Pharmacists of Germany as Immunizers: A Country Comparison and Opportunity Assessment

By

Arslan Ahmed Malik

Matriculation Number [redacted]

Winter Semester 2017 – Winter Semester 2021

Primary Supervisor: Prof. Dr. (multd) Walter Leal, HAW Hamburg

Secondary Supervisor: Prof. Dr. York Zöllner, HAW Hamburg

Table of Contents

Abstract 5

List of Abbreviations: 6

Introduction: 7

Worldwide Situation: 7

Situatuion In Germany 8

Study Rationale and Scope: 9

Methodology: 10

Country Selection: 10

Searched Sources: 12

Keywords and Structure of Research: 16

Inclusion/exclusion Criteria: 17

Results 19

Chapter 1 – Ireland 19

1. Legislations: 19
2. Professional Qualifications and Training: 19

2.1 Undergraduate Vaccination Training Program for Pharmacists: 21

2.2. Tools and Resources available to pharmacists 21

3. Premises Requirements: 21
4. Vaccination Off-Premises: 22
5. National Vaccination Recommendations and Contraindications: 23
6. Pre and post Vaccination Key Events: 25

6.1. Record Maintenance: 25

7. Vaccination Uptake and Promotion: 26
8. Vaccine Payments and Reimbursements: 26
9. Vaccine Adverse Event Reporting and Injury Compensation: 27

Chapter 2 – Great Britain 28

1. Legislation: 28

2. Professional Qualifications and Training: 28
2.1. Undergraduate Vaccination Training Program for Pharmacists: 29
2.2. Tools and Resources available to pharmacists: 29
3. Premises Requirements: 30
4. Vaccination Off-Premises: 30
5. National Vaccination Recommendations and Contraindications: 31
6. Key Events In Vaccination Process: 33
6.1. Record Maintenance: 34
7. Vaccination Uptake and Promotion: 35
8. Vaccine Payments and Reimbursements: 35
9. Vaccine Adverse Event Reporting and Injury Compensation: 36
Chapter 3 – United States Of America 38
1. Legislation: 38
2. Professional Qualifications and Training: 39
2.1. Undergraduate Immunization Training for Pharmacists: 41
2.2. Tools and Resources available to pharmacists: 41
3. Premises Requirements: 42
4. Vaccination Off-Premises: 43
5. National Vaccination Recommendation and Contraindications: 43
6. Key Events in Vaccination Process: 45
6.1. Record Maintenance: 46
7. Vaccination Uptake and Promotion: 46
8. Vaccine Payments and Reimbursements: 47
9. Vaccine Adverse Event Reporting and Injury Compensation: 48
Chapter 4 – Australia 49
1. Legislation: 49
2. Professional Qualifications and Training: 50
2.1. Undergraduate Pharmacist Training: 52
2.2. Tools and Resources available to pharmacists: 52
3. Premises Requirements: 52
4. Vaccination Off-Premises: 53
5. National Vaccination Recommendation and Contraindications: 53
6. Key Events In Vaccination Process: 55

6.1. Record Maintenance: 55
7. Vaccination Uptake and Promotion: 56
8. Vaccine Payments and Reimbursements: 56
9. Vaccine Adverse Event Reporting and Injury Compensation: 57
Chapter 5 – Germany 58
1. Legislation: 58
2. Professional Qualifications and Training: 58
2.1. Undergraduate Pharmacist Training: 61
2.2. Tools and Resources available to pharmacists: 61
3. Premises Requirements: 61
4. Vaccination Off-Premises Premises: 62
5. National Vaccination Recommendation and Contraindications: 62
6. Key Events in Vaccination Process: 63
6.1. Record Maintenance: 64
7. Vaccination Uptake and Promotion: 65
8. Vaccine Payments and Reimbursements: 65
9. Adverse Event Reporting and Injury Compensation: 66
Chapter 6: 68
Comparison of Countries in Tables Concerning topics: 68
1. Legislation: 68
2. Professional Qualifications and Training: 69
3. Premises Requirements: 72
4. Vaccination Off-Premises: 74
5. Vaccine Recommendations and Contraindications: 75
6. Key Events In Vaccination Process: 76
7. Vaccination Uptake and Promotion: 78
8. Vaccine Payments and Reimbursements: 80
9. Adverse Event Reporting and Injury Compensation: 81
Discussions: 83
Limitations 87
Conclusion: 87
References: 88
Appendix 97

Abstract

Introduction:

Until recently, vaccine administration in Germany was carried out by physicians and pharmacists who were only advising about vaccines. However, Germany refreshed its laws and allowed pharmacists to administer vaccines to patients in pharmacies. Therefore, the Flu Model project was started in the pharmacies in the last quarter of 2020. A literature review comparing Germany with countries having high vaccination rates was vital to assess which protocols, elements, and components involved in the systematic provision of vaccines through pharmacists were taken up by Germany and where does it lack.

Methods:

A comprehensive literature search was conducted for all five countries. After the application of inclusion/exclusion criteria 89 studies, government pdfs, compilations, documents from national health departments and associations were finalized for the literature.

Results:

The results from the literature review demonstrated that Germany as compared to the United States, Great Britain, Ireland, and Australia; has developed a systematic approach to equip pharmacists with necessary skills, protocols, laws, and resources. With exceptions to patient's age accessible to the pharmacy for vaccination, undergraduate training, social media usage for awareness purposes, and vaccine administration limited to only pharmacy premises; Germany has required elements to carry out successful vaccinations at the pharmacy premises.

Conclusion:

In a nutshell, several opportunities are evident from results and could be focused on by Germany. With exceptions to those gaps, Germany has necessary protocols, elements, and components that make up the system meant for an organized provision of vaccines at pharmacy premises through a pharmacist.

List of Abbreviations:

Abbreviation	Complete Words
AJP	Australian Journal of Pharmacy
AJGP	Australian Journal of General Practice
SGB	*Sozialgesetzbuch*
IIOP	Irish Institute of pharmacy
NPA	National Pharmacy Association
NCPA	National Cooperative Purchasing Alliance
CMS	The Centers for Medicare and Medicaid Services
HPSO	Healthcare Providers Service Organization
RKI	Robert Koch Institute
DAZ	*Deutsche Apotheker Zeitung*
PZ	*Pharmazeutische Zeitung*
DAP	*Deutsches apotheken portal*
FIP	International Pharmaceutical Federation
BVDAK	*Bundesverband Deutscher Apothekenverband*
PSI	pharmaceutical society of Ireland
HSE	Health Service Executive
NHS	National Health Service
PSNC	Pharmaceutical Services Negotiating Committee
APhA	American Pharmacists Association
IAC	Immunization Action Coalition
CDC	The Centers for Disease Control and Prevention
ASTHO	Association of State and Territorial Health Officials
NCIRS	National Centre for Immunization Research and Surveillance
PSA	The Pharmaceutical Society of Australia
TGA	The Therapeutic Goods Administration
BVDAK	*Bundesverband Deutscher Apothekenverband*
ABDA	Bundesvereinigung Deutscher Apothekerverbände

Introduction:

Worldwide Situation:

Vaccines are considered as one of the greatest pharmaceutical accomplishments in history and worldwide they prevent about 2.5 million deaths per year. They act as the most inexpensive line of defense against infectious diseases. The World Health Organization (WHO) observed that 26 vaccines have been developed against infectious diseases, out of which the majority of them are meant for disease prevention in children. (1)

According to WHO, the prevalence of influenza in adults is between 5-10 percent whereas in children it falls between 20-30% globally. In the case of Europe, about 30 infectious diseases prevail in the continent. However, influenza alone accounts for the highest incidence (about 5.9 infections per 100,000 people) and mortality (about 5.89 deaths per 100,000 people) in Europe. (2)

The Global Vaccine Action Plan (GVAP), initiated by WHO in 2012, was developed to reduce the prevalence of infectious diseases, to increase access to vaccines, and to reduce the number of mortalities throughout the world. The main purpose of the plan was to increase public access to vaccination services. (3) Until the last decade, most of the vaccination services were carried out by nurses and doctors in hospitals, clinics, and schools. Various vaccination projects helped to prevent infectious diseases worldwide; however, the rate of vaccination has remained low throughout the world. (1)

If a severe influenza pandemic situation occurs, the usual health care providers in clinics and hospitals could be overwhelmed by soaring viral caseloads. Thus, additional public health strategies or already at hand health care points could be considered for patients to be administered with a vaccine. One such strategy, for tackling low vaccination rates and the likely hood of increased viral loads during a pandemic, includes the incorporation of the pharmacist in the vaccination workforce. Leveraging pharmacists to provide immunization services in pandemic situations is becoming increasingly popular since they are trained, health professionals. (4)

Pharmacists are already helping their communities by providing consultation and education services to patients as part of their professional practice. (1) According to Lunghini (2017) Pharmacists are already immunizing patients within the pharmacies in thirteen countries. Vaccination services by pharmacists are being provided in Argentina, Australia, Canada, Costa Rica, Denmark, Ireland, New Zealand, the Philippines, Portugal, South Africa, Switzerland, Great Britain, and the United States of America. (5) International Pharmaceutical Federation-FIP (2016) states that worldwide up to 655 million people could be reached and vaccinated if pharmacists are included in the immunization workforce. (6)

Situatuion In Germany

Every year, Germany faces an Influenza viral season between December and March. From 2000 to 2010 a total of 19,000 deaths out of the reported cases were caused by the Influenza virus. (7) According to the summary report by Robert Koch Institute published in the year 2019, there were approximately 3.8 million influenza-related acute respiratory illnesses in the 2018/19 season alone. However, the number of hospitalization cases were recorded to be 18,000. The preceding season 2017/18, according to RKI, was extraordinarily severe, was strongest in 30 years, and caused 25,000 people to lose their lives. (8)

Germany has inadequate rates for influenza vaccine uptake among the general population. With an increase in age the vaccine uptake in the population, however, shows a decrease. Until recently, physicians were the only healthcare professional allowed to administer vaccines to patients in Germany. As a preventive measure to help the general population against influenza, pharmacists of Germany were only advising patients about vaccinations and keeping their vaccination status up to date. (9)

However, the *"Gesetz zur Stärkung der Vor-Ort-Apotheken (VOSG)- Artikel 1- „§ 132i*" Law to strengthen the on-site pharmacies, came into force on 15th December 2020. This allows pharmacists of Germany to carry out influenza vaccine administration at community pharmacies as part of Model Projects. Moreover, *May und Bauer,* on the behalf of

Bundesverband Deutscher Apothekenverband (BVDAK), gave a conceptual framework for the practical implementation of flu vaccinations at the pharmacy. This framework, including practical recommendations for influenza vaccination service at pharmacies, is based on a study by Frank Egbe which represents related experiences of Great Britain, France, and Switzerland. (10)

In several cities of Germany, Model Projects on small scale between pharmacies and health insurance companies has begun in October 2020. Few pharmacies in North Rhine, Saarland, Essen, and Düsseldorf have been incorporated in the Model Projects for flu. However, there are concerns about the vaccine itself, billing, and insurance issues among pharmacists. Doris Schönwald, deputy chairwoman of North Rhein Pharmacists Association (ANVR) Believes that though pharmacies integrated into the Model Project can provide the service of vaccine administration; however, there is a shortage of influenza vaccines. The project started on 1st October in Bavaria has already seen a temporary stop in the second half of the month due to a bottleneck shortage of vaccines. However, to cover this shortage The *Bundesministerium für Gesundheit* (BMG) Federal Ministry of Health in Germany has procured an additional 6 million influenza doses. (11,12)

Study Rationale and Scope:

With German law, allowing pharmacists to vaccinate against influenza, being there; a study comparing Germany with some of the best performing countries, regarding influenza vaccine administration by a pharmacist, is vital to assess the components and capability of the German system involved in empowering pharmacists as immunizers. This study is about the comparison and assessment of necessary factors involved in vaccine administration by pharmacists of Germany (Model Project) with the systematic approach of four other countries. It compares the elements, involved in a systematic vaccine provision, between Germany, Ireland, the United States of America, Australia, and Great Britain.

The main goal of the study is to access components of the system involved in the professional up-gradation of pharmacists as immunizers in Germany. This study tends to see insights into what the system is doing to equip pharmacists regarding required aspects of vaccine administration at pharmacies. This leads to the main question under observation:

Is the current system in Germany capable of empowering pharmacists as immunizers?

To answer the research question, this literature review aims at answering the following questions:

- What steps or protocols have been taken by Ireland, Great Britain, America, and Australia to implement vaccine administration by pharmacists?
- Which factors have been adopted by Germany to strengthen the system and carry out vaccinations through pharmacists in the Model Project?
- Which gaps could be filled by Germany regarding vaccine administration by pharmacists?
- To assess if required components, involved in a systematic vaccine provision, are present in the system of Germany?

Methodology:

Country Selection:

A comprehensive literature search was conducted to capture a detailed picture of pharmacist-led vaccinations in five countries viz. Germany, Australia, Great Britain, America, and Ireland. Countries were selected based on language (English and German only), availability of data, influenza vaccination rates among the elderly (65+ age), and health expenditure as a share of GDP.

Health expenditure is the overall spending on healthcare services (including preventive and public health measures) as a whole or its various components by individuals, groups, nations, or private or public organizations. It is measured as a share of GDP. (13)

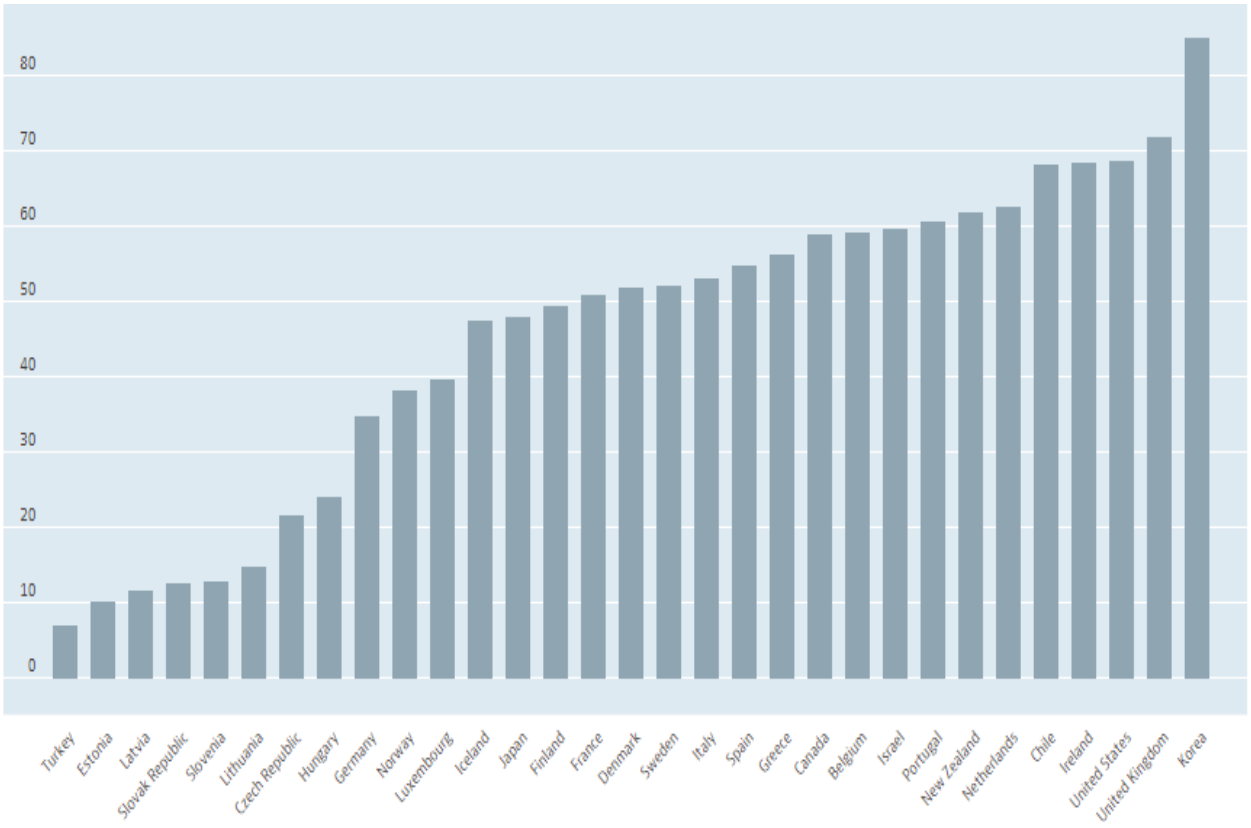

Figure 1: OECD/2019, Influenza Vaccination Rates, Total % of the population aged 65+; https://data.oecd.org/healthcare/influenza-vaccination-rates.htm

Second only to Korea; Great Britain, the United States, and Ireland have the highest influenza vaccination rates among the elderly with percentages being 72%, 68.7%, 68.5% respectively.

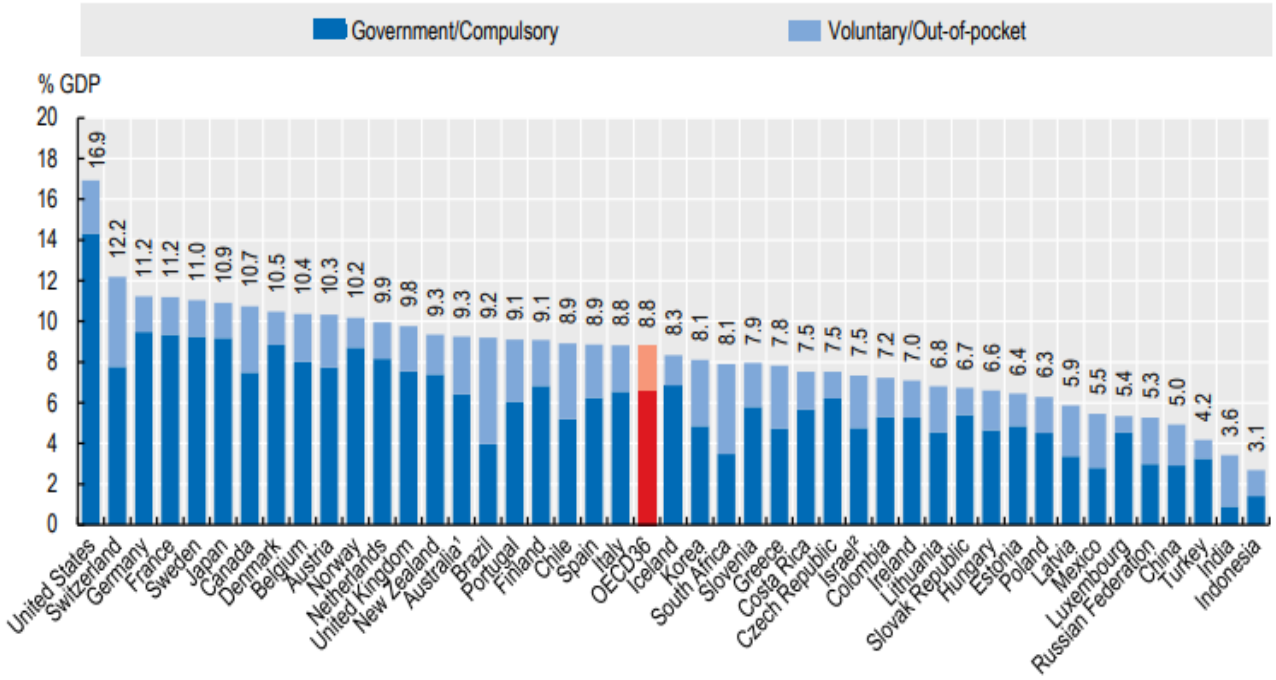

Figure 2: OECD/2018, Health Expenditure as a share of GDP; URL: shorturl.at/iwFIO

The health expenditure as a share of the GDP of Ireland (7.0%) falls behind Australia (9.3%) and Great Britain (9.8%). The health expenditure of Germany (11.2%) and the United States of America (16.9%) are the highest.

Searched Sources:

Table 1 lists resources searched by category: (1) bibliographic databases, searched for peer-reviewed articles, reviews, and meeting abstracts; (2) Internet searching for government released pdfs, books, meeting abstracts, and government, health departments, or associations reports; and (3) compilations of pharmaceutical reference materials. Search strategies were tailored according to the database or resource used.

Resources Searched	Coverage
Bibliographic databases	
Gov.GB	GB government database covers services and information
PubMed	database of references and abstracts on life sciences and biomedical topics
Europe PubMed Central (Europe PMC)	database of references and abstracts on life sciences and biomedical topics
BMC Public Health	database of references and abstracts on the disease, health, and public health
health.gov.au	Australian government database covers health-related resources
eurosurveillance.org	Europe's journal covering infectious disease surveillance, epidemiology, prevention and control
Australian Journal of Pharmacy (AJP)	Independent source of pharmacy news, views, education, and information (Australia)
Australian Journal of General Practice (AJGP)	Provides relevant, evidence-based information to Australian general practitioners
Sozialgesetzbuch (SGB)	Database of German laws
OECD Library	Database of statistics, books, and papers
Bundesministerium der Justiz und für Verbraucherschutz	Inform German citizens of current Federal laws
Internet searching	
Irish statute book	Covers legislation directory (Ireland)
IIOP (Irish institute of pharmacy)	continued professional development for pharmacists (Ireland)
	Innovation in primary care support (Ireland)

Hibernian healthcare	Covers vaccine injury support (Ireland)
Irish vaccine injury support	Independent association of pharmacists (Great Britain)
NPA (National Pharmacy Association)	Independent health think tank (Great Britain)
Nuffield Trust	A full-service pharmacy media resource
Pharmacy Times	A leading national government purchasing cooperative (United States)
NCPA (National Cooperative Purchasing Alliance)	A federal agency within the United States Department of Health and Human Services
The Centers for Medicare and Medicaid Services (CMS)	Covers professional liability insurance (United States)
Healthcare Providers Service Organization (HPSO)	Federal government agency and research institute responsible for disease control and prevention
Robert Koch Institute (RKI)	Provides independent pharmaceutical information and news
Deutsche Apotheker Zeitung (DAZ)	German newspaper for physicians and medical professionals
Ärzte Zeitung	Specialist pharmaceutical journal functions under ABDA
Pharmazeutische Zeitung (PZ)	Service partner of German pharmacies
Deutsches apotheken portal (DAP)	Leading insurance journal in Germany
Versicherungs magazin	

Compilations	
FIP (International Pharmaceutical Federation)	Covers Immunization report
BVDAK *(Bundesverband Deutscher Apothekenverband)*	Covers current development in the area of pharmaceuticals in Germany
PSI (pharmaceutical society of Ireland)	The statutory body responsible for health regulation in Ireland
HSE (Health Service Executive)	Covers health provision (Ireland)
NHS (National Health Service)	Government-funded medical and health care services (Great Britain)
Pharmaceutical Services Negotiating Committee (PSNC)	Covers the interests of all NHS community pharmacies
American Pharmacists Association (APhA)	the largest association of pharmacists in the United States
Immunization Action Coalition (IAC)	covers disease prevention and immunizations (United States)
The Centers for Disease Control and Prevention (CDC)	National public health institute (United States)
ASTHO (Association of State and Territorial Health Officials)	A national nonprofit organization representing public health agencies (United States)
National Centre for Immunization Research and Surveillance (NCIRS)	Policy and planning for immunization services in Australia

The Pharmaceutical Society of Australia (PSA)	National professional pharmacy organization (Australia)
The Pharmacy Guild of Australia	contribute towards community pharmacies in the Australian health care system
The Therapeutic Goods Administration (TGA)	The regulatory body for therapeutic goods (Australia)
Bundesministerium für Gesundheit (Federal Ministry of Health)	Cabinet-level ministry of Germany
Bundesverband Deutscher Apothekenverband (BVDAK)	A federal association representing health (Germany)
Bundesvereinigung Deutscher Apothekerverbände (ABDA)	Federal association of German Pharmacists' associations

Table 1 Resources Searched by Category

Keywords and Structure of Research:

Search terms for the literature were combined in multiple ways for all the selected countries using Boolean operators (AND, OR, NOT). A combination of keywords was used which are as follows: pharmacists, influenza, vaccine, laws, influenza vaccine, pharmacist administered influenza vaccine, legislation, pharmacist vaccine legislation, training, pharmacist vaccine training, curriculum, influenza curriculum pharmacists, e-learning, e-learning influenza pharmacists, curriculum vaccine administration pharmacists, pharmacy premises, pharmacy premises vaccine administration, vaccine records, vaccine administration records pharmacy, vaccine resources, vaccination rate, pharmacist administered vaccine rate, off-premises, pharmacy vaccination process, vaccination by pharmacists, vaccine recommendations, vaccine

contraindications, pharmacy vaccine reactions, pharmacy adverse reaction reporting, vaccine injury compensation, injury compensation pharmacy/pharmacist, vaccine adverse reaction reporting, vaccine adverse reaction, pharmacy vaccination rates, vaccine fee, pharmacy vaccination fee, vaccine reimbursement, vaccination claims, pharmacist vaccine claim, pharmacist vaccine reimbursement.

The initial search yielded 166 resources which were downloaded into a bibliographic software tool. The total was reduced to 89 studies, articles, government reports, pdfs by government, pharmacy associations, healthcare departments; and were included in the literature review.

The keywords used were translated into German to search German data. The literature in the German language was understood and translated with the help of a native speaker and own B2 Deutsch proficiency level (attached in appendix).

The literature review was divided into country wise chapters (n=1-5) with topics (n=9) and subtopics (n=3) for ease of comparison and understanding. The review under consideration follows a general to a specific approach. It starts with a chapter (country) and follows a line of topics with subtopics. The division of chapters in topics and subtopics were based on the repetitive components found in the literature of all countries. Chapter 6 comprise country comparison with respect to the summary of the topic and concludes the key findings of the literature review.

Inclusion/exclusion Criteria:

To maintain the focus on pharmacists as immunizers in the respective countries, the following exclusion criteria were employed. Articles were excluded if they: (1) were in a language other than English and German; (2) were focusing on vaccines other than influenza; (3) were focusing on immunizations by other health professionals; (4) focused on protocols of influenza vaccinations in clinics; (5) were not by government-run bodies or associations.

Studies, pdfs, articles that focus solely on country protocols for influenza vaccine administered by pharmacists were selected. Figure 3 depicts the inclusion, exclusion criteria applied.

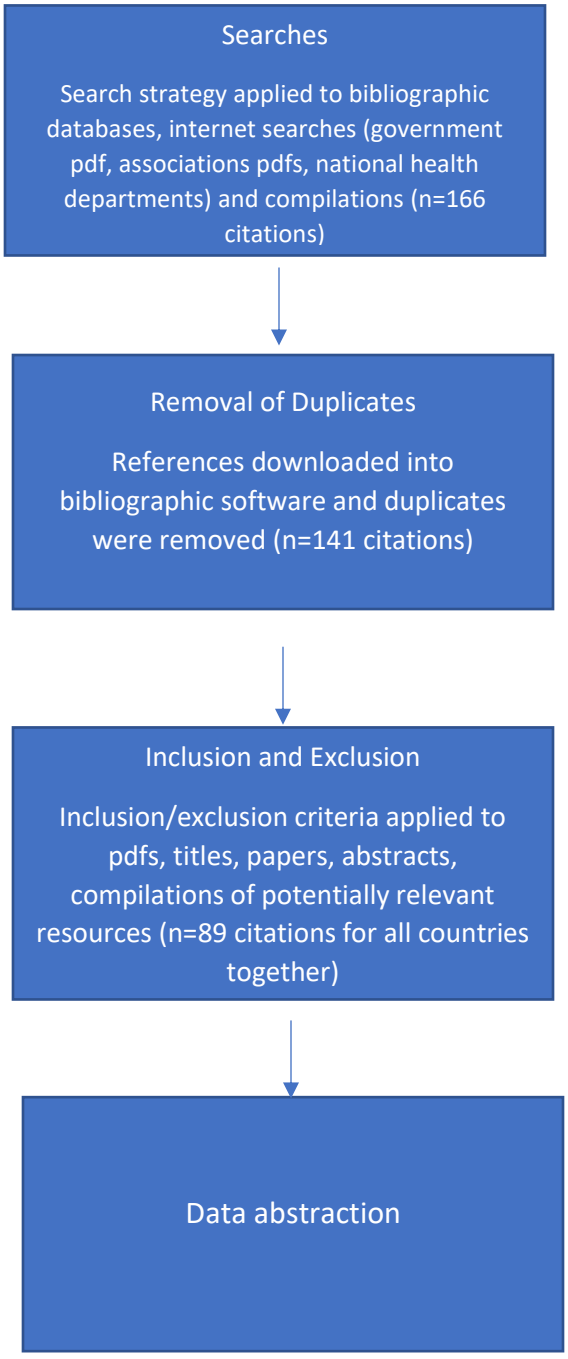

Figure 3: The inclusion/exclusion criteria

Results

Chapter 1 – Ireland

1. Legislations:

According to the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), which came in October 2011 states that Pharmacists, after completing an approved course, can administer specific vaccines to individuals without the need of a prescription. These vaccines include the seasonal influenza vaccine, pneumococcal polysaccharide, and herpes zoster vaccine. (14)

The Medicinal Products (Prescription and Control of Supply) (Amendment)(No.4) Regulations 2020- (S.I. No. 241/2020), which came on 10th July 2020 states that Pharmacists, after successful completion of training, can administer influenza vaccine to children from 6 months of age in the 2020/2021 season. They can also administer influenza nasal spray suspension to children from 2 years of age. (15)

2. Professional Qualifications and Training:

According to the Pharmaceutical Society of Ireland (PSI) (2019), pharmacists must get training to administer a vaccine to patients. A pharmacist can also vaccinate in different pharmacies but for that, there should be a copy of the training certificate in each of those pharmacies. Certificates obtained after training course completion can also be displayed in the vaccination room where pharmacists perform vaccine administration. (16) The training course, meant for registered pharmacists, is mandatory and they must show their competency in training to be able to practice vaccination provisions in pharmacies. For a pharmacist to practice influenza vaccine provision he or she must take the following training courses for successful vaccine delivery.

CPR

All pharmacists who wish to vaccinate patients must take a mandatory PSI approved CPR course for children and adults. Two providers i.e. Irish Heart Foundation and Pre-Hospital Emergency Care Council are approved for CPR course for pharmacists. (17) The course is valid for two years. (18)

Responding to an emergency and management of anaphylaxis (RESMA)

The free, 4-Hour, self-study, e-learning program equip pharmacists to deal with an emergency in the pharmacy. This short course enables them to observe the symptoms of a vaccine reaction (anaphylaxis) in a patient (child or adult), recognize them, and administer a drug (adrenaline) meant for emergency management. (19) RESMA course is valid for two years and must be repeated once that period is over. (18)

Medicines Administration (Parenteral) (PAMT)

This full-day course is provided by Hibernian Healthcare. This enables pharmacists to learn how to draw vaccines from a vial and ampule, choosing the correct vaccination site, and administering a subcutaneous and intramuscular vaccine to a child and an adult. (20) This course is meant for those pharmacists who are willing to administer adrenaline to patients. RESMA allows pharmacists to administer adrenaline in the form of autoinjector only; while the PAMT course equips pharmacists to administer adrenaline by drawing it from an ampoule and administering it to a patient. This course is to be taken by a non-trained pharmacist or when a pharmacist has not administered a vaccine or emergency medicine in the past 12 months. (18)

The Administration of Influenza Vaccine Training Programme

The free, two-hour, self-study, e-learning program enables pharmacists to learn how to give flu shots safely to patients. To take this course, pharmacists must fulfill the pre-requirements of this course and must take CPR, RESMA, and Medicine administration (parenteral) (PAMT) courses first. Once they complete this course, they receive a certificate that shows their competency in the process involved in vaccine administration. This includes responses and preparation following a request for a flu shot, patient assessment, and vaccine administration to children and adults. (19) This course is repeated every influenza season or when a pharmacist has not vaccinated any patient in the past 12 months. (18)

A pharmacist should complete a self-declaration form every year. This consists of key requirements for a successful practice of vaccination service in a pharmacy and allows pharmacists to self-access against a checklist whether a required course is missing which he or she should take to continue vaccination practice. (18)

2.1 Undergraduate Vaccination Training Program for Pharmacists:

A review of the Vaccinations and Emergency Medicine Training Requirement issued by the Pharmaceutical Society of Ireland (PSI-2019), shows that different stakeholders, involved in the provision of vaccination training programs, were sent a questionnaire to assess and suggest the betterment of vaccination training program for pharmacists. Only one stakeholder believed that the training program should be incorporated into the undergraduate pharmacy programs to save time and resources. (21)

2.2. Tools and Resources available to pharmacists

According to International Pharmaceutical Federation (FIP-2016), the Irish Pharmaceutical Society (PSI) has issued a "Guidance on the provision of Vaccination Services by Pharmacists in Retail Pharmacy Business" as a helping tool for community pharmacists to refer to during their professional vaccine practice. Furthermore, National Immunization Advisory Committee (NIAC) has prepared "Immunization Guidelines for Ireland" which is regularly updated by the NIO-Northern Ireland Office. The NIO also issues leaflets, guidelines, and other materials including "A Practical Guide to Immunization".(6)

3. Premises Requirements:

This section presents a review of recent literature available on the space requirement and necessities involved in vaccination at a pharmacy. The Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses issued by PSI (2019) shows that a pharmacy must have a specific area designated for vaccine administration. This specific private area is required if the patient consultation area does not meet the minimum requirements for vaccine provision or a pharmacy is vaccinating patients on a large scale. The patient consultation area (where the pharmacist and patient discuss therapy) must be available for its main function, which is vaccine administration.

The minimum requirements of a vaccination service to be carried out at pharmacies include an area close to a dispensary so that pharmacists can easily access it without hindering the normal workflow. It should be a private area with a professional finish. To provide optimum privacy doors, opaque glass, other barriers or shutters could be used. Its layout and size should be such that it would allow the easy workflow for pharmacists and should be safe and comfortable for the patient. There should be enough seating for the comfort of the patient and the accompanying person. The place should be able to hold necessary documents and equipment to manage any adverse events following a vaccine administration.

Along with the layout specifications, necessary equipment should also be in a place e.g. refrigerator, infection control equipment like alcohol disinfectant for hands and surfaces; vaccine administration tools i.e. hand gloves and swabs; waste bins for sharps and other waste material; emergency apparatus including CPR mask, epinephrine injections for 2 people, protective tools to deal with an event following a vaccine spillage including turtle skin gloves and aprons. Apart from the necessary equipment warm and cold drinking water should be present. (16)

4. Vaccination Off-Premises:

This section reviews the literature related to Influenza vaccine administration by pharmacists at places other than pharmacy premises. The Medicinal Products (Prescription and Control of Supply) (Amendment)(No.5) Regulations 2020- (S.I. No. 241/2020), came into effect in October 2020 and states that pharmacists, after appropriate training, can provide influenza vaccine as a pre-filled syringe, suspension, nasal spray to individuals at places other than the pharmacy premises. The place should be suitable and appropriate and should provide convenience to the general public for the sake of health protection and safety of the public. According to legislation, this service can be practiced by a registered pharmacist, who can vaccinate after appropriate training, under the name of a registered pharmacy business.

PSI has issued a guideline for pharmacists for the successful provision of influenza vaccine at places other than the pharmacy premises. The guide states the necessary steps involved in the

provision of influenza vaccine off-premises. Pharmacists must stick to the strict code of conduct and the guidelines issued by PSI for this service provision.

PSI states that to plan offsite service similar standards as to those on the pharmacy premises be maintained to ensure service quality and patient safety. The location should be such that it provides privacy to the patient. Guidelines issued by HSE to maintain the cold chain, during movement from pharmacy to patient off-premises, must be followed. Moreover, the pharmacist providing the service must be equipped with the necessary tools for a successful flu shot off the premises. This equipment includes vaccination kits, cold storage boxes, related documents, an anaphylaxis kit, and waste disposal equipment. Vaccinations must be recorded on the spot if the internet is available there or it can be filled once the pharmacist returns to the pharmacy. The possible additional places where a pharmacist can immunize a patient include the patient's home, residential care homes, community or sports halls, offices, and schools. (22)

5. National Vaccination Recommendations and Contraindications:

The literature review shows that HSE has recommendations and contraindications for the Influenza vaccine. Recommended people receive the Influenza vaccine on a priority basis. Those who are contraindicated are not provided with a flu shot. Table 2 represents the groups recommended and contraindicated for influenza vaccine by the Irish Government. (23)

Recommendations	• Individuals with 65 years of age, and above • Pregnant women (any trimester) • Children who fall into the age range between two to twelve years. For this age group, LAIV is recommended and QIV is only to be given to this group if LAIV is contraindicated for an individual. • Two age groups; namely six to twenty-three months of age and thirteen to sixty-four years of age are recommended a flu shot if they have a certain clinical risk factor that includes:

	○ Chronic diseases; namely chronic heart, liver, neurological, respiratory, renal failure, diabetes mellitus, or hemoglobinopathies. ○ weak immunity as a result of any disease or treatment; namely HIV/AIDs, Cancer treatment, asplenia, or hyposplenism. ○ Compromised respiratory function; namely neuromuscular or seizure disorder and spinal cord injury. Individuals who are enrolled in special schools or daycare institutes are included in this group. ○ Children suffering from moderate to severe neurodevelopmental disorders; namely intellectual disability or cerebral palsy ○ Children who are taking aspirin as a long-term therapy ○ Individuals who are overweight and have a BMI index of more than 40 ○ Individuals who are living in long-stay residential or nursing care homes or other such care facilities. The virus can spread fast in these places; endangering other housemates if one or more individuals have the virus. ○ Individuals who are suffering from Down Syndrome • Individuals who can transmit the flu virus to individuals who are already at a higher risk of getting the influenza virus. These includes: ○ Health care staff ○ Individuals living with at-risk persons ○ Individuals proving care outside of the home to people who are included in the high-risk group

	• people who work or remain in close contact with poultry, pigs, or waterfowl
Contraindications	• Individuals with a history of confirmed anaphylactic reaction to a flu vaccine or the contents/excipients within the vaccine. • Individuals who are at risk of immune-related reactions to the vaccine and are taking combination checkpoint inhibitors; namely ipilimumab and nivolumab. • Individuals who are suffering from severe neutropenia, having a neutrophil count below 0.5 x 10^9/L, are contraindicated for the flu vaccine to prevent an acute febrile episode. (23)

Table 2 Groups Recommended and Contraindicated for Influenza Vaccine - Ireland

6. Pre and post Vaccination Key Events:

This section involves a review of literature related to key events that take place during a vaccination process at a pharmacy. According to the Irish statute book (2015), pharmacists do not require a prescription for vaccinating a patient at the pharmacy. (14) As a patient comes for a flu shot, the pharmacist checks their data including name, date of birth, and immunization history. Patients also get disease-related information for which the vaccine is to be used. The immunizer pharmacist checks for any contraindications to the vaccine followed by the consent form which is filled by the patient before being vaccinated. After vaccination patient is observed for at least fifteen minutes to check for vaccine-related adverse reactions. (16)

6.1. Record Maintenance:

International Pharmaceutical Federation (2016) states that according to the Irish legislation 2015, certain records must be kept by the pharmacies. Administration records including the

date on which the vaccine is administered; patient-related information that includes the date of birth, name, sex, address, and personal public service number (PPSN). Vaccine related details are also recorded that includes the name of the vaccine, its dose and batch number, administration site, the date on which the vaccine is going to be expired. Pharmacists related record includes name, PSI identification number, and pharmacy address. The details of the patient's doctor are also recorded that includes name, address, and contact details. Consent of the patient is recorded. Moreover, in case of emergency i.e. in case of anaphylactic reaction the epinephrine administered is recorded too. A vaccine supply and details record must also be kept by the pharmacy. (16)

According to the Irish statute book (2015) Vaccine record must be kept by pharmacists, pharmacy owner, or a person who supplies and administer vaccines in emergency conditions. (14) The vaccination record is also shared with the Health Services Executive (HSE) and patient's GP.(16) All records must be available for inspection at the premises for at least two years and must be stored confidentially for a further 6 years. (6)

7. Vaccination Uptake and Promotion:

Logan (2020) states in a report that more than one thousand pharmacies offer vaccination services across Ireland now and account for a little more than 16% of the overall vaccinations being carried out in the region. Since 2011, when pharmacists were allowed to vaccinate patients, about a 59.5% increase in overall vaccine uptake is observed. (24)

FIP (2016) says that leaflets and posters by the Irish Pharmacy Union (IPU) are distributed among pharmacies to be advertised. Radio ads are used to spread the message, especially during the flu vaccination campaigns. (6)

8. Vaccine Payments and Reimbursements:

This section reviews the literature giving insights on free or paid vaccines available and how pharmacists claim for their reimbursements. According to FIP (2016), patients included in the

HSE recommended group get their vaccines free of charge at pharmacies. All those patients who fall out of this category must pay out of pocket for the service which is 20 Euros. (6)

For the 2020/2021 influenza season starting from October, pharmacists receive 15 euros for every vaccine administered through the intramuscular route (QIV) and 20 euros for every live attenuated influenza vaccine (LAIV) administered through the nasal route. Moreover, the pharmacy contractor receives an additional payment of 100 euros for 10 patients who gets QIV flu shot. The contractors also receive 150 euros for every 10 patients ranging between 2 to 12 years of age who get their LAIV shot as per nasal route. (25)

The number of vaccines administered by the pharmacists can be claimed via the Primary Care Reimbursement Service (PCRS) which is part of the Health Service Executive (HSE). Pharmacists can submit their claims electronically on the PCRS website and are advised to upload their claims on the first day of the month. (26)

9. Vaccine Adverse Event Reporting and Injury Compensation:

The literature sheds light on the reporting of vaccine-related side effects, pharmacist's indemnity, and compensation schemes available in Ireland for patients experiencing harm from vaccines. It is the duty of the pharmacy owner or the superintendent pharmacist to ensure that letting vaccinations to be carried out at the pharmacy are covered by appropriate professional indemnity for pharmacists. Any adverse reaction, after a vaccine administration at the pharmacy, is to be reported to the Health Products Regulatory Authority (HPRA) immediately. The HPRA monitors adverse reactions of vaccines at the national level. The report sent to HPRA via their online portal includes vaccine brand name, batch number, and the harm it inflicted on the patient. (16)

A person affected by a vaccine administered in Ireland is supported by the Irish Vaccine Injury Support Program. This program lets individuals access them via their helpline, email, or online portal for support and advice. Moreover, they act as a mediator and communicate between the state and the affected person for compensation for the harm caused by the vaccine. (27)

Chapter 2 – Great Britain

1. Legislation:

A review of literature for legislation around the Influenza virus and pharmacists of Great Britain shows that Influenza vaccination is an advanced service being practiced by pharmacists. According to service specifications by the National Health Service (NHS) and Pharmaceutical Services Negotiating Committee (PSNC 2020), Immunization services offered by community pharmacies of Great Britain came into effect on 1st September 2015. Every flu season, the service is offered from 1st September to 31st March and covers individuals who are 18 years of age or older. Patients, recommended by NHS, are prioritized and focused on between 1st September and 31st January to increase vaccination uptake. (28)

2. Professional Qualifications and Training:

A review of PSNC, NHS (2020) shows that the professional qualifications and training of the pharmacists are to be ensured by the pharmacy contractor before registering their pharmacy for the immunization services. Registered pharmacists must ensure their competencies in the immunization area and must sign a Declaration of competency (DOC) form before they can start practicing vaccination services. The DOC must be signed every two years to ensure competency in aspects involved in a vaccination process and the pharmacist's continuity of practice. Copies of these forms are to be kept at the pharmacy and contractors have to ensure their availability at the premises. (28)

National Pharmacy Association (NPA), (2020) states that pharmacists must take online and face-to-face training to prove their competency for the advanced service of vaccine administration. The online training is accessed via NPA's online portal. The face to face training includes basic life support, anaphylaxis management, and pediatrics training. Moreover, a refresher course is to be taken by a pharmacist every three years. (29)

According to Public Health Great Britain and Royal College of Nursing (2018) the core curriculum for health care workers, including a pharmacist, to ensure a successful immunization service includes several focus areas. The core curriculum focuses on the aims and goals associated with Immunization, their policies, recommendations, contraindications, and schedules. Moreover, Immune responses to vaccines, vaccine types, composition, and functionality in the human body, issues around them, and vaccine-preventable diseases are also included in the curriculum. Other focus areas include pharmacist-patient communication, legalities around vaccines, their storage, administration, adverse reaction management, documentation, record maintenance, and strategies to maximize vaccine uptake in the population. (30)

National Pharmacy Association (NPA) offers an NPA PGD Programme. This program offers different packages like the PGD Flu package and PGD Travel package. Patient Group Direction Flu package course equips pharmacists with the necessary theoretical and hands-on practical knowledge on vaccine administration to patients without the need for a prescription. This Package consists of further two packages for NPA members and non-members; for members, the full vaccination training including theoretical and face-to-face classes cost 96.25 British Pounds and Refresher online training cost 27.50 British Pounds. For non-members, the full vaccination training costs 110 British pounds and 30.50 pounds for refresher training. After the course, completion pharmacists are provided with a certificate proving their competency on the subject. (29)

2.1. Undergraduate Vaccination Training Program for Pharmacists:

No data were found regarding the training of undergraduate pharmacy students for vaccination purposes.

2.2. Tools and Resources available to pharmacists:

According to Public Health Great Britain and Royal College of Nursing (2018), the pharmacists involved in immunization services have access to the following related resources: An online version of Green Book. It consists of up to date information about immunization procedures and practices. The Vaccine Update, a national newsletter containing information about up to date information concerning vaccine developments, policies, and procedures. (30)

3. Premises Requirements:

This section includes a review of literature available around the requirements of space, design, and equipment necessary for vaccinations to be carried out at the pharmacies of Great Britain. According to PSNC, NHS (2020) A consultation room within the participating pharmacies is a core requirement. The consultation area within the pharmacy where vaccination takes place must provide optimum privacy to the patient. It should be separate from the general pharmacy area where usual business takes place. It should have a proper sitting area where the vaccine provider, patient, and the person accompanying the patient can sit and talk privately. Standards for infection control are maintained in the consultation room. A copy of the declaration of competence (DoC) must be present on the premises. (28) According to Green book chapter 8, it should be the responsibility of the health professional who administers a vaccine that an anaphylaxis pack is present where vaccines are being administered. (31)

To maintain infection control standards, PSNC expects the contractors to maintain the pharmacy area meant for vaccination purposes. It should have a refrigerator for proper storage of vaccines, hand hygiene facilities, material for personal protection, material to manage sharps and dispose of waste, and material for cleaning and disinfection purposes. (32)

4. Vaccination Off-Premises:

Along with vaccination at the pharmacy area, pharmacists in Great Britain can administer vaccines to patients in their homes, long-stay residential care homes, and other community places. (28) For this kind of service provision, a pharmacist receives a vaccination request from the general practitioner of a patient or any of the places mentioned above. Then the pharmacist who must deal with the patient outside of the pharmacy (in any of the settings mentioned above) must send an email to NHS Great Britain.

In this email pharmacist must mention; the name of the patient, the address where vaccination is to be carried out, mention the reason for which one must be vaccinated outside of the pharmacy, the patient's GP's approval, and the pharmacists' indemnity notification. The email also contains certain confirmations from the contractors; this includes confirmation about up to

date Disclosure and barring service (DBS) certificate of the pharmacist, waste disposal equipment, cold chain integrity to move vaccine from pharmacy premises to the patient. Moreover, confirmation about the setting area being in line with NHS, PSNC service specifications and check for infection control measures are also required from the contractor by NHS.

After the email, the pharmacy contractor receives NHS Great Britain approval to vaccinate patients outside of the pharmacy. The vaccinating pharmacist then rechecks whether the patient is eligible to receive a vaccine and confirms the date and time for vaccination provision to the patient. Necessary documents and equipment including consent forms, leaflets, questionnaires to assess patient satisfaction, and anaphylactic kits are taken along to the vaccination setting. To maintain the cold chain, special cool boxes are utilized that must maintain the temperature between 2-8 degrees. Waste disposal boxes are taken along for proper waste disposal after vaccine administration. Relevant data are uploaded to the sonar within 48 hours of service provision for record maintenance. (33)

5. National Vaccination Recommendations and Contraindications:

A review of NHS (2020/21) Influenza Vaccination Patient Group Directions (PGD), created by Public Health Great Britain and approved by NHS shows that there are a certain group of people for whom influenza vaccine is recommended. Others, however, are indicated against it and should not be administered with the vaccine. To administer influenza vaccine to a patient, a pharmacist must assess if the patient is recommended for influenza vaccine by NHS and is eligible for inclusion in the NHS funded National Influenza Immunisation Programme. Patients recommended by NHS get the influenza vaccine free of cost. Table 3 represents the influenza vaccine recommendations and contraindications for the flu season of 2020/21 for Great Britain.

Inclusion Criteria	• Individuals with 65 years of age, and above
	• Individuals who fall in the age range between 18 and 65 years with one or more clinical risk factors that include:
	  ○ Chronic respiratory disease; for instance, bronchitis, severe asthma, or chronic obstructive pulmonary disease (COPD)
	  ○ Chronic heart disease including heart failure
	  ○ Chronic kidney disease with the third, fourth or fifth stage
	  ○ Chronic liver disease
	  ○ Chronic neurological disease; for instance, Parkinson's or motor neuron disease
	  ○ Individuals having learning disabilities
	  ○ Diabetes patients
	  ○ Asplenia or splenic dysfunction
	  ○ Individuals with weak immunity as a result of any disease or treatment; namely HIV/AIDs and Cancer treatment respectively.
	  ○ Individuals with a BMI of 40kg/m2 and are obese
	  ○ Women who are pregnant or those becoming pregnant in the course of the flu season
	• Individuals (18 years or above) who are living in long-stay residential care homes or other such care facilities excluding prisons, young offender institutions, or university dorms. The virus can spread easily in these places; endangering other housemates if one or more individuals have the virus. This can cause a great number of morbidity and mortalities.
	• Individuals (age 18 or older) who are carers of the old or disabled person or those who fall into the category of getting care from a carer.
	• Individuals who are living closely (sharing a house) to patients who are immunocompromised or are included in the NHS shielded patient list (updated weekly depending on data from hospitals, clinics, etc.) and

	cannot avoid being in close contact with those patients during the winter or flu season. • Health and social care workforce (18 years or older) who are in close contact with individuals who are vulnerable to influenza if exposed to the virus and are living in registered residential or domiciliary care or nursing homes. • Health and social care workforce (18 years or older) working for a voluntary hospice provider and are being in close contact with people with increased risk of influenza • Health and social care workforce who provides domiciliary care to patients.
Exclusion Criteria	• Individuals with age less than 18 years • Individuals with a history of confirmed anaphylactic reaction to the flu vaccine or the contents within the vaccine that are other than ovalbumin. These contents could be any excipient used for vaccine manufacturing. • Individuals who have already got their recommended flu shot for the current season. • Individuals who feel ill resulting from acute severe febrile illness. If the infection is minor then the vaccine is not contraindicated. (34)

Table 3 Groups Recommended and Contraindicated for Influenza Vaccine - Great Britain

6. Key Events In Vaccination Process:

As per PSNC (2019) guidance on flu shots service, the flu vaccine is only available to patients with a prescription in Great Britain. (35) When a prescription is provided, the patient undergoes a screening process in which their data is checked. This includes their age, eligibility for a free vaccination, medical history, and whether they are included in the at-risk patient group. (36) A

consent form, which is to be signed by the patient, is provided before vaccine administration. The patient is also informed that the consent form would be shared with the patient's doctor, NHS Great Britain and NHS Improvement (NHSE&I), and NHS Business Service Authority (NHSBSA) so that records are updated and pharmacists can claim successful vaccination provision i.e. for Post Payment Verification. (35) After the vaccine is administered the patient can leave the pharmacy. (37)

6.1. Record Maintenance:

A review of PSNC, NHS (2020) shows how and which records are being maintained in the pharmacies. Pharmacies must maintain records of service provision for which a Vaccination Record Form is mandatory and must be present on the premises. The form is scanned appropriately and is included in the patient's file or third-party data transfer software. In the patient details portion of the record form a patient must give their name, surname, address, postcode, telephone number, date of birth, NHS number, and details of their general practitioner. Then comes the second part of the record form in which the pharmacists ask for the patient's emergency contact; including the name of the person, their phone number, their relationship with the patient. The eligibility group, i.e. in which NHS pre-defined group they fall to get free vaccination, of the patient is also assessed and recorded. The third part of the record form is meant for the pharmacists only and he or she has to fill in details of the vaccine being administered; for instance, vaccine name, its manufacturer, batch number, expiry date, the date on which vaccine is being administered, injection site used, the route through which vaccine is being administered, the location where the patient is being vaccinated, if an adverse effect is observed or not, and related advice given by the pharmacist. At the end of the record form, pharmacists must give their name, signature, and registration number.

The patient's consent is taken in written on the service consent form and a record is kept. It is shared with the patient's General practitioner and NHS Great Britain to ensure service provision and is also used to claim vaccine reimbursement. (28) Records are kept safe for ten years. (6)

7. Vaccination Uptake and Promotion:

Previous stats show that in the flu season 2018/2019 pharmacists of the GB managed to vaccinate slightly more than 1.4 million people. More than nine thousand pharmacies (78.2%) are working for this service provision. The mean vaccinated patient count per pharmacy was 158. Few pharmacies performed better than others with one pharmacy vaccinating 2,500 patients in the season. (38) In the flu season of 2005-2006 the goal set by WHO was achieved. The WHO goal is to achieve 75% vaccination uptake among people aged 65 or more. The percentage achieved by Great Britain was 75.3%. Ever since the uptake has been in-between 70-75%. In the flu season between 1st September to 31st December 2019, the vaccine uptake reached 70.6%. (39)

Perman, Kwiatkowska, Gjini (2018) concludes several studies conducted on vaccination uptake in the GB. There were mixed results. Two of the studies under observation suggested a rise in vaccination uptake by 6.2%. Two of the included studies concluded that there was no rise or fall in the vaccination uptake since pharmacists began to vaccinate in the GB. Two pieces of research showed reduced uptake by 1.1%. One other study concludes that there was about a 1.8-3% decrease in vaccination uptake in two seasons between 2013-2015. (40) Ecarnot et al. (2019) discusses two studies related to vaccination rates in the GB and concludes weak evidence of an increase in vaccination uptake in the GB.(41)

Pharmacies in the GB use promotion material as posters on windows and brochures placed on the pharmacy counter to spread awareness among incoming patients. In 2009, Pharmacists have also worked along with doctors to increase awareness of patients about the necessity of vaccination. Other promotion strategies include the NHS website and social media promotion through Instagram and Twitter. (6)

8. Vaccine Payments and Reimbursements:

In Great Britain, patients not included in NHS recommended groups must pay for the required vaccine and the vaccination service at the pharmacy which costs between 9.99-13 pounds

(11.03-14.35 Euros). Individuals included in the NHS recommendations get a free flu vaccine. The contractor of the pharmacy can claim a reimbursement of 8.08 pounds for the vaccine and an additional fee of 1.50 pounds per vaccine as the cost of service provision. (6,10) According to PSNC (2020/21), the total fee per vaccination is 10.08 British Pounds (11.14 Euros). The base price for the vaccine, funded by the NHS vaccination budget, is 9.58 Pounds but for this season i.e. 2020/2021 flu season an additional .50 pounds (funded by transition fund) is added to the 9.58 pounds which makes it a total of 10.08 pounds per vaccine. (42) Service specification (2020) states that Claims for this amount can be made monthly or within six months of the vaccine administration through the Manage your service platform which is offered by NHS Business Service Authority (NHSBSA). However, no claims can be made for vaccine provision to individuals not included in the National Influenza Vaccination program.(28)

Moreover, PSNC (2020/21) states that an additional 200 pounds could be claimed up to five or more times depending on the local need, by the pharmacy contractor through NHSBSA, if an additional venue outside of pharmacy is rented for vaccine provision. The contractor must get authorization beforehand on a first come first serve basis from NHS Great Britain and NHS Improvement (NHSE&I) for the additional venue and cold storage facility to be used within the venue. The NHSE&I approves the venue if there is no other venue rented in the same area to avoid over-provision and competition for the same patients by different providers. Approval for venue also depends upon whether the contractors can ensure prevention control standards for COVID-19 set by General Pharmacy Council and if they have an adequate amount of vaccines. If the venue costs more than 200 pounds then only 200 pounds can be claimed but if it is rented for less than 200 pounds then only the actual cost is reimbursed. The contractors can take only 20 vaccines at the venue. (42)

9. Vaccine Adverse Event Reporting and Injury Compensation:

Patient Group Directions (PGDs) provide specific guidelines to healthcare professionals including pharmacists to carry out successful immunizations. There are several requirements to be fulfilled by the practitioners. They should be approved to practice under the terms and conditions of the PGDs. They cannot deviate from the professional guidelines mentioned in the PGDs for the

current service of vaccination provision. Pharmacists must stick strictly to the framework provided by PGD. NHS takes the responsibility and authorization of the content present within the PGDs and stands responsible for the protection and liability of the practitioners. However, the practitioners still stand accountable for their professional actions. The practitioners must practice within their professional limits and code of conduct mentioned in the PGDs documents.

When a vaccination ends up with a side effect it is to be noted immediately in the records and the patient's GP is also informed of the harm it caused. The adverse reactions can be reported by the affected person, their carers, parents, or the health care staff to the Medicines and Healthcare products Regulatory Agency (MHRA) through their online portal. (43)

If a patient gets a rare but serious vaccine side effect, they can reach for Vaccine Damage Payment which is a program offered by the GB government to compensate those individuals who get a disability following a vaccine shot. The individuals can be compensated by a tax-free payment of 120,000 pounds. (44)

Chapter 3 – United States Of America

1. Legislation:

Burson, Buttenheim, Armstrong, Feemster (2016) states that in the USA, pharmacies have offered vaccine administration services since 1984. A timeline of vaccination services offered by pharmacists in community pharmacies is as follows:

1984- Vaccinations in pharmacies were carried out on a large scale. However, the service was not carried out by pharmacists at first rather it was provided by nurses and other health professionals. **1996**- Pharmacists were included in the provision of vaccination services to adults. Other states began asynchronously by including pharmacists as immunizers and began accepting their new role. **1997**- Vaccination services which were started in 1984 became so successful that it was being practiced on a large-scale and became extensive in the next 10 years. The practice became so popular that in 1997 fifteen thousand pharmacies administered a total number of 5 million influenza vaccines to patients.

2009- By this time all American states and federal districts of Washington and Puerto Rico included pharmacists, only after certification, in the adult influenza vaccination workforce. Moreover, forty-six states authorized pharmacists to offer a full range of adult vaccination services. **2015**- Till this time a total of two hundred eighty thousand pharmacists were certified and included in the vaccination service provision workforce. (45)

The age from which a patient can get a flu shot by a pharmacist based in America is different in different states. In 27 American states, a pharmacist can administer a vaccine to a patient of any age group. In 34 American states pharmacists, by law, are administering vaccines to patients 18 years of age or more. 18 states allow pharmacists to vaccinate patients with ages starting from 3 years and 14 years.(6)

2. Professional Qualifications and Training:

FIP (2016) states that in the United States are several different providers for vaccination training programs. Accordingly, the fee for these training programs varies with the providers.(6) The mandatory training program "Pharmacy-Based Immunization Delivery certificate training program" for pharmacists is offered by the American Pharmacist Association (APhA). This program is established keeping the National educational standards, set by the Centre for Disease Control and Prevention, in focus. The 20-hour course, updated on 30th March 2020, consists of a live seminar and self-study modules. (46) The curriculum for the training course offered by APhA has two main parts. A self-study part and a live seminar.

The Self-Study Modules:

In total there are five theory-based e-learning modules in the self-study portion of the training curriculum. These modules are planned so that the pharmacists have in-depth knowledge of informative areas surrounding vaccines and their administration.

Module 1: "Pharmacists, Vaccines, and Public Health"

In this module, pharmacists learn the role of vaccines to avoid diseases and how they are useful to prevent human mortality and morbidity. They also learn their role as vaccinators under state laws as well as their role in emergency preparedness activities. Moreover, what additional resources and blueprints are available to them for a consultation to provide vaccination, related education, and advocation respectively.

Module 2: "Overview of Immunology and Vaccine Development":

In this module, pharmacists learn about herd immunity, the key points regarding active and passive immunity. How the immune system reacts to vaccines and how do vaccines prevent the disease. What are the attributes and features that differentiate live, recombinant, inactivated, and polysaccharide vaccines? Logical based grounds on when to administer a vaccine and when a gap between doses is needed.

Module 3: "Vaccine-Preventable Diseases":

In this module, pharmacists learn about the diseases which can be avoided through vaccinations and what kinds of vaccines are there to prevent those diseases. They also learn who is eligible to receive these vaccinations and under what conditions certain people are not allowed to receive a flu shot.

Module 4: "Patient Care Consideration for Immunizing Pharmacists":

In this module, pharmacists learn to use the pharmacists' patient care process which involves steps from a patient entering the pharmacy till receiving a vaccine and leaving the premises. They learn how to assess patients who have vaccination needs and what are the questions they need to ask a patient for screening purposes. Moreover, they learn the steps involved in patient education regarding benefits, concerns, and different myths surrounding vaccination. Then comes vaccine selection, their doses, and routes. Who is contraindicated to a vaccine and if a vaccine-related adverse effect occurs, how to recognize it, and what steps pharmacists need to take under such a situation? They also learn to manage the Vaccine Adverse Event Reporting System and related documentations.

Module 5: "Operating A Pharmacy-Based Immunization Program":

In this module, pharmacists learn about the work area requirements like space required, different workflow options, storage facilities, and vaccine handling. Moreover, they learn about the Vaccine injury compensation program and occupational safety to avoid or handle the possible injuries that can take place in the workplace. They also go through different strategies to promote vaccinations and how they can claim for vaccines administered by them.

At the end of the modules, pharmacists must take an assessment test and must score at least 70 percent to pass this 12-credit hour self-study e-learning.

Live Seminar:

What pharmacists learn in self-study modules come in handy as they attend the 8-credit hour live seminar. The live seminar is about the process and the steps involved in the practical provision of the vaccine. Pharmacists must demonstrate competency in patient history evaluation, communication, vaccine administration, vaccine safety, and adverse event

management. They also have to show knowledge of different strategies that can be utilized to increase vaccination rates which includes coordinating with other practitioners and community-based activities.

A “Certificate of Achievement” is granted to those pharmacists who complete the requirements of the course excluding CPR as it is not a pre-requirement of the training program. The certificate, however, is not valid until pharmacists provide evidence in ink that they have successfully taken a CPR (Cardiopulmonary resuscitation) or BCLS (Basic Cardiac Life Support) certificate. (46) The completion certificate awarded to the pharmacist does not expire. Every year immunizing pharmacists are updated and must take one to two hours of training as part of Continuing Pharmacy Education (CPE). (6)

2.1. Undergraduate Immunization Training for Pharmacists:

A Pharmacy Times article by Xavioer and Goad (2017) states that training is a requirement for pharmacists to offer vaccination services and are offered to registered pharmacists as well as undergraduate pharmacists. About 47 states and the District of Columbia allow pharmacists who are still undergraduate students to vaccinate, only under-trained pharmacist’s supervision and only after they have acquired professional training within the course of their studies. However, four states i.e. Puerto Rico (PR), New Jersey (NJ), New Hampshire (NH), and New York (NY) do not allow undergraduate pharmacists to vaccinate patients. (47)

The majority of the pharmacy schools in the United States are utilizing the Pharmacy-Based Immunization Delivery Program, offered by the APhA, to train the undergraduates during their studies. However, the course is more focused on the immunization of adults only.(48)

2.2. Tools and Resources available to pharmacists:

There are several resources available to pharmacists who take APhA's course for optimum vaccination service provision. These include a pink book, “APhA's Immunization Handbook”, several recommendations, schedules, and guides on vaccine administration, management,

safety, and storage. Some useful tools include CoCASA which is " Comprehensive Clinical Assessment Software Application" and VACMAN which is "Vaccine management software".(49)

3. Premises Requirements:

Bach, Goad (2015) states that initially, most of the pharmacies were built without considering the need for a private area where patients could have their vaccinations on the spot. Therefore, a semiprivate area would suffice the need for a private area for vaccine provision activities to be carried out in pharmacies. In the USA the pharmacies offering vaccination services have either redesigned their pharmacy structure to allocate a private patient area or have changed the layout of the floors to achieve the need. (50)

Certain workspace requirements should be considered by the pharmacy owner. There should be a waiting area for the patients, where they can wait for their turn for vaccination. This waiting area should contain posters or service material to be read by the patient so that he or she during waiting for his or her turn can educate themselves and be able to ask questions once it's their turn to be vaccinated. The overall workplace should provide enough systematic space to easily continue the workflow without the hindrance of space and time.(51)

The vaccination should take place in a specifically designated area meant solely for vaccine administration. This area should have enough space to prepare vaccines, adequate light, ventilation, hygiene facilities including a sink, enough area for a fridge to securely store vaccines, enough area to keep waste disposal containers that are to be used to dispose of sharps and needles. Moreover, the designated area must have space for additional racks and cabinets so that additional material can be placed there; namely syringes, alcohol swabs, informational documents, supplies for an emergency, record stacks, forms. If patient data is also taken and recorded in the vaccination area, then there should be enough space for a computer and scanner.(52)

4. Vaccination Off-Premises:

According to APhA, pharmacies can conduct a small scale or a large-scale immunization event based on local needs. Vaccination venues include any reasonable place from a clinical entrance space to a large community hall that can serve the purpose. However, a complete vaccination setup should be in place. This setup includes what is needed for a vaccination process; namely documents including consent forms and Vaccine Information Statement (VIS) form, proper entrance with signage, seating in waiting area, separate vaccine administration area, waste disposal material, and equipment, waiting area for post-vaccination observation and proper exit with signs. To execute these events, the APhA has provided checklist documents and resources to help pharmacies achieve their immunization goals.(53) (54)

5. National Vaccination Recommendation and Contraindications:

According to the Advisory Committee on Immunization Practices (ACIP – 2020/21), there are influenza vaccine recommendations and contraindications for certain groups. According to ACIP Influenza vaccine is recommended for everyone with age starting from six months and above. However, if they have any contraindications to the influenza vaccine, they should not be administered with one. A pharmacist must make sure that the current vaccine is suitable for the patient according to his or her age and health status. To make this sure the informational material that comes along with the vaccine can be consulted. High priority is to be given to people included in high-risk groups and the people providing them care.(55) Table 4 below depicts the groups recommended and contraindicated for influenza vaccine in the United States:

	• Children who are six months to fifty-nine months old • Adults who are fifty and above

Vaccine Recommendations	• Individuals who are suffering from a certain chronic illness
	  ○ Chronic pulmonary disease; namely asthma
	  ○ Chronic cardiovascular diseases; this does not include isolated hypertension
	  ○ Renal diseases
	  ○ Metabolic disorders; namely diabetes mellitus
	  ○ Hepatic disorders
	  ○ Chronic neurologic or hematologic diseases
	• Individuals who, as a result of medications or HIV infections, are immunocompromised
	• Pregnant women; this also includes women who will become pregnant in the course of flu season
	• Individuals 6 months to 18 years of age who are on medications; namely aspirin or which have active ingredients like salicylate. This is because they are at a higher risk of suffering from Reye syndrome associated with Influenza
	• Individuals living in nursing facilities or long-term care homes
	• American Indians/Alaska natives
	• Individuals with a BMI of more than 40 who are adults and obese
	• Individuals who are giving care to and are in close contact with at-risk groups. These includes:
	  ○ Paid or unpaid health care workers who are working in the health sector are at risk of being exposed to influenza even if they are not involved in direct patient care

	○ Household contact and care givers who are giving care to children aged equal to or less than fifty-nine months or less than five years. Especially if they are giving care to children with less than 6 months of age or to adults who are equal to or more than 50 years of age ○ Household contact and care givers of those individuals who have a higher risk of critical health complications associated with influenza
Vaccine Contraindications	• Individuals who have a previous history of getting an allergic reaction from the vaccine itself or any of the excipients within (According to ACIP recommendations, individuals who have egg allergies of any severity can be given flu shots – vaccine informational material within the package is to be consulted) • Children < 6months old. (55)

Table 4 Groups Recommended and Contraindicated for Influenza Vaccine - United States

6. Key Events in Vaccination Process:

In a newspaper article, Authority and scope of vaccination, published in pharmacy times, Xavioer and Goad states different immunization models being followed throughout the country. Three models are being followed in the United States right now i.e. prescription-based, protocol-based, and independent model. In the prescription-based model, the pharmacist as an immunizer needs a prescription from a doctor to provide vaccines to patients coming in pharmacies. The protocol-based model is based on conditions and procedures which can be followed by a pharmacist to vaccinate. In an independent model, a pharmacist can carry out

routine screening and administration of vaccines without the requirement of a prescription or a protocol. Currently, American states are following more than one model simultaneously. (47)

Before immunization at the pharmacy, the patient is given a consent form and is checked for any contraindications to the vaccine. Along with the consent form the patient is also provided with a Vaccine Information Statement (VIS) form. (56) After vaccine administration, the patient is observed for fifteen minutes for any adverse reactions. (57)

6.1. Record Maintenance:

According to the Immunization Action Coalition (2017) by law, a "Vaccine Information Statement" (VIS) must be given to the patient before getting the vaccine. This VIS consists of information giving an overview of the specific vaccine which is to be given to the patient, the disease for which the vaccine is to be used, adverse reactions that can happen post-vaccination, and contact details of the "National Vaccine Injury Compensation Program" and "Vaccine Adverse Event Reporting System".

Vaccine administration information is to be recorded. This includes vaccine administration date, batch code, manufacturer details, details of the person administering the vaccine, date of issue of VIS, and the date it was provided to the patient. Post-vaccination adverse events are to be reported and recorded in the "Vaccine Adverse Event Reporting System (VAERS)" which is a government database. (58) All records are to be maintained for 7 years in general but this period is not fixed and varies with states. (6)

7. Vaccination Uptake and Promotion:

According to Drozd, Miller, Johnsrud (2017) the immunization rates among adults, age 18 years or older, increased from 2003 to 2013. The rate increased from 32.2% in 2003 to almost 40.3% in 2013. There was, however, a drop in 2005 with vaccination rates being 25.3%.

The immunization rate among people aged 18-24 years was 21.8%, whereas, 71.3% rate was observed for people aged ≥75 years. This shows vaccination uptake increased with age among

Americans. An increase in the immunization rates was observed for people with four or more years of education (39.7%) as compared to people without high school education (30.8%). Similarly, the rate of immunization was more among people with an annual income of more than fifteen thousand dollars (32.1%) as compared to people earning more than seventy-five thousand dollars annually (37.7%). Immunization rates were also observed to be twofold in people who had health insurance (38.5%) as compared to those without health insurance (16.2%). (59)

For a successful vaccination program, the USA uses the following strategies to let people know about necessary information regarding vaccinations; Display flyers, signs, and brochures are used to inform the general public about the details of the immunization campaigns. Broadcast news and other prerecorded messages are conveyed to the general public with the help of radio and television. Social media applications like Twitter and Facebook are used to spread the message by utilizing ad campaigns. (60)

8. Vaccine Payments and Reimbursements:

Vaccines are provided free of cost to pharmacies by the Local Health State department. Administration fees can be charged from the patients. Vaccines can also be provided free of cost if it's a jurisdiction requirement or the patient is not able to pay for the vaccination. (56)
As per the 2014 analysis by Puneet K.Singhal and Dongmu Zhang, the cost of the influenza vaccine at the pharmacies was less as compared to what the patient pays at a doctor's clinic. The average cost of the influenza vaccine was found to be 21.57 dollars (17.58 Euros). (61)
Patients either pay for immunization services in the pharmacies or vaccine provision is covered by health insurance. However, they have to pay for the service. (6)
There are several ways through which pharmacists can file a claim for vaccines administered by them. These are Medicare, Medicaid, private insurances, and self-pay and are utilized individually by different states. Pharmacists can claim their dues under pharmaceutical benefits. (56) Medicare part B is used extensively for influenza vaccine reimbursements. It is there since 1993 and reimburses 95% of the average wholesale price of the vaccine. Claimable

payment allowance varies from 9.403 to 60.982 dollars (7.66-49.69 Euros) depending on the brand of the vaccine. (62) To file a claim through Medicare, pharmacists don't require physician approval and can be done without it in most states. (56)

9. Vaccine Adverse Event Reporting and Injury Compensation:

Healthcare providers Service Organization (HPSO), is sponsored by the American Pharmacists Association (APhA) and provides pharmacists with professional liability insurance coverage that covers vaccinations. (63)

Proceeding a flu shot, if an adverse event like anaphylaxis is experienced by an individual the health care professional and the manufacturer of the vaccine must report the event to Vaccine Adverse Event Reporting System (VAERS). VAERS is co-managed by the CDC and FDA and is a system for the collection of reports about adverse reactions occurring after the administration of a vaccine. (57)

To help patients who have experienced an adverse reaction to a vaccine, the federal government of America has two programs in place. The National Vaccine Injury Compensation Program (VICP) and Countermeasure Injury Compensation Program (CICP). The VICP provides financial compensation for medical costs, rehabilitation, special education, pain, suffering, and for the overall harm or injury caused by a vaccine reaction. Parents, guardians, or any legal representative of the affected person can file a claim on the behalf of the person. The CICP provides compensation and help to those individuals who experience serious vaccine reactions. Influenza vaccine is covered by both programs. (64)

Chapter 4 – Australia

1. Legislation:

The National Centre for Immunization Research and Surveillance (NCIRS) (2019) states the years in which immunization by pharmacists was taken up and allowed by Australian jurisdictions. A timeline of jurisdictions allowing pharmacists to vaccinate is as follows:

2013- "Pharmacy Board of Australia" declared that the practice of vaccination at the community pharmacies is within the professional scope of pharmacists. They can practice this role once they undergo a preparatory course certified by the "Australian Pharmacy Council". The actions of a pharmacist during their vaccination practice at the clinical pharmacies must be by the standards set by the Director-General of the Pharmacy Board of Australia.

2014- Western Australia refreshed its laws and permit pharmacists to practice their new role as vaccinators "Poison and Therapeutic Goods Act 1966". **2015-** South Australia refreshed its laws and allowed pharmacists after specific training to vaccinate individuals older than 16 years against the influenza virus. Only those individuals are included to get this service at the pharmacy by a pharmacist who is not entitled to receive influenza vaccine through the National Immunization Program (NIP) "Poison and Therapeutic Goods Act 1966". New South Wales revised its law "Poisons and Therapeutic Goods Regulation 2008" and included pharmacists to vaccinate individuals who are 18 years of age or are older than that at a community pharmacy.

2016- Laws of Northern Territory were revised to include trained pharmacists in the vaccination workforce. They can vaccinate an individual in compliance with the accepted treatment regimen for scheduled substances. "Medicines, Poisons and Therapeutic Goods Act - Pharmacist-Led Administration of Vaccines to Adults at Pharmacy Premises in the Northern Territory – January 2016". Australian Capital Territory authorized pharmacists after specific training to vaccinate individuals (older than 18 years) against influenza without the requirement of a prescription "Medicines, Poisons and Therapeutic Good Regulation 2008, s.352". Queensland let pharmacists practice vaccine provision only after training to individuals (18 years or older) against influenza, pertussis, and measles at a pharmacy "Health (Drugs and

Poisons) Regulation 1996". Tasmania refreshed its laws and permitted pharmacists after proper training to vaccinate individuals (older than 18 years) against influenza virus in an approved setting "Tasmanian Poisons Regulations 2008 (S.R. 2008, No. 162)". Victoria revised its laws and permitted pharmacists to vaccinate patients (18 years or older) against influenza and pertussis "Secretary Approval for Pharmacist Immunizers s.140."(65)

According to NCIRS (May 2020), there is a slight difference in the vaccination legislation across the Australian states and territories. After 2014 all Australian states and territories allowed pharmacists to vaccinate individuals at the pharmacy. In March 2020, all states agreed that the minimum patient age-eligible to receive vaccines at the pharmacy to be >16 years. In few jurisdictions; namely VIC, WA, TAS, QLD, and NSW, pharmacists can vaccinate children aged 10 years or more than 10 years of age at the community pharmacy. (66)

2. Professional Qualifications and Training:

According to NCIRS (2020), Registered pharmacists must practice vaccination services only after completing a training course accredited by "The Australian Pharmacy Council" which also sets Immunization standards to be followed by different course providers for course provision to Australian pharmacists. The standards provided by the council also synchronize with the "National Immunization Education Framework for Health Professionals" created by the "National Immunization Committee".

These standards (set by the Australian Pharmacy Council) and the Framework (provided by the NIC) play a decisive role in concluding a nationally recognized vaccination training program for pharmacists. However, the power remains with the states and territories to decide which course is to be included for further Immunization education of Pharmacists. (66)

Before pharmacists can register for the vaccination training course, they must provide evidence of completed short courses on first aid, cardiopulmonary resuscitation (CPR), and anaphylaxis management.

The course provided by the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia has similar components. One component is an e-learning and must be completed online while the other component is face to face and consists of practical techniques involved in vaccine administration. The main modules included in the online e-learning component of the course are as follows:

- Vaccination background and information
- Disease epidemiology and the diseases that can be avoided through vaccination
- Laws and regulation requirements
- Vaccine related side effects management. (66)

The second component requires pharmacist presence to learn the various techniques of Immunization administration in the practical workshop and includes the following:

- Vaccine administration demonstration
- Learning injection techniques by pairing up with other participants. Participants use saline to practice immunization techniques(67)

A refresher course is required every three years in Northern Territory (NT) and South Australia (SA). For Queensland (QL) based pharmacists, refresher training is required when a pharmacist had not vaccinated in the previous 12 months. Tasmania (TAS) based pharmacists must complete a six-hour refresher course every year. New South Wales (NSW), Australian Capital Territory (ACT), West Australia (WA), and Victoria (VIC) does not have a refresher course requirement for vaccinating pharmacists. (6)

There are two main providers for the vaccination training program for pharmacists. The Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia. The course provided by the two runs in synchronization with each other. (66) The cost of training is as follows:

- The course provided by PSA costs around 560 dollars for PSA members whereas nonmembers pay 680 dollars for the same course. (67)

- The course provided by Guild Australia is for 500 dollars for Guild members whereas nonmembers pay 640 dollars for the course. (68)
- FIP (2019) states that after successful completion of the course pharmacists receive a certificate from course providers(69)

2.1. Undergraduate Pharmacist Training:

According to NCIRS (2020), some Australian jurisdictions i.e. West Australia (WA), Australian Capital Territory (ACT), and New South Wales (NSW) allow both graduate and undergraduate pharmacists to practice vaccinations. However, undergraduate pharmacists can vaccinate, only after receiving mandatory training and under-trained superintendence. In Tasmania students can train for vaccination provision during their studies, however, they are not allowed to practice it. Four Australian jurisdictions; namely South Australia (SA), Northern Territory (NT), Queensland (QL), Victoria (VIC) allow only registered graduate pharmacists for vaccination provision.

2.2. Tools and Resources available to pharmacists:

Some of the necessary tools and resources by PSA available to Australian pharmacists include; Patient screening tool, Guidelines for vaccination provision, Jurisdiction specific Immunization registers, Immunization related webinars(70)

3. Premises Requirements:

The Pharmacy Guild of Australia and guild clinic (2016) says that to guarantee the quality of the vaccination services provided at the pharmacy the “Quality Care Pharmacy Program” provides a checklist to ensure uniformity of pharmaceutical services including a dedicated vaccination room. An audit is conducted every two years to ensure the accredited pharmacies are following the set standards. (71) According to the Pharmacy Guild of Australia (2018), the premises for vaccination should have a separate area with privacy as a priority. This area must have easy access and there should be no interruptions during the vaccination process. There should be a

facility for washing hands in the immunization area. There should be enough space for the patient to lie down in case of an emergency. The area should have seating where the patient can wait for 15 minutes post-vaccination. A fridge, with a maintained temperature, for vaccine storage should be at the premises. The area must have enough light. (72)

Along with these requirements, the area must contain waste disposal equipment, gloves, liquid sanitizers, and an anaphylaxis response kit. An emergency response protocol should also be present within the area where vaccination takes place. A copy of the "Australian Immunization Handbook" and "National Vaccine Storage Guidelines-strive for 5" should be at the premises for consultation. (71)

4. Vaccination Off-Premises:

According to NCIRS (2020), along with vaccinations at the community pharmacies all states of Australia (excluding New South Wales and West Australia) allow pharmacists to vaccinate individuals outside of the pharmacy premises too; for instance, they can vaccinate patients in hospitals, separate pharmacy area or depots where patients collect their medicines, in community, public health, and workplace settings. (66)

According to the Pharmaceutical Society of Australia, the West Australia government (November 2020), and the government of New South Wales (May 2020) has allowed pharmacists to administer a vaccine outside the premises of community pharmacies to protect the most vulnerable and at-risk individuals from influenza. These additional places, where a pharmacist can administer a vaccine, include residential homes, old care settings, community health centers, Aboriginal Medical Services, and private hospitals. (73) (74)

5. National Vaccination Recommendation and Contraindications:

According to the Australian Immunization Handbook, the Influenza vaccine is recommended for a certain group of people. Table 5 represents the groups recommended and contraindicated for influenza vaccine in Australia.

Vaccine Recommendation	• For Infants and children, ≥6 months and <5 years, flu shots are recommended each year
	• Each year flu shots are recommended for Individuals aged ≥65
	• Individuals with Aboriginal and Torres Strait Islander background
	• Individuals who are of 6 months and older with chronic clinical conditions that can cause an increased risk of getting the Influenza virus
	• Pregnant women or women are breastfeeding
	• Individuals included in occupational groups such as
	  ○ Health care employees, household contact, and individuals who provide care to those included in high-risk groups
	  ○ Employees, volunteers, visitors, and individuals living in long term residential homes and age care homes
	  ○ Individuals who are working in pork and poultry industries
	  ○ Individuals who travel during flu season
	  ○ Homeless individuals

Vaccine Contraindications	Individuals with a history of confirmed anaphylactic reaction to a flu vaccine or the contents within the vaccine that are other than ovalbumin. These contents could be any excipient used for vaccine manufacturing. (75)

Table 5 Groups Recommended and Contraindicated for Influenza Vaccine - Australia

6. Key Events In Vaccination Process:

According to the Pharmacy Guild of Australia (2020), Australian pharmacists can vaccinate patients without the requirement of a prescription. (76) The patient, before getting an immunization shot, undergoes a screening procedure in which the pharmacist uses a checklist to determine whether there is any contraindication against a vaccine. Patients get information if they can get the same vaccine for free. A consent form is filled by the patient. Using AIR, the immunization status of a patient is also checked before administering a vaccine. Patients are observed for 15 minutes after getting a vaccine for possible adverse effects. (66)

6.1. Record Maintenance:

According to NCIRS (2020) vaccination records are maintained using software that is merged with the "Australian Immunization Register – AIR" reporting system. To date, there are two such software i.e. "Guildcare NG" and "MedAdvisor". The collected records are shared with AIR. The software is used to maintain the following records:

- The details of the patient i.e. name, residential location, and Medicare number.
- Vaccine related information that includes vaccine details i.e. dose and manufacturing number, time and date of vaccine provision, which brand is used, administration site, and the name of the Immunizer.
- The "Guildcare NG" provides a consent form within the software which, before vaccination, is provided to the incoming patients. The record of the consent form is maintained along with the immunization records. (66)
- FIP (2016) states that the records are kept for 2 years in WA jurisdiction. Whereas, the immunization records in New South Wales, Australian Capital Territory, South Australia, and Tasmania are kept for 7 years. (6)

Any adverse reaction that occurs post-vaccination is to be reported to the health department of the jurisdiction and is also shared with the general practitioner of the patient. (77)

7. Vaccination Uptake and Promotion:

According to Sullivan et al. (2017), Australia's vaccination rates were about 27% across the population in 2017. (78) NCIRS (2020) had recorded the number of pharmacist-led vaccinations forwarded to AIR between 2016 and 2019. It is estimated that around 5.5 per 1000 aboriginals and 22.1 per 1000 non-aboriginals Australians received vaccination from a pharmacist. Whereas according to age groups people aged between 50-59 years have the highest percentage (24.3%) of immunization by a pharmacist. Pharmacist led vaccinations in every Australian jurisdiction has seen an increase with every passing year between 2016 and 2019. (66)

Immunizations in pharmacy are advertised utilizing media like television and radios. Moreover, pharmacies use flyers and posters to advertise pharmacist-based immunization services. (6)

8. Vaccine Payments and Reimbursements:

Pharmacy Guild of Australia (2020) and NCIRS (2020) states that in some jurisdictions namely Australian Capital Territory, Victoria, and Western Australia, pharmacies are incorporated into the National Immunization Program (NIP) and provide vaccine free of cost to individuals aged 65 or older, pregnant women, children aged 6 months and below five years of age, Aboriginal and Torres Strait Islander and individuals aged six months and over with certain medical conditions that increase the chances of getting influenza. Apart from these jurisdictions pharmacies are not included in the NIP. (79) (76)

Individuals living in Australian states other than the Australian Capital Territory, Victoria, and Western Australia must pay a vaccination fee of 19.95-25 dollars (12.63-15.82 Euros) for influenza vaccine at the pharmacy. Pharmacists of Australia do not receive public funding for the vaccines administered. A consultation fee of 10-dollars (6.33 Euros) is charged from the patients. This covers the service provision to both NIP recommended groups and non-NIP recommended individuals regardless of the states in which pharmacies are included in NIP.(80,81)

9. Vaccine Adverse Event Reporting and Injury Compensation:

To practice vaccine provision, the pharmacy must ensure that it has suitable pharmacy indemnity insurance. (71) If an adverse event occurs after vaccine provision it is reported to Therapeutic Goods Administration (TGA) via their online portal. TGA is a regulatory authority and is involved with the supply, import, export, manufacturing, advertising, and assessment of therapeutic goods including vaccines. Both consumers and health professionals including pharmacists can report adverse reactions to the TGA.(82)

Currently, Australia has no compensation scheme for individuals getting rare side effects from a vaccine. The affected person must bear all the vaccine injury-related expenses by themselves. Individuals have access to the public-funded health system but get no compensation for their sufferings. (83)

Chapter 5 – Germany

1. Legislation:

On March 1, 2020, the "*Gesetz für den Schutz vor Masern und zur Stärkung der Impfprävention (Masernschutzgesetz)*" Law to protect against measles and to strengthen vaccination prevention (measles protection law) came into force. Along with measles protection law "*Gesetz zur Stärkung der Vor-Ort-Apotheken (VOSG)- Artikel 1- „§ 132i*" Law to strengthen the on-site pharmacies, came into force on 15th December 2020. According to this law, Section 132i SGB V Germany allows flu vaccinations to be carried out in pharmacies as part of regional model projects. (10)

Under this law Pharmacies, groups of pharmacies, or pharmacists' organizations can form contracts with health insurance companies at the regional level to implement Pharmacy Model Projects for flu vaccinations to be practiced by pharmacists in community pharmacies. The contracts are formed once the requirements, implementation, remuneration, and billing of vaccines, and the vaccination process is considered and agreed upon by both parties. Moreover, an opinion on the content of the contract from the Robert Koch Institute (RKI) and the Paul Ehrlich Institute (PEI) is a requirement.

A pharmacist can practice vaccination provision, under the law, to people over the age of 18 years in the pharmacy if they have first completed a training course and the pharmacy has a suitable room and equipment for this practice. The model projects for flu vaccinations in Germany are limited to five years and have an aim to increase the vaccination uptake in the community .(84)

2. Professional Qualifications and Training:

The German Law to strengthen the on-site pharmacies i.e. *"Gesetz zur Stärkung der Vor-Ort-Apotheken (VOSG)- Artikel 1- „§ 132i"* also states that a pharmacist must undergo a medical training course to practice vaccine provision to patients. This course must equip pharmacists with knowledge, skills, and abilities regarding influenza vaccine administration, communication

with patients, taking consent forms from the patient, vaccine contraindications, and dealing with emergencies following a vaccine administration. (84)

The *Bundesapothekerkammer* (BAK), which is a voluntary association of the 17 regional chambers of pharmacists and is tasked with cooperations between the regional chambers of pharmacists, organizing training events, and setting guidelines for quality assurance in pharmacies has devised a curriculum for pharmacists training by RKI and PEI. This curriculum named "Grippeschutzimpfung in öffentlichen Apotheken – Theorie und Praxis "came into effect on 10 September 2020. It has 5 main modules. Module 1 and 2 can be provided as internet-based, e-learning modules and are to be completed by the pharmacists before participating in modules 3,4, and 5. For module 3,4 and 5 requires the physical presence of the pharmacist and are event-based modules. The total time required to complete the training course is slightly more than 9 hours. At the end of the course, pharmacists must undergo an assessment test. Upon successful completion of the course, pharmacists receive a training completion certificate. The main contents of the curriculum are as follows:

Influenza-Theory (1-hour):

This is a theory-based module and includes important information on the influenza virus, its epidemiology, treatment, prevention, people at risk, and its complications.

"Grippeschutzimpfung-Theory" (2-hours):

The second module consists of STIKO recommendations, which is a standing committee on Vaccination and recommends the use of licensed vaccine nationally, and special patient groups for the influenza vaccine. Moreover, a pharmacist must undergo theoretical knowledge regarding influenza season time slot, influenza types, pharmacology, vaccine reactions, complications, preparation, applications, and influenza vaccine impact on public health.

"Information und Beratung (2-hours)":

In this module, pharmacists undergo a practical information influx regarding vaccine suitability to the patient, how to execute the vaccine process, measures for protection against influenza, treatment, benefits, reactions, and contraindications. They also undergo minor details;

including where to get educational materials in foreign languages, arguments for or against the benefits of vaccinations, and how to take consent forms from patients.

“Durchführung der Impfung (2-hours)”:

In this module, pharmacists undergo theoretical and practical steps involved in the process of vaccination. The module starts with vaccine preparation, then a theory-based part allows them to understand each step in the process including getting the patient in position for the vaccine, selection of injection site, how to give vaccine without pain, and disinfection methods. Then comes the part in which steps after vaccination are to be studied. These include disposal of used material, caring for the patient post-vaccination, post-vaccination reactions or emergency, pharmacovigilance, and documentations.

The fourth module also contains a practical demonstration based on the above-mentioned steps. This includes injection techniques, preparation, selection of injection site, intramuscular injection administration on a dummy or human, and vaccine-related documentation to be maintained at the pharmacy.

“Maßnahmen der Ersten Hilfe bei Impfreaktionen (2-hours) Schwerpunkt: Anaphylaktische Reaktionen, inkl. Schock”:

This module includes the first aid measures in the event of vaccination reaction which is focused on the anaphylactic reactions including anaphylactic shock. Pharmacists undergo emergency plans, managing the emergency including anaphylactic reaction, examining the patient if he or she is conscious following an adverse event and the vitals are functioning, performing the resuscitation, and using ventilation aids. They also undergo steps to be taken to protect themselves if such cases arise. (85), (10)

The cost of the training is to be borne by the participating pharmacists. It is proposed by the BVDAK that every three years there should be a video dependent, e-learning online refresher course. At the end of the refresher course, an online test should be conducted to access continued professional competency. The authority to practice vaccination provision at the pharmacy expires if a refresher course is not passed by a pharmacist. (10)

2.1. Undergraduate Pharmacist Training:

No data were found regarding vaccination administration training for undergraduate students of pharmacy in Germany.

2.2. Tools and Resources available to pharmacists:

ABDA “Bundesvereinigung Deutscher Apothekerverbände” which is the Federal Association of German Pharmacists' Associations, has provided several additional tools and resources available to pharmacists for ease of vaccination process in the pharmacy. There are guidelines to carry out flu vaccinations in public pharmacies, SOPs to help in vaccine administration, working aids like hygiene plan and waste disposal, vaccination certificate, template for declaration of consent are also available at the website of ABDA.(87)

3. Premises Requirements:

In the case of pharmacy premises the German Law to strengthen the on-site pharmacies i.e. “Gesetz zur Stärkung der Vor-Ort-Apotheken (VOSG)- Artikel 1- „§ 132i” states that there should be a suitable private room equipped with necessary apparatus required to carry out vaccination successfully. According to BAK (BundesApothekerKammer), there are certain requirements to be fulfilled by the pharmacies to practice vaccine provision. These include; private room separated from the general working area of the pharmacy with either opaque glass or blinds, the room should meet hygiene requirements, proper sitting area for the patient e.g. couch or chair, writing desk, waste disposal equipment to dispose of sharps, and swabs, a hand basin either in the room itself or close to the room. Moreover, the pharmacist has access to bandages, disinfectants, disposable gloves, and a large refrigerator. Along with these materials, documents like educational material for the patient, consent forms, vaccination certificate forms, and vaccine informational material should be present on the pharmacy premises.

To manage any adverse events in the pharmacy, a pharmacy must have a first aid kit. The first aid kit consists of an H1 antihistamine, two adrenaline auto-injector pens, and an automatic blood pressure monitor. (10) (88)

4. Vaccination Off-Premises Premises:

The German Law "Gesetz zur Stärkung der Vor-Ort-Apotheken (VOSG)- Artikel 1- „§ 132i" came into action to strengthen the on-site pharmacies and to pay pharmacists more for their increased professional scope. According to law, pharmacists in Germany are allowed to practice vaccine provision within the premises of the pharmacy. (84)

5. National Vaccination Recommendation and Contraindications:

The Standing Vaccination Committee of Deutschland (STIKO) has been providing recommendations for the vaccines used nationally. The recommendations and contraindications for the influenza vaccine are the same regardless of the professional person who administers the vaccine. However, in the case of a pharmacist administering a vaccine in the pharmacy, STIKO recommends flu shots to be given to people who have completed their 18 years of age and have no contraindications to the vaccine itself.(10,89) Table 6 represents the recommendations and contraindications for the influenza vaccine by STIKO.

Vaccine Recommendation	• All people who are over 60 years of age • Pregnant women from the second trimester. If they have an underlying disease and have health risks, then they can be given a vaccine from the first trimester. • For people who are suffering from an underlying disease which includes; chronic respiratory, cardiovascular, kidney, or neurological disease. Furthermore, individuals suffering from congenital or acquired immunodeficiency or have HIV. • Individuals living in nursing or retirement homes

	• Individuals living with high-risk patients or sharing the same house or individuals taking care of people at risk of getting influenza. • Individuals who are at high risk of getting influenza due to occupation e.g. medical staff or people who must deal extensively with the public. • Individuals who are in close contact with birds and poultry. • Travelers who are more than 60 years of age and whose vaccination status is not up to date.(10,89)
Vaccine Contraindication	• A vaccine is contraindicated for individuals allergic to the vaccine or any of its components. • Individuals who have experienced an anaphylactic reaction following the oral intake of egg protein. (89) • Individuals who are suffering from an acute illness with a fever (>38.5 degrees Celsius) that requires treatment should not be vaccinated. • Patients taking a blood thinner Marcumar are not to be vaccinated at the pharmacy. • If a patient has a surgical operation within the next three days after the vaccination. (88)

Table 6 Groups Recommended and Contraindicated for Influenza Vaccine - Germany

6. Key Events in Vaccination Process:

Before vaccinating a patient, the pharmacist asks questions from the patient and fills a questionnaire. The purpose of this questionnaire is to screen the patient and access if he or she

belongs to any of the recommended target groups mentioned in “vaccine recommendation from STIKO” or if he or she has a contraindication to the influenza vaccine or its components. Moreover, patient screening also consists of questions to access if the patient has completed his or her 18 years of age, If the patient has statutory health insurance and whether the health insurance company is taking part in the flu Model project. If a vaccine is recommended for the patient, is aged enough, patient’s health insurance is part of the Model project and no contraindication is there, the patient must then sign a consent form “*Einverständniserklärung*” declaring that he or she is willing to be vaccinated by the pharmacist and the patient data collected can be shared with authorities. A copy of the consent form is to be given to the patient. Before the patient can sign the consent form, the pharmacist must educate the patient about the disease and the vaccine easily and clearly so that the patient understands it completely and decide for vaccination. This is achieved with an information sheet “*Aufklärungsmerkblatt*” provided to the patient and contains all the necessary information regarding the disease and the vaccine itself. The pharmacist then prepares the vaccination, administer it, and discard all the waste material. The patient is asked to sit or lie down for at least 15 minutes post-vaccination to observe any symptoms of a vaccine reaction such as dizziness and malaise. Then the pharmacist must prepare documentation which includes filling vaccine details on the vaccination card. If a vaccination card is not available, a vaccination certificate is to be issued by the pharmacist to the patient with details of the vaccine administered. (10,88)

6.1. Record Maintenance:

According to the German law, section 22 IfSG of “Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)” which is the law for the prevention and control of infectious diseases in humans, a pharmacist after vaccinating a patient should write the vaccination details in the vaccination card of the patient. If the patient does not have a vaccination card, then the vaccinator pharmacist should provide a vaccination certificate to the patient. The information on the vaccination certificate is to be entered into the vaccination card when available. The details to be documented on the vaccination card or the certificate consists of the following; date of vaccination, name and batch number of the

vaccine, name of the disease for which the vaccine is being used, name and address of the pharmacy, name, and signature of the vaccinating pharmacist. The record of the consent form and the documentation is to be kept at the pharmacy for 10 years. (88) (90)

7. Vaccination Uptake and Promotion:

According to OECD influenza vaccination rates, in 2001 55.80% of the population, aged 65+ were vaccinated against seasonal influenza in Germany. This percentage increased to 63% in 2005. However, there has been a drop in influenza coverage after 2005 and in 2017, the rate decreased to 34.80%. (91)

The message about vaccinations is also conveyed by mouth, flyers, and posters at the pharmacy. (92)

8. Vaccine Payments and Reimbursements:

The “Bundesverband Deutscher Apothekenkooperationen e.V. (BVDAK)” states in the conceptual framework for the practical implementation of the Flu vaccination in the pharmacy, based on the information from France, GB, and Switzerland, that within the model projects for flu in the pharmacies, only statutory health insured individuals who fall into the recommended people for influenza vaccine are entitled to reimbursements. Other people, who are insured by the statutory health insurance but do not fall in the recommended group must pay out of pocket at the pharmacy and the fee is not reimbursed. The vaccine billing and reimbursement takes place between the pharmacy and the health insurance company taking part in the “Modellprojekt” model project for the influenza vaccine at the pharmacy.

It is recommended by the BVDAK conceptual framework that to make billing easier the participating health insurance companies can send “Gutscheinformulare” i.e. voucher forms upon request from the insured individuals if they fall in the recommended group. These voucher forms can be sent to the patient electronically or by post. The patient can then present it at the pharmacy for a free vaccination.

The BVDAK recommendation states that the total time spent for one complete vaccination process is 12 minutes. Thus, the reimbursement value for pharmacists should reflect an appropriate value in the sense of an imputed hourly wage of a highly qualified medical professional. It is recommended by BVDAK that the pharmacy receives a flat-rate fee of 15 euros plus VAT for the complete service including advice to the patient, vaccination process, documentation, and provision of equipment and material. (10)

The vaccine reimbursement for pharmacists is analogous to vaccine reimbursement to doctors. However, this is dependent on the "Krankenversicherung" health insurance company. The fee reimbursed for the influenza vaccine by insurance companies is different in different cities of Germany. The influenza vaccine fee reimbursed to doctors in Berlin and Hessen is 7.15 euros and 9.43 euros respectively. (93)

The contract between the pharmacies included in the Model project in Lower Saxony, Germany, and AOK has set a reimbursement price for the pharmacist to be 7.37 Euros plus VAT which is the same as for the doctors. The pharmacy is also reimbursed the purchased price of the vaccine plus a surcharge of 1.00 Euro plus VAT per vaccine. Besides, 4.66 Euros plus VAT per vaccination is reimbursed to the pharmacy for the collection of data which is used for project evaluation at the AOK Scientific Institute. (94)

The contract signed between North Rhein Pharmacists Association (AVNR) and AOK Rhineland/ Hamburg agreed on the flat fee per vaccine to be 12.61 excluding VAT. With VAT added, the fee increases. (92,95)

9. Adverse Event Reporting and Injury Compensation:

To manage post-vaccination adverse events like anaphylaxis, the pharmacists should follow a written emergency plan and perform first aid measures. The adverse events are to be reported to the "Arzneimittelkommission der Deutschen Apotheker (AMK)" which is the Drug Commission of the German Pharmacists. AMK is an institute of ABDA "Bundesvereinigung Deutscher Apothekerverbände" which is the Federal Association of German Pharmacists'

Associations. AMK records the risks associated with pharmaceutical practice and evaluates drug quality, side effects, and other drug risks.(96,97)

In case of injury the pharmacist, who administered the vaccine, should be notified. If the health damage caused by the vaccine is beyond the usual vaccine reactions, then the pharmacist must forward the case to AMK. According to "Bundesversorgungsgesetzes (§ 60 Abs. 1 IfSG)" Federal Supply Act of Germany, the patient has the right to claim compensation to cater to the disability caused. The claims can be filed in the responsible pension office, which are the authorities responsible for the implementation of the Federal Supply Act.(98,99) The first vaccine injury compensation scheme was introduced by Germany in 1961 and covers all the recommended vaccines for adults and children. The person who has experienced a vaccine reaction is compensated for its related Medical costs, disability pension, and funeral costs. (100)

BVDAK conceptual framework recommends that it should be the responsibility of every pharmacist taking part in the flu model projects to get themselves insured with health insurance that provides suitable and enough coverage in case of vaccine provision as increased professional scope. Insurance offers, that covers the pharmaceutical field of activity including vaccination, are available in the German Market. (10)

According to "*versicherungsmagazin*", Alte Leipziger Versicherung AG extends professional liability for pharmacists. With the enhanced scope of practice, Alte Leipziger health insurance company has adapted to this new scope of vaccine provision by the pharmacists and has devised professional liability insurance accordingly. (101)

Chapter 6:

Comparison of Countries in Tables Concerning topics:

This section contains the comparison of countries in the form of topic-specific summaries and key points observed in the literature review.

1. Legislation:

The topic legislation for all countries is summarized in the table below. Table: 7-8, show all five countries with the summary of the topic and key points observed in the review.

Legislation	**Ireland (IR):** Pharmacists are allowed by law to practice vaccination provisions since 2011. The Minimum Eligible age to get a flu shot from a pharmacist is 6 months. (14,15)
	Great Britain (GB): Pharmacists are allowed by law to administer influenza vaccines since 2015. The minimum eligible age to get a flu shot at the pharmacy is 18 years or older. (28)
	United States (US): Pharmacists are vaccinating patients against influenza since 1984. By 2009 all 52 states allowed pharmacists to vaccinate patients against influenza. The minimum eligible age for a patient to get vaccinated by a pharmacist is different in different states of America. (6,45)
	Australia (AUS): Pharmacists are allowed by law to practice vaccine provision since 2013. By 2016 all major states and territories included pharmacists in the vaccination workforce. By March 2020 all states agreed on the minimum patient age, eligible for vaccination by a pharmacist, to be >16 years. However, pharmacists in VIC, WA, TAS, QLD, and NSW can vaccinate patients who are 10 years of age. (65) (66)
	Germany (GER): Pharmacists are allowed by law to vaccinate patients against influenza since December 2020 n the form of model pharmacy projects meant for 5 years. Patients who have completed 18 years of life are eligible to get a flu shot from a pharmacist. (10,84)

Table 7 Country comparison by Legislation

Key Findings	IR	GB	USA	AUS	GER
Pharmacists are allowed, by law, to vaccinate patients against Influenza	Yes	Yes	Yes	Yes	Yes
The minimum age a patient can be vaccinated at the pharmacy	6 months	18 years	3 years to any age group (Varies by state)	>16 years	>18 years

Table 8 key findings of Country comparison by Legislation

2. Professional Qualifications and Training:

The topic of professional qualifications and training for all countries is summarized in the table below. Table: 9-10, show all five countries with the summary of the topic and key points observed in the review.

Professional Qualification and Training	**Ireland:** The training course is mandatory and is a blend of both e-learning and face to face modules. It covers patient assessment, vaccine preparation and administration, reanimation, and dealing with an emergency. Courses like CPR (Duration: not mentioned, Course validity: two years), RESMA (Duration: 4-hours, Course validity: two years), and PAMT (Duration: full day, Course validity: To be repeated if not vaccinated a patient in 12 months) are pre-requisites for The Administration of Influenza Vaccine Training Program (Duration: 2-hours, Course validity: to be repeated every influenza season or when not vaccinated a patient in last 12 months). On completion of all requirements of the training course, a certificate is given to the pharmacist. A self-declaration form is to be completed every year. Additional tools and resources like guidelines are available and are consulted when required. Vaccination training for undergraduate pharmacy students is still under discussion. (6), (16), (17), (18), (19), (21)

Professional Qualification and Training **(continued)**	**GB:** The training course is mandatory, and DOC must be signed every two years to ensure continuity of the practice. The course contains both face to face and e-learning modules and covers patient communication, policies, and legalities surrounding vaccines, information on the disease and vaccine, administration, strategies to increase vaccine uptake, ADR and emergency management, record maintenance, and documentation. A certificate of competency is issued on successful completion of the course. Course validity is three years. Its Duration is not mentioned. Additional resources and material are available for continued learning. No data was found on vaccination training for Undergraduate pharmacy students. (28), (29), (30)
	United States: Training is compulsory and consists of e-Learning modules (duration 12-hours, validity: certificate does not expire) and live seminar (duration 8-hours, validity: certificate does not expire). The course consists of information on vaccines, vaccine-preventable diseases, pharmacist's role, patient care, immunology, setting a pharmacy for vaccination services, strategies for more vaccine uptake; and complete vaccination process including patient communication, vaccine administration, safety, and adverse vaccine reaction management. On a successful course, the completion of pharmacist gets a certificate. The certificate is valid if evidence of CPR or BCLS course is present. Training is to be repeated every year for 1-2 hours. 47 states have allowed undergraduate students to vaccinate adults with exceptions to PR, NJ, NH, and NY. Additional tools and resources are available to pharmacists for continued learning. (6), (46), (47), (48), (49)
	Australia: First aid, CPR, and anaphylaxis management are pre-requirement for the mandatory training course. Training consists of both e-learning and face to face modules. The course comprises information on vaccines, preventable diseases, laws around vaccines, administration, and adverse reaction management. Successful course completion results in certificate provision. Refresher course: Every three years for NT and SA, for QL if a pharmacist has not vaccinated a person in 12 months, for TAS every year, for NSW, ACT, WA, and VIC no requirement for a refresher course. Undergraduate training for pharmacy students and vaccine administration allowed in WA, ACT, and NSW only. TAS only trains undergraduate students for vaccine provision. Additional tools and resources are available to pharmacists for continued learning. (6), (66), (67), (68), (69), (70)
	Germany: The training course is compulsory, which consists of 5 modules as a blend of e-learning and face to face modules. The duration, of course, is 9 hours. The course ends with a test and a certificate is provided who complete it. The course covers knowledge on disease and vaccine, patient assessment and communication, complete vaccination process, and

	adverse reaction management. Refresher course every three years is recommended. Additional tools and resources are available for continued learning. No data on undergraduate student training was found. (10), (84), (85), (86)

Table 9 Country comparison by Professional Qualifications and Training

Key Findings	IR	GB	USA	AUS	GER
Training is mandatory for vaccine provision by a pharmacist	Yes	Yes	Yes	Yes	Yes
The training course consists of both E-learning and Face to Face learning	Yes	Yes	Yes	Yes	Yes
The training is to be repeated every…	**CPR:** 2 years **RESMA:** 2 years **PAMT:** When not vaccinated a patient in 12 months **Administration of Influenza Vaccine Training Program:** Every season or When not vaccinated a patient in 12 months	3 years	Every year	NT, SA: 3 years QL: When not vaccinated a patient in 12 months TAS: Every year NSW, ACT, WA, VIC: no course repetition	3 years (BVDAK)
Successful training completion results in certificate provision	Yes	Yes	Yes	Yes	Yes
Additional tools and resources are available for continuous reference and learning	Yes	Yes	Yes	Yes	Yes
Undergraduate pharmacists can practice vaccine administration	Under discussion	No Data found	Yes, in 47 states except for PR, NJ, NH, and NY	Yes, in WA, ACT, and NSW only. TAS only allow training	No Data found

Table 10 Key Findings of Country comparison by Professional Qualifications and Training

3. Premises Requirements:

The topic premises requirements for all countries are summarized in the table below. Table: 11-12, show all five countries with the summary of the topic and key points observed in the review.

Premises Requirements	**Ireland:** Minimum requirements for flu vaccination provision include a private consultation area providing easy workflow, proper seating for a patient and accompanying person, hygiene measures, refrigerator, equipment for infection control management and vaccine reaction management, and documentation. (16)
	GB: Minimum requirements include a private consultation room with proper seating for the patient and the accompanying person. Along with hygiene measures, standards for infection control should be maintained. Other equipment includes a refrigerator and equipment to manage vaccine reactions and necessary documents. (28), (31), (32)
	United States: Minimum requirements for vaccine provision in the pharmacy include a waiting area, semi-private vaccination area providing easy workflow, refrigerator, hygiene facilities, emergency supplies, infection control standards, and necessary documents. (50), (51), (52)
Premises Requirements **(continued)**	**Australia:** Minimum requirements include A separate private area with enough light, easy access, and workflow, refrigerator, place to sit and lie down, hygiene and infection control management, equipment to deal with emergency and necessary documents. (71), (72)
	Germany: Minimum requirements include a private room with a couch, hygiene facilities, infection control management, refrigerator, necessary documents, and supplies to manage adverse vaccine reactions. (10), (87)

Table 11 Country comparison by Premises Requirements

Key Findings	IR	GB	USA	AUS	GER
A private room must be available for vaccine provision	Yes	Yes	No, only semi-private room	Yes	Yes
Easy workflow is ensured	Yes	Not Mentioned	Yes	Yes	Not Mentioned
Proper seating is available	Yes	Yes	Yes, but only in the waiting area	Yes	Yes
Refrigerator for proper vaccine storage is ensured	Yes	Yes	Yes	Yes	Yes
Equipment to ensure hygiene is ensured	Yes	Yes	Yes	Yes	Yes
Infectious control measures are in place	Yes	Yes	Yes	Yes	Yes
Supplies to manage vaccine reactions are in place	Yes	Yes	Yes	Yes	Yes

Table 12 Key Findings of Country comparison by Premises Requirements

4. Vaccination Off-Premises:

The topic of vaccination off-premises for all countries are summarized in the table below. Table: 13-14, show all five countries with the summary of the topic and key points observed in the review.

Vaccination Off-Premises	**Ireland:** Pharmacists can vaccinate patients outside the general pharmacy premises. It can be a patient's home, residential care homes, or community halls. However, pharmacists must fully equip themselves, they must stick to a strict code of conduct and follow PSI guidelines. Similar standards as to those on the pharmacy premises are maintained to ensure service quality and patient safety. (22)
	GB: Pharmacists can vaccinate patients outside the general pharmacy premises. It can be the patient's home, residential care homes, and other community places. The pharmacists must be fully equipped, and the service must be in line with the service specifications by NHS and PSNC. (28), (33)
	United States: Pharmacists can vaccinate patients outside the general pharmacy premises in a small- or large-scale immunization event conducted by the pharmacy. However, the service must be according to checklists provided by APhA. (53), (54)
	Australia: All Australian states allow pharmacists to vaccinate patients outside the general pharmacy premises. These areas include hospitals, residential care homes, old care settings, Aboriginal Medical Service areas, separate pharmacy areas, depots where patients collect their medicines, community health centers, public health, and workplace settings. (66), (73), (74)
	Germany: According to law, pharmacists in Germany can practice vaccine provision within the premises of the pharmacy. (84)

Table 13 Country comparison by Vaccination Off-Premises

Key Findings	IR	GB	USA	AUS	GER
Pharmacists can vaccinate patients at places other than the pharmacy premises	Yes	Yes	Yes	Yes	No

Table 14 Key Findings of Country comparison by Vaccination Off-Premises

5. Vaccine Recommendations and Contraindications:

The topic premises requirements for all countries are summarized in the table below. Table: 15-16, show all five countries with the summary of the topic and key points observed in the review.

Vaccine Recommendations and Contraindications	**Ireland:** Influenza vaccine is recommended for: 65 years and above, pregnant women, children (2-12 years), chronically ill patients (6-23 months old and 12-64 years old), obese (BMI>40), long term aspirin users (children), people staying in the long term or nursing homes, carers, people in close contact with poultry, pigs and waterfowl. Exceptions: those who have a history of anaphylaxis or are allergic to vaccine contents, who are at risk of immune-related reactions to the vaccine, individuals suffering from neutropenia (<0.5 x 10^9/L). (23)
	GB: Influenza vaccine is recommended for: 65 and above, 18-65 year old with chronic illness, obese (BMI>40), pregnant women, people living in long-stay or nursing homes, carers, or people who live or are in close contact with at-risk individuals, health and social care workers. (34) Exceptions: who are less than 18 years of age, history of an anaphylactic reaction, who already got their flu shot for the season, people suffering from acute severe febrile illness.
	United States: Influenza vaccine is recommended for: children (6-59 months old), adults (50 and above), chronically ill patients, immunocompromised patients, pregnant women, individuals on long term aspirin use (6 months-18 years old), living in nursing or old age homes, American Indians/Alaska natives, obese (BMI>40), carers and individuals working in the health sector. Exceptions: a history of anaphylaxis or reaction to any vaccine contents (not egg protein), children <6 months. (55)
	Australia: Influenza vaccine is recommended for: Children (≥6 months and <5 years), people aged ≥65, individuals with chronic illness, pregnant women, carers, healthcare workers, people living in long-term residential homes, who work in pork and poultry industries, who travel during flu season, and Homeless individuals. Exceptions: Those who have a history of anaphylaxis reaction to the vaccine or its components. (75)

Vaccine Recommendations and Contraindications (continued)	**Germany:** Influenza vaccine is recommended for: 60 years and above, pregnant women, chronically ill patients, living in nursing or retirement homes, carers, healthcare staff, who work with birds and poultry, and travelers. Exceptions: who are allergic to vaccine components or who have a history of anaphylaxis reaction after intake of egg protein, fever (>38.5 degree Celsius), who are taking a blood thinner, who have a surgical operation within three days of vaccine shot. (10), (87), (88)

Table 15 Country comparison by Vaccine Recommendations and Contraindications

Key Findings	IR	GB	USA	AUS	GER
Influenza Vaccine recommendation and contraindications are in place	Yes	Yes	Yes	Yes	Yes

Table 16 Key Findings of Country comparison by Vaccine Recommendations and Contraindications

6. Key Events In Vaccination Process:

The topic of key events in the vaccination process, for all countries, is summarized in the table below. Table: 17-18, show all five countries with the summary of the topic and key points observed in the review.

Key Events in Vaccination Process	**Ireland:** Vaccinations are carried out without the need of a prescription. The patient undergoes screening for contraindications and a consent form is taken before vaccine provision. Post-vaccination, the patient is observed for vaccine-related reactions for 15 minutes. Vaccination records are maintained and kept for 2 years on the premises and stored confidentially for further 6 years. (14), (16), (6)
	GB: Vaccination provision requires a prescription. The patient is screened and a consent form is taken. Patients do not have to wait after getting the flu shot. Records are maintained and are kept for 10 years. (6), (28), (35), (36), (37)

Key Events in Vaccination Process (continued)	**United States:** Different immunization models are followed throughout the country. Prescription based, protocol-based, and independent model. Before flu shot provision by the pharmacist, the patient is screened for contraindications, the consent form is taken from the patient, and VIS is provided to the patient. Post-vaccination, the patient is observed for 15 minutes. Records are maintained and kept for 7 years, which varies by state. (6), (47), (56), (57), (58)
	Australia: Vaccinations at the pharmacy do not require a prescription. Before vaccination takes place, the patient is screed for contraindications, and a consent form is taken from the patient. Post-vaccination, the patient is observed for 15 minutes. Records are maintained and are kept for 2 years in WA; while they are kept for 7 years in NSW, ACT, SA and TAS. (6), (66), (76), (77)
	Germany: The requirement for Vaccine provision to patients in Modell Project is based on whether the patient is 18 or more, has statutory health insurance, and if the health insurance is taking part in the Model Project. Before vaccination provision, the patient is screened for contraindications, and consent is taken. Post-vaccination, the patient is observed for 15 minutes. Records are maintained and are kept for 10 years. (10), (87), (89)

Table 17 Country comparison by Key Events in Vaccination Process

Key Findings	IR	GB	USA	AUS	GER
Vaccination provision in pharmacy is prescription dependent	No	Yes	Yes, in some states. Other models include the protocol and independent models.	No	No, depends on the patient's age and health insurance
The patient is screened for contraindications before vaccine administration	Yes	Yes	Yes	Yes	Yes

Patients consent is taken before vaccine administration	Yes	Yes	Yes	Yes	Yes
Post vaccination patient is observed for 15 minutes for any vaccine related reactions	Yes	No	Yes	Yes	Yes
Vaccination records are kept and maintained in the pharmacy	Yes	Yes	Yes	Yes	Yes
Records are kept for…	2 years on-premises, further 6 years confidentially	10 years	7 years (varies by state)	WA: 2 years NSW, ACT, SA, and TAS: 7 years	10 years

Table 18 Key Findings of Country comparison by Key Events in Vaccination Process

7. Vaccination Uptake and Promotion:

The topic of vaccination uptake and promotion for all countries is summarized in the table below. Table: 19-20, show all five countries with the summary of the topic and key points observed in the review.

Vaccination Uptake and Promotion	**Ireland:** Since pharmacists started to vaccinate, overall vaccination uptake increased by 59.5%. Pharmacies account for 16% of the overall vaccinations (2020). To promote vaccinations at the pharmacy leaflets, posters, radio ads are utilized. (24), (6)
	GB: Mixed data observed for the GB. Two studies show an increase in vaccine uptake (6.2%), Two studies show neither increase nor decrease in uptake, three studies show a decrease in vaccination uptake by 1.1-3%.(40). **In-** 2018/2019 flu season, pharmacists of the GB managed to vaccinate almost 1.4 million people.

	Immunization promotion strategies include posters, brochures, Promotion through Instagram, and Twitter. (6), (38), (39), (40), (41)
	United States: Vaccination coverage among people aged 65 years or older increased up to 10.7% between 1995-1999. Among adults, age 18 years or older, uptake increased between 2003 to 2013. The immunization uptake increased from 32.2% in 2003 to almost 40.3% in 2013 (8.1% increase). There was a drop in 2005 with vaccination rates being 25.3%. Immunization promotion strategies include Display flyers, signs and brochures, Broadcast news, Pre-recorded messages on radio and TV, Social media promotion through Facebook and Twitter. (59), (60)
	Australia: Around 5.5 per 1000 aboriginals and 22.1 per 1000 non-aboriginals Australians received vaccination from a pharmacist. Pharmacist lead vaccinations in every Australian jurisdiction has seen an increase with every passing year between 2016 and 2019. Immunization promotion strategies include advertisements through TV and Radio, Flyers, and posters. (6), (66), (78)
	Germany: The 2017 Influenza vaccine rate in Germany is 34.80%. Immunization promotion strategies include Word of mouth, flyers, and posters. (90), (91)

Table 19 Country comparison by Vaccination Uptake and Promotion

Key Findings	IR	GB	USA	AUS	GER
Since pharmacists started to vaccinate, overall vaccination uptake increased in the general population	Yes	Mixed data observed	Yes	Yes	No Data Found
Conventional media utilized to promote vaccinations at the pharmacy	Yes	Yes	Yes	Yes	Yes
Social media utilized to promote vaccinations at the pharmacy	No	Yes	Yes	No	No

Table 20 Key Findings of Country comparison by Vaccination Uptake and Promotion

8. Vaccine Payments and Reimbursements:

The topic of vaccine payments and reimbursements, for all countries, is summarized in the table below. Table: 21-22, show all five countries with the summary of the topic and key points observed in the review.

Vaccine Payments and Reimbursements	**Ireland:** Patients included in HSE recommended group gets free vaccines. Others pay about 20 Euros. Pharmacists are reimbursed 15 (QIV)-20 (LAIV) Euros per vaccine administered through Primary Care Reimbursement Service (PCRS) which is part of the Health Service Executive (HSE). Pharmacy contractors receive 100 (QIV)-150 (LAIV) Euros per 10 patients (age 2-12 years). (25), (26), (6)
	GB: Patients get free flu shots if they fall into the NHS recommended group. Otherwise, they pay between 9.99-13 Pounds (11.03-14.35 Euros). Pharmacists are reimbursed 10.08 Pounds (11.14 Euros) per vaccine through Manage your service platform offered by NHSBSA. Up to 200 pounds (for 5 or more times) can be claimable for additional venues utilized for vaccination purposes by the pharmacy. (6), (10), (28), (42)
	United States: Patients either pay for a flu shot (16.30-32.60 Euros) or the service is covered by the health insurance (patient pays only service fee). Pharmacists can claim reimbursements through Medicare Part B and receives 7.66-49.69 Euros depending on the brand used. (6), (56), (61), (62)
	Australia: Pharmacies in ACT, VIC, and WA are included in NIP and offer free vaccinations to the recommended group they only pay for the service, not the vaccine. Patients living in other states where pharmacies are not incorporated in NIP pay 12.63-15.82 Euros plus 6.33 Euros for the service. Pharmacists of Australia do not receive public funding for the vaccines administered. (76), (79), (80), (81)
	Germany: Free vaccines for people with statutory health insurance (taking part in the flu model project) and falls in the STIKO recommended group. Others must pay out of pocket for the vaccine and the service. The vaccine and the service offered by pharmacists are reimbursable. The reimbursable fee for pharmacists is different in different regions of Germany and lies between 7.37-12.61 Euros. BVDAK recommends a flat reimbursable fee of 15 Euros plus VAT per vaccination. For effective reimbursement, voucher forms are recommended by BVDAK. (10), (91), (92), (93), (94)

Table 21 Country comparison by Vaccine Payments and Reimbursements

Key Findings	IR	GB	USA	AUS	GER
Influenza Vaccine is free for recommended groups	Yes, by HSE	Yes, by NHS	Yes, through health insurance companies	Yes, but only in ACT, VIC, WA	Yes, covered by health insurance
Patients must pay for their vaccines	Yes, if not in HSE recommended group	Yes, if not in the NHS recommended group	Yes, patients without health insurance	Yes, at pharmacies excluded from NIP	Yes, if not in STIKO recommended group or patients without health insurance
Reimbursement system for vaccines is present	Yes	Yes	Yes	No	Yes

Table 22 Key Findings of Country comparison by Vaccine Payments and Reimbursements

9. Adverse Event Reporting and Injury Compensation:

The topic of adverse event reporting and injury compensation, for all countries, is summarized in the table below. Table: 23-24, show all five countries with the summary of the topic and key points observed in the review.

Adverse Event Reporting and Injury Compensation	**Ireland:** Appropriate professional indemnity for pharmacists is in place. Vaccine adverse events are reported to HPRA. Patients are compensated for the damage caused by the vaccine. (16) (27)
	GB: NHS stands responsible for the protection and liability of the practitioner. Vaccine reactions are reported to MHRA. Patients can be compensated for the damage caused by the vaccine. The compensation could be as high as 120,000 British Pounds. (43), (44)
	United States: Professional liability insurance is present for pharmacists. Vaccine adverse reactions are reported to VAERS. Patients can be compensated for the damage caused by vaccines through VICP and CICP. (57), (63), (64)

	Australia: Pharmacists indemnity insurance is in place. Adverse reactions are reported to TGA. No compensation is granted to patients who suffer damage from the vaccine. The affected person must bear all costs. (71), (82), (83)
	Germany: Pharmacists indemnity insurance, which covers vaccine provision, is present and it is the responsibility of the pharmacist to get insured. Vaccine reactions are reported to AMK. Germany is the first country to introduce a compensation scheme (1961) for patients who suffer damage by the vaccine. (10), (95), (96), (99), (100)

Table 23 Country comparison by Adverse Event Reporting and Injury Compensation

Key Findings	IR	GB	USA	AUS	GER
Professional Indemnity insurance for pharmacists is present	Yes	Yes	Yes	Yes	Yes
Vaccine reactions are reported	Yes	Yes	Yes	Yes	Yes
Patients are compensated for harm caused by a vaccine reaction	Yes	Yes	Yes	No	Yes

Table 24 Key Findings of Country comparison by Adverse Event Reporting and Injury Compensation

Discussions:

Pharmacists of Germany were recently been allowed by law to administer influenza vaccine to individuals at the pharmacy. For this, Model Projects between pharmacies and health insurance companies were started on a small scale in Germany. With the help of the literature country protocols were compared and assessed. The components that make up the system for vaccine provision were compared.

It can be inferred from the results that in all five countries pharmacists are allowed by law to vaccinate individuals against the Influenza virus. It can be observed that in Ireland and America individuals as young as 6 months and 3 years respectively are being vaccinated at a pharmacy. Both these countries have seen an uptake in vaccination rate. However, In Germany, pharmacies included in the flu Model Project are vaccinating individuals who have completed their 18 years of age intending to increase vaccination uptake among the general population. Including younger cohorts as in Ireland and America could broaden the population access to pharmacies which could be influential to vaccination uptake in Germany.

In all countries, including Germany, a preparatory course for pharmacists is mandatory to practice vaccine administration. This equips them with the necessary knowledge about the vaccination process, administration, and dealing with emergencies. Moreover, the training curriculum for all countries has both e-learning and face to face learning. Once the training is completed certificate is provided to pharmacists and additional tools and resources for future reference and continued learning are made available to pharmacists by all countries.

The time to refresh training is different in all countries. Based on results it is observed that in four Australian jurisdictions i.e. NSW, ACT, WA, and VIC there is no need for repetition of the training course by pharmacists. Whereas Ireland and the USA have a similar recommendation for their main training course. They recommend the course be repeated every season (every year in the USA) or when a pharmacist has not vaccinated a patient in 12 months. For Germany, however, it is recommended by BVDAK, based on studies on Switzerland, France, and Great Britain, that the training be repeated every 3 years.

Since training provides pharmacists with the required skills and knowledge to administer vaccines safely and effectively.(21) It can be inferred that if pharmacists do not vaccinate a patient in 12 months, the ability, skill, or confidence to administer a vaccine safely could be at stake. Thus, repeating a course yearly could impact positively the confidence, skill, or ability of the pharmacist to vaccinate. It could be learned from Ireland, where 16% of the overall influenza vaccinations are taking place at the pharmacies (2020), and America, where an 8.1% increase in vaccination uptake was seen between 2003-2013. Both countries have seen an improvement in vaccination uptake. Both countries have a course repetition every year (in Ireland every season).

Undergraduate pharmacy students can vaccinate under supervision in 47 American states and 3 Australian states. Since incorporating immunization course in the pharmacy curriculum is not new in America and Australia and has resulted in increased knowledge, skills, and confidence of students. It also equips students with practicalities of vaccination provision and aligns the skills gained during graduation time with the increased professional scope of pharmacy practice. Pharmacy students receiving vaccination training can increase the immunization workforce and can contribute to vaccinating children and adults. (102,103) Vaccination training could be incorporated into the pharmacy curriculum in Germany to prepare undergraduates for the emerging role of pharmacists.

Premises requirements include the necessary equipment, measures, and practices that account for a timely, safe, and comfortable vaccine administration at the pharmacy. For Germany, SOPs by BAK must be followed. It can be inferred from the literature results that, apart from ease of workflow, the SOPs provided by BAK has the necessary components for a successful flu campaign at a German pharmacy. Patient privacy is of utmost importance and, inferred from results, is being followed by all countries including Germany except for America which requires only a semiprivate room for vaccine provision.

In all the countries, excluding Germany, pharmacists can vaccinate individuals outside the general pharmacy area. They can vaccinate individuals at places like homes, hospitals, community places, as in Ireland, Great Britain and Australia or pharmacies can even host small

to large scale immunization events as in America. Since Germany has an intention to increase vaccination uptake which is evident from the legislation. Allowing pharmacists to vaccinate patients outside the premises of the pharmacy could result in increased access to influenza vaccine to vulnerable and at-risk patients and could affect the overall influenza vaccine uptake.

The results provide an insight into the key events involved in a vaccination process in pharmacies of included countries. In all countries, including Germany, the patient is screened for contraindications to the vaccine and a signed consent form is taken from patients before the vaccine is administered. Vaccination records are being maintained by all countries. All countries, except Great Britain, observe the patient for at least 15 minutes for rare but harmful reactions to the influenza vaccine. Although vaccine reactions could take place within 2 minutes after the administration, Germany has a recommendation for 15 minutes. This time is appropriate to observe for a reaction and to manage it accordingly as it is being practiced in other countries.

Through literature, it is observed that the overall vaccination uptake in respective countries, excluding Great Britain and Germany, increased as pharmacists begin to practice vaccination administration. This could be since pharmacies are easy to access and saves patient time as compared to vaccination carried out at clinics. A typical vaccination visit to a clinic is of 45 minutes on average which is three to almost fourfold the time required for vaccination at the pharmacy i.e. 12 minutes.(10)

Great Britain has mixed results with some studies pointing towards an increase in the vaccination uptake while others conclude a decrease. However, in the 2018/19 Influenza season, pharmacists of Great Britain vaccinated approximately 1.4 million people. Given that the total population of Great Britain is 66.65 million. 1.4 million people make a total of 2.1% of the population. Hence it can be inferred that pharmacists in Great Britain vaccinated 2.1% of the overall community in the 2018/2019 season alone. This, however, is below Ireland where pharmacists account for almost 16% of the overall vaccinations in 2020 alone. This percentage of people being vaccinated at pharmacies of Ireland is greater than observed for any other country included in the study. America comes second to Ireland with an 8.1% increase seen

among 18 years or older patients between 2003-2013. Germany, on the other hand, has only started flu vaccination at pharmacies included in model projects and thus data regarding the influence of pharmacists on vaccination uptake is not present.

All five countries utilize conventional media to promote vaccinations at pharmacies. However, social media is utilized by only Great Britain and America. Out of the total population of Germany (83.02 Million), there are 77.79 million internet users. Out of these 77.79 million people, 38 million people use social media. (104) Hence utilizing the ad campaigns of social media networks could impact public awareness of the fact that pharmacies have started vaccination services which could increase pharmacy visits for vaccinations.

The results give an insight into Influenza vaccine recommendations and contraindications. In all five countries, the general recommendations and contraindications for the Influenza vaccine are present. Free vaccines for recommended groups are being provided by HSE, NHS in Ireland, and Great Britain or are covered by health insurance companies as in America and Germany respectively. Only those patients who pay for the vaccine and the service are either not included in HSE, NHS recommendations (Ireland and Great Britain), or who don't have health insurance covering vaccines (America and Germany). Though vaccines are free for recommended people in Australia, however, the patient can only access free vaccines in jurisdictions where pharmacies are incorporated in NIP.

In all countries, except for Australia, reimbursement systems are present where pharmacists can file a claim for either the vaccine itself or for the vaccination process. Pharmacists in Australia do not have a reimbursement system and do not receive any public funding for vaccines.

It could be deduced from the results that all countries ensure professional indemnity insurance for pharmacists. Vaccination reactions are to be reported to relative authorities which are present in all countries included in the study. It is important to note that Germany is the first country to have introduced a compensation scheme for individuals affected by a vaccine (1961). Whereas, Australia has no compensation scheme for people who experience harm by vaccine and must pay relative expenses out of pocket.

Except for certain indirect elements that provide no hindrance to vaccine provision and which could be focused on, important components of the system are observed to be present in Germany. Germany has the main elements required for vaccine provision within the pharmacy premises. The system of Germany is providing pharmacists with training courses for vaccine administration (BAK); helping material for reference and SOPs for premises and equipment (BAK); influenza vaccine recommendations and contraindications (STIKO); vaccine reimbursement system (Health Insurance Companies), and vaccine reaction reporting (AMK). Moreover, it is the first country with an injury compensation scheme. These elements equip pharmacists for a successful flu vaccine administration in pharmacies. The gaps which could be worked on by Germany are; integration of younger cohorts to access pharmacies for their vaccination, integration of pharmacist training in undergraduate pharmacy course, permission to vaccinate individuals off pharmacy premises, social media usage for public awareness as illustrated by results. Since the system of Germany has required elements to carry out successful vaccinations at the pharmacy premises through the pharmacist. Hence the German system is capable of empowering pharmacists as immunizers.

Limitations

Though the literature review illustrates a novel study comparing systematic approach, regarding vaccination services by pharmacists, of five countries; it is still subjected to several limitations: (1) The studies included were mostly grey literature comprising of government, health department, or pharmaceutical association released pdfs, compilations and reports. This is subjected to a lack of topic related published studies in reputable journals; (2) The review was limited to studies around influenza vaccine and pharmacists only.

Conclusion:

In a nutshell, several opportunities are evident from results and could be focused on by Germany. Apart from patient's age accessible to the pharmacy for vaccination, undergraduate training, social media usage for awareness purposes, and vaccine administration limited to only pharmacy premises; Germany has necessary protocols, elements, and components that make up the system meant for an organized, systematic provision of vaccines at pharmacy premises

through the pharmacist. The system has provided pharmacists with the required components for the new scope of practice and thus the current system is capable of empowering pharmacists as immunizers.

References:

1. Nissen L, Poudel A, Lau E, Deldot M, Campbell C, Waite N, et al. Pharmacist role in vaccination: Evidence and challenges. Vaccine. 2019 Aug 1;37.

2. Rößler S, Ankert J, Baier M, Pletz MW, Hagel S. Influenza-associated in-hospital mortality during the 2017/2018 influenza season: a retrospective multicentre cohort study in central Germany. Infection [Internet]. 2020 Sep 27 [cited 2021 Jan 13]; Available from: http://link.springer.com/10.1007/s15010-020-01529-x

3. Buicu C-F, Moldovan I, Cotoi CT, Chiotoroiu A-L, Moisi RE, Rafila A. VACCINATION IN COMMUNITY PHARMACIES – A GLOBAL REVIEW AND THE ROMANIAN OPPORTUNITY. 2018;66:8.

4. Fitzgerald TJ, Kang Y, Bridges CB, Talbert T, Vagi SJ, Lamont B, et al. Integrating pharmacies into public health program planning for pandemic influenza vaccine response. Vaccine. 2016 Nov;34(46):5643–8.

5. territory W society and. List of countries where vaccine administration in pharmacy is allowed [Internet]. West. [cited 2020 May 9]. Available from: https://www.west-info.eu/list-of-countries-where-vaccine-administration-in-pharmacy-is-allowed/

6. An overview of current pharmacy impact on immunisation-Global report.pdf [Internet]. [cited 2020 May 9]. Available from: https://www.fip.org/www/streamfile.php?filename=fip/publications/FIP_report_on_Immunisation.pdf

7. Böhmer MM, Walter D, Falkenhorst G, Müters S, Krause G, Wichmann O. Barriers to pandemic influenza vaccination and uptake of seasonal influenza vaccine in the post-pandemic season in Germany. BMC Public Health. 2012 Oct 31;12(1):938.

8. RKI - Infectious Diseases in Germany - Report on the Epidemiology of Influenza in Germany 2018/2019 [Internet]. [cited 2020 May 9]. Available from:

https://www.rki.de/EN/Content/infections/epidemiology/inf_dis_Germany/influenza/summary_2018-19.html

9. Fuchs J. The provision of pharmaceutical advice improves patient vaccination status. Pharm Pract Granada [Internet]. 2006 Dec [cited 2021 Jan 13];4(4). Available from: http://scielo.isciii.es/scielo.php?script=sci_abstract&pid=S1885-642X2006000400003&lng=es&nrm=iso&tlng=en

10. May B. Konzeptrahmen zur praktischen Umsetzung der Grippeschutzimpfung in der Apotheke. :99.

11. Apotheken können impfen – kriegen aber keinen Impfstoff | APOTHEKE ADHOC [Internet]. [cited 2021 Jan 14]. Available from: https://www.apotheke-adhoc.de/nachrichten/detail/apothekenpraxis/impf-modellprojekt-apotheken-koennen-impfen-kriegen-aber-keinen-impfstoff-doris-schoenwald-im-video/

12. Adhoc A. Impfstoff-Engpässe: Bayern stoppt Modellprojekt [Internet]. APOTHEKE ADHOC. [cited 2021 Jan 14]. Available from: https://m.apotheke-adhoc.de/nc/nachrichten/detail/politik/impfstoff-engpaesse-bayern-stoppt-modellprojekt/

13. Health resources - Health spending - OECD Data [Internet]. theOECD. [cited 2021 Jan 14]. Available from: http://data.oecd.org/healthres/health-spending.htm

14. Book (eISB) electronic IS. electronic Irish Statute Book (eISB) [Internet]. Office of the Attorney General; [cited 2020 May 27]. Available from: http://www.irishstatutebook.ie/eli/2015/si/449/made/en/print

15. Book (eISB) electronic IS. electronic Irish Statute Book (eISB) [Internet]. Office of the Attorney General; [cited 2020 Sep 29]. Available from: http://www.irishstatutebook.ie/eli/2020/si/241/made/en/print

16. PPGF_02_8_Guidance_on_the_Provision_of_Vaccination_Services_by_Pharmacists_in_a_Retail_Pharmacy_Businesses.sflb.pdf [Internet]. [cited 2020 May 23]. Available from: https://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/PPGF_02_8_Guidance_on_the_Provision_of_Vaccination_Services_by_Pharmacists_in_a_Retail_Pharmacy_Businesses.sflb.ashx

17. CPR Training Information | IIoP Portal [Internet]. [cited 2020 Oct 30]. Available from: https://iiop.ie/content/cpr-training-information

18. Training for Pharmacists -Emergency Medicines and Vaccination- PSI [Internet]. [cited 2020 Oct 27]. Available from: https://www.thepsi.ie/gns/education/Training_for_Pharmacists.aspx

19. All Courses | IIoP Portal [Internet]. [cited 2020 Oct 31]. Available from: https://iiop.ie/cbs/selector

20. Medicines Administration for Pharmacists - [Internet]. [cited 2020 Sep 30]. Available from: https://hibernianhealth.com/pharmacists/

21. Review_of_Vaccinations_and_Emergency_Medicines_Training_Requirements.sflb.pdf [Internet]. [cited 2020 Oct 27]. Available from:

https://www.thepsi.ie/Libraries/Education/Review_of_Vaccinations_and_Emergency_Medicines_Training_Requirements.sflb.ashx

22. Guidance_to_support_pharmacies_in_providing_safe_influenza_vaccination_services_offsite_from_the_pharmacy_premises.sflb.pdf [Internet]. [cited 2020 Dec 30]. Available from: https://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/Guidance_to_support_pharmacies_in_providing_safe_influenza_vaccination_services_offsite_from_the_pharmacy_premises.sflb.ashx

23. faq.pdf [Internet]. [cited 2020 Nov 12]. Available from: https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/faq.pdf

24. Logan P. Flu vaccination in challenging times. 2020;3.

25. pharmacy-circular-nco-12-2020.pdf [Internet]. [cited 2020 Oct 31]. Available from: https://www.hse.ie/eng/staff/pcrs/circulars/pharmacy/pharmacy-circular-nco-12-2020.pdf

26. pcrs-handbook-for-pharmacists.pdf [Internet]. [cited 2020 Oct 31]. Available from: https://www.hse.ie/eng/staff/pcrs/contractor-handbooks/pcrs-handbook-for-pharmacists.pdf

27. Irish Vaccines Injuries Support Group Ireland | Vaccine Injury Support [Internet]. [cited 2020 Dec 30]. Available from: http://vaccineinjury.ie/

28. 20-21_Service_specification_for_seasonal_flu_FINAL.pdf [Internet]. [cited 2020 Oct 10]. Available from: https://www.england.nhs.uk/wp-content/uploads/2017/08/20-21_Service_specification_for_seasonal_flu_FINAL.pdf

29. 2020 PGD Packages, Training and Pricing [Internet]. NPA. 2018 [cited 2020 Aug 17]. Available from: https://www.npa.co.uk/pgdindetail

30. Craig L. National minimum standards and core curriculum for immunisation training for registered healthcare practitioners. :35.

31. Green-Book-Chapter-8-v4_0.pdf [Internet]. [cited 2021 Jan 5]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf

32. Infection_prevention_tool.pdf [Internet]. [cited 2021 Jan 5]. Available from: http://archive.psnc.org.uk/services_db/docs/789/Infection_prevention_tool.pdf

33. Offsite-Vaccination-Procedure.pdf [Internet]. [cited 2020 Nov 5]. Available from: http://psnc.org.uk/kensington-chelsea-and-westminster-lpc/wp-content/uploads/sites/73/2014/09/Offsite-Vaccination-Procedure.pdf

34. Pharmacy_Influenza_Vaccination_Patient_Group_Direction_FINAL.pdf [Internet]. [cited 2020 Nov 11]. Available from: https://www.england.nhs.uk/wp-content/uploads/2017/08/Pharmacy_Influenza_Vaccination_Patient_Group_Direction_FINAL.pdf

35. PSNC-Briefing-031.19-Guidance-on-the-Seasonal-Influenza-Vaccination-Advanced-Service-2019-20.pdf [Internet]. [cited 2020 Oct 3]. Available from: https://psnc.org.uk/wp-content/uploads/2019/08/PSNC-Briefing-031.19-Guidance-on-the-Seasonal-Influenza-Vaccination-Advanced-Service-2019-20.pdf

36. Pharmacy-London-Community-Pharmacy-Seasonal-Flu-Vaccination-Enhanced-Service-v31.pdf [Internet]. [cited 2020 Oct 3]. Available from: http://psnc.org.uk/city-and-hackney-lpc/wp-content/uploads/sites/69/2013/08/Pharmacy-London-Community-Pharmacy-Seasonal-Flu-Vaccination-Enhanced-Service-v31.pdf

37. PSNC. Flu Vaccination FAQs [Internet]. PSNC Main site. [cited 2020 Aug 18]. Available from: https://psnc.org.uk/services-commissioning/advanced-services/flu-vaccination-service/flu-vaccination-faqs/

38. PSNC. Flu vaccination data for 2018/19 [Internet]. PSNC Main site. [cited 2020 Aug 20]. Available from: https://psnc.org.uk/services-commissioning/advanced-services/flu-vaccination-service/flu-vaccination-statistics/flu-vaccination-data-for-2018-19/

39. Adult flu vaccination coverage [Internet]. The Nuffield Trust. 2018 [cited 2020 Aug 20]. Available from: https://www.nuffieldtrust.org.uk/resource/adult-flu-vaccination-coverage

40. Perman S, Kwiatkowska RM, Gjini A. Do community pharmacists add value to routine immunization programmes? A review of the evidence from the UK. J Public Health. 2018 Dec 1;40(4):e510–20.

41. Ecarnot F, Crepaldi G, Juvin P, Grabenstein J, Del Giudice G, Tan L, et al. Pharmacy-based interventions to increase vaccine uptake: report of a multidisciplinary stakeholders meeting. BMC Public Health. 2019 Dec 18;19(1):1698.

42. PSNC. Flu vaccination funding for 2020/21 [Internet]. PSNC Main site. [cited 2020 Nov 11]. Available from: https://psnc.org.uk/our-news/flu-vaccination-funding-for-2020-21/

43. NHSEI-PHE-Inactivated-Influenza-PGD-v08.00.pdf [Internet]. [cited 2020 Dec 31]. Available from: https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2020/08/NHSEI-PHE-Inactivated-Influenza-PGD-v08.00.pdf

44. Vaccine Damage Payment [Internet]. GOV.UK. [cited 2020 Dec 31]. Available from: https://www.gov.uk/vaccine-damage-payment

45. Burson RC, Buttenheim AM, Armstrong A, Feemster KA. Community pharmacies as sites of adult vaccination: A systematic review. Hum Vaccines Immunother. 2016 Dec 1;12(12):3146–59.

46. Pharmacy-Based Immunization Delivery [Internet]. [cited 2020 Oct 4]. Available from: https://www.pharmacist.com/pharmacy-based-immunization-delivery

47. Authority and Scope of Vaccination: How States Differ [Internet]. Pharmacy Times. [cited 2020 Aug 29]. Available from: https://www.pharmacytimes.com/publications/supplementals/2017/immunizationsupplementjune2017/authority-and-scope-of-vaccination-how-states-differ

48. Prescott WA, Bernhardi C. Immunization Education in US Pharmacy Colleges and Schools. Am J Pharm Educ [Internet]. 2019 Jun [cited 2020 Nov 18];83(5). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6630863/

49. Immunization Resources [Internet]. [cited 2020 Aug 29]. Available from: https://www.pharmacist.com/immunization-resources

50. Bach AT, Goad JA. The role of community pharmacy-based vaccination in the USA: current practice and future directions. Integr Pharm Res Pract. 2015 Jul 1;4:67–77.

51. dro-immunization-enhancing-vac-workflow.pdf [Internet]. [cited 2020 Nov 17]. Available from: http://www.ncpa.co/pdf/dro-immunization-enhancing-vac-workflow.pdf

52. vacc-adults-step2.pdf [Internet]. [cited 2020 Nov 17]. Available from: https://www.immunize.org/guide/pdfs/vacc-adults-step2.pdf

53. 832111R0_APhA Event Guide 2.pdf [Internet]. [cited 2020 Nov 18]. Available from: https://www.pharmacist.com/sites/default/files/832111R0_APhA%20Event%20Guide%202.pdf

54. 832113R0_APhAEventGuide3.pdf [Internet]. [cited 2020 Nov 18]. Available from: https://www.pharmacist.com/sites/default/files/832113R0_APhAEventGuide3.pdf

55. Grohskopf LA. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season. MMWR Recomm Rep [Internet]. 2020 [cited 2020 Nov 17];69. Available from: https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm

56. Pharmacy-Legal-Toolkit.pdf [Internet]. [cited 2020 Sep 1]. Available from: https://www.astho.org/Infectious-Disease/Pharmacy-Legal-Toolkit/

57. ACIP Adverse Reactions Guidelines for Immunization | Recommendations | CDC [Internet]. 2020 [cited 2020 Oct 3]. Available from: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html

58. vacc-adults-entire.pdf [Internet]. [cited 2020 Sep 2]. Available from: https://www.immunize.org/guide/pdfs/vacc-adults-entire.pdf

59. Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. 2017 Aug;39(8):1563-1580.e17.

60. 832114R0_APhA Event Guide 4.pdf [Internet]. [cited 2020 Sep 2]. Available from: https://www.pharmacist.com/sites/default/files/832114R0_APhA%20Event%20Guide%204.pdf

61. Singhal PK, Zhang D. Costs of Adult Vaccination in Medical Settings and Pharmacies: An Observational Study. J Manag Care Pharm. 2014 Sep;20(9):930–6.

62. Seasonal Influenza Vaccines Pricing | CMS [Internet]. [cited 2020 Nov 19]. Available from: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing

63. Pharmacist Professional Liability Insurance [Internet]. [cited 2020 Dec 31]. Available from: http://www.hpso.com/individuals/professional-liability/pharmacist-professional-liability-insurance

64. Two federal programs compensate for vaccine-related injuries [Internet]. [cited 2020 Dec 20]. Available from: https://www.pharmacist.com/article/two-federal-programs-compensate-vaccine-related-injuries-0

65. Immunisation policy and practice in Australia. 2019;7.

66. Review of pharmacist vaccination reporting to the AIR_Final report_May 2020.pdf [Internet]. [cited 2020 Sep 20]. Available from: http://ncirs.org.au/sites/default/files/2020-06/Review%20of%20pharmacist%20vaccination%20reporting%20to%20the%20AIR_Final%20report_May%202020.pdf

67. Training Track: Manage the delivery and administration of injections and immunisations ACT [Internet]. [cited 2020 Sep 23]. Available from: https://my.psa.org.au/s/training-track/a167F000003CTda/manage-the-delivery-and-administration-of-injections-and-immunisations-act

68. Australia TPG of. Pharmacy Guild Immunisation Course [Internet]. The Pharmacy Guild of Australia; [cited 2020 Sep 23]. Available from: https://www.guild.org.au/guild-branches/qld/training/guild-education-and-cpd/upcoming-sessions/national-vaccination-course-for-pharmacists

69. FIP-VaccinationToolkit.pdf [Internet]. [cited 2020 Sep 27]. Available from: https://www.fip.org/files/content/fip-council-documents/Council-documents/FIP-VaccinationToolkit.pdf

70. AsKnowledgeListPage [Internet]. [cited 2020 Sep 23]. Available from: https://my.psa.org.au/s/asknowledgelistpage?categories=%7B%22categoryMap%22%3A%7B%22Clinical_Category%22%3A%5B%22Immunisation__c%22%5D%7D%7D

71. final-guidelines-for-conducting-vaccination-services-within-community-pharmacy-080416.pdf [Internet]. [cited 2020 Sep 1]. Available from: https://www.guild.org.au/__data/assets/pdf_file/0018/6174/final-guidelines-for-conducting-vaccination-services-within-community-pharmacy-080416.pdf

72. Primary-care-consultation-The-Pharmacy-Guild-of-Australia.pdf [Internet]. [cited 2020 Sep 27]. Available from: https://www.safetyandquality.gov.au/sites/default/files/migrated/Primary-care-consultation-The-Pharmacy-Guild-of-Australia.pdf

73. WA pharmacists now able to vaccinate outside pharmacy [Internet]. Pharmaceutical Society of Australia. 2020 [cited 2020 Nov 22]. Available from: https://www.psa.org.au/wa-pharmacists-now-able-to-vaccinate-outside-pharmacy/

74. Pharmacists in NSW now able to administer vaccinations outside of pharmacy [Internet]. Pharmaceutical Society of Australia. 2020 [cited 2020 Nov 22]. Available from: https://www.psa.org.au/pharmacists-in-nsw-now-able-to-administer-vaccinations-outside-of-pharmacy/

75. Health AGD of. Influenza (flu) [Internet]. The Australian Immunisation Handbook. The Australian Immunisation Handbook; 2018 [cited 2020 Nov 22]. Available from: https://immunisationhandbook.health.gov.au/vaccine-preventable-diseases/influenza-flu

76. Australia TPG of. Vaccination Services [Internet]. The Pharmacy Guild of Australia; [cited 2020 Sep 27]. Available from: https://www.guild.org.au/programs/vaccination-services

77. White L (Health). Pharmacist vaccinations - frequently asked questions. :3.

78. Sullivan SG, Chilver MB, Carville KS, Deng Y-M, Grant KA, Higgins G, et al. Low interim influenza vaccine effectiveness, Australia, 1 May to 24 September 2017. Eurosurveillance [Internet]. 2017 Oct 26 [cited 2020 Oct 13];22(43). Available from: http://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2017.22.43.17-00707

79. NCIRS Information Sheet- Vaccines from community pharmacy_updated 10 June 2020_final.pdf [Internet]. [cited 2020 Sep 27]. Available from: http://ncirs.org.au/sites/default/files/2020-06/NCIRS%20Information%20Sheet-%20Vaccines%20from%20community%20pharmacy_updated%2010%20June%202020_final.pdf

80. Flu vax charges under scrutiny [Internet]. AJP. 2019 [cited 2020 Nov 25]. Available from: https://ajp.com.au/news/flu-vax-charges-under-scrutiny/

81. Houle SKD, Grindrod KA, Chatterley T, Tsuyuki RT. Publicly funded remuneration for the administration of injections by pharmacists. Can Pharm J CPJ. 2013 Nov;146(6):353–64.

82. Administration AGD of HTG. Report a problem or side effect [Internet]. Therapeutic Goods Administration (TGA). Australian Government Department of Health; [cited 2020 Dec 31]. Available from: https://www.tga.gov.au/reporting-problems

83. Wood N, Macartney K, Leask J, McIntyre P. Australia needs a vaccine injury compensation scheme: Upcoming COVID-19 vaccines make its introduction urgent. Aust J Gen Pract [Internet]. 2020 Sep 9 [cited 2020 Dec 30];49. Available from: https://www1.racgp.org.au/ajgp/coronavirus/australia-needs-a-vaccine-injury-compensation-sche

84. Vor-Ort-Apotheken_BT-110920.pdf [Internet]. [cited 2020 Oct 7]. Available from: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/A/Vor-Ort-Apotheken_BT-110920.pdf

85. Curriculum_Grippeschutzimpfung_20_09_10.pdf.

86. Leitlinien und Arbeitshilfen | ABDA [Internet]. [cited 2020 Dec 20]. Available from: https://www.abda.de/fuer-apotheker/qualitaetssicherung/leitlinien/leitlinien-und-arbeitshilfen/

87. Grippeschutzimpfung_Apo_20_03_04_ABDAGV_Anl03_Kommentar.pdf.

88. 34_2017_engl.pdf [Internet]. [cited 2020 Dec 20]. Available from: https://www.rki.de/EN/Content/infections/Vaccination/recommandations/34_2017_engl.pdf?__blob=publicationFile

89. § 22 IfSG Impfdokumentation [Internet]. [cited 2020 Dec 25]. Available from: https://www.sozialgesetzbuch-sgb.de/ifsg/22.html

90. Influenza vaccination rates [Internet]. OECD; [cited 2020 Dec 27]. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/influenza-vaccination-rates/indicator/english_e452582e-en

91. Apotheker DAE. Honorar für Grippeimpfung: „Mehr war aktuell einfach nicht möglich“ [Internet]. DAZ.online. 2020 [cited 2021 Jan 7]. Available from: https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/07/14/honorar-fuer-grippeimpfung-mehr-war-aktuell-einfach-nicht-moeglich

92. Impfstoffe, Honorar, Bestellmengen – so sind regionalen Regeln [Internet]. AerzteZeitung.de. [cited 2020 Dec 25]. Available from: https://www.aerztezeitung.de/Medizin/Impfstoffe-Honorar-Bestellmengen-so-sind-regionalen-Regeln-401818.html

93. GmbH A-MDA. Impfen in der Apotheke: Grippeimpf-Modellprojekt in Niedersachsen kann losgehen [Internet]. Pharmazeutische Zeitung online. [cited 2020 Dec 12]. Available from: https://www.pharmazeutische-zeitung.de/grippeimpf-modellprojekt-in-niedersachsen-gestartet-121637/

94. Apotheker DAE. Honorar für Grippeimpfung: „Mehr war aktuell einfach nicht möglich“ [Internet]. DAZ.online. 2020 [cited 2021 Jan 7]. Available from: https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/07/14/honorar-fuer-grippeimpfung-mehr-war-aktuell-einfach-nicht-moeglich

95. GmbH A-MDA. Impfen in der Apotheke: Bundesapothekerkammer legt Curriculum vor [Internet]. Pharmazeutische Zeitung online. [cited 2020 Dec 27]. Available from: https://www.pharmazeutische-zeitung.de/bundesapothekerkammer-legt-curriculum-vor/seite/3/

96. GmbH DN. Arzneimittelkommission der Deutschen Apotheker (AMK) [Internet]. DeutschesApothekenPortal. [cited 2020 Dec 27]. Available from: https://www.deutschesapothekenportal.de/rezept-retax/dap-lexikon/arzneimittelkommission-der-deutschen-apotheker-amk/

97. FB_Impfbescheinigung_Grippeschutzimpfung (1).docx.

98. § 60 IfSG - Einzelnorm [Internet]. [cited 2021 Jan 5]. Available from: https://www.gesetze-im-internet.de/ifsg/__60.html

99. Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. Bull World Health Organ. 2011 May 1;89(5):371–8.

100. Alte Leipziger weitet Berufshaftpflicht für Apotheker aus [Internet]. versicherungsmagazin.de. [cited 2020 Dec 27]. Available from: https://www.versicherungsmagazin.de/rubriken/produkte/alte-leipziger-weitet-berufshaftpflicht-fuer-apotheker-aus-2692454.html

101. Hopeetal2014-AJPIncorporatingVaccineAdministrationPages60-63.pdf.

102. Bushell M, Frost J, Deeks L, Kosari S, Hussain Z, Naunton M. Evaluation of Vaccination Training in Pharmacy Curriculum: Preparing Students for Workforce Needs. Pharmacy. 2020 Aug 20;8(3):151.

103. Digital 2020: Germany [Internet]. DataReportal – Global Digital Insights. [cited 2021 Jan 11]. Available from: https://datareportal.com/reports/digital-2020-germany

Appendix

telc
LANGUAGE TESTS

Zertifikat

telc Deutsch B2

Europaratsstufe B2 · *Council of Europe level B2*

Malik	**Arslan Ahmed**
Name	Vorname

[redacted]