; Vasiliu *et al.*, 2023).

As pharmacists participating in pharmacist-led vaccination services it is important to be able to know where and how to look for updated information on vaccines. For example, the European Centre for Disease Prevention and Control (ECDC) has a tool on the website called *Vaccine Scheduler* which has available vaccine schedules in all countries within the European Union and European Economic Area. It is updated regularly and so it is a good source and tool to be used. Appendix 1 contains a table summarising the vaccination schedules for different diseases organized by age and country⁵. Countries also have their own sources where the national guidelines are available.

Competencies Checklist

Trainee shows an understanding and capability of accessing:

- Current national immunization schedules ☐
- Current vaccine guidelines for special populations including paediatric ☐
- immunocompromised patients, ☐
- immigrants ☐
- Current vaccine guidelines for healthcare providers ☐

⁵ European Centre for Disease Prevention and Control (ECDC). Vaccine schedules in all countries in the European Union and European Economic Area [Internet]. European Union: ECDC; 2024 [cited 2024 Jul 28]. Available from: <https://vaccine-schedule.ecdc.europa.eu>

- Current, vaccine guidelines for pregnant and lactating women ☐
- Current, updated vaccine guidelines for international travellers ☐
- Accessing updated information and guidelines in special populations or new vaccines ☐

3.3 RESPONDING TO PATIENT NEEDS

Pharmacists are positioned to recognise and respond to patient needs. Pharmacists have to be equipped with the right tools such that they are able to communicate with the patient and explain clearly the information they want to convey. Pharmacists have also to be knowledgeable and help the patient identify which vaccine is suitable (Harnett *et al.*, 2023). For example, guiding the patient which travel vaccines they should take for their trip, or advocating for immunization against influenza especially in high risk patient groups. The pharmacist has to be able to recognise signals that increase patient risk and to provide a personalised patient service. At the same time even if there is a legal framework to allow for pharmacist administration of vaccines, pharmacists have to acquire the skills and competency to provide this service. This could be through undergraduate training or a postgraduate training programme. Practising competently within a collaborative practice and identifying patients and scenarios where referral to a physician is required (El Hajj *et al.*, 2023). Such situations may include administration of vaccines to particular age groups, e.g. paediatrics.

Competencies Checklist

Trainee shows an understanding and capability of:

- Communicating information on vaccines/vaccination and patient education ☐
- Selecting which vaccine is appropriate for the patient ☐
- Identifying any contraindications ☐
- Identifying situations when pharmacist is competent to administer the vaccine and when to refer ☐

3.4 VACCINE HANDLING AND STORAGE

Prior to the preparation and reconstitution of vaccines, there has to be procurement of vaccines. Vaccines have to be procured from reliable sources and facilities which are registered with competent authorities and which were manufactured according to Good Manufacturing Practice so as to ensure that the vaccines procured are of good safety, quality and efficacy. Vaccines having the tamper-proof seal and Falsified Medicines' Directive (FMD) barcode, and having a status as "Active" show that the vaccine is coming from a registered facility and was produced under GMP conditions.

Vaccines are medicinal products which have special storage requirements. It is important that vaccines are stored according to their storage conditions. Most vaccines are stored in a fridge at a temperature between 2-8°C. Therefore, it is important to monitor the fridge temperature, and carry out calibration of thermometers and fridge maintenance periodically. It is also important to practice stock rotation and FEFO (first expire first out) so as to ensure that the vaccines which are going to expire first are used first. It is also advisable to separate vaccines which look similar or have similar names or doses, as well as separate adult vaccines from paediatric ones so as to reduce the risk of errors. The fridge which is used cannot contain any personal belongings (e.g. food, lunch boxes, drinks) of pharmacy staff and should be used to store medicinal products only. Should there be a power outage, it is important to leave the refrigerator closed and transfer the vaccines to another fridge as soon as possible.

Competencies Checklist

Trainee shows an understanding and capability of:

- Ensuring vaccine legitimacy ☐
- Identifying special storage conditions e.g. cold chain vaccines ☐
- Monitoring fridge temperature and recognising need for calibration periodically ☐
- Separating vaccines with similar names and/or packaging, and separating adult and paediatric vaccines accordingly ☐
- Dedicating a fridge to vaccines and/or other medicinal products, and not placing any personal belongings in the fridge ☐
- Having a Standard Operating Procedure (SOP) should there be a power outage and the ability to appraise risk posed to product due to power outage ☐

3.5 PREPARATION AND RECONSTITUTION OF VACCINES

Prior to preparing or reconstituting the vaccine it is important to prepare all of the items which will be used including alcohol pads, ampoule/vial containing the powder/liquid, syringe and the respective needles, sterile water, gauze swabs, plasters and adrenaline injection. It is also important for the pharmacist to wash their hands thoroughly with soap and water, allow to air dry and wear disposable gloves, and also wipe the surface of the table which will be used. Additionally, it is also important to examine the ampoule/vial and its contents. It is important to check the expiry date, confirm that there are no visible cracks/faults in the ampoule/vial glass, check the colour and appearance of the powder/liquid in the ampoule and whether there is any particulate matter. This can be checked by confirming that the characteristics one is observing match with those stated in the Summary of Product Characteristics (SmPC). After this is carried out, the appropriate amount of sterile water is added to the ampoule/vial. The characteristics of the liquid in the ampoule/vial are rechecked and compared with those stated on the SmPC. If the characteristics are the same, then the pharmacist can move on to the administration of the vaccine.

Competencies Checklist

Trainee shows an understanding and capability of:

- Preparing all equipment/materials to be used before vaccine preparation/reconstitution ☐
- Practising good hand hygiene before and after vaccine preparation/reconstitution ☐
- Making use of the appropriate Protective Personal Equipment (PPE) e.g. disposable gloves ☐
- Examining the physical appearance of the ampoule/vial and its contents before vaccine preparation/reconstitution and comparing it with the SmPC ☐
- Examining the physical appearance of the ampoule/vial and its contents after vaccine preparation/reconstitution and comparing it with the SmPC ☐

3.6 ADMINISTRATION OF VACCINES

There are various routes of administration including the intradermal route, subcutaneous route and the intramuscular route and there are also various sites of injection including the arm, shoulder/deltoid

or thigh. First it is important to confirm the name of the vaccine which will be administered to the patient, together with the dose, route of administration and the site of injection. It is important for the pharmacist to wash their hands thoroughly with soap and water and allow to air dry. This is followed by wearing disposable gloves. The area is checked for any cuts, bruises or redness which may be present and if none are present the procedure can be continued. If present, another area has to be found. Using the syringe, the desired volume of liquid from the ampoule/vial is retrieved, avoiding touching the plunger and barrel from the inside. Then using an alcohol wipe, the area of injection is wiped and allowed to air dry, always wiping from the centre and outwards in a circular motion. The needle is injected at the angle according to the route of administration (Table 1), the plunger is pushed down and then the needle is removed at the same angle it was injected. Using a gauze swab, gentle pressure is applied over the site for 1-2 minutes. Fifteen minutes are allowed to ensure that the patient does not experience immediate side effects and anaphylactic reactions, and if patient does, the necessary treatment has to be provided. The patient is advised that paracetamol may be used in cases where there is fever and pain.

Table 1. Routes of administration and the angle of insertion

Route of Administration	Angle of insertion
Intramuscular	90°
Subcutaneous	45°
Intradermal	45°

Competencies Checklist

Trainee shows an understanding and capability of:

- Identifying the different routes of administration ☐
- Practising good hand hygiene before and after vaccine administration ☐
- Making use of the appropriate Protective Personal Equipment (PPE) e.g. disposable gloves ☐
- Examining and identifying a suitable area as a site for needle insertion ☐
- Handling a syringe and drawing the desired volume of liquid ☐

- Inserting the needle at the correct angle of insertion according to the route of administration ☐
- Retrieving the needle at the same angle it was inserted ☐
- Allowing fifteen minutes for the patient to be kept under observation ☐
- Educating the patient on making use of paracetamol should there be fever and/or pain ☐

3.7 DOCUMENTATION PRACTICES

Documenting a process or a decision which has been taken, is essential so as to have a point of reference should a query comes back, to reduce risk of errors and to provide traceability as required. It is important to document any vaccines which have been administered. Apart from the vaccine generic name, it is important to register the date of when the vaccine was administered, the brand name, the batch/lot number and expiry date as well. This is because should there be a quality complaint or a recall, it is important to know which batch the patient was administered, so that the appropriate action can be taken accordingly. Additionally, documenting vaccination records helps identify whether a patient would need a booster shot or not. In a report published by FIP³ in 2020, 67% of respondents said that pharmacists do not have access to vaccination records. Given the benefits of documentation, apart from proper training of pharmacists on how to handle vaccines and administer them, pharmacists should have access to vaccination records, so as to provide seamless healthcare together with other healthcare professionals. Confidentiality is an important consideration to be observed by pharmacists so as to maintain a healthy pharmacist-patient relationship and to be in-line with the code of ethics.

Competencies Checklist

Trainee shows an understanding and capability of:

- Documenting vaccine generic name, date of administration, vaccine brand name, batch number and expiry date ☐
- Providing document to patient and sharing with patient's physician as needed

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Appendix 1

Table A1.1. Vaccine Recommendation Guidelines in different European countries

DISEASE	AGE GROUP	COUNTRY/COUNTRIES
COVID-19	≥6 months	Germany, Greece, Ireland, Spain*
	≥5 years	Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, France, Hungary, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia
	≥12 years	Finland, Latvia
	≥18-64 years	Sweden*
	≥65 years	Denmark*
Diphtheria	≥2 months	Belgium, <u>Bulgaria</u> , <u>Croatia</u> , Cyprus, France, Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, <u>Malta</u> , Netherlands, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain
	≥3 months	Austria, <u>Czech Republic</u> , Denmark, Estonia, Finland, Iceland, <u>Italy</u> , Norway, <u>Slovenia</u> , Sweden
Haemophilus influenzae type b infection	≥2 months	Belgium, <u>Bulgaria</u> , <u>Croatia</u> , Cyprus, France, Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands*, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain
	≥3 months	Austria, <u>Czech Republic</u> , Denmark, Estonia, Finland, Iceland, <u>Italy</u> , Norway, <u>Slovenia</u> , Sweden
Hepatitis A	At 13 months	Austria
	15-18 months	Italy* (recommended for highly endemic areas)
	At 2 years	Cyprus, Greece
	≥12 years	Belgium*
	≥18 years	<u>Czech Republic</u> *
Hepatitis B	At birth*	Austria, Belgium, Croatia, Cyprus, <u>Czech Republic</u> , Denmark, Estonia, Finland, France,

		Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Netherlands, Slovakia, Slovenia, Spain, Sweden
	At birth	Bulgaria, Lithuania, Poland, Portugal, Romania
	3 months first dose	Norway
Herpes zoster	≥18 years	Greece*, Luxembourg*, Spain*
	≥50 years	Austria, Czech Republic, Italy*
	≥60 years	Germany
	≥65 years	Estonia, France, Liechtenstein*
Human papillomavirus infection	≥9 years	Germany, Greece, Luxembourg
	≥10 years	Austria, Bulgaria, Finland, Netherlands, Portugal, Sweden
	≥11 years	Cyprus, France, Liechtenstein, Lithuania, Romania, Slovenia
	≥12 years	Belgium, Denmark, Estonia, Hungary, Iceland, Ireland, Italy, Latvia, Malta, Norway, Poland, Slovakia, Spain
	≥13 years	Czech Republic
	≥14 years	Croatia
Influenza	6 weeks	Spain
	≥6 months	Belgium*, Croatia*, Cyprus*, Czech Republic*, Estonia*, Finland, Greece*, Italy*, Latvia, Malta*, Norway*, Poland, Slovakia, Slovenia, Sweden*
	≥7-23 months	Austria
	≥2 years	Denmark, France, Ireland
	≥60 years	Germany, Hungary, Iceland, Netherlands
	≥65 years	Bulgaria, Liechtenstein, Lithuania, Luxembourg, Portugal, Romania
Measles	≥6 months	France*
	≥9 months	Liechtenstein
	≥10 months	Austria

	≥11 months	<u>Germany, Slovenia</u>
	≥12 months	Belgium, <u>Croatia</u> , Cyprus, Estonia, Finland, Greece, Ireland, <u>Latvia</u> , Luxembourg, Portugal, Romania, Spain
	≥13 months	<u>Bulgaria, Czech Republic, Italy, Malta, Poland</u>
	≥14 months	Netherlands, <u>Slovakia</u>
	≥15 months	Denmark, <u>Hungary</u> , Lithuania, Norway
	≥18 months	Iceland, Sweden
Meningococcal disease	≥2 months	Czech Republic, Greece*, Hungary, Ireland, Malta, Poland, Portugal, Slovakia, Spain
	≥3 months	Austria*, France, Italy, Lithuania, Luxembourg*,
	6 months	Iceland
	12 months	Cyprus, Germany
	≥14 months	Netherlands,
	≥15 months	Belgium
	≥2 years	Liechtenstein
Mumps	≥9 months	Liechtenstein
	≥10 months	Austria
	≥11 months	<u>Germany, Slovenia</u>
	≥12 months	Belgium, <u>Croatia</u> , Cyprus, Estonia, Finland, <u>France</u> , Greece, Ireland, <u>Latvia</u> , Luxembourg, Portugal, Romania, Spain
	≥13 months	<u>Bulgaria, Czech Republic, Italy, Malta, Poland</u>
	≥14 months	Netherlands, <u>Slovakia</u>
	≥15 months	Denmark, <u>Hungary</u> , Lithuania, Norway
	≥18 months	Iceland, Sweden
Pertussis	≥2 months	Belgium, <u>Bulgaria, Croatia</u> , Cyprus, <u>France</u> , Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands*, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain
	≥3 months	Austria, <u>Czech Republic</u> , Denmark, Estonia, Finland, Iceland, <u>Italy</u> , Norway, <u>Slovenia</u> , Sweden

Pneumococcal disease	≥2 months	Belgium, <u>Bulgaria</u> , <u>Croatia</u> , Czech Republic, <u>France</u> , Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, Malta, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain
	≥3 months	Austria, Cyprus, Denmark, Finland, Iceland, Italy, Netherlands, Norway, Slovenia, Sweden
	≥65 years	Estonia
Poliomyelitis	≥2 months	<u>Belgium</u> , <u>Bulgaria</u> , <u>Croatia</u> , Cyprus, <u>France</u> , Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, <u>Malta</u> , Netherlands*, Portugal, Romania, <u>Slovakia</u> , Spain
	≥3 months	Austria, <u>Czech Republic</u> , Denmark, Estonia, Finland, Iceland, <u>Italy</u> , Norway, <u>Poland</u> , <u>Slovenia</u> , Sweden
Rabies	≥18 years	Czech Republic*
Rotavirus infection	≥6 weeks	Czech Republic, Germany, Italy, Norway, Poland, Spain*, Sweden
	≥2 months	Austria, Belgium, Estonia, Finland, France, Greece, Ireland, <u>Latvia</u> , Lithuania, Luxembourg
Rubella	<12 months	Austria, Germany, Liechtenstein, <u>Slovenia</u>
	≥12 months	Belgium, <u>Bulgaria</u> , <u>Croatia</u> , Cyprus, <u>Czech Republic</u> , Denmark, Estonia, Finland, <u>France</u> , Greece, <u>Hungary</u> , Iceland, Ireland, <u>Italy</u> , <u>Latvia</u> , Lithuania, Luxembourg, Malta, Netherlands, Norway, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain, Sweden
Tetanus	≥2 months	Belgium, <u>Bulgaria</u> , <u>Croatia</u> , Cyprus, <u>France</u> , Germany, Greece, <u>Hungary</u> , Ireland, <u>Latvia</u> , Liechtenstein, Lithuania, Luxembourg, <u>Malta</u> , Netherlands*, <u>Poland</u> , Portugal, Romania, <u>Slovakia</u> , Spain

	≥3 months	Austria, Czech Republic, Denmark, Estonia, Finland, Iceland, <u>Italy</u> , Norway, <u>Slovenia</u> , Sweden
Tick-borne encephalitis	≥12 months	Czech Republic, Latvia*
	≥13 months	Austria
	≥3 years	Finland*, Slovenia
Tuberculosis	At birth	<u>Bulgaria</u> , <u>Croatia</u> , Cyprus*, Czech Republic*, Estonia, Finland*, France*, Greece*, Hungary, <u>Latvia</u> , Liechtenstein*, Lithuania, Luxembourg*, Malta*, Netherlands*, <u>Poland</u> , Portugal*, Romania, <u>Slovenia</u> *
	≥6 weeks	Norway*, Sweden*
Varicella	<12 months	Germany, Liechtenstein, Poland*
	≥12 months	Austria, Belgium*, Cyprus, Czech Republic*, Finland, Greece, Hungary, Iceland, <u>Italy</u> , <u>Latvia</u> , Luxembourg, Spain

Adapted from: <https://vaccine-schedule.ecdc.europa.eu>

Countries which are underlined require mandatory vaccination. Some vaccines are recommended only when the patient is at higher risk of contracting the disease (countries marked with an asterisk).

B.5 Validation Report

University of Malta

Faculty of Medicine & Surgery

Department of Pharmacy

ESTABLISHING AN EDUCATION FRAMEWORK FOR PHARMACIST-LED VACCINATION SERVICES

Tamara Attard

Information for members of the validation panel

My name is Tamara Attard and I am currently reading for a Master of Pharmacy. As part of my degree requirements I am carrying out a study entitled *Establishing an Education Framework for Pharmacist-Led Vaccination Services*, under the supervision of Prof. Lilian Azzopardi. I have prepared an education framework which will be distributed to pharmacy schools in Europe to be used as a guide for their student vaccination training programme.

I would like to ask you to participate as a member of this expert panel to validate the education framework. Kindly mark with an 'X' the appropriate field for the attributes "Comprehensiveness" and "Applicability" for the education framework as a whole, and "Specificity", "Relevance" and "Clarity" according to the corresponding section of the framework.

Comprehensiveness:

1 = Not comprehensive

2 = Somewhat comprehensive

Applicability:

1 = Not applicable

2 = Somewhat applicable

3 = Don't know

3 = Don't know

4 = Quite comprehensive

4 = Quite applicable

5 = Very comprehensive

5 = Very applicable

Specificity:

Relevance:

Clarity:

1 = Not specific

1 = Not relevant

1 = Not clear

2 = Somewhat specific

2 = Slightly relevant

2 = Slightly clear

3 = Don't know

3 = Don't know

3 = Don't know

4 = Quite specific

4 = Quite relevant

4 = Quite clear

5 = Very specific

5 = Very relevant

5 = Very clear

1. Comprehensiveness of Education Framework document

1	2	3	4	5

2. Applicability of Education Framework document

1	2	3	4	5

3. Specificity

	1	2	3	4	5
3.1 Regulatory Aspects					
3.2 National Guidelines					
3.3 Responding to Patient Needs					
3.4 Vaccine Handling and Storage					

3.5 Preparation and Reconstitution of Vaccines					
3.6 Administration of Vaccines					
3.7 Documentation Practices					

4. Relevance

	1	2	3	4	5
3.1 Regulatory Aspects					
3.2 National Guidelines					
3.3 Responding to Patient Needs					
3.4 Vaccine Handling and Storage					
3.5 Preparation and Reconstitution of Vaccines					
3.6 Administration of Vaccines					
3.7 Documentation Practices					

5. Clarity

	1	2	3	4	5
3.1 Regulatory Aspects					
3.2 National Guidelines					
3.3 Responding to Patient Needs					
3.4 Vaccine Handling and Storage					
3.5 Preparation and Reconstitution of Vaccines					
3.6 Administration of Vaccines					
3.7 Documentation Practices					

6. Comments

Thank you for your time.

Appendix C - List of Publications and Abstracts

C.1 Abstract accepted by European Association of Faculties of Pharmacy presented at the EAFP Annual Conference 2023 held between 17-19 May 2023 in Valencia, Spain

Pharmacy Student Training for Pharmacist-led Vaccination Services in Malta

T. Attard, F. Wirth, L.M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Malta

Tamara Attard: 0000-0002-2116-1714

Francesca Wirth: 0000-0002-3225-2363

Lilian M. Azzopardi: 0000-0002-3811-0761

Introduction

A vaccination training programme was developed and delivered to pharmacy students in the first year of the pharmacy course for the first time during academic year 2021-22. This training programme involves: 1) Three hands-on laboratory practical sessions using injection simulators to practise preparation and reconstitution of vaccines and administration via the intramuscular, subcutaneous and intradermal routes, 2) Three observation sessions within the National Immunisation Service-Primary Healthcare, and a 3) First aid course. Upon successful completion, a skills checklist and pharmacy-based vaccination delivery certificate are issued. Skills in documentation post-administration and management of post-vaccination reactions are practiced. The aim was to assess knowledge, skills and confidence of pharmacy students who followed the vaccination training programme.

Method

A self-administered questionnaire was developed and validated. The questionnaire consists of three sections: Participant demographics, knowledge on preparation and administration of vaccines, and skills. Following ethics approval, the questionnaire was distributed to all students (N=17) who completed the training programme.

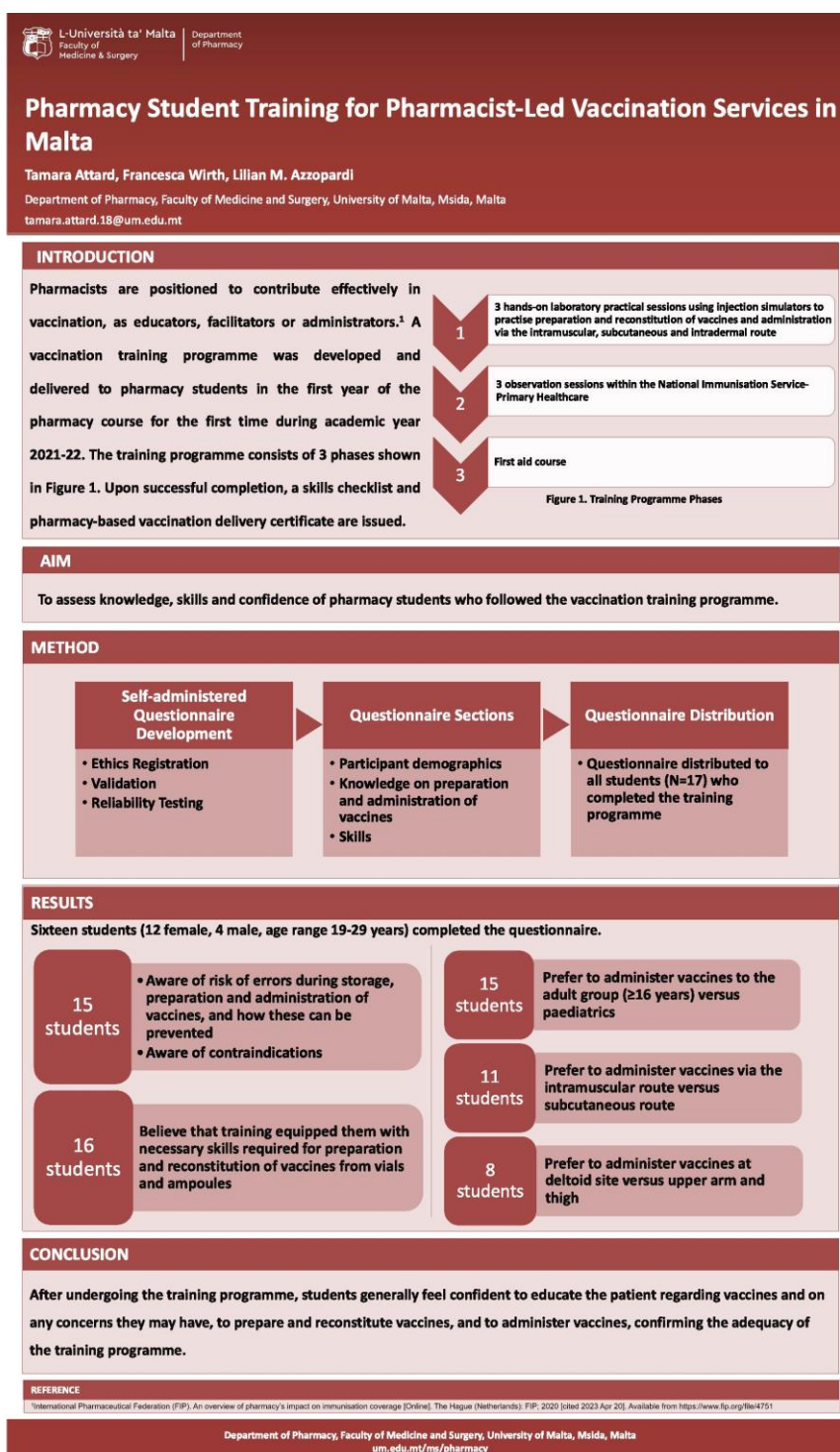
Results

Sixteen students (12 female, 4 male, age range 19-29 years), completed the questionnaire. Fifteen students are aware of errors during storage, preparation and administration of vaccines, and how these can be prevented. These 15 students are aware of contraindications. All respondents believe that the training equipped them with necessary skills required for preparation and reconstitution of vaccines from vials and ampoules. Fifteen students prefer to administer vaccines to the adult group (≥ 16 years) over paediatrics. The preferred route of administration is the intramuscular (n=11) over the subcutaneous route (n=5), and the preferred site of injection is the deltoid (n=8), followed by the upper arm (n=6) and thigh (n=2).

Conclusions

After undergoing the training programme, students generally feel confident to educate the patient regarding vaccines and on any concerns they may have, to prepare and reconstitute vaccines, and to administer vaccines, confirming the adequacy of the training programme.

Poster presented at the EAFP Annual Conference 2023 held between 17-19 May 2023 in Valencia, Spain



C.2 Abstract accepted by European Association of Hospital Pharmacists presented at the EAHP 28th Annual Congress 2024 held between 20-22 March 2024 in Bordeaux, France

INVESTIGATING NEED AND APPROPRIATENESS FOR PHARMACIST-LED VACCINATION SERVICES WITHIN A HEALTHCARE SYSTEM

T. Attard, F. Wirth, L.M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
tamara.attard.18@um.edu.mt

Background and Importance

Pharmacist-led vaccination services are an opportunity to improve patient access to vaccination and improve uptake.

Aim and objective

To assess drivers for pharmacist-led vaccination services and to understand patient expectations and pharmacist-preparedness for pharmacist-led vaccination services.

Materials and methods

Two self-administered questionnaires were developed and validated; one for pharmacists and the other for general public. The pharmacist questionnaire evaluated knowledge and skills on the preparation and administration of vaccines and service provision. The patient questionnaire evaluated vaccine education and administration by pharmacists. The questionnaires were distributed electronically (n=40 pharmacists; n=140 patients) and physically from 2 community pharmacies and snowball sampling (n=22 pharmacists; n=23 patients).

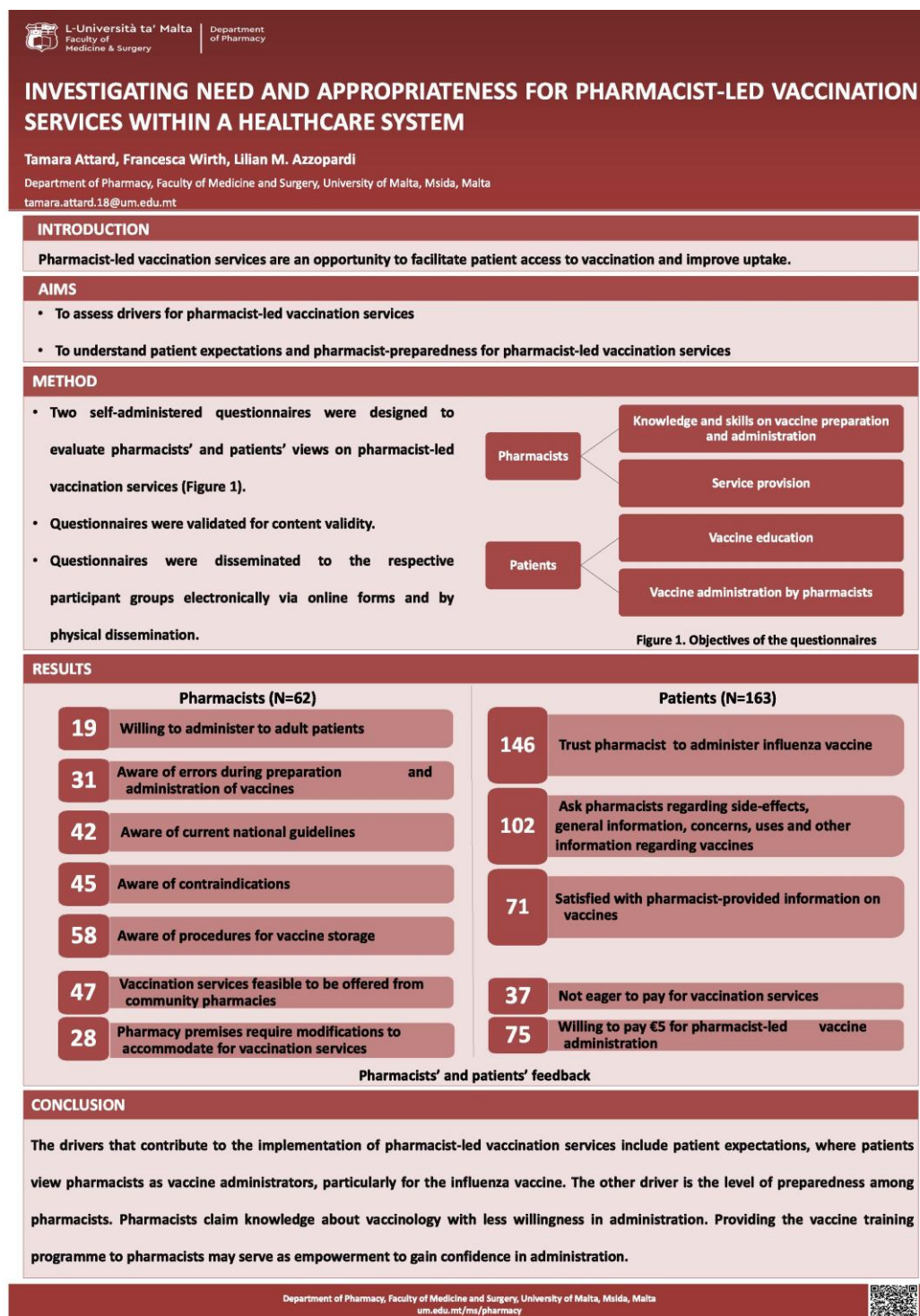
Results

Pharmacist questionnaire (N=62): 45 female, 17 male, 23-69 years, where 19 pharmacists prefer to administer vaccines to the adult group over the paediatric group (n=3). Pharmacists are aware of errors during preparation and administration of vaccines (n=31), as well as contraindications (n=45), the current national guidelines (n=42) and the procedure of vaccine storage (n=58). Community pharmacists agreed that it is feasible to carry out vaccination services at the pharmacy (n=47), some of whom stated that the premises require further modifications (n=28). Pharmacists commented on the importance of proper training for the service to be carried out efficiently.

Patient questionnaire (N=163): 97 female, 66 male, 18-70+ years, where 102 patients approach pharmacists with concerns on varying aspects including side effects, general information, concerns, uses and other information regarding vaccines, 71 reported that they were satisfied with the pharmacist's responses, and 146 trust the pharmacist to administer the influenza vaccine. Seventy-five patients are willing to pay €5 for the service provided by pharmacists, and 37 patients are not willing to pay.

Conclusions and relevance

The drivers that contribute to the implementation of pharmacist-led vaccination services include patient expectations and the level of preparedness among pharmacists.



Appendix D – Statistics

Overview

Statistical tests were run using Microsoft XLStat for analysis of responses gathered from all 3 questionnaires disseminated and the validation report.

D.1 Phase 1: Stakeholders' Questionnaires

D.1.1 Pharmacy Students

Table D.1. Statistical ranking of questions for the pharmacy students' questionnaire using the Pairwise t-test

Question Number	Question	Pairwise t-test
1	Gender	1.000
2	Age	1.000
3	Aware of errors during preparation and how to prevent them	1.000
6	Aware of the current guidelines of the national immunization scheme and where to find them	1.000
8	Aware of how to dispose of the waste during handling	1.000
10	Skills required for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules	1.000
15b	Confidence to prepare/reconstitute vaccines	1.000
11a	Confidence to provide immunization services in compliance with documentation requirements	0.611
12b	Confidence to administer a vaccine safely to Adults (16 and over)	0.611
12a	Confidence to administer a vaccine safely to Paediatrics (0-15 years)	0.465
4	Aware of vaccination administration errors which can occur and how to prevent them	0.363
5	Aware of contraindications and how to identify contraindications in a patient	0.363
7	Know the storage procedure involved in refrigeration and handling of the vaccines, prior to administration.	0.363
11b	Confidence to recognize post-vaccination reactions	0.363
11d	Confidence to describe relevant first aid procedures	0.363
14c	Confidence to administer a vaccine safely in the Deltoid/ Shoulder	0.363
15a	Confidence to educate the patient regarding vaccines and any concerns they may have	0.363
15c	Confidence to administer vaccines	0.363
11c	Confidence to manage post-vaccination reactions	0.296
9	Aware of the procedure should I get a needle stick injury.	0.175
14b	Confidence to administer a vaccine safely in the Thigh	0.102

11e	Confidence to educate patients regarding vaccines	0.076
13a	Confidence to administer a vaccine safely via the Intramuscular (IM)	0.076
13b	Confidence to administer a vaccine safely via the Subcutaneous (SC)	0.076
14a	Confidence to administer a vaccine safely in the Arm	0.076

Table D.2. Statistical outputs from questionnaire responses (Descriptive statistics and Spearman correlations)

Variable\Statistic	No. of observations	Mode frequency	Categories	Frequency per category
Q1	16	12	F	12.000
			M	4.000
Q3	16	14	N	2.000
			Y	14.000
4	16	15	N	1.000
			Y	15.000
5	16	15	N	1.000
			Y	15.000
6	16	8	N	8.000
			Y	8.000
7	16	14	N	2.000
			Y	14.000
8	16	16	Y	16.000
9	16	9	N	7.000
			Y	9.000
10	16	16	Y	16.000
15a	16	14	N	2.000
			Y	14.000
15b	16	14	N	2.000
			Y	14.000
15c	16	13	N	3.000
			Y	13.000

Statistic	No. of observations	Median	Mean
11a	16	4.000	3.813

11b	16	4.000	3.750
11c	16	3.000	3.125
11d	16	3.000	3.063
11e	16	4.000	3.938
12a	16	3.000	2.750
12b	16	4.000	4.188
13a	16	4.000	4.250
13b	16	3.000	3.375
14a	16	4.000	4.000
14b	16	3.000	3.063
14c	16	4.000	4.375

Correlation matrix (Spearman): Question 11					
Variables	Provide Service	Recognize PVR	Manage PVR	First Aid	Educate
Provide Service	1	0.921	0.395	0.658	0.872
Recognize PVR	0.921	1	0.711	0.816	0.821
Manage PVR	0.395	0.711	1	0.632	0.462
First Aid	0.658	0.816	0.632	1	0.359
Educate	0.872	0.821	0.462	0.359	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 12		
Variables	Paediatrics	Adults
Paediatrics	1	-0.395
Adults	-0.395	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 13		
Variables	Intramuscular	Subcutaneous
IM	1	0.344
SC	0.344	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 14			
Variables	Arm	Thigh	Deltoid/Shoulder
Arm	1	0.200	0.975
Thigh	0.200	1	0.051
Deltoid/Shoulder	0.975	0.051	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

*Question 2 was omitted since all students filled in the same age group (18-29).

D.1.2 Pharmacists

Table D.3. Statistical ranking of questions for the pharmacists' questionnaire using the Pairwise t-test

Question Number	Question	Pairwise t-test
1	Gender	1.000
2	Age	1.000
3	Years of Practice	1.000
8	Aware of the current guidelines of the national immunization scheme and where to find them.	1.000
10	Aware of how to dispose of the waste during handling.	1.000
12	Skills to manage possible side effects of the vaccine (15 minutes after administration).	1.000
15a	Confidence to administer a vaccine safely to Paediatrics (0-15 years)	1.000
19	Would you attend a short training course covering the basic concepts and skills required for immunization?	1.000
5	Aware of errors during preparation and how to prevent them.	0.676
14a	Confidence to provide immunization services in compliance with documentation requirements	0.676
17a	Confidence to administer a vaccine safely in the Arm	0.676
14c	Confidence to manage post-vaccination reactions	0.371
6	Aware of vaccination administration errors which can occur and how to prevent them.	0.341
9	Know the storage procedure involved in refrigeration and handling of the vaccines, prior to administration.	0.341

13	Skills required for the preparation and reconstitution of injectable medications and vaccines from vials and ampoules.	0.341
14d	Confidence to action relevant first aid procedures	0.341
18	Received training to administer vaccines in the past	0.341
20	Willingness to administer vaccines to patients?	0.341
21	Do you think it is feasible to carryout immunization services in community pharmacies?	0.341
15b	Confidence to administer a vaccine safely to Adults (16 and over)	0.277
16a	Confidence to administer a vaccine safely via the Intramuscular (IM)	0.277
16b	Confidence to administer a vaccine safely via the Subcutaneous (SC)	0.176
23	Would you be open to a service fee for preparing and administering the vaccine?	0.167
17c	Confidence to administer a vaccine safely in the Deltoid/ Shoulder	0.111
4	Area of Practice	0.085
22	Do you think the premises where you practise, requires modifications to carry out immunization services?	0.082
7	Aware of contraindications and how to identify contraindications in a patient.	0.038*
11	Aware of the procedure should I get a needle stick injury	0.038*
14e	Confidence to educate patients regarding vaccines	0.038*
17b	Confidence to administer a vaccine safely in the Thigh	0.038*
14b	Confidence to recognise post-vaccination reactions	0.016*

*p<0.05

Table D.4. Statistical outputs from questionnaire responses (Descriptive statistics and Spearman correlations)

Correlation matrix (Spearman): Question 14					
Variables	Provide Service	Recognise PVR	Manage PVR	First Aid	Educate
Provide Service	1	-0.105	0.703	0.730	-0.949
Recognise PVR	-0.105	1	0.359	0.564	0.200
Manage PVR	0.703	0.359	1	0.921	-0.462
First Aid	0.730	0.564	0.921	1	-0.564
Educate	-0.949	0.200	-0.462	-0.564	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 15		
Variables	Paediatrics	Adults
Paediatrics	1	0.400
Adults	0.400	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 16		
Variables	IM	SC
IM	1	0.359
SC	0.359	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman): Question 17			
Variables	Arm	Thigh	Deltoid/Shoulder
Arm	1	0.667	0.700
Thigh	0.667	1	0.975
Deltoid/Shoulder	0.700	0.975	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman):		
Variables	Age	Practice Years
Age	1	0.929
Practice Years	0.929	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman):		
Variables	Age	Former training
Age	1	0.204
Former training	0.204	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman):		
Variables	Former training	Future training
Former training	1	0.210
Future training	0.210	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

Correlation matrix (Spearman):			
Variables	Practice	Future training	Vaccine Administration
Practice	1	-0.023	-0.123
Future training	-0.023	1	0.426

Vaccine Administration	-0.123	0.426	1
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Values in bold are different from 0 with a significance level $\alpha=0.05$

D.1.3 Patients

Table D.5. Statistical ranking of questions for the patients' questionnaire using the Pairwise t-test

Question Number	Question	Pairwise t-test
1	Gender	1.000
2	Age	1.000
3	Nationality	1.000
4	Education Level	1.000
8	Trust your pharmacist to give you an influenza vaccine?	1.000
9	Trust your pharmacist to give your child an influenza vaccine?	1.000
10	Trust your pharmacist to give you other types of vaccines e.g. Tetanus, Hepatitis B?	1.000
11	Trust your pharmacist to give your child other types of vaccines e.g. Diphtheria, Hepatitis B?	1.000
6	Type of information did you ask for? General Info, Uses, Concerns, Side effects, Others	0.494
5	Asked your pharmacist questions regarding vaccines?	0.343
7	Were you satisfied?	0.343
12	Pay for an immunization service by your pharmacist? €5, €3, €2, No	0.279

Table D.6. Statistical outputs from questionnaire responses (Descriptive statistics and Spearman correlations)

		Willingness to Pay		Total
		Yes	No	
Seeking advice from the pharmacist	Yes	79	20	99
	No	47	17	64
Total		126	37	

Correlation matrix (Spearman):		
Variables	Advice	Fee
Advice	1	0.074
Fee	0.074	1

Values in bold are different from 0 with a significance level $\alpha=0.05$

D.1.4 Comparison of pharmacy student and pharmacist responses for selected questions from the respective questionnaires

Table D.7. Comparison of pharmacy student and pharmacist responses for selected questions from the respective questionnaires.

Question	Students' t-Test p-value
Aware of errors during preparation	0.009
Aware of errors during administration	0.003
Aware of contraindications and how to identify contraindications in a patient	0.075
Aware of the current guidelines of the national immunization scheme and where to find them	0.192
Know the storage procedure involved in refrigeration and handling of the vaccines, prior to administration	0.425
Aware of how to dispose of the waste during handling	0.200
Aware of the procedure should I get a needle stick injury	0.807
Confident to provide immunisation services in compliance with documentation requirements	0.000
Confident to recognise post-vaccination reactions	0.093
Confident to manage post-vaccination reactions	0.512
Confident to describe relevant first aid procedures	0.443
Confident to educate patients regarding vaccines	0.811
Confident to administer a vaccine safely to Paediatrics (0-15 years)	< 0.0001
Confident to administer a vaccine safely to Adults	< 0.0001
Confident to administer a vaccine safely via the Intramuscular (IM) route	< 0.0001
Confident to administer a vaccine safely via the Subcutaneous (SC) route	0.055
Confident to administer a vaccine safely in the Arm	0.001
Confident to administer a vaccine safely in the Thigh	0.018
Confident to administer a vaccine safely in the Deltoid/Shoulder	< 0.0001
Received training to administer vaccines	< 0.0001
Willing to administer vaccines to patients (post-training)	0.352