# Pharmacy-based vaccination: Development, Evaluation and Application of Vaccination Training for pharmacy undergraduates using high-fidelity Simulation

Inaugural-Dissertation

zur Erlangung des Doktorgrades
der Mathematisch-Naturwissenschaftlichen Fakultät
der Heinrich-Heine-Universität Düsseldorf

vorgelegt von

**Shahzad Ahmad Sayyed**

aus Düsseldorf

Neuss, August 2024

aus dem Institut für Klinische Pharmazie und Pharmakotherapie

der Heinrich-Heine-Universität Düsseldorf

Gedruckt mit der Genehmigung der
Mathematisch-Naturwissenschaftlichen Fakultät der

Heinrich-Heine-Universität Düsseldorf

Berichterstatter:

1. Frau Prof. Dr. Stephanie Läer

2. Herr Prof. Dr. Gerhard Jocham

Tag der mündlichen Prüfung: 21.01.2025

*„Was in den Himmeln und was auf Erden ist, verkündet die Herrlichkeit Allahs,*
*und Er ist der Allmächtige, der Allweise.*
*Sein ist das Königreich der Himmel und der Erde. Er gibt Leben und Tod,*
*und Er vermag alle Dinge zu tun.*
*Er ist der Erste und der Letzte, der Sichtbare und der Verborgene,*
*und Er ist der Wisser aller Dinge.“*

(Hlg. Quran 57:2-4)

**Eidesstattliche Erklärung**

Hiermit versichere ich an Eides statt, dass die vorgelegte Dissertation mit dem Titel:

Pharmacy-based vaccination: Development, Evaluation and Application of Vaccination Training for pharmacy undergraduates using high-fidelity Simulation

von mir selbstständig und ohne unzulässige fremde Hilfe unter Beachtung der Grundsätze zur Sicherung guter wissenschaftlicher Praxis an der Heinrich-Heine-Universität Düsseldorf erstellt worden ist. Die Dissertation wurde in der vorgelegten oder in ähnlicher Form noch bei keiner anderen Institution eingereicht. Ich habe bisher keinen erfolglosen Promotionsversuch unternommen.

Düsseldorf, den 27.01.2025 Shahzad Ahmad Sayyed

## Danksagung

الحمد لله

*„Aller Preis gebührt Allah“*

An dieser Stelle möchte ich mich bei all denjenigen bedanken, die mich bei der Anfertigung der vorliegenden Arbeit unterstützt haben.

Zunächst einmal bedanke ich mich bei Frau Prof. Dr. Läer für die Möglichkeit meine Arbeit im Rahmen der Promotion am Institut für klinische Pharmazie und Pharmakotherapie der Heinrich-Heine-Universität Düsseldorf durchzuführen. Die fachlichen und konstruktiven Gespräche haben mich in meiner persönlichen Entwicklung sehr geprägt.

Bei Herrn Prof. Dr. Gerhard Jocham bedanke ich mich herzlich für die Übernahme der Mentorenschaft sowie des Korreferates.

Herrn Prof. Dr. Holger Schwender danke ich für die fachliche Unterstützung in allen statistischen Fragestellungen.

Ebenso danke ich Herrn Prof. Dr. Christoph Ritter aus der Universität Greifswald und Prof. Dr. Ulrich Jaehde und Dr. Ronja Woltersdorf aus der Universität Bonn für die besondere Mitwirkung bei der zweiten Studie.

Weiterhin bedanke ich mich bei allen ehemaligen Kolleginnen und Kollegen am Institut für jegliche Unterstützung und Übernahme verschiedener Rollen während der Studien. Ebenso bedanke ich mich für den regen Austausch und die gemeinsame Zeit mit schönen Erinnerungen. Ganz besonders möchte ich mich bei Herrn Florian Kinny und Herrn Sharkas Ahmed für die Begleitung und wichtige Hilfe während der zweiten Studie bedanken. Allen Wahlpflicht- und Pharmaziestudierenden, die an den Studien teilgenommen und mitgewirkt haben, danke ich ebenfalls.

Ein besonderer Dank gilt meinen Eltern, ohne die ich heute nicht hier wäre. Ihre Liebe und Erziehung haben in mir die Motivation und Kraft zur harten Arbeit, Standhaftigkeit und immerwährender Anstrengung erzeugt.

Zu guter Letzt bedanke ich mich ganz besonders bei meiner liebevollen Ehefrau und meiner Tochter, für die Geduld, das Verständnis und die Lebensenergie, die ich durch euch bekomme. Ohne euch wäre alles nicht möglich gewesen. Ich bin dankbar euch in meinem Leben zu haben.

## Zusammenfassung

Um eine höhere Impfquote zu erreichen wurde im Mai 2022 die Impfung in der Apotheke gegen Influenza für Personen ab 18 Jahren und gegen das SARS-CoV-2 für Personen ab 12 Jahren in das Infektionsschutzgesetz als Regelversorgung in den Apotheken aufgenommen. Vorausgegangen war ein in 2020 gestartetes Modellprojekt und die Einbeziehung der Apotheken in das Impfkonzept der Regierung während der Corona Pandemie in 2021. Global äußerte sich die Einbeziehung der Apotheken in die Impfung in eine gesteigerte Impfquote in der Bevölkerung, als auch eine erhöhte Aufklärung und Bereitschaft zum Impfen. Jedoch ist in Deutschland das Thema Impfen nicht in das Curriculum der Pharmazie integriert und daher stößt das Vorhaben auf Kritik seitens der Ärzteschaft, dass Apotheker gemäß ihrer Ausbildung nicht zum Impfen qualifiziert sind, vor Allem bei aufkommenden Notfällen nicht ausreichend vorbereitet sind. Daher müssen zurzeit Apotheker und Apothekerinnen eine Zusatzqualifikation durch die Teilnahme an einer ärztlich geführten Schulung erreichen.

In dieser Arbeit wurde eine spezieller Impfkurs für Pharmaziestudierende entwickelt und in zwei Studien untersucht. Dabei wurde die innovative high-fidelity Simulation genutzt um Notfälle bestmöglich zu simulieren. Die high-fidelity Simulation bietet die höchste Stufe an Realismus und ist eine lebensgroße Puppe, die über eine Software gesteuert wird, um verschiedene Vitalparameter wie Blutdruck, Puls oder Atemfrequenz beliebig zu verändern. Die erste Studie, eine randomisierte klinische Studie, untersuchte in einem Pre-Post-Design den neu konzipierten Kurs gegen das Standardtraining ähnlich zu der Schulung für Apotheker und Apothekerinnen. Dabei erhielt die Interventionsgruppe das Training mit der high-fidelity Simulation und die Kontrollgruppe das Standardtraining. Vorher und nachher wurden die Teilnehmer in objektiven strukturierten klinischen Examinationen (OSCEs) hinsichtlich ihrer Leistung bewertet. Ebenso wurde die Selbsteinschätzung der Teilnehmer hinsichtlich des Wissens und der Kompetenz zur Durchführung einer Impfung durch einen Fragebogen erhoben. Die Ergebnisse zeigten, dass beide Gruppen nach dem Training bessere Leistungsergebnisse erzielten, aber die Interventionsgruppe besser als die Kontrollgruppe war. Darüber hinaus gaben beide Gruppen in der Selbsteinschätzung an, dass Sie sich nach dem Training hinsichtlich der Durchführung einer Impfung in der Apotheke ausreichend vorbereitet fühlten. Um die Akzeptanz und Durchführbarkeit des Kurses zu untersuchen wurde in der zweiten Studie der Kurs an weiteren Universitäten durchgeführt. In der darauf aufbauenden zweiten Studie wurde an den Universitäten Bonn, Greifswald und Düsseldorf mit den Studierenden das Impftraining mit der high-fidelity Simulation durchgeführt und vor und nach dem Training die Selbsteinschätzung und die Zufriedenheit durch Fragebögen ermittelt. Dabei gaben die Teilnehmer in der Selbsteinschätzung ebenfalls an, dass sie sich durch das Training kompetenter fühlten und sehr zufrieden mit dem Trainingskurs waren.

Die high-fidelity Simulation stellt sich als ein effektives und für die Studierenden ein attraktives Trainingswerkzeug zur Ausbildung von Pharmaziestudierenden zum

Impfen für die zukünftige Apothekentätigkeit heraus. Das in dieser Dissertation konzipierte Impftraining mit der high-fidelity Simulation bekräftigt zum einen die Integration eines Impftrainings in das Curriculum der Pharmazie und zum anderen die Einbeziehung von Simulationstechniken zur Ausbildung von klinischen Fähigkeiten.

## Summary

In order to achieve a higher vaccination rate, pharmacy-based vaccination against influenza for people aged 18 years and older and against SARS-CoV-2 for people aged 12 years and older was included in the Infection Protection Act as standard care in pharmacies in May 2022. This follows a pilot project launched in 2020 and the inclusion of pharmacies in the government's vaccination concept during the coronavirus pandemic in 2021. Globally, the inclusion of pharmacies in vaccination efforts has resulted in higher vaccination rates among the population, as well as increased awareness and willingness to vaccinate. In Germany, however, vaccination training is not part of the pharmacy curriculum, which has led to criticism from the medical profession that pharmacists are not qualified to administer vaccinations and are not adequately prepared, especially to handle emergency situations potentially arising after the vaccination process. For this reason, the practicing pharmacists currently have to obtain an additional qualification by attending a physician-led training course.

In this dissertation, a special vaccination course for pharmacy students was developed and evaluated in two studies. The innovative high-fidelity simulation was used to simulate emergency scenarios. The high-fidelity simulation offers the highest level of realism. It is a life-size mannequin that is controlled by a software to change various vital parameters such as blood pressure, pulse and the respiratory rate. The first study, a randomized clinical trial, compared the developed high-fidelity simulation-based vaccination training course with the standard training similar to the regular pharmacist training in a pre-post design. The intervention group received the high-fidelity simulation training and the control group received the standard training. Participants' performance was assessed before and after the training using objective structured clinical examinations (OSCEs). The participants' self-assessment was also obtained using a questionnaire. The results showed that both groups achieved higher scores in performance after the training, but the intervention group was better than the control group. In addition, both groups reported that they felt sufficiently prepared to provide vaccinations in the pharmacy after the training. Secondly, to assess the acceptability and feasibility of the developed vaccination course, the high-fidelity simulation training was conducted at three other universities including universities of Bonn, Greifswald, and Düsseldorf. Pharmacy students’ self-assessment and satisfaction were assessed using questionnaires before and after the training. The participants at all three universities indicated in their self-assessment that the high-fidelity based vaccination training course made them feel more competent and that they were satisfied with it. The high-fidelity simulation proves to be an effective and attractive training tool for pharmacy students' education on pharmacy-based vaccination. The vaccination training using high-fidelity simulation developed in this dissertation strongly supports the integration of vaccination training into the pharmacy curriculum and the use of simulation techniques for clinical skills training.

**Table of Contents**

## List of Abbreviations

| | |
|---|---|
| ACE 2 | Angiotensin Converting Enzyme 2 |
| ACPE | Accreditation Council for Pharmacy Education |
| BAK | German Federal Chamber of Pharmacist |
| BPhD e.V. | Federal Association of Pharmacy Students in Germany (Bundesverband der Pharmaziestudierenden in Deutschland e. V.) |
| COVID-19 | Coronavirus Disease 2019 |
| FIP | International Pharmaceutical Federation |
| HA | Hemaglutinin |
| HFS | High-fidelity Simulation |
| i.e. | *Id est*, that is |
| IfSG | Infectious Diseases Act (Infektionsschutzgesetz) |
| LFS | Low-fidelity Simulation |
| M2 | Matrixprotein 2 |
| NA | Neuraminidase |
| OSCE | Objective structured clinical examination |
| RCT | Randomizde controlled trial |
| RKI | Robert-Koch-Institut |
| RNA | Ribonucleid acid |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus type 2 |
| SD | Standard deviation |
| STIKO | Permanent Vaccianation Commission (Ständige Impfkommision) |
| UK | United Kingdom |
| US/USA | United States of America |
| VOC | Variants of concern |
| VOI | Variants of interest |
| WHO | World Health Organization |

## List of Tables

## List of figures

# 1. Introduction

## 1.1 Influenza Virus

The influenza virus is a microscopic but significant threat to human health [1]. Elderly people are particularly at risk due to their weakened immune systems [2]. People with diabetes, asthma and cardiovascular disease are also at risk [3]. The influenza virus belongs to the family of orthomyxoviruses and is divided into different subtypes, including the well-known A, B and C [4]. It is a single-stranded RNA virus and has the following important structural characteristics. Haemagglutinin (HA) and neuraminidase (NA) are the two major surface proteins of the influenza virus. Haemagglutinin enables the virus to adhere to and enter host cells. The virus enters the host cell through endocytosis and releases its RNA to form new viral components through protein biosynthesis. New viruses are formed by budding and are then released from the infected cells with the help of neuraminidase. The envelope of the influenza virus consists of lipid bilayers interspersed with proteins and glycoproteins. This envelope is important for the interaction with the host cell and gives the virus its structure. Inside the virus is the single-stranded RNA genome, which contains the genetic information for virus replication and production. The nucleoprotein encapsulates the RNA of the virus and plays a key role in stabilizing the genome and replicating the virus. The M2 ion channel facilitates the entry of protons into the virus and plays a role in the release of viral RNA into the host cell [1,3,4]. Typically, infection of the ciliated epithelium of the lower respiratory tract occurs, leading to complications such as pneumonia [1,4,5]. Other common symptoms include high fever, headache, body aches and a dry cough. Cardiovascular problems are also possible [4]. These infections are lytic, meaning that the host cell dies when the new viruses are released [6]. An average of 6000 virions are released per cell [6,7].

The flu season begins in the 40th week of the calendar year and lasts until the 20th week of the following year [1]. On average, between 294.000 and 518.000 people are infected with influenza each year, 67% of whom are over the age of 65 [8,9]. This does not include deaths from cardiovascular causes as a result of influenza infection. The World Health Organization (WHO) estimates that between 3 and 5 million people are hospitalized each year as a result of influenza infection [2]. In Germany, almost 300,000 people have been infected with the influenza virus [8]. Notable outbreaks include the Spanish flu of 1918 with nearly 50 million deaths or the swine flu of 2009 with 12220 deaths worldwide [3,10].

The constant mutation and emergence of new subtypes make influenza particularly dangerous [1]. These are characterized by the processes of gene drift and gene shift [1]. Seasonal influenza is caused by group A (H1N1), group A (H3N2) and two group B viruses [4] . The composition of the vaccine is therefore changed each year to provide protection against the influenza viruses most likely to dominate infection in the coming season [1,4]. Reference laboratories analyze the influenza viruses circulating worldwide and report their findings to the WHO, which then determines the composition of the seasonal vaccine [1].

The vaccines available in Germany are usually inactivated vaccines [11]. These can be either whole inactivated pathogens or so-called split or subunit vaccines, in which the surface proteins haemagglutinin and neuraminidase are enriched after fragmentation of the pathogen [12]. A live vaccine, i.e. attenuated viruses that cannot replicate, is available as a nasal spray for children [11]. In the case of inactivated vaccines, the relevant antigens are identified and then incubated in chicken eggs [12,13]. This method is still well established and widely used. Another production method is to multiply the relevant strands in cell cultures [13]. Such production is advantageous for people with a protein allergy [13].

## 1.2 Severe acute respiratory syndrome coronavirus type 2 (SARS-CoV 2)

The corona virus caused a global pandemic in 2019 [14]. Originating in the Chinese city of Wuhan in December 2019, the virus spread rapidly around the world, infecting more than 9.000 people within two months [15]. By the end of March 2020, more than 40.000 deaths had been reported [16]. On 21 December 2020, Pfizer/BioNTech's Comirnaty vaccine was approved in Germany as the first vaccine against SARS-CoV [17]. More than 1.8 Mio. deaths have been reported worldwide to that date [16].

As with the influenza virus, high-risk patients such as asthmatics, diabetics, cancer patients and the elderly are particularly vulnerable [14]. The COVID-19 virus belongs to the coronavirus family and is an enveloped single-stranded RNA virus [14,18]. The membrane protein is responsible for the structure of the virus and the transmembrane envelope protein has ion channel activity [18]. Of particular importance is the spike protein, a homotrimer of glycoproteins responsible for entry into the host cell [15,18]. Entry occurs via the ACE2 receptors after the transmembrane serine protease activates the virus for entry by cleaving the spike protein [15,18]. After entry into the host cell, the viral RNA is released and is divided into non-structural and structural protein parts [15,18]. On the one hand, the RNA polymerase and the viral structural proteins are translated [15,18]. After transport and assembly by the Golgi apparatus and vesicles, the newly formed viruses are released by exocytosis [18].

As with the influenza virus, the respiratory tract is particularly affected by infection [14,15]. In addition, neurological symptoms such as olfactory and taste disturbances, cardiovascular symptoms such as blood clotting or dermatological diseases can also occur [15].

Like all viruses, SARS-CoV-2 has evolved over time through mutations that occur in the genome with each replication. As a result, new variants with altered pathogenesis emerge over time [19]. WHO classifies these as "variants of interest" (VOI) or "variants of concern" (VOC) based on increased risk to global public health [20]. It assesses increased transmissibility, disease severity, immune escape, reduction in the effectiveness of current social interventions, and available vaccines and therapeutics [21]. At the end of 2021, the WHO classified five variants (labeled as Alpha, Beta, Gamma, Delta and Omicron) as VOC [22]. To contain the devastating pandemic, vaccination was urgently needed [23]. As a result, several types of vaccines were developed [24]. The first approved vaccine was the mRNA vaccine developed by Biontech/Pfizer. Nuclear-based vaccines involve injecting a gene construct encoding the antigen into the body, where the SARS CoV-2 virus S protein is translated after the mRNA is taken up by the host cell. The University of Oxford and AstraZeneca have developed a viral vectored vaccine in which the immunogen is delivered into the body by a viral vector to induce the desired immune response. The Chinese company SinoVac has developed an inactivated vaccine that induces a humoral or antibody-mediated immune response. In Germany, SinoVac was approved specifically for citizens of China [25].

## 1.3 Vaccination and legal stipulations in Germany

According to the German Federal Government's Health Report, vaccination is defined as "the artificial induction of specific immunity as a preventive measure against bacterial and viral infectious diseases" [26]. Pathogens or toxins are administered in an attenuated or killed form [27]. This is usually done by intramuscular or subcutaneous injection, but in some cases, it is also administered orally or nasally [27,28]. The vaccine triggers an immune response in the body in which B lymphocytes, after differentiating into plasma cells, produce antibodies against components of the pathogen [29]. In the event of re-infection with the same pathogen, the body is able to respond more quickly, preventing a potentially severe outcome due to a lack of or delayed immune response [29]. This occurs through the adaptive immune system, which generates antigen-specific memory cells [30]. When antigens are ingested, the cellular components of the adaptive immune system, the lymphocytes, can specifically recognize and bind them.

Vaccination was first described in the 18th century by the British physician Edward Jenner [27]. He inoculated an eight-year-old boy with cowpox virus, which resulted in immunity [27]. Today, vaccination is an important preventive measure against many infectious diseases caused by viruses or bacteria [29]. In Germany, the Infection Protection Act (IfSG) was introduced to provide uniform regulations for infectious diseases [26]. Paragraph 1 Section 1 states: "The purpose of the Act is the prevention of infectious diseases in humans, the early detection of infections and the prevention of their spread". The IfSG also specifies which diseases must be reported by name in the event of suspicion. These include COVID-19 and zoonotic influenza. The Robert Koch Institute was also institutionalized by the IfSG. The Robert-Koch-Institute (RKI) is responsible for coordinating data collection and for analyzing and evaluating infectious diseases [31]. To do this, epidemiological and laboratory analyses are developed and carried out. Research is also carried out into the causes, diagnosis and prevention of infectious diseases. The results are published in the Epidemiological Bulletin and the Federal Health Gazette. Another important task of the RKI is to recommend vaccinations. For this purpose, a permanent vaccination commission (STIKO) is appointed, which carries out a risk-benefit assessment based on scientific findings on vaccines and their efficacy and safety, and thus makes a recommendation for or against vaccination [32]. For the influenza virus, the STIKO recommends standard vaccination for people over the age of 60 [33]. To protect this group in particular, the WHO recommends a vaccination rate of 75% for people over the age of 65 [34]. In addition, people with chronic diseases, residents of old people's and nursing homes and pregnant women from the second trimester should be vaccinated [33,34]. People who work in health care or have contact with people at risk should also be vaccinated [33,34]. For COVID-19, basic vaccination is recommended for all persons over 18 years of age, residents of nursing homes, children over 6 months of age with underlying disease, persons at increased occupational risk of infection, and pregnant women [35]. Basic immunity exists after three contacts with a SARS-CoV-2 antigen, i.e. infection and vaccination. In addition, the STIKO recommends further booster vaccinations for certain groups of people, especially those over 60 years of age or with an underlying disease. These include chronic diseases of the respiratory tract, cardiovascular system, the metabolic system or immunodeficiency.

According to the IfSG, doctors are authorized to administer vaccinations [26]. Specialized physicians are authorized to administer vaccinations irrespective of their specialization. Data from Eurostat show that Germany achieved a vaccination rate of 43.3% in 2022 [36]. In comparison, many countries in and outside Europe are ahead. Denmark had a vaccination rate of 78% and Ireland 75.8%. In Mexico, 68.4% of people aged 65 and over were vaccinated against influenza. Countries with a lower vaccination rate than Germany include Lithuania (21.5%) and Croatia (31%).

## 1.4 Vaccination in pharmacies worldwide

Pharmacies are considered one of the most accessible healthcare providers [37,38]. Pharmacists not only play a key role in dispensing and counselling, but also support healthcare by providing pharmaceutical services such as blood pressure monitoring, medication analysis and screenings for various diseases [39]. For a number of years, pharmacies around the world have also been providing vaccinations to increase vaccination coverage [40]. In Argentina, the legal framework for vaccination in pharmacies dates back to 1983. In 1996, pharmacies in 14 US states were authorized to provide vaccinations. In Europe, the United Kingdom has been the pioneer of pharmacy-based immunization since 2002, followed by Portugal and Ireland. Statistics show that including pharmacies in the vaccination service increases both the vaccination rate and people's information and awareness [37,41].

The influenza vaccine is the most commonly administered vaccine in pharmacies worldwide, with the ultimate goal of reaching the WHO's target of 75% vaccination coverage for people over 65 years of age [34,42]. Examples of countries that have reported an increase in immunization coverage following the introduction of pharmacy-based vaccination are presented. In the UK, the number of flu vaccinations given to people aged 65 and over increased 8.15-fold between 2015 and 2022, resulting in a vaccination rate of 82.3% in the 2021/22 season [43,44]. In Ireland, where flu vaccination has been available in pharmacies since 2011, the service revealed that 23% of those vaccinated in a pharmacy were receiving the vaccine for the first time, and 83% of these were at-risk patients [45]. Norway also experienced a 32.1% increase in vaccination coverage between 2016 and 2020 following the introduction of pharmacy-based vaccination [37]. Germany achieved a vaccination coverage of 43.3% in the population aged over 60 years in 2022 [36]. Pharmacist administration of vaccines has been shown to increase vaccination coverage and reach different patient groups than conventional methods [38].

During the COVID-19 pandemic in Germany, pharmacists were involved in vaccination campaigns alongside doctors and veterinarians to meet the immense demand for primary and booster vaccinations, as the main objective is to immunize a large number of people, similar to other infectious diseases [46]. This also provides protection for those who cannot be vaccinated [47,48]. Initially, vaccination coverage for COVID-19 was estimated at 60-70%, but this changed when cases of waning immunity and re-infection were reported [48,49]. Repeated booster vaccinations have been recommended in response to this problem [49,50].

According to the International Pharmaceutical Federation survey, vaccinations are administered in pharmacies in 36 countries, and pharmacists are authorized to administer vaccinations in 26 countries [42]. In addition to flu vaccinations, some countries also offer vaccinations against other pathogens, such as diphtheria, hepatitis B or tetanus. The distribution of people who can be vaccinated in pharmacies also varies. For instance, 13 countries reported that pregnant women can be vaccinated in pharmacies, and in 11 countries even children.

## 1.5 Pharmacy-based vaccination in Germany

Since May 2022, vaccination against influenza for persons over 18 years of age and against COVID-19 for persons over 12 years of age has been included in standard pharmacy services in Germany. Pharmacies are allowed to offer and administer vaccinations, which are then reimbursed [26,51]. This follows a pilot project in 2020 in which a small number of pharmacies offered the flu vaccination in cooperation with a health insurance company [51]. Pharmacists were also involved in the COVID-19 vaccination campaign in 2021 [46]. These positive experiences led to pharmacists being able to offer vaccination against these two viruses as standard care under the Infection Protection Act [26].

In 2022, 305.100 vaccinations against COVID-19 were administered in German pharmacies [52]. In the 2022/2023 season, 57.600 vaccinations against influenza were administered in pharmacies, compared to only 5.600 in the 2021/2022 season. Of the patients surveyed, 20% stated that this was their first flu vaccination and 13% would not have been vaccinated if it had not been offered in pharmacies. In fact, 90% indicated that they would like to get another flu shot or other vaccinations at the pharmacy.

However, not all pharmacies offer the flu vaccine. In a brief survey conducted by the German Federal Chamber of Pharmacists, 28% of the responding pharmacies reported offering COVID-19 vaccinations, and only 7% plan to offer it [53]. For the influenza vaccination, 27% of the responding pharmacies stated that a vaccination is offered in their pharmacy and 13% are planning to do so. Reasons given for not offering vaccination in the pharmacy were additional staff costs, space requirements or concerns about relations with neighboring physicians.

Nonetheless, the current German Minister of Health, Karl Lauterbach, presented a draft pharmacy reform in June that would allow pharmacies to offer more services [54,55]. In addition to flu and coronavirus vaccinations, pharmacies would be allowed to offer other vaccinations in order to increase the vaccination rate among people over the age of 18. Pharmacies will be allowed to administer vaccines that do not contain pathogens capable of reproduction, so-called inactivated vaccines, which include tetanus and diphtheria.

## 1.6 Vaccination training

Since the introduction of vaccination by pharmacists in Germany, critical voices have been raised, particularly from the medical profession [56]. They argue that pharmacists are not adequately trained through their academic studies for the vaccination administration and related other tasks. In many countries, pharmacists must complete an additional qualification in immunization after completing their pharmacy studies [42]. In its 2020 report, the FIP states that 35 countries worldwide allow pharmacists to administer vaccines, but only 16 of these provide training for students, and only 15 countries have obligatory training.

In Germany, additional training with defined content is offered to train pharmacists as part of a continuing education program [26]. The training covers the following areas: practical administration of the vaccination, obtaining patient information and consent, observing contraindications and recognizing emergency situations and taking appropriate measures. The course consists of a theoretical part and a practical part in which the injection is carried out on a model arm or a portable pad with a tissue-like structure. In addition, participants have the opportunity to give a sodium chloride injection to a real person with their consent, and the entire course is supervised by a trained physician.

The FIP recommends the inclusion of vaccination courses in pharmacy curricula to adequately prepare future pharmacists and increase the number of pharmacists providing vaccinations [42]. In addition, increasing the number of pharmacists providing vaccinations may reduce workload during certain seasons. The effectiveness of a university course to train pharmacy students in the administration of vaccines has been demonstrated and evaluated in numerous studies [57–60].

## 1.7 High fidelity simulation

Simulation in the teaching of clinical skills can lead to improved student performance, knowledge and satisfaction [61,62]. Simulation is widely used in medical and nursing education to practice and rehearse clinical skills in a low-risk environment [63–65]. In addition, simulation can be used to create tasks and educational content on demand [66]. This improves the transfer of learning into practice. Depending on the learning objective, the type and nature of the simulation is important. The term "fidelity", which describes the similarity of the simulation to the simulated system, is important for categorization [67]. The higher the fidelity, the higher the degree of realism represented by the simulation. The following classifications of simulators are generally known [61,67,68]: Part-task trainers; these form only one specific area and are mainly used to train psychomotor skills. These can also be called low-fidelity simulators. For example, manikins of human body parts with a tissue-like structure are used to practice injections, punctures or blood sampling. Computer-based systems; these can be used to model aspects of human physiology or pharmacology, simulate tasks or situations and allow interaction with them via a computer interface. An extension of computer-based systems is virtual reality, where virtual objects or environments are created for all human senses to replicate the natural environment. Simulated or standardized patients; an actor taking on the role of a patient, which can be used to train communication and history taking in particular. Realistic patient simulators, also known as high-fidelity simulators, are the most technically advanced type of simulation. These are usually patient simulators or manikins that are controlled by built-in computers and software to simulate human vital parameters and signs. For example, as well as varying blood pressure, pulse or respiratory rate, an HFS can simulate invasive procedures or the administration of medication. In addition, a built-in microphone can be used to communicate via the HFS. This type of simulation allows complex and high-risk clinical situations to be practiced realistically. Team-building exercises can also be conducted [69].

In 1912, the first manikin called "Mrs. Chase" was used to train nursing students [70]. High-fidelity simulation was first introduced in the 1960s and reinvented in the late 1980s [61]. Since 1990, there has been a significant increase in knowledge and research into simulation-based learning and several companies have developed computerized manikins. HFS is now a proven and important teaching method for training healthcare providers [64,71].

In pharmacy education, such simulators are used in various areas such as emergency care, advanced life support, teamwork or communication and have been shown to increase knowledge, skills, self-assessment and satisfaction [62,63,65,69]. As a result, the Accreditation Council for Pharmacy Education (ACPE) in the United States of America has established criteria and approved the use of simulation in introductory pharmacy practice courses [69].

**Figure 1-1**.
High-fidelity Simulator (Gaumard HAL® S1000) with Software showing vital functions.

**Figure 1-2.**
Low-fidelity Simulator; wearable pad with tissue-like structure.

## 1.8 Aims

The involvement of pharmacists in the flu or COVID-19 vaccination has been shown to increase the vaccination rate in the population in several countries such as the UK, USA and even Norway [37,43–45]. In Germany, vaccination is not part of the pharmacy curriculum and is therefore a target for physicians in particular, who argue that pharmacists are not adequately trained to deal with potential emergency situations following vaccination process [56]. The FIP and the Federal Association of Students of Pharmacy in Germany therefore recommend that the subject of vaccination with practical training should be included in the curriculum of pharmacy studies [72,73]. Similarly, the use of simulation techniques in the education of pharmacy students in Germany is not particularly common. Therefore, the aim of this dissertation is to investigate the development and evaluation of a practical vaccination training course for pharmacy students including handling of emergencies using the HFS as a training tool. For this, two studies were conducted among fourth year pharmacy students and the vaccination training was implemented in the clinical pharmacy course at the Heinrich-Heine-University. The specific aims of the dissertation were:

1. to develop and evaluate a vaccination training with integrated emergency situations using high-fidelity simulation in a randomized controlled trial to assess the performance and self-assessment of pharmacy students.
2. to further investigate the acceptance of the developed vaccination course in a multicenter observational study at the universities of Bonn, Düsseldorf and Greifswald.
3. to integrate the vaccination training course into the clinical pharmacy education at the Heinrich-Heine-University of Düsseldorf.

# 2. Development and Assessment of Innovative high-fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy Undergraduates – a randomized controlled study

## 2.1 Background and Aim

Vaccination is the best and most successful method with respect to preventing infectious diseases [74]. In addition to reducing significant morbidities, disabilities, and mortalities, extensive immunization also possesses non-health benefits, such as improved cost-effectiveness, less of a disease burden, and increased educational achievements among children—due to their subsequent improved health [75–78]. There has been a substantial need for mass vaccinations since the COVID-19 pandemic began [79,80]. Similar to actions taken against other infectious diseases, immunizing a large number of people through numerous vaccinations is the main purpose. Furthermore, the immunization process is conducted for multiple reasons, including protecting those who cannot receive immunizations [47,48]. In order to address this demand for immunizations, physicians, veterinarians, dentists, and pharmacists were all asked to support the vaccination program in Germany [81]. Most pharmacists support the WHO's target of a 75% vaccination rate for people aged 65 and over or for other risk groups [82,83]. This is due to the fact that retail pharmacies are considered to be the most accessible health care facilities [39]. It must be noted that the involvement of pharmacists in the vaccination process has resulted in an increased coverage rate, awareness, and education [37,41,84,85]. This was most particularly the case for those groups of people who cannot, or do not, want to be reached by conventional means [38].

In order to meet these—as well as future—challenges, vaccination administration training should be implemented into the curriculum of pharmaceutical education. For instance, Australia and the USA have included teaching content related to immunization in the pharmacy curriculum [86,87]. The efficacy of a university course for the purposes of training pharmacy students in vaccine administration has been demonstrated and evaluated by many studies [57–60]. However, in Germany, additional training with defined content has been offered recently for the purposes of training pharmacists in a continuous education and training program [88].

Using simulation in the training of clinical skills can lead to improved knowledge, performance, and satisfaction among students and health-care professionals [61,62]. Further, high-fidelity simulation (HFS) is the most cutting-edge simulation technique currently available [65]. This kind of simulation is already being utilized in medical and nursing education [63,64] and is also being utilized in pharmacy education in order to train various clinical skills, as well as to enhance student competence and knowledge [89–91]. The impact of this type of clinical skills training can be measured by the objective structured clinical examination (OSCE), which is a common and established method of assessing clinical skills [92–94].

Traditional pharmacy education regarding vaccines only provides didactic knowledge about vaccines and their administration. The authors were not aware of any practical vaccination training courses that were available to pharmacy students at German universities. Neither were there any documented evidence on the integration and impact of HFS for the purposes of training pharmacy students' vaccination administration skills, nor in regard to the simulation of various emergency scenarios. Therefore, in this study, the aim is to develop an innovative training course with an HFS approach that integrates emergency handling. In addition, whether the HFS leads to better performance in comparison to the standard training (which utilizes LFS) is investigated; further, this was achieved by using an analytical checklist for the purposes of evaluation. The primary endpoint is, therefore, to demonstrate the difference in performance; additionally, the secondary endpoint is to demonstrate the variations in the participants' self-assessment and knowledge scores, if any.

## 2.2 Methods

### 2.2.1 Study Design and Participants

A pre and post randomized controlled trial with pharmacy students was conducted in order to investigate the effect of the HFS training approach on vaccination administration skills. This was then followed by an OSCE evaluation. The investigation was carried out, in German, from November 2021 to December 2021 as part of the “Clinical Pharmacy” course in the winter semester of 2021/2022. All the data were collected in pseudonymous form and were anonymized in the following analysis. In addition, approval of this study was granted by the responsible ethics committee (Nr.: 2021–1689). In October 2021, 46 fourth year pharmacy students were invited to participate in the study at the Heinrich-Heine- University in Duesseldorf. After completing the informed consent procedure, participants were randomized either into a control group or into an intervention group using RStudio (Version 1.4.1106) [95]. Participants were first sorted alphabetically and pseudonymized with “WS01” in increasing order. Then, the function “sample()” in the statistical software environment R was used to assign the participants to two equally sized groups A and B, where A was the control group and B the intervention group. Further, the overall study design is illustrated in Figure 2-1.

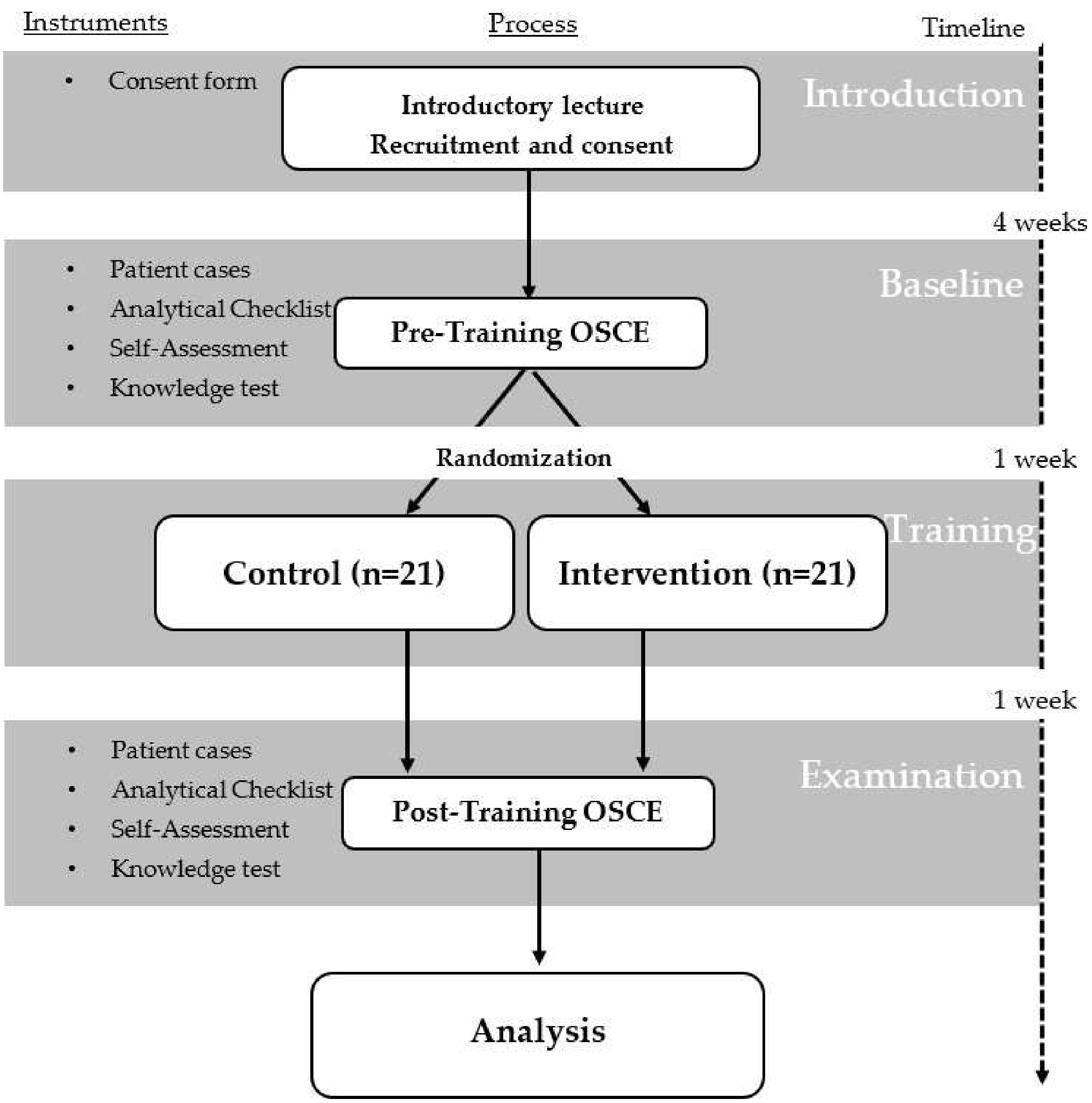



**Figure 2-1**
Flow Chart of the randomized controlled study. OSCE = objective structured clinical Examination

### 2.2.2 Study Procedure

At the beginning, an introductory lecture on influenza vaccination was conducted in order to ensure the same level of theoretical knowledge among all students. The contents included background information on the influenza virus and influenza vaccination; worldwide community pharmacy-based vaccination practices; the current status and legal requirements for vaccination administration in Germany; and the possible role of a community pharmacist. On the same day, the participants were informed in detail about the study and the consent forms for participation were then distributed. After 4 weeks, the participants completed a pre-training OSCE, a multiple-choice test, and a self-assessment questionnaire. In the next week, the respective vaccination administration training was conducted, which included emergency scenarios that was initiated for both groups. The control group received the standard training by using injection pads. The intervention group was trained via undertaking the HFS approach [96]. Finally, one week later, the participants completed a post-training OSCE, a second multiple-choice test, and another self-assessment questionnaire.

### 2.2.3 Development of the training course

Several pilot studies were conducted in advance, including two elective rotations of 4 students each and an international student exchange with 2 students. During the pilot study, students were asked to undertake a self-study of the background of vaccination and HFS, as well as the current situation of pharmacy-based vaccination globally. In addition, possible emergency scenarios were to be developed and transferred to the HFS. Cases and corresponding OSCE checklists were then created. Finally, the developed cases and checklists were used in OSCEs for further optimization. This allowed the methodology to be tested in several stages before the course was assessed in the randomized controlled trial.

### 2.2.4 Objective Structured Clinical Examination

Participants were assessed individually with respect to vaccination administration through pre- and post-training OSCEs. This was conducted with an intent to measure any differences in performance, if present. Five OSCE cases were prepared and reviewed by faculty members during focused group discussions. During the OSCEs, each participant was required to simulate a pharmacy-based vaccination administration process involving a standardized patient and was assessed by an observer who utilized an analytical checklist. A pharmacy-like environment was created for this purpose, where all necessary items were available. Participants were provided with individual time slots and received a brief description of the whole simulation process after registration. An OSCE lasted a maximum of 12 min. Faculty members and fourth year pharmacy students, who did not participate in the study, were trained and instructed to serve either as standardized patients or as observers. Standardized patients were replaced after each OSCE, while observers were replaced after every five OSCEs. After obtaining the participants' consent, certain OSCEs were recorded for quality assurance purposes. Randomly selected videos were then evaluated independently by two faculty members and the checklist scores were adjusted, as necessary.

### 2.2.5 Training Sessions

The 2.5 h-long training sessions were conducted separately for each study group. Both groups received blended theoretical and practical training with respect to anamnesis; patient education and information; vaccination preparation and administration; potential emergency situations; and the necessary measures to deal with them. The control group was trained in vaccination administration skills via the standard approach using LFS, i.e., utilizing injection pads. The intervention group interacted with an HFS and injected the vaccine intramuscularly. In addition, participants could talk directly to the HFS via an integrated microphone. A faculty member controlled the simulator remotely and responded to the participants. Further, various emergency scenarios were simulated by changing vital parameters through an in-built software program.

### 2.2.6 Instruments

High- and Low-Fidelity Simulator

For the purposes of training participants' vaccination administration skills, two different kinds of simulators were employed. The control group practiced intramuscular injection using a wearable LFS injection pad with a tissue-like structure (Erler-Zimmer Impftrainer; Figure 1-2); it must be noted that, currently, standard training uses simulators of this kind. In order to simulate the insertion of a needle into tissue, the injection pad enables for proper placement around the arm, as well as simulating the actual depth of injection and withdrawal of the needle. The intervention group completed the vaccination administration training on an HFS (Gaumard HAL® S1000; Figure 2). The simulator can be operated on by an in-built software and includes various controllable features. Important features include palpable pulse, heart and lung sounds, chest and abdominal movements, and an attached cuff for blood pressure measurement. A built-in microphone allows a person to speak directly through the mannequin to communicate with participants. An intramuscular injection can be performed on the upper arm. Changes of vital parameters, such as heart/respiratory rate or blood pressure, can be transferred either immediately or after specified time on the simulator.

Cases for OSCEs

Five different patient cases with emergency scenarios were developed and reviewed by faculty members during focused discussion groups and faculty meetings. The emergency scenarios dealt with asthma exacerbation, hypoglycemic events, angina attacks, anaphylactic shock, and vasovagal syncope [96] following vaccine administration. All cases possessed the pattern of a patient coming to the pharmacy for a flu vaccination and an emergency arising after receiving the vaccination. In addition, a medication plan was also prepared for each case. In the case of an asthma attack and angina attack, there were also emergency medications, which the standardized patients carried with them. Specific checklists were prepared for each case, which differed in content only in Station 4 (which is related to emergency scenarios). Standardized Patients were faculty members or pharmacy students who were trained to imitate respective emergency situations with verbal and non-verbal cues. Particular attention was paid to acting breathing and case-specific symptoms.

Pathological characteristics, according to the emergency situation, were given in a short case description (Appendix).

Analytical Checklist

In order to quantify the performance of the participants, they were assessed during the OSCEs by an observer using an analytical checklist. The analytical checklist was created by faculty members and thoroughly discussed during several meetings. However, it must be stated that the Federal Chamber of Pharmacists' official guidelines for flu vaccination in community pharmacies were followed in order to ensure that all relevant points and steps were included [97]. The checklist was also reviewed by a medical specialist and consisted of four stations. Each station contained subcategories and subitems with different total scores. Station 1 was related to taking a patient's medical history, with a total of 8 or 9 points, depending on the individual cases. This station also dealt with identifying the patient's eligibility for receiving the vaccination. Station 2 comprised tasks related to providing patient education and the necessary information regarding the vaccine and vaccination process. Station 3 included the necessary hygienic measures for the preparation of vaccines, the preparation on a personal basis and of the premises, and vaccination administration tasks. Further, Stations 2 and 3 each contained 12 points. Finally, Station 4 possessed 7 achievable points, which included tasks related to recognizing emergency situations and, thus, taking the necessary course of action. If a respective subitem was fulfilled, 1 point was awarded and if not zero points were given.

Multiple-Choice Test

In order to determine the participants' knowledge related to the influenza virus and the vaccination process, a multiple-choice test was developed consisting of five multiple-choice questions. There were different sets of questions for the pre- and post-training OSCEs.

Self-Assessment Questionnaire

In order to ascertain the participants' self-assessment regarding their competency and use of simulations in vaccine administration and pharmacy teaching, a pre- and post-training OSCE self-assessment questionnaire was developed. This consisted of nine questions with a 6-point Likert scale where 1 was full disagreement and 6 was full agreement. Questions 1 to 6 were related to personal ability regarding the vaccination process and questions 7 to 9 were related to the use of simulations in clinical skill-based pharmacy training sessions. The same survey was also completed in the pre- and post-training OSCEs

### 2.2.7 Statistical Methods

In this study, the effects of the HFS training approach on vaccination administration skills compared to the standard training (with LFS methods) through OSCEs were analyzed. The results of these are given in percentages in order to ensure comparability between pre- and post-training OSCEs, as well as the intervention and control groups. Since proportions, i.e., percentages of achieved points in the OSCEs, were considered in the comparison of the performance of the intervention and the control group, non-parametric tests were used for these comparisons. More precisely, in order to measure the success between pre- and post-training OSCEs of the respective groups, a one-sided paired Wilcoxon signed-rank test with a significance level of alpha = 0.05 was performed. In order to determine the difference between the intervention group and the control group with respect to the pre- and post- training OSCEs, a one-sided Mann–Whitney test was performed with a significance level of alpha = 0.05. Hence, a p-value below 0.05 was considered significant. In addition, Microsoft Excel 2019 [98] was utilized for the purposes of data entry and OriginPro 2021 [99] for statistical analysis.

## 2.3 Results

### 2.3.1 Participant Characteristics

Forty-two students in their fourth year of pharmacy studies, after providing their informed consent, were available to participate in this study. Only one participant was excluded from the analysis of the self-assessment questionnaire due to missing information. Table 2-1 describes the participant characteristics for both the intervention and the control groups.

**Table 2-1: Demographic characteristics of the participants**

| | Control Group (n = 21) | Intervention Group (n = 21) | *p*-Values |
|---|---|---|---|
| Age | | | |
| Mean (±SD) | 25 (±2,67) | 24.38 (±2.35) | |
| Median | 24 | 23 | 0.337 |
| Range | 22–32 | 22–31 | |
| Gender | | | |
| Female, n (%) | 17 (81) | 18 (86) | 1 |
| Male, n (%) | 4 (19) | 3 (14) | |
| Previous or current experience (e.g., pharmaceutical technician, vaccination centre) | | | |
| Yes (%) | 6 (29) | 0 (0) | 0.021 |
| No (%) | 15 (71) | 21 (100) | |

SD = standard deviation

### 2.3.2 Analytical Checklist Score of OSCEs

The participants' performance during the OSCEs was assessed and quantified using an analytical checklist. The analytical checklist scores reflect the participants' ability to successfully conduct the vaccination process, i.e., from initiation to handling the untoward reactions. In total, 39 or 40 points could be achieved, depending on the individual case. The point-based scores were then converted to percentage points in order to enable comparisons between the groups and different OSCEs. For visualization of the data, box plots were generated. At baseline, the control group performed significantly better than the intervention group ($p < 0.01$; Table 2-2; Figure 2-2). Additionally, both groups demonstrated significant improvement in their overall performance from pre- to post-training OSCEs (intervention group: $p < 0.01$; control group: $p < 0.01$; Figure 2-2). However, the intervention group showed a significantly greater improvement in their analytical checklist scores when compared to the control group ($p < 0.01$; Figure 2-3). Accordingly, the intervention group showed significantly greater improvement in each station ($p < 0.01$ for station 2–4; Figure 2-4) except in Station 1, which is related to taking patient history, in comparison to the control group ($p = 0.210$ for station 1; Figure 2-4). It is interesting to note that every individual of the intervention group improved from pre- to post-training OSCEs (Figure 2-2). In Station 4, which is related to handling emergency situations, the intervention group demonstrated a significantly improved performance ($p= 0.014$) from pre- to post-training OSCEs when compared to the control group ($p= 0.216$).

**Table 2-2: Achieved scores by intervention and control group in each stations of analytical checklist during pre and post Training OSCEs**

| Group | Pre-Training OSCE-Score | Post-Training OSCE-Score | Score Difference |
|---|---|---|---|
| | Mean (SD) % | Mean (SD) % | Mean (SD) % |
| **Station 1** | | | |
| Intervention | 26.06 (14.81) | 69.38 (15.72) | 43.34 (23.18) |
| Control | 27.65 (18.53) | 63.89 (18.92) | 36.24 (21.54) |
| **Station 2** | | | |
| Intervention | 7.54 (9.83) | 45.64 (17.00) | 38.10 (16.79) |
| Control | 22.22 (13.26) | 43.25 (28.34) | 21.03 (32.13) |
| **Station 3** | | | |
| Intervention | 49.60 (15.47) | 84.52 (11.87) | 34.92 (17.60) |
| Control | 53.18 (17.38) | 67.86 (22.10) | 14.68 (26.10) |
| **Station 4** | | | |
| Intervention | 51.70 (19.42) | 65.99 (17.77) | 14.29 (27.85) |
| Control | 61.22 (26.40) | 63.95 (27.71) | 2.72 (19.50) |
| **Total** | | | |
| Intervention | 32.10 (7,70) | 66.12 (8,89) | 34.03 (11.66) |
| Control | 39.73 (8,21) | 58.79 (19,84) | 19.06 (18.20) |

SD= standard Deviation; OSCE= objective structured clinical examination

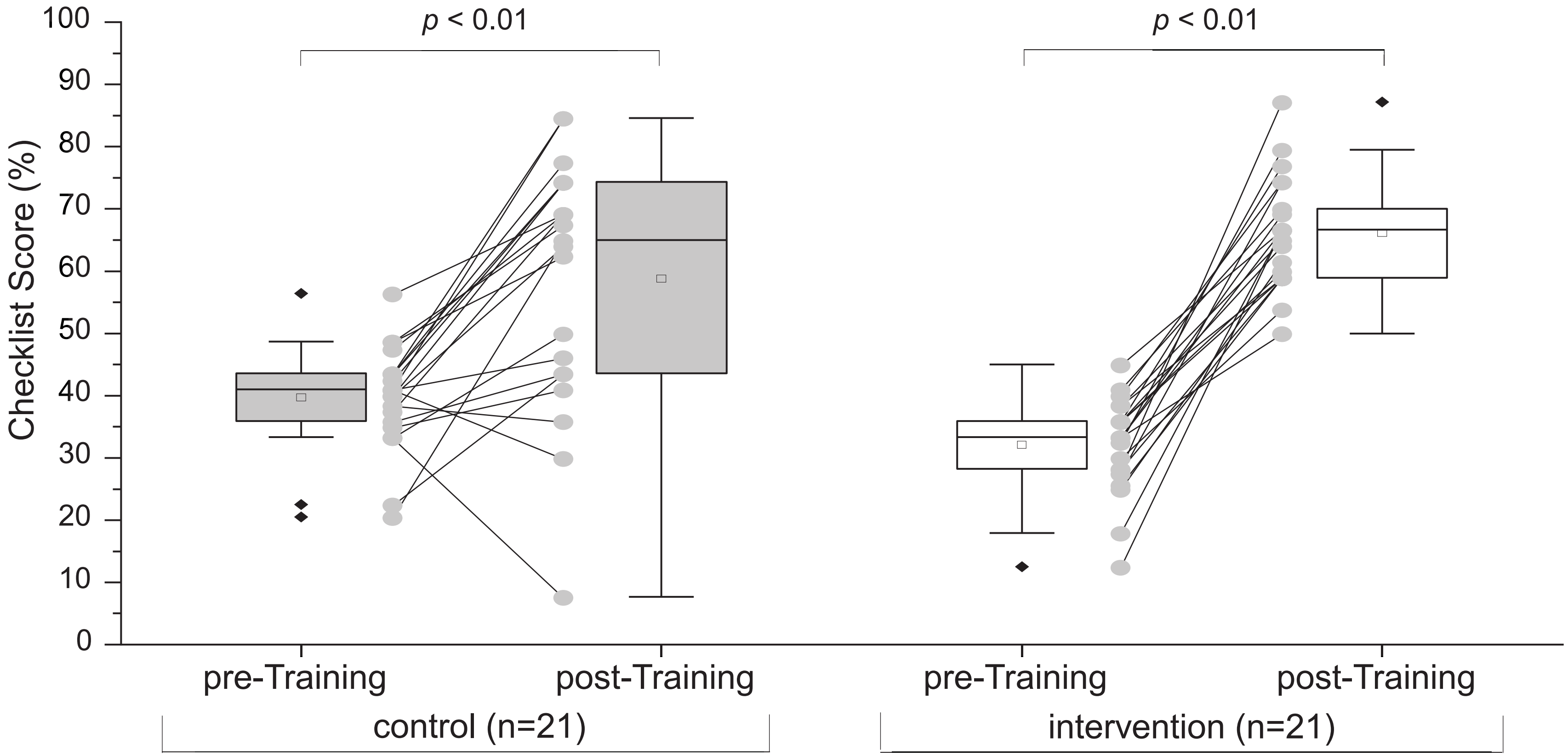



**Figure 2-2:**

Box plots of analytical Checklist scores between pre- and post-Training OSCEs. The grey dots and lines show the difference in performance of each participant. The black diamonds (♦) indicate the outliers. A one-sided paired Wilcoxon signed-rank test with a significance level of alpha = 0.05 was used to compare OSCE scores between pre- and post-Training of the respective groups.

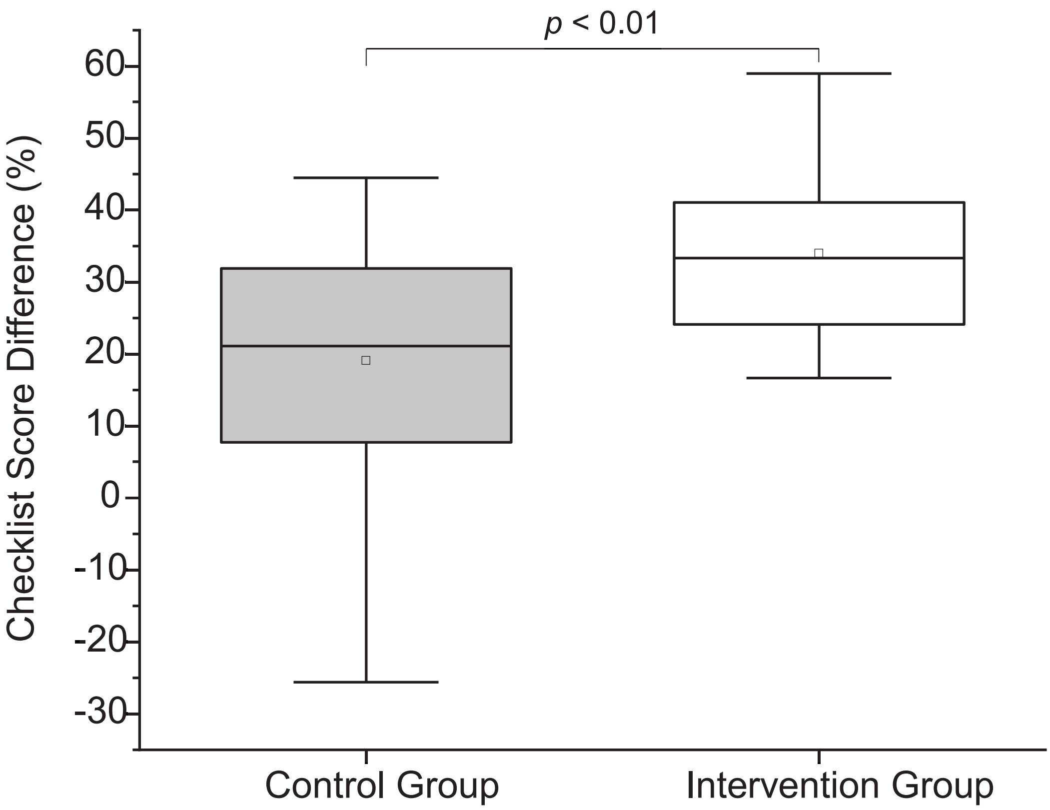



**Figure 2-3:**
Box plots of analytical checklist score difference between pre- and post-Training OSCE. A one-sided Mann–Whitney test with a significance level of alpha = 0.05 was used to compare OSCE scores between groups.

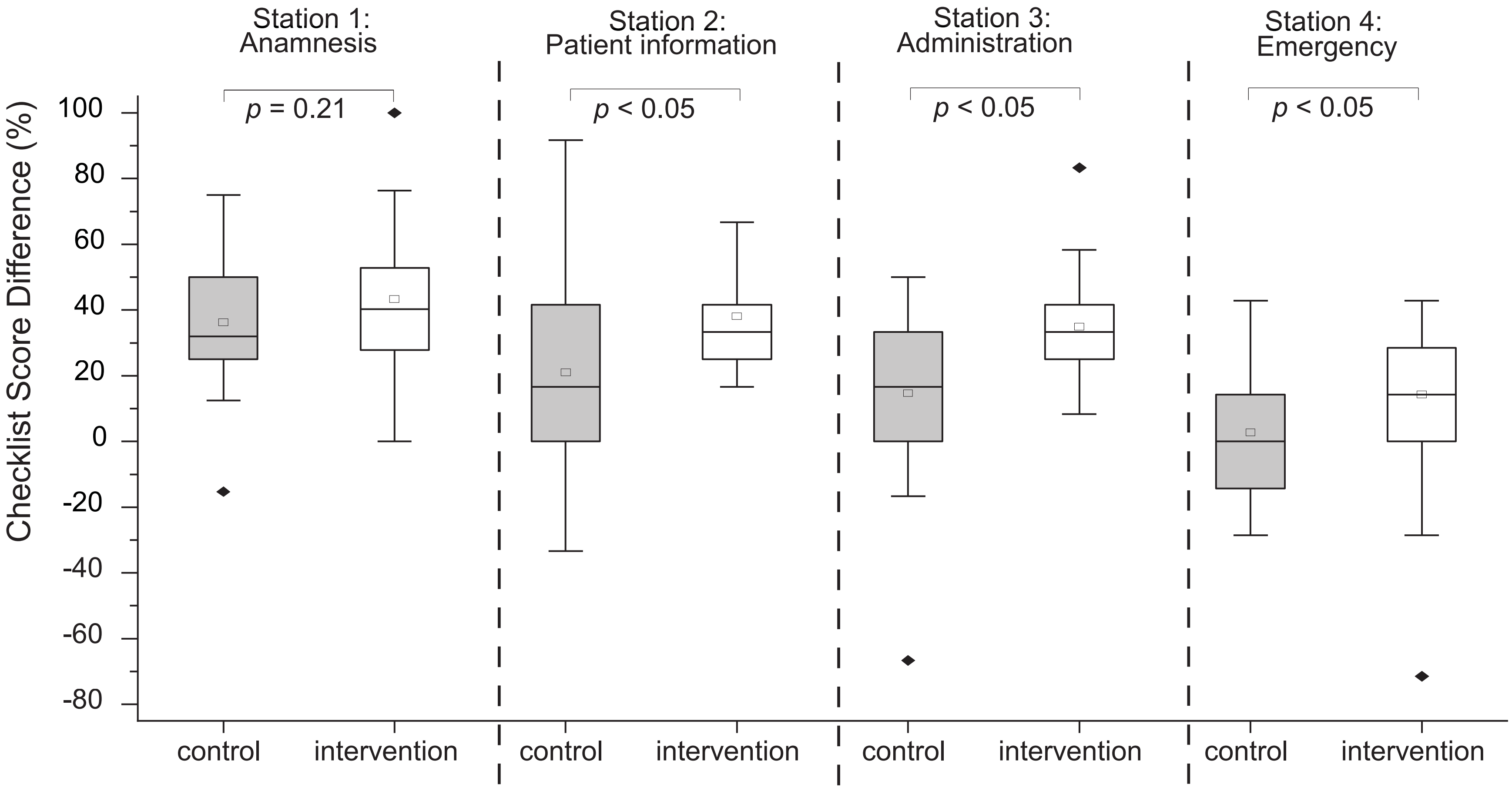



**Figure 2-4:**

Box plots of analytical Checklist score differences for each station between pre- and post-training OSCE for respective groups. The black diamonds (♦) indicate the outliers. A one-sided Mann–Whitney test with a significance level of alpha = 0.05 was used to compare OSCE scores between groups.

### 2.3.3 Multiple-Choice Test

The participants showed no significant ($p = 0.471$) increase in knowledge scores points in both groups from the pre- to post-training multiple-choice tests (see Table 2-3).

**Table 2-3: Achieved scores by intervention and control group in pre- and post-training multiple-choice-test**

| Group | Pre-Training | Post-Training |
|---|---|---|
| | Mean (%) | Mean (%) |
| **Intervention** | 3.00 (60) | 3.43 (68.57) |
| **Control** | 2.7 (55.24) | 2.86 (57.14) |

### 2.3.4 Self-Assessment Questionnaire

Both groups demonstrated a similar increase in self-assessment scores when evaluated through a 6-point Likert scale. There were no significant differences between the intervention and control groups in regard to baseline ($p = 0.505$). This was also the case for the post-training self-assessment questionnaire scores ($p = 0.568$). Both groups reached significantly greater scores (intervention and control group: $p < 0.01$) from the pre- to post-training self-assessments. However, on question 5, which concerns the competency of recognizing and classifying possible vaccination reactions within the first 15 min after vacation, certain participants from the intervention group showed signs of disagreement (Figure 2-5). A few participants from both the intervention and control group disagreed with the statement regarding their self-efficacy for acting appropriately in an emergency situation during the first 15 min (Figure 2-5). Statistical computation of the questionnaire and results for question 7 to 9 are depicted in Appendix.

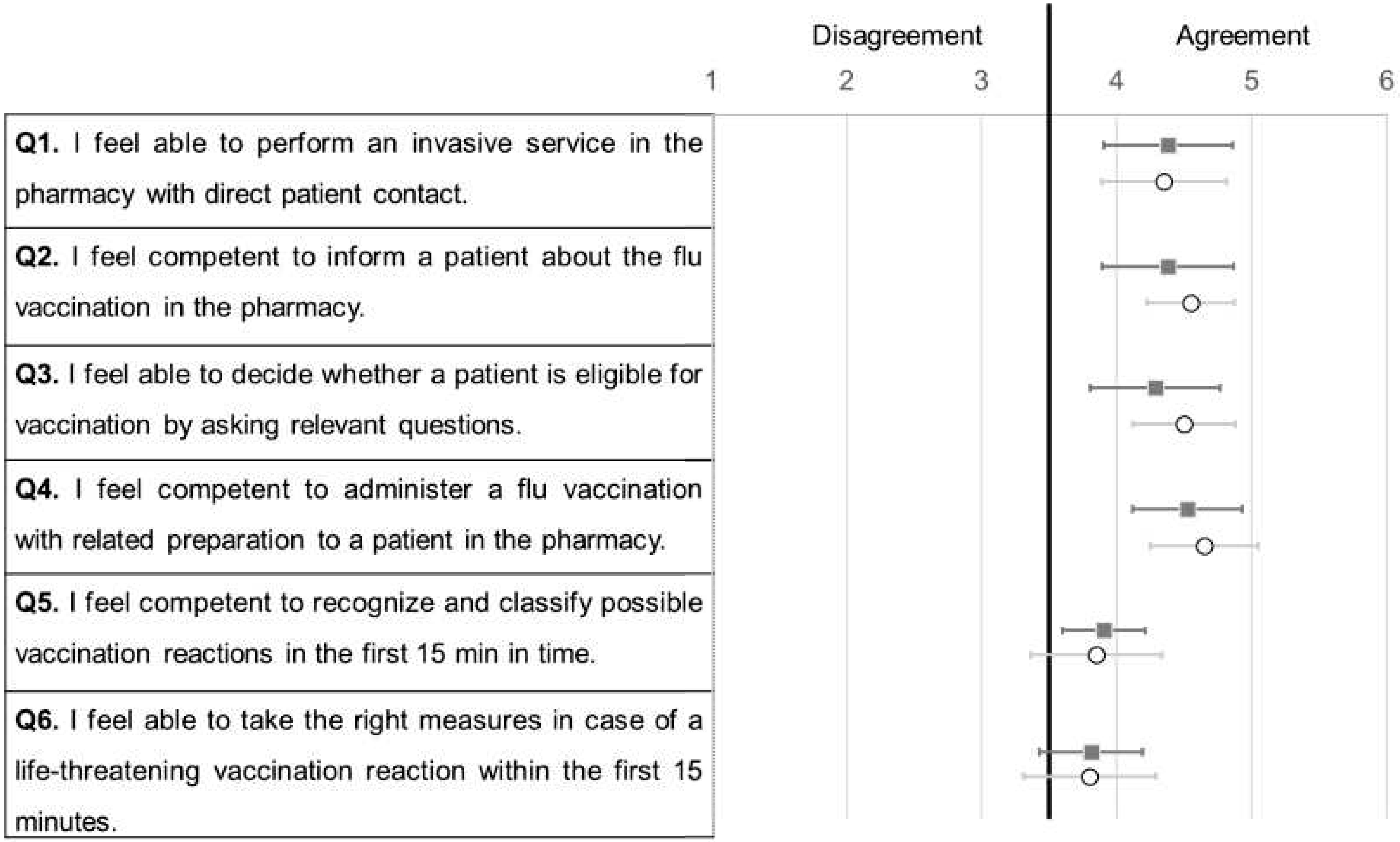



**Figure 2-5:**

Forest plot of mean values with 95% confidence interval of self-assessment scores for question 1 to 6 in post-Training (6-point Likert scale). White dots (○) = intervention group (n = 20); grey square (▪) = control group (n = 21).

## 2.4 Discussion

In the present study, simulation-based training for pharmacy students in order to better educate them regarding vaccination administration was successfully implemented. In this study, positive students' outcomes, as evidenced in the improved performance and overall self-assessment scores when compared to the control group who were trained in the standard teaching method, were demonstrated. Both groups significantly improved their performance from pre- to post-training. However, the participants of the intervention group with their HFS-based training were able to perform significantly better in terms of dealing with patient information, vaccination administration, and the handling of emergency situations. Importantly, the HFS training proved to be an effective teaching tool as every individual in the intervention group improved their performance; whereas in the standard training, some participants remained at the same level and some even decreased in ability.

High-fidelity simulation proved to be very effective for the purposes of vaccination training and resulted in significantly better outcomes in terms of participants' performance. This may be attributed to the fact that HFS offers a patient-centered experience and can truly imitate the situation in a safe environment [66]. Other studies undertaking simulation- based vaccination training for pharmacy students showed similar results [100,101]. However, the comparability to our study is partially limited as they have not utilized a high-fidelity mannequin. For instance, Skoy et al. used two forms of simulators: an injection arm as a higher fidelity form of a simulator and an injection pad [101]. Similarly, Bushell et al. utilized roleplays, low-fidelity mannequins, standardized patients, and a mixed reality in order to create a realistic experience. Both reported improved knowledge and confidence level among students [100]. Furthermore, a key focus of this study was to train the participants in safe vaccination administration skills. Through the application of HFS in this study, there was an integration of different emergency cases, potentially arising after vaccination administration, that may or may not be directly related to vaccination, such as asthma exacerbation. As an aside, other studies on vaccination training have only focused on anaphylactic reactions [100,102,103]. Students in the HFS group particularly demonstrated significantly better performance in terms of recognizing and handling emergency situations. In addition, they also demonstrated a better performance in terms of the station dealing with patient information and vaccination administration.

Abajas-Bustillo et al. found that communication skills could also be promoted by using HFS [104]. In addition, Tokunaga and colleagues demonstrated that students' self-reports increased in understanding in monitoring vital signs and their measurements, including intramuscular injection [105]. In line with our findings, it could be shown that HFS training enhances competence with respect to specific clinical areas and skills. However, in contrast, Massoth et al. demonstrated that HFS did not lead to a significant improvement in performance, but the participants in this group were overconfident in their self-assessment [106].

We believe that through interaction with the HFS, clinical skills can be perceived and performed more efficiently. In our study, every single participant improved after training with the HFS, while certain participants who did not receive training with the HFS performed lower in their pre- to post-training OSCEs. Improved performances were, however, reported in several studies among nursing [107,108], medical [109], and pharmacy students [110–112]. This was specifically in regard to teaching clinical skills by the use of HFS. However, training should ultimately qualify and improve each participant. In a previous study, simulation performance was shown to correlate with clinical performance [113]. Thus, simulation performance was considered the best predictor of clinical performance. Therefore, it seems appropriate that simulation-based learning should be included in the curriculum in order to teach clinical skills at an early stage.

The fact that simulation-based teaching is generally accepted by students is also shown in the results of the self-assessment questionnaire. The questions seven to nine, regarding using simulations in pharmacy education, were all answered with a general agreement both before and after the respective trainings. It was surprising to note that despite the improved performances, certain students disagreed in their self-assessment regarding their ability in recognizing and handling emergency situations. This fact contrasts with the findings reported by Zamami. Y and colleagues. Their study demonstrated a higher confidence with respect to the participants in handling emergency patients after undertaking pharmaceutical life-saving skills training [114]. This lack of agreement in our study could be attributed to two factors. Firstly, the participants have had no patient interaction, nor exposure to clinical situations during their pharmacy studies in Germany; as such, they will still, therefore, possess a certain lack of self-assurance. Secondly, the training sessions were their first hands-on experience in which they had to make real time decisions in a close-to-real environment. Therefore, nervousness could be a possible reason for the low confidence level reported as well [112]. However, it must be stressed that these participants' perception of their ability was at variance from their actual performance during the study. Their lack of confidence could be addressed by scheduling trainings at an early stage and assigning the students with a responsibility to vaccinate, such as what was demonstrated by Peter R. Caroll and colleagues when they developed a student-led vaccination clinic for the purposes of training medical, nursing, and pharmacy students [102].

We are aware that our study is subject to certain limitations. Firstly, the present study did not determine any significant increase in terms of knowledge among the participants. The questions asked in the pre-training OSCE, as well as in the post-training OSCE, were of a general nature and, therefore, are possibly solvable, independently of the training. Therefore, the results of the multiple-choice tests cannot be correlated with the results of performance. Secondly, the patients were played by pharmacists, technical assistants, or pharmacy students instead of professional actors. In order to avoid a possible bias, both instructive and demonstrative instructions were given in several sessions. These included, in addition to medical history and medication, acting out certain symptoms and signs for emergency situations. In addition, the actors were not the observers filling out the checklist. The reason for this was to keep the focus entirely on their role rather than on completing a checklist. Additionally, the actors were given at least 15 min between OSCEs in order to prepare for the next case. Thirdly, the observers were pharmacists or pharmacy students, and in order to avoid possible inter-observer scoring bias, the analytical checklist was discussed in several sessions and example sentences or actions were explained. Additionally, each participant was assessed by the same observer in the pre- and post-training OSCE. In order to maintain concentration, the observers changed after every five examinations. The students who assisted in conducting the OSCEs were involved in a pilot study and, therefore, participated as members of the study team. Fourthly, due to legal and ethical reasons, it was not possible to allow students to perform an injection on a real person, as is offered in the standard training. Additionally, the constant presence of a doctor for supervision is still difficult to facilitate. Therefore, we used standardized patients, who wore a vaccination pad around their upper arm during the OSCEs, in order to imitate a real vaccination process in a community pharmacy. In addition, a pharmacy-like environment was created in order to simulate the situation as realistically as possible. Fifthly, despite randomization, all participant with previous pharmaceutical work experience were in the control group. This could be a possible explanation, that the control group reached significant greater scores during pre-Training OSCEs compared to the intervention group. In addition, the difference in Station 2 in pre-OSCE between the two groups was very high. However, when asked about pharmaceutical work experience, participants were also asked to specify whether they had worked or were working as a pharmaceutical technical assistant, in vaccination centers or similar, or in other areas. None of the participants worked in vaccination centers or similar, excluding previous experience in this field. We performed a sensitivity analysis in this respect excluding the six participants with pharmaceutical work experience. All results remain the same except for Station 2 (patient information) where no statistically significant difference could be shown in terms of performance between the two groups. The results of the sensitivity analysis are given in the Supplementary Materials. Finally, the number of participants seems to be low, and the study was only conducted at one university. Therefore, a power analysis was performed using the resulting means, standard deviations, and sample sizes, which yielded a power of 92%. Therefore, even though number of participants seems to be low, a statistical power was reached that is larger than the usually targeted power of 80 or 90%. However, further studies with a larger number of participants as well as the inclusion of more universities are recommended. Moreover, the training courses employing the high-fidelity simulator can be very expensive [63], especially for low-income countries where there is a high need for pharmacist-led vaccination administration. Collaborations at the university or even at the national level can address this issue, as the simulator can be transported. This could also increase vaccination rates in poorer or rural communities.

## 2.5 Conclusions

Pharmacists are becoming increasingly involved in vaccination in Germany as well as in many other countries. In order to ensure safe vaccinations being conducted by pharmacists, training with HFS proved to be superior to standard training in this study. Particularly, it could be shown that emergency situations can be addressed in a very effective manner. Furthermore, the introduction of such a course into the pharmacy curriculum should be considered in order to prepare students for future challenges.

## 2.6 Disclosure

Parts of this chapter were previously published as "Sayyed, S.A.; Sharkas, A.R.; Ali Sherazi, B.; Dabidian, A.; Schwender, H.; Laeer, S. Development and Assessment of Innovative High-Fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy Undergraduates—A Randomized Controlled Study. *Vaccines* **2023**, *11*, 324. https://doi.org/10.3390/vaccines11020324"

The author of this dissertation had a lead role in and substantially contributed to the conceptualization, methodology, formal analysis, investigation, resources, project administration, visualization, writing - original drafts, as well as writing - review and editing.

# 3. Vaccination Training for Pharmacy Undergraduates as a Compulsory Part of the Curriculum? - A Multicentric Observation

## 3.1 Background and Aim

Since May 2022, the German government has included vaccination against influenza for persons older than 18 years and against COVID-19 for persons older than 12 years in pharmacies as regular care [115,116]. Under certain conditions, pharmacies are now allowed to offer these vaccinations and be reimbursed by health insurance companies. This was preceded by a model project since 2020, in which a few pharmacies had offered the flu vaccination in cooperation with a health insurance company [115]. The positive experiences finally led to permitting pharmacists to offer vaccinations against these two viruses as regular care under the Infection Protection Act [116].

Vaccination in pharmacies, however, is not a novelty from a global perspective. Pharmacies in many countries offer vaccination services to achieve higher coverage, especially for people older than 65 years of age, for whom a 75% vaccination rate is recommended by the World Health Organization (WHO) [117,118]. The evidence shows enabling pharmacists to administer vaccines increases vaccination uptake and reaches out to different patient groups compared to conventional means [37,117,119–122]. In Germany, as in other countries such as the USA and Australia, pharmacists are the most accessible healthcare providers [37–39,41]. The average density of pharmacies in Germany is 32 pharmacies per 100,000 inhabitants [123]. Here, the services offered play an important role, as well as offering the opportunity for people to speak to a healthcare provider, in this case a pharmacist [124]. This means that more people can be approached and educated about vaccinations [37,38].

Training on vaccination should take place at an early stage in the education of pharmacists. The International Pharmaceutical Federation (FIP) also recommends the incorporation of vaccination training into curricula for pharmacy undergraduates to adequately prepare future pharmacists and to increase the number of vaccinating pharmacists [73]. Furthermore, an overload of the workforce during certain seasons can be reduced by an increased number of vaccinating pharmacists [125]. In Germany, pharmacists must complete an additional training course after graduation in order to obtain permission for vaccination in pharmacies [116]. However, in a brief survey by the Federal Chamber of Pharmacists in Germany, only 13% of the participants said they would offer flu vaccination in the future [126]. In order to increase pharmacists' perception of vaccination at an early stage, vaccination training should be integrated into the curriculum. Therefore, the Institute of Clinical Pharmacy and Pharmacotherapy in Duesseldorf developed a vaccination course for pharmacy students, which uses high-fidelity simulation (HFS) as training tool [127]. In a randomized controlled study, it was found that training with HFS resulted in better performance among students compared to LFS. Also, students showed increased self-assessment using training with simulators. In this and some other studies, the efficacy of a university course for training pharmacy students on vaccination administration could be demonstrated and evaluated. In order to investigate whether this specific training on vaccination is not only accepted by the students from Heinrich Heine University Duesseldorf but also by other German pharmacy schools, we expanded our vaccination training course to some other German universities. The primary objective was to ask the students to assess their vaccination performance. Secondly, the satisfaction of the students with the course was also assessed. These two aspects were evaluated by using questionnaires.

## 3.2 Methods

### 3.2.1 Study Design and Participants

In this investigation, the self-assurance and satisfaction of pharmacy students at different universities participating in vaccination training was assessed using a pre- and post-training questionnaire. Four universities were invited to introduce the training course. Of these four universities, two universities agreed to offer the course at their respective universities. In May and June 2023, the vaccination training was given at the universities of Duesseldorf, Bonn and Greifswald. This training was conducted as part of the “clinical pharmacy” course at the respective universities. The responsible faculty members of the respective universities divided the students into groups of 8–12 students and prepared the time schedule. Students were invited to give their consent for the collection of study-related data after receiving detailed participant information. The data were collected pseudonymously and anonymized following analysis. To identify themselves, students should use a code composed of the initials and the last four digits of their student identification number. Approval for this study was granted by the ethics committee of the medical faculty of Heinrich Heine University Duesseldorf (Nr.: 2023-2422).

### 3.2.2 Training Course

A training course was designed for 8–12 students and lasted 2 h. In the beginning, a short lecture was given to the participants. Thereby, relevant information about the structure and epidemiology of influenza virus and SARS-CoV-2 were given first. Then, the background and global achievements regarding the involvement of pharmacies in vaccination were shown. After this, the content of vaccination training that is required by the regulations was presented, and an introduction to HFS was given. Then, the practical part of the course began, where the participants were asked first to list the requirements for the room and equipment needed for a vaccination in a pharmacy. Second, the important aspects of medical history to determine patient eligibility for vaccination in a pharmacy were listed. In the same way, the aspects of patient education prior to vaccination were stated. The interview for medical history and patient education was then demonstrated by a participant with the HFS. Thereafter, the actions to be taken in an emergency situation and the measurement of patients' vital signs were explained. At this point, each participant was to perform the vaccination on the simulator, including preparation and injection. During this procedure, five randomly selected participants had to manage an emergency scenario that addressed one of the following cases: anaphylactic reaction, vasovagal syncope, asthma attack, angina attack and hypoglycemic attack. The cases were supervised by a medical doctor and were used in the previous study [127]. Here, the lecturer guided the participants in the proper treatment of the respective scenario. The vaccination and emergency situations were all carried out using the HFS.

### 3.2.3 Instruments

High-Fidelity Simulator

A high-fidelity simulator (Gaumard HAL®S1000; Gaumard Scientific, Miami, FL, USA) was used for the vaccination training and to simulate emergency scenarios. The simulator can be controlled using software, and vital parameters, such as blood pressure, respiratory frequency or pulse, can be changed immediately or after a specified time on the simulator. Participants can also communicate directly with the simulator via a built-in microphone. The injection can be performed in the upper arm. For control during the training sessions, a faculty member sat in a nearby room and answered students' questions during the scenarios if necessary.

Self-Assessment Questionnaire

To assess the self-assessment of the participants in terms of competency in vaccination in a pharmacy, a self-assessment questionnaire was used, which was developed following the intensive group discussion of faculty members in the previous randomized controlled study [127]. It consisted of six questions with a 6-point Likert scale, where 0 was full disagreement and 5 full agreement. The participants had the possibility to access and complete the questionnaire on a mobile device via QR code. The questionnaire was completed before and after the training course.

Satisfaction Questionnaire

A further questionnaire was designed to evaluate participants' satisfaction with the vaccination training course. This questionnaire consisted of six questions with a 6-point Likert scale where 0 was full disagreement and 5 full agreement. The questions were related to the use of simulation for clinical practice. Participants also had the possibility to leave a comment or a suggestion for the improvement of the training session. This questionnaire was part of the post-training questionnaire.

### 3.2.4 Statistical Analysis

In this study, the self-assessment and satisfaction of pharmacy students at multiple universities with the HFS vaccination training was investigated. For the comparison between universities, as well as between pre- and post-training, non-parametric tests were applied. More precisely, to measure the change from the pre-to post-training questionnaire, a Wilcoxon signed-rank test with a significance level of alpha = 0.05 was performed. To determine the difference between the universities in the pre- and post-training questionnaire, the Kruskal–Wallis test with a significance level of alpha = 0.05 was performed. Microsoft Excel 2019 [98] was used for the data entry and OriginPro 2021 [99] for the statistical analysis. The design of the questionnaires and data collection was carried out using the Qualtrics software 2005 [128].

## 3.3 Results

### 3.3.1 Participant Characteristics

Ultimately, 130 pharmacy students in the eighth semester participated in the vaccination training and provided informed consent for study-related data collection. Six participants were excluded from the analysis due to missing data and the inability to match pre- and post-training. The participants' characteristics are described in Table 3-1.

**Table 3-1: Demographic characteristics of the participants**

| | **Bonn (n = 33)** | **Duesseldorf (n = 42)** | **Greifswald (n = 49)** | **Total (n = 124)** |
|---|---|---|---|---|
| **Age** | | | | |
| **Mean (±SD)** | 23.91 (±1.88) | 24.79 (±3.54) | 23.31 (±1.79) | 23.97 (±2.60) |
| **Median** | 24 | 24 | 23 | 23 |
| **Range** | 21-28 | 21-38 | 21-28 | 21-38 |
| **Gender** | | | | |
| **Female, n (%)** | 23 (69.70) | 32 (76.19) | 28 (57.14) | 83 (66.94) |
| **Male, n (%)** | 10 (30.30) | 10 (23.81) | 21 (42.86) | 41 (33.06) |
| **Previous or current experience (e.g. pharmaceutical technician, vaccination center)** | | | | |
| **No, n (%)** | 28 (84.85) | 35 (83.33) | 37 (75.51) | 100 (80.65) |
| **Yes, n (%)** | 5 (15.15) | 7 (16.67) | 12 (24.49) | 24 (19.35) |

SD = standard Deviation

### 3.3.2 Self-Assessment Questionnaire

All the participants of the respective universities demonstrated a similar increase in the self-assessment score when ascertained using a six-point Likert scale (Figures 3-1 – 3-4). The scores for each question were significantly higher from the pre-to post-training self-assessment questionnaire at each university (Table 3-2; Figures 3-1 – 3-4)). At the University of Bonn, questions 1–5 in the pre-training questionnaire could not be clearly assigned to agreement or disagreement (Figure 3-1). In contrast, the answers in the pre-training questionnaire at the University of Düsseldorf were assigned firmly to disagreement (Figure 3-2). At the University of Greifswald, questions 1, 2 and 4 from the pre-training questionnaire could not be assigned clearly to agreement or disagreement (Figure 3-3). In total, all the results from the pre-training questionnaire are in the range of disagreement, with the exception of question 2 (Figure 3-4). In the post-training questionnaire, all the results at all three universities were in the range of agreement (Figures 3-1 – 3-4). Furthermore, the results do not differ significantly when comparing the universities in both the pre- and post-training self-assessment questionnaires (Table 3-2). Only in questions 1 and 4 of the pre-training questionnaire were the results significantly different between the three universities, where pairwise comparisons using a Mann–Whitney test showed that the results of the university of Duesseldorf significantly differed from those of the other two (p-value $< 0.05$ in head-to-head comparison of Duesseldorf and other respective universities).

**Table 3-2: Achieved scores by participants in self-assessment questionnaire**

| | | Bonn (n=33) Mean (±CI) | Duesseldorf (n=42) Mean (±CI) | Greifswald (n=49) Mean (±CI) | Total (n=124) Mean (±CI) | $p_2$-value |
|---|---|---|---|---|---|---|
| Q1 | Pre-Training | 2.42 (0.53) | 1.24 (0.41) | 2.04 (0.47) | 1.87 (0.28) | < 0.01 |
| | Post-Training | 3.88 (0.27) | 3.76 (0.25) | 3.98 (0.26) | 3.88 (0.15) | 0.26 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |
| Q2 | Pre-Training | 2.39 (0.43) | 2.07 (0.33) | 2.61 (0.40) | 2.37 (0.23) | 0.17 |
| | Post-Training | 3.82 (0.28) | 3.60 (0.28) | 3.90 (0.23) | 3.77 (0.15) | 0.31 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |
| Q3 | Pre-Training | 2.45 (0.48) | 1.93 (0.32) | 2.06 (0.34) | 2,12 (0.22) | 0.18 |
| | Post-Training | 4.00 (0.24) | 4.14 (0.25) | 4.16 (0.23) | 4.11 (0.14) | 0.47 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |
| Q4 | Pre-Training | 2.12 (0.57) | 1.12 (0.34) | 2.04 (0.45) | 1.75 (0.27) | < 0.01 |
| | Post-Training | 3.94 (0.27) | 3.81 (0.33) | 3.94 (0.30) | 3.90 (0.18) | 0.74 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |
| Q5 | Pre-Training | 2.30 (0.40) | 1.81 (0.35) | 2.00 (0.36) | 2.02 (0.21) | 0.24 |
| | Post-Training | 3.48 (0.23) | 3.43 (0.25) | 3.57 (0.27) | 3.50 (0.15) | 0.65 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |
| Q6 | Pre-Training | 1.85 (0.39) | 1.14 (0.34) | 1.51 (0.39) | 1.48 (0.22) | 0.04 |
| | Post-Training | 3.33 0.30) | 3.14 (0.23) | 3.33 (0.32) | 3.27 (0.17) | 0.37 |
| | $p_1$-value | < 0.01 | < 0.01 | < 0.01 | < 0.01 | |

CI = 95% confidence interval; $p_1$-value = intragroup comparison;

$p_2$-value = intergroup comparison

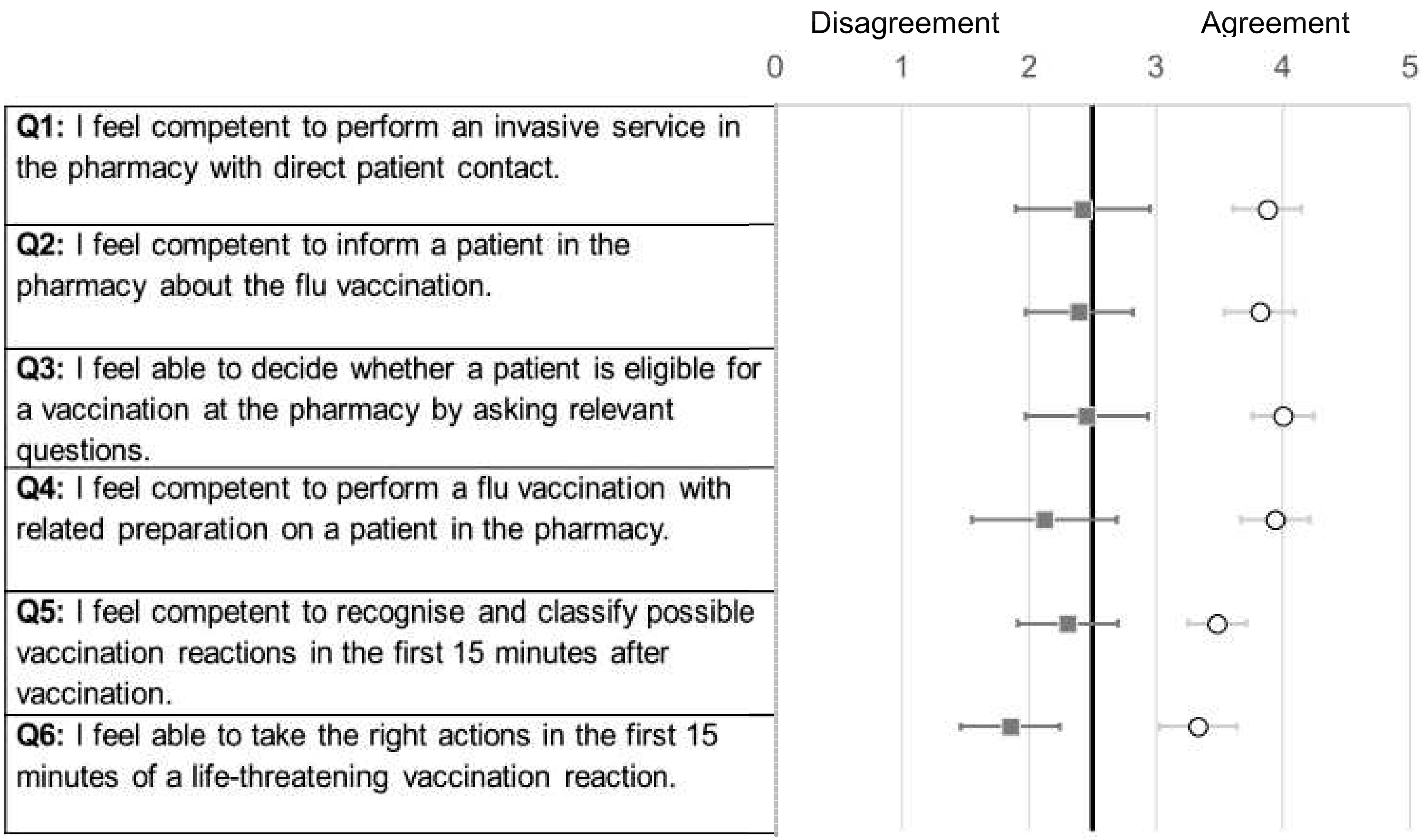



**Figure 3-1:**

Forest plot of mean values with 95% confidence interval of self-assessment scores pre- and post-Training questionnaire (6-point Likert scale) in University of **Bonn**. Grey squares (■) = pre-Training; white dots (○) = post-Training; n = 33.

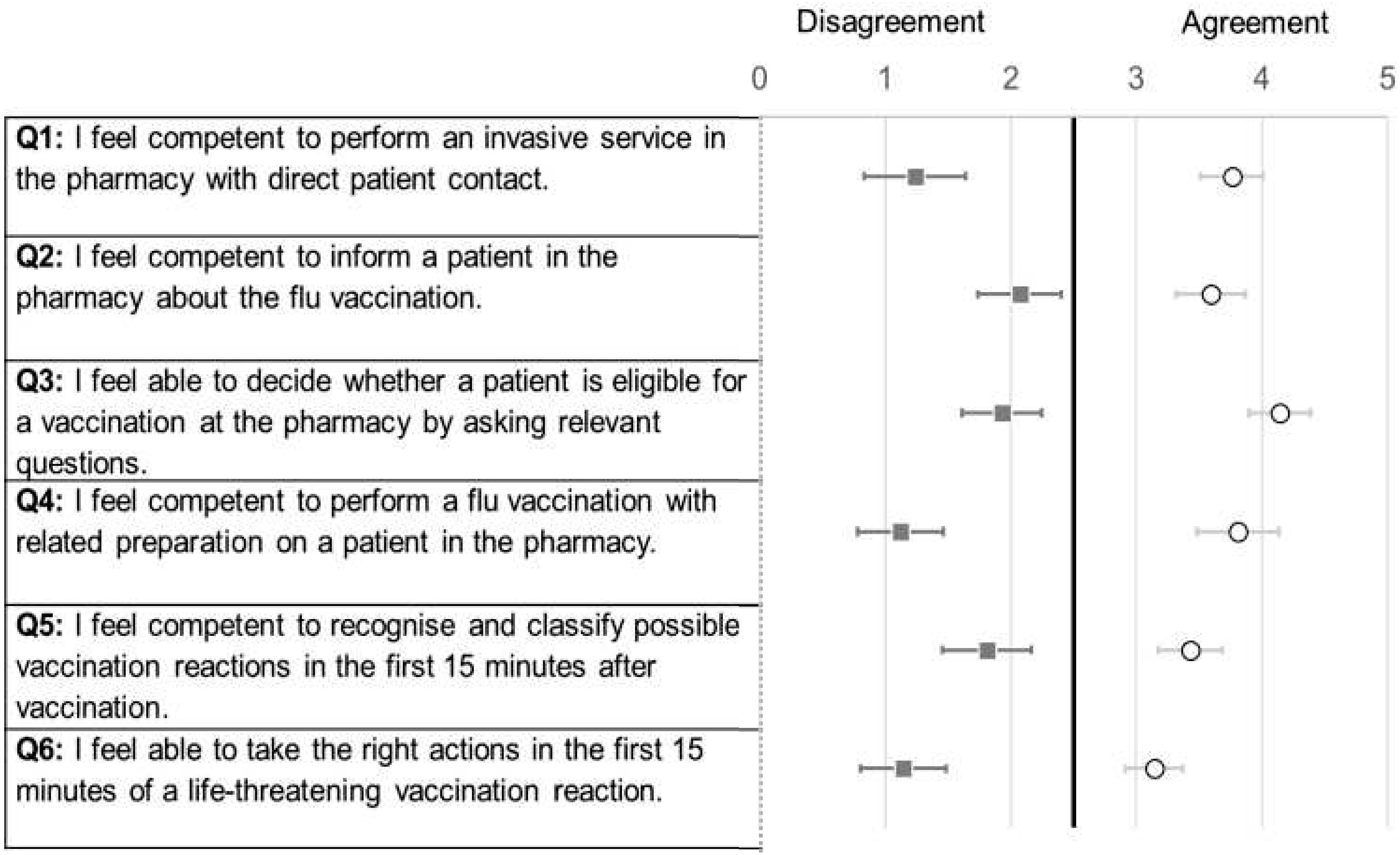



**Figure 3-2:**

Forest plot of mean values with 95% confidence interval of self-assessment scores pre- and post-Training questionnaire (6-point Likert scale) in University of **Duesseldorf**. Grey squares (■) = pre-Training; white dots (○) = post-Training; n = 42.

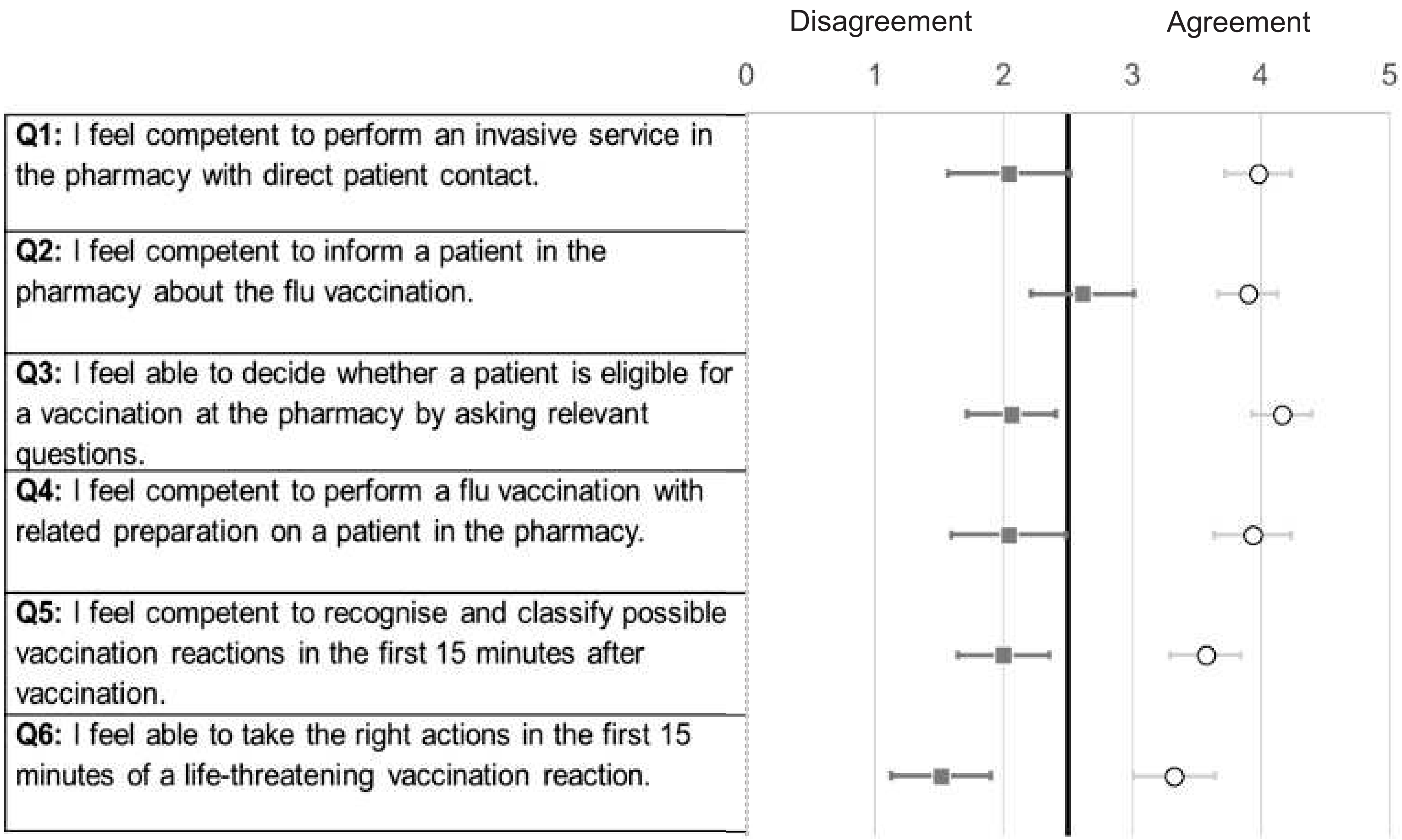



**Figure 3-3:**

Forest plot of mean values with 95% confidence interval of self-assessment scores pre- and post-Training questionnaire (6-point Likert scale) in University of **Greifswald**. Grey squares (■) = pre-Training; white dots (○) = post-Training; n = 49.

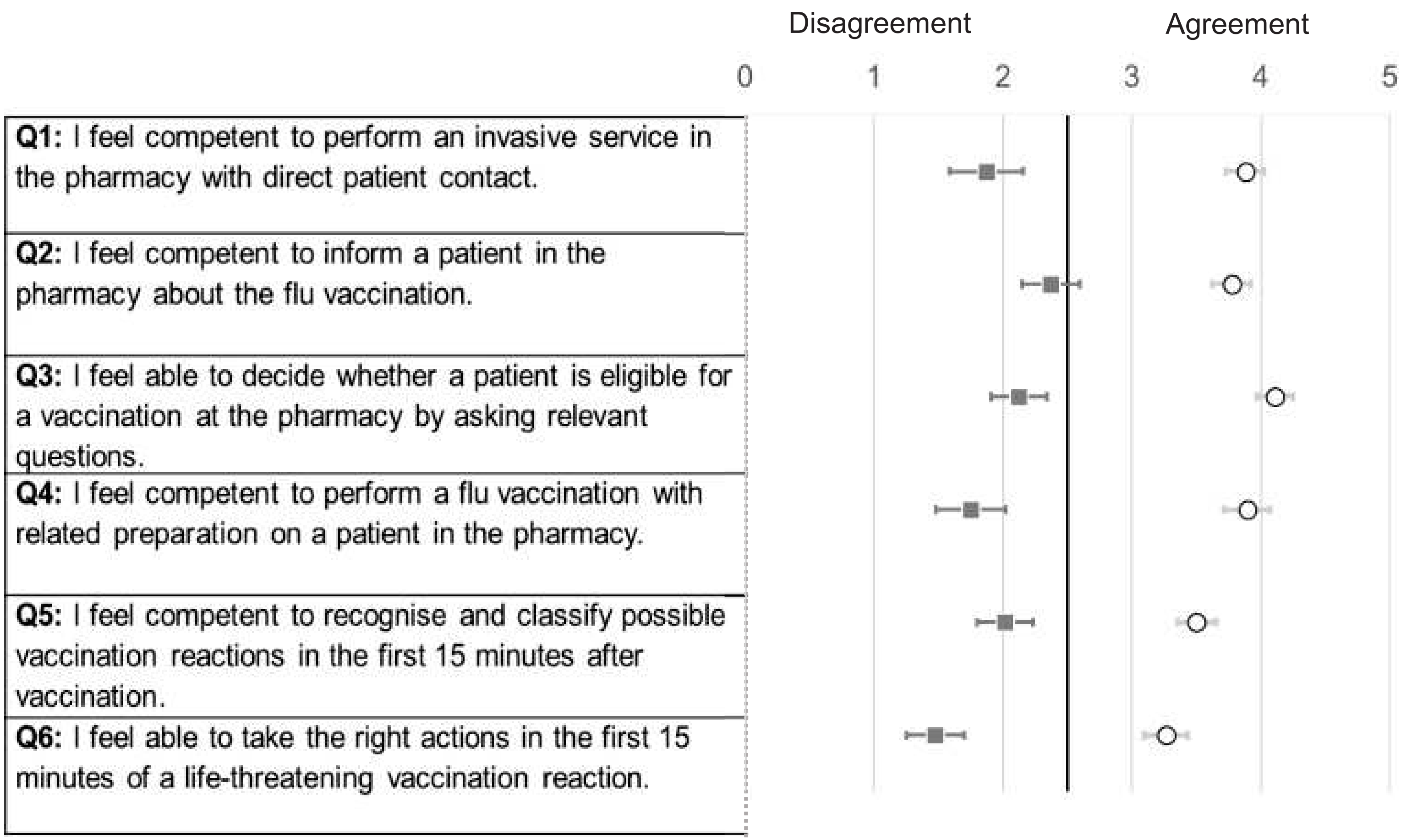



**Figure 3-4:**

Forest plot of mean values with 95% confidence interval of self-assessment scores pre- and post-Training questionnaire (6-point Likert scale) in **all universities**. Grey squares (■) = pre-Training; white dots (○) = post-Training; n = 124.

### 3.3.3 Satisfaction Questionnaire

Participants declared high satisfaction as rated using a six-point Likert scale. Thereby, the scores of the satisfaction questionnaires did not differ significantly between the universities (Table 3-3). With the exception of question 5 at the University of Bonn, the scores of all questions were high at all universities (Figure 3-5). Students described the highest satisfaction in question 1 with the use of simulations in the teaching of clinical pharmacy, whereas the lowest satisfaction was shown in question 5 with the encouragement to become a pharmacist.

**Table 3-3: Achieved scores by participants in satisfaction questionnaire**

| | **Bonn (n = 33) Mean (±CI)** | **Duesseldorf (n = 42) Mean (±CI)** | **Greifswald (n = 49) Mean (±CI)** | **Total (n = 124) Mean (±CI)** | ***p*-Value** |
|---|---|---|---|---|---|
| **Q1** | 4.55 (0.24) | 4.69 (0.18) | 4.49 (0.21) | 4.57 (0.12) | 0.22 |
| **Q2** | 3.67 (0.30) | 3.69 (0.29) | 3.88 (0.25) | 3.76 (0.16) | 0.60 |
| **Q3** | 4.48 (0.27) | 4.55 (0.20) | 4.43 (0.22) | 4.48 (0.13) | 0.64 |
| **Q4** | 4.39 (0.26) | 4.38 (0.23) | 4.39 (0.24) | 4.39 (0.14) | 0.94 |
| **Q5** | 2.88 (0.47) | 3.10 (0.38) | 3.39 (0.41) | 3.15 (0.24) | 0.25 |
| **Q6** | 4.36 (0.25) | 4.24 (0.24) | 4.39 (0.21) | 4.33 (0.13) | 0.67 |

CI = 95% confidence interval; Q = Question Nr.

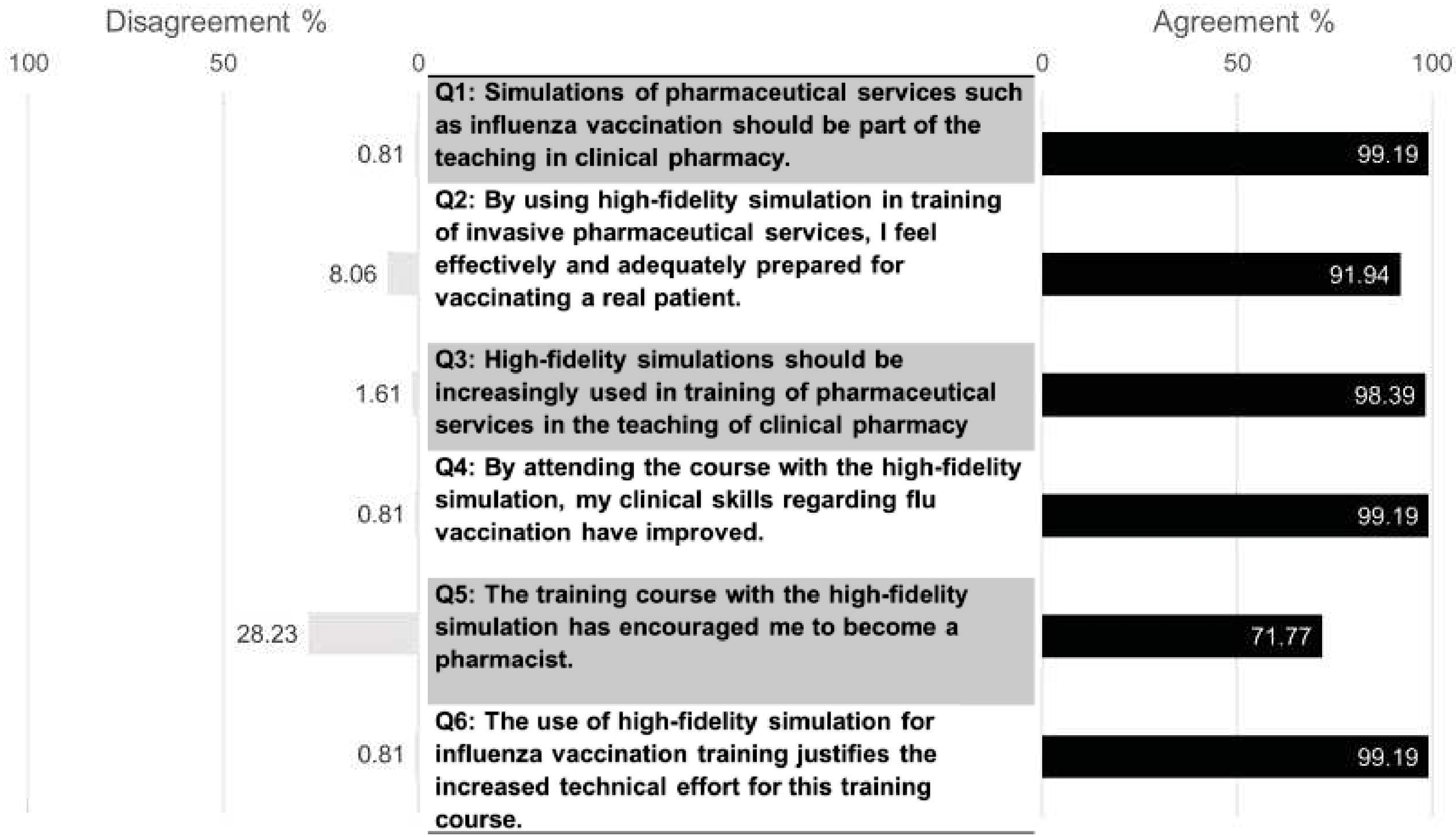



**Figure 3-5**:

Participants' satisfaction of all universities in percentage. Agreement indicates positive responses (“strongly agree”, “agree”, “slightly agree”). Disagreement indicates negative responses (“strongly disagree”, “disagree”, “slightly disagree”). n=124

## 3.4 Discussion

In this study, vaccination training using HFS was successfully carried out at three different German universities. It could be demonstrated that the increase in the self-assessment of pharmacy students was significant and similar at all participating universities. At the respective universities, each participant achieved higher self-assessment scores, resulting in a significant increase from pre- to post-training. The participants reported high levels of satisfaction with the training. There were also no significant differences in the results between these universities. Hence, it can be raised that such a vaccination training course could sufficiently prepare students at these universities for vaccination in a pharmacy.

We hypothesize that the integration of a vaccination training course into the pharmacy curriculum could be recommended to these universities. We believe since influenza and COVID-19 vaccination has been included into the standard care offered by pharmacists, such vaccination training during pharmacy school should lead to certification for vaccination practice. In this, as well as in the previous, study, positive outcomes were demonstrated in terms of the student performance and self-assessment at the participating universities. These results line up with the findings of Bushell et al., who also assessed the learning and teaching in vaccination training in pharmacy education in Australia [100]. They observed an increase in knowledge and confidence among students after the training. Mills et al. evaluated the change in attitude, confidence, knowledge and clinical skills among pharmacy students in Australia using pre- and post- questionnaires [59]. They also showed a significant increase in the aforementioned aspects. Marcum et al. assessed the impact of a training program for pharmacy-based immunization for pharmacy students in the USA [129]. The training was found to have a positive impact on students' knowledge and skills. Another investigation examined the impact of inter-professional training on vaccination administration, where participants from the health disciplines of medicine, nursing and pharmacy received training and ran an immunization clinic [102]. The investigators found a significant increase in knowledge, confidence and skills regarding influenza vaccination. The majority of students who received a vaccination would also recommend it to others. Such an approach shows that using a university training program on vaccination, students are sufficiently qualified to administer vaccinations. Our results underline this with high satisfaction and a significant increase in self-assessment for the students from all participating universities. Also, the comments that the students left in the satisfaction survey after the training were mostly positive. One student wrote “The seminar was very informative and gave a practical insight into the vaccination routine. The concept is very good”. Many other students reported that the training was very helpful and enjoyable. But, from other comments, we can also see that further training sessions are desired, such as in this comment: “More sessions would be helpful. For a more secure feeling, it would be helpful for me to simulate similar emergency situations again at a later date to check that you really recognize situations and take the right measures”.

In this study, HFS was used for the vaccination training, including emergency cases. We believe that by using HFS for vaccination training, besides developing clinical skills, especially the emergency situations that can occur immediately after vaccination can be practiced for effectively. Using the HFS, students can perform inappropriate and unsafe interventions on patients without consequences, and then learn from the effects and further develop their skills and achieve confidence in their interventions using re-attempt and feedback from the instructor [66]. In our studies, the students administered vaccinations and treated emergency scenarios, resulting in increased confidence and satisfaction [127]. Thereby, most students also indicated that HFS should be increasingly used for teaching clinical skills. Numerous studies in various healthcare disciplines have shown an increase in clinical skills among students with the use of HFS [107,109]. More precisely, Jessee et al. showed in an observational study that pharmacy students increased their confidence in applying clinical skills in the field of oncology pharmacy when using HFS training [130]. Morris et al. showed that HFS increases the competence of pharmacists during a medical emergency [89]. We were also able to confirm this in our study, as every student improved in their performance after receiving training with the HFS compared to training with a LFS. However, the effective use of HFS in terms of performance, knowledge and confidence were also shown in other health disciplines and clinical aspects, such as communication, emergency management and inter-professional collaboration [69,91,104,107,131].

We are aware that our study is subject to certain limitations. Firstly, the training was only conducted at three universities. The pharmacy schools from the universities recruited via email were not representative concerning the size or regional diversity of Germany. The approach was to ask those universities where some scientific collaboration with the clinical pharmacy department had already been established to increase the chance of collaborating in this scientific approach in the novel vaccination teaching project. To implement such training, the number of students as well as the time schedule during the semester matters. Also, the acquisition of HFS is an expensive undertaking. However, integrating vaccination training into the curriculum is preferable, and using our study, we were able to describe a possible approach to embedding effective vaccination training into the teaching of pharmacy. Future studies should include as many universities as possible in order to make a comprehensive evaluation. Secondly, the duration of the course was limited to 120 min. It was not possible to give a background and general information on influenza, COVID-19 and vaccinations, which would be beneficial to overall knowledge. The training course for pharmacists in Germany and in comparative international settings describes lasts several hours, usually divided into theoretical and practical parts. More precisely, the course for pharmacists in Germany lasts 10.5 h [132]. Similarly, the course offered in Australia includes an 8 h online course and a full-day workshop [133]. However, if vaccination training is integrated into the curriculum, it is necessary to analyze which relevant content needs to be taught in order to obtain certification for vaccination in public pharmacies. In order to ensure a high level of learning during the practical exercise with the HFS, we purposely limited the size of the groups. The number of participants in one group did not exceed 12 [134]. This can also be confirmed by the positive comments of the participants after the course, as they experienced lots of enjoyment and benefited from the course. Theoretical contents should therefore be introduced in a separate lecture. Thirdly, in this study, we did not measure the performance outcomes before and after training. Instead, we collected the participants' self-assessment before and after the training. We were able to demonstrate a positive effect on performance in the previous study [127]. Also, in terms of the scheduling, time and staffing, it would not be possible to measure performance using objective structured clinical examinations (OSCEs) or other methods. Therefore, during the training sessions, each participant was closely monitored and corrected immediately by the instructor in case of errors.

## 3.5 Conclusion

Pharmacists in Germany and globally occupy a special role in patient care, including vaccination. Accordingly, pharmacists must already be adequately and effectively prepared for future challenges during their professional education. Therefore, a vaccination course seems to be highly accepted by the students at these three different locations. It could be integrated into the pharmacy curriculum. Furthermore, students recommended this kind of training also to colleagues. Therefore, other pharmacy schools in Germany might also profit from this kind of vaccination training program using innovative technologies such as high-fidelity simulation.

## 3.6 Disclosure

Parts of this chapter were previously published as “Sayyed, S.A.; Kinny, F.A.; Sharkas, A.R.; Schwender, H.; Woltersdorf, R.; Ritter, C.; Laeer, S. Vaccination Training for Pharmacy Undergraduates as a Compulsory Part of the Curriculum? - A Multicentric Observation. *Pharmacy* 2024, *12*, 12. https://doi.org/10.3390/pharmacy12010012”

The author of this dissertation had a lead role in and substantially contributed to the conceptualization, methodology, funding acquisition, formal analysis, investigation, resources, data curation, visualization, writing - original drafts, as well as writing - review and editing.

# 4. Integrating Vaccination Training using HFS for Pharmacy undergraduates

This research showed that vaccination training with the HFS gives pharmacy students a first-hand experience of pharmacy-based vaccination and prepares them for future challenges. In the summer semester of 2022, the vaccination course was offered for the first time in the "Clinical Pharmacy" seminar at the Institute for Clinical Pharmacy at the Heinrich Heine University and has been offered to students every semester since. A 2.5-hour lecture provides information and background on influenza, SARS-CoV-2, the legal framework for immunization, and pharmacy-based vaccination. On two further days, the practical vaccination exercise with the HFS takes place. In groups of 10-12 students, patient history and information, documentation, implementation, and emergency situations are covered for 90-120 minutes each. Each student has the opportunity to interact with the HFS individually. The HFS is controlled by a faculty member who also communicates through the HFS, i.e. as a patient. Each student is observed and corrected as necessary. A feedback session is then held to highlight important points and provide a summary of the emergency scenarios. As in the studies, the emergency scenarios are anaphylaxis, asthma attack, angina attack, vasovagal syncope and hypoglycemia. In this way, each student received the theoretical basis and the practical implementation of a vaccination in the pharmacy.

Following the successful implementation of vaccination training in the "Clinical Pharmacy" seminar, the Institute for Clinical Pharmacy and Pharmacotherapy at the Heinrich Heine University in Düsseldorf, Germany, purchased a pediatric HFS to practice vaccination on children (Figure 4-1). In some countries, children and adolescents are also vaccinated in pharmacies. With the pediatric HFS, it is now possible to address this unexplored area in Germany. The HFS is also used in other areas to train clinical skills. Other areas of research and use of the HFS at the Institute include patient counseling in hospital settings and blood pressure measurement.

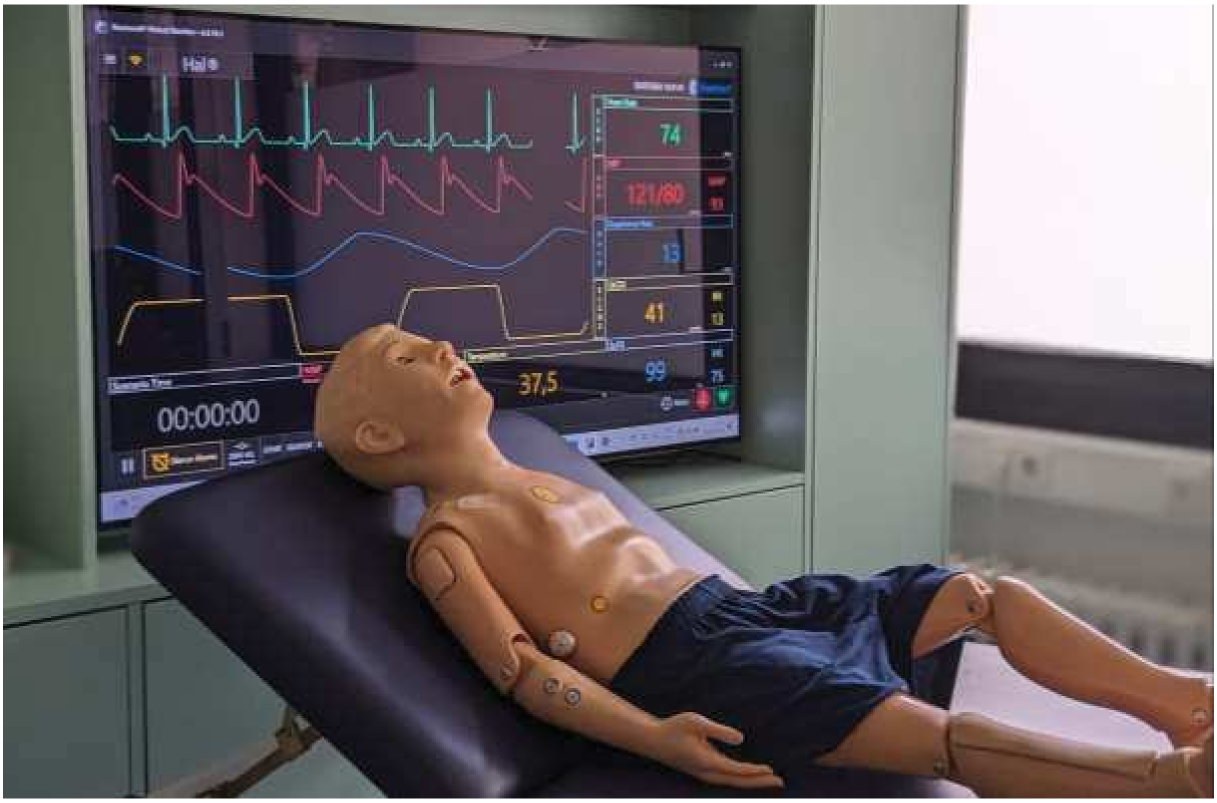



**Figure 4-1:**

Pediatric Simulator (Gaumard HAL® S1000) with Software showing vital functions.

# 5. Overall Discussion and Outlook

This dissertation evaluates the use of HFS and the implementation of a developed vaccination training program for pharmacy students. Student performance and self-assessment were assessed. This work shows that the use of the HFS can adequately prepare pharmacy students for pharmacy-based vaccinations and that the HFS is an appropriate tool for teaching these clinical skills.

In general, this work indicates that vaccination training should be integrated into the pharmacy curriculum. Both studies showed an increase in student self-assessment and satisfaction [127,135]. They reported increased self-assessment of their overall performance and administration of vaccinations, as well as their communication with patients during vaccination. In the randomized clinical trial, both groups showed similarly high self-assessment scores, which were confirmed in the second study at other universities. An important aspect of the first study was the assessment of performance using OSCEs. Here, the intervention group showed greater results with the HFS than the control group, which only interacted with an LFS. Particularly noteworthy are the results for emergency management, where the intervention group performed better. In the first and second study, students were very satisfied with the vaccination course and indicated that simulations should be used more often in pharmacy education to train clinical skills.

The second study did not assess student performance, nor was there a control group, as this aspect was investigated in the first randomized trial. Objective assessment of performance is associated with higher personnel costs and is very time consuming. The first study required 5 simulated patients and 4 observers to complete the checklist. Four of the observers were pharmacy students who were already trained in the scope of an elective practical course on vaccination. Therefore, the approach used in the second study should be followed as a framework for the integration of simulation training into the curriculum. Here, the practical part was carried out in 120 minutes and required 2-3 staff members. It should be noted that important background information would have to be covered in a separate lecture. Furthermore, in both settings, each student could only interact with the HFS once. For this reason, the groups were kept as small as possible, as the learning effect is proven to be greater in a smaller group [134]. In addition, the purchase of an HFS is very expensive and may not be affordable for all universities. However, the acquisition of an HFS opens up further possibilities for teaching in clinical pharmacy.

A strength of this dissertation is the investigation of student performance and self-assessment in a randomized controlled trial. Additionally, the second study at several universities was able to generate data from considerably larger number of participants and thus provide robust results. Students reported a high level of satisfaction with the course and a positive self-assessment. Most of them also stated that such a course and simulation-based learning methods should be included in the curriculum. Based on these successful results, vaccination was introduced into the clinical pharmacy curriculum at Heinrich Heine University.

The development and evaluation of a vaccination course with integrated emergency situations using the HFS was a further step towards patient-oriented and simulation-based teaching in pharmacy in Germany. The course was very well accepted by the students of the universities of Düsseldorf, Bonn and Greifswald. The integration of the vaccination course into the pharmacy curriculum should therefore be promoted in order to effectively prepare students for future challenges, as the current German Minister of Health, Karl Lauterbach, is proposing additional pharmacy-based vaccinations such as tetanus or diphtheria [55]. Such a project can also increase the number of pharmacies providing vaccination services, leading to a higher vaccination rate in the population. This would also reduce the burden on general practitioners and the healthcare system, The HFS has many other uses in education. For example, communication and counseling of patients or emergency management in interprofessional clinical teams can be trained. By using the HFS, students can be effectively prepared for patient-oriented services and further develop their competence in clinical skills.

# 6. Acknowledgement/Funding

The publishing costs for the following publications as well as the travel expenses were funded by Henrich Heine University:

1. Sayyed SA, Sharkas AR, Ali Sherazi B, Dabidian A, Schwender H, Laeer S. Development and Assessment of Innovative High-Fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy Undergraduates-A Randomized Controlled Study. Vaccines (Basel). 2023 Jan 31;11(2):324. doi: 10.3390/vaccines11020324

2. Sayyed SA, Kinny FA, Sharkas AR, Schwender H, Woltersdorf R, Ritter C, Laeer S. Vaccination Training for Pharmacy Undergraduates as a Compulsory Part of the Curriculum? - A Multicentric Observation. Pharmacy (Basel). 2024 Jan 11;12(1):12. doi: 10.3390/pharmacy12010012

# 7. References


1. Nypaver, C.; Dehlinger, C.; Carter, C. Influenza and Influenza Vaccine: A Review. *J. Midwifery Womens. Health* **2021**, *66*, 45–53, doi:10.1111/jmwh.13203.
2. Paget, J.; Staadegaard, L.; Wang, X.; Li, Y.; van Pomeren, T.; van Summeren, J.; Dückers, M.; Chaves, S.S.; Johnson, E.K.; Mahé, C.; et al. Global and national influenza-associated hospitalisation rates: Estimates for 40 countries and administrative regions. *J. Glob. Health* **2023**, *13*, 4003, doi:10.7189/jogh.13.04003.
3. Al Hajjar, S.; McIntosh, K. The first influenza pandemic of the 21st century. *Ann. Saudi Med.* **2010**, *30*, 1–10, doi:10.4103/0256-4947.59365.
4. Guertler, L.G. Influenza. *DoctorConsult - The Journal. Wissen für Klinik und Praxis* **2010**, *1*, e111-e115, doi:10.1016/j.dcjwkp.2010.06.009.
5. Piper, W. Infektionskrankheiten. *Innere Medizin* **2013**, 841–951, doi:10.1007/978-3-642-33108-4_10.
6. Stray, S.J.; Air, G.M. Apoptosis by influenza viruses correlates with efficiency of viral mRNA synthesis. *Virus Research* **2001**, *77*, 3–17, doi:10.1016/S0168-1702(01)00260-X.
7. Mahmoudabadi, G.; Milo, R.; Phillips, R. Energetic cost of building a virus. *Proc. Natl. Acad. Sci. U. S. A.* **2017**, *114*, E4324-33, doi:10.1073/pnas.1701670114.
8. Robert-Koch-Institut, Survstat@RKI 2.0. saisonale Influenza Statistik. Available online: https://survstat.rki.de/ (accessed on 12 February 2024).
9. Paget, J.; Spreeuwenberg, P.; Charu, V.; Taylor, R.J.; Iuliano, A.D.; Bresee, J.; Simonsen, L.; Viboud, C. Global mortality associated with seasonal influenza epidemics: New burden estimates and predictors from the GLaMOR Project. *J. Glob. Health* **2019**, *9*, 20421, doi:10.7189/jogh.09.020421.
10. Taubenberger, J.K.; Morens, D.M. 1918 Influenza: the mother of all pandemics. *Emerg. Infect. Dis.* **2006**, *12*, 15–22, doi:10.3201/eid1201.050979.
11. Robert-Koch-Institut. Influenza (Teil 1): Erkrankungen durch saisonale Influenzaviren: RKI-Ratgeber. Available online: https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Influenza_saisonal.html#doc2382022bodyText13 (accessed on 11 May 2024).
12. Ellebedy, A.H.; Webby, R.J. Influenza vaccines. *Vaccine* **2009**, *27 Suppl 4*, D65-8, doi:10.1016/j.vaccine.2009.08.038.
13. Influenza Vaccine Production and Design. Available online: https://www.niaid.nih.gov/diseases-conditions/influenza-vaccine-production-and-design (accessed on 15 January 2024).
14. Baloch, S.; Baloch, M.A.; Zheng, T.; Pei, X. The Coronavirus Disease 2019 (COVID-19) Pandemic. *Tohoku J. Exp. Med.* **2020**, *250*, 271–278, doi:10.1620/tjem.250.271.
15. Siddiqui, S.; Alhamdi, H.W.S.; Alghamdi, H.A. Recent Chronology of COVID-19 Pandemic. *Front. Public Health* **2022**, *10*, 778037, doi:10.3389/fpubh.2022.778037.
16. Worldometer. Weltweite Zahl der Todesfälle in Zusammenhang mit dem Coronavirus (COVID-19) seit Februar 2020. Available online: https://de.statista.com/statistik/daten/studie/1103240/umfrage/entwicklung-der-

weltweiten-todesfaelle-aufgrund-des-coronavirus/ (accessed on 27 February 2024).

17. Koock, U. Sorgen (ernst) nehmen: Die Covid-Impfung. *Heilberufe* **2021**, *73*, 40–41, doi:10.1007/s00058-021-1971-x.
18. Huang, Y.; Yang, C.; Xu, X.-F.; Xu, W.; Liu, S.-W. Structural and functional properties of SARS-CoV-2 spike protein: potential antivirus drug development for COVID-19. *Acta Pharmacol. Sin.* **2020**, *41*, 1141–1149, doi:10.1038/s41401-020-0485-4.
19. Duchene, S.; Featherstone, L.; Haritopoulou-Sinanidou, M.; Rambaut, A.; Lemey, P.; Baele, G. Temporal signal and the phylodynamic threshold of SARS-CoV-2. *Virus Evol* **2020**, *6*, veaa061, doi:10.1093/ve/veaa061.
20. World Health Organization. Tracking SARS-CoV-2 variants. Available online: https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (accessed on 10 June 2024).
21. World Health Organization. WHO announces simple, easy-to-say labels for SARS-CoV-2 Variants of Interest and Concern (accessed on 10 June 2024).
22. Sigal, A. Milder disease with Omicron: is it the virus or the pre-existing immunity? *Nat. Rev. Immunol.* **2022**, *22*, 69–71, doi:10.1038/s41577-022-00678-4.
23. Dai, L.; Gao, G.F. Viral targets for vaccines against COVID-19. *Nat. Rev. Immunol.* **2020**, *21*, 73–82, doi:10.1038/s41577-020-00480-0.
24. Muhar, B.K.; Nehira, J.; Malhotra, A.; Kotchoni, S.O. The Race for COVID-19 Vaccines: The Various Types and Their Strengths and Weaknesses. *J. Pharm. Pract.* **2022**, *36*, 953–966, doi:10.1177/08971900221097248.
25. Pharmazeutische Zeitung. Einfuhrerlaubnis für chinesischen Corona-Impfstoff. Available online: https://www.pharmazeutische-zeitung.de/einfuhrerlaubnis-fuer-chinesischen-corona-impfstoff-137211/ (accessed on 13 June 2024).
26. *Infection Protection Act*: *IfSG*, 2000.
27. Saleh, A.; Qamar, S.; Tekin, A.; Singh, R.; Kashyap, R. Vaccine Development Throughout History. *Cureus* **2021**, *13*, e16635, doi:10.7759/cureus.16635.
28. Francis, M.J. Recent Advances in Vaccine Technologies. *Vet. Clin. North Am. Small Anim. Pract.* **2018**, *48*, 231–241, doi:10.1016/j.cvsm.2017.10.002.
29. Bartlett, B.L.; Pellicane, A.J.; Tyring, S.K. Vaccine immunology. *Dermatol. Ther.* **2009**, *22*, 104–109, doi:10.1111/j.1529-8019.2009.01223.x.
30. Zepp, F. Principles of Vaccination. *Methods Mol. Biol.* **2016**, *1403*, 57–84, doi:10.1007/978-1-4939-3387-7_3.
31. Robert-Koch-Institut. Das Robert Koch-Institut im Überblick: Das Public Health Insitut. Available online: https://www.rki.de/DE/Content/Institut/OrgEinheiten/Ueberblick.pdf?__blob=publicationFile (accessed on 12 May 2024).
32. Robert-Koch-Institut. Ständige Impfkommission. Available online: https://www.rki.de/DE/Content/Kommissionen/STIKO/stiko_node.html (accessed on 12 May 2024).
33. Michaelis, K.; Scholz, S.; Buda, S.; Garbe, E.; Harder, T.; Ledig, T.; Terhardt, M.; Wichmann, O.; Wicker, S.; Zepp, F.; et al. Beschluss und Wissenschaftliche Begründung der Ständigen Impfkommission (STIKO) für die Aktualisierung der Influenza-Impfempfehlung für Personen im Alter von ≥ 60 Jahren **2020**, doi:10.25646/7655.

34. World Health Organization. Seasonal influenza vaccines: an overview for decision-makers. Available online: https://apps.who.int/iris/bitstream/handle/10665/336951/9789240010154-eng.pdf (accessed on 12 May 2024).
35. Koch-Institut, Robert. Aktualisierung der COVID-19-Impfempfehlung in den allgemeinen Empfehlungen der STIKO 2024 und die dazugehörige wissenschaftliche Begründung **2024**, doi:10.25646/11894.
36. Eurostat. *Vaccination against influenza of population aged 65 and over*, 2022.
37. Czech, M.; Balcerzak, M.; Antczak, A.; Byliniak, M.; Piotrowska-Rutkowska, E.; Drozd, M.; Juszczyk, G.; Religioni, U.; Vaillancourt, R.; Merks, P. Flu Vaccinations in Pharmacies-A Review of Pharmacists Fighting Pandemics and Infectious Diseases. *Int. J. Environ. Res. Public Health* **2020**, *17*, doi:10.3390/ijerph17217945.
38. Ecarnot, F.; Crepaldi, G.; Juvin, P.; Grabenstein, J.; Del Giudice, G.; Tan, L.; O'Dwyer, S.; Esposito, S.; Bosch, X.; Gavazzi, G.; et al. Pharmacy-based interventions to increase vaccine uptake: report of a multidisciplinary stakeholders meeting. *BMC Public Health* **2019**, *19*, 1698, doi:10.1186/s12889-019-8044-y.
39. Kelling, S.E. Exploring Accessibility of Community Pharmacy Services. *Innov Pharm* **2015**, *6*, doi:10.24926/iip.v6i3.392.
40. International Pharmaceutical Federation. An overview of current pharmacy impact on immunisation: a global report. Available online: https://www.fip.org/files/fip/publications/FIP_report_on_Immunisation.pdf (accessed on 12 May 2024).
41. Isenor, J.E.; Edwards, N.T.; Alia, T.A.; Slayter, K.L.; MacDougall, D.M.; McNeil, S.A.; Bowles, S.K. Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis. *Vaccine* **2016**, *34*, 5708–5723, doi:10.1016/j.vaccine.2016.08.085.
42. International Pharmaceutical Federation. An overview of pharmacy’s impact on immunisation coverage: A global survey: The Hague **2020**.
43. Community Pharmacy England. Flu Vaccination - Statistics. Available online: https://cpe.org.uk/national-pharmacy-services/advanced-services/flu-vaccination-service/flu-vaccination-statistics/ (accessed on 22 August 2023).
44. Nuffield Trust. Adult flu vaccination coverage. Available online: https://www.nuffieldtrust.org.uk/resource/adult-flu-vaccination-coverage (accessed on 22 August 2023).
45. The Pharmaceutical Society of Ireland. *Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacy 2014/2015*, 2015. Available online: https://www.thepsi.ie/Libraries/Pharmacy_Practice/PSI_2014_15_Report_on_Seasonal_Influenza_Vaccination_Service.sflb.ashx (accessed on 18 August 2022).
46. ABDA. COVID-19 vaccinations in pharmacies start on 8 February: Press release. Available online: https://www.abda.de/aktuelles-und-presse/newsroom/detail/covid-19-impfungen-in-apotheken-starten-am-8-februar/ (accessed on 17 October 2023).
47. Betsch, C.; Böhm, R.; Korn, L.; Holtmann, C. On the benefits of explaining herd immunity in vaccine advocacy. *Nat Hum Behav* **2017**, *1*, doi:10.1038/s41562-017-0056.

48. Kadkhoda, K. Herd Immunity to COVID-19. *Am. J. Clin. Pathol.* **2021**, *155*, 471–472, doi:10.1093/ajcp/aqaa272.
49. Krause, P.R.; Fleming, T.R.; Peto, R.; Longini, I.M.; Figueroa, J.P.; Sterne, J.A.C.; Cravioto, A.; Rees, H.; Higgins, J.P.T.; Boutron, I.; et al. Considerations in boosting COVID-19 vaccine immune responses. *Lancet* **2021**, *398*, 1377–1380, doi:10.1016/S0140-6736(21)02046-8.
50. Federal Ministry of Health. *Auffrischungsimpfung*, 2022. Available online: https://www.zusammengegencorona.de/faqs/impfen/auffrischungsimpfung/ (accessed on 7 October 2022).
51. ABDA. Grippeschutzimpfungen. Available online: https://www.abda.de/themen/grippeschutzimpfungen/ (accessed on 22 August 2023).
52. ABDA-Bundesvereinigung Deutscher Apothekerverbände e.V. Die Apotheke: Zaheln, Date, Fakten 2023. Available online: https://www.abda.de/fileadmin/user_upload/assets/ZDF/ZDF-2023/ABDA_ZDF_2023_Broschuere.pdf (accessed on 9 February 2024).
53. Thomas Benkert. Symposium "Vaccination in Pharmacies", March 21, 2023.
54. *Referentenentwurf - Gesetz für eine Apothekenhonorar- und Apothekenstrukturreform*, 2024.
55. Alexander Müller. Lauterbach legt Apothekenreform vor: Honorarumbau, Zweigapotheken, PTA-Vertretung. Available online: https://www.pharmazeutische-zeitung.de/lauterbach-legt-apothekenreform-vor-147969/seite/2/?cHash=447680fec7babe0fe28575fdf7d0b5f5 (accessed on 24 June 2024).
56. Aerzteblatt. Harsh criticism of planned flu vaccinations in pharmacies [Online], April 28, 2022. Available online: https://www.aerzteblatt.de/nachrichten/133758/Scharfe-Kritik-an-geplanten-Grippeimpfungen-in-Apotheken (accessed on 1 September 2022).
57. Turner, C.J.; Ellis, S.; Giles, J.; Altiere, R.; Sintek, C.; Ulrich, H.; Valdez, C.; Zadvorny, E. An introductory pharmacy practice experience emphasizing student-administered vaccinations. *Am. J. Pharm. Educ.* **2007**, *71*, 3, doi:10.5688/aj710103.
58. Terriff, C.M.; McKeirnan, K. Training student pharmacists to administer emergency pediatric influenza vaccine: A comparison of traditional vs. just-in-time training. *Curr. Pharm. Teach. Learn.* **2017**, *9*, 560–567, doi:10.1016/j.cptl.2017.03.006.
59. Mills, S.; Emmerton, L.; Sim, T.F. Immunization training for pharmacy students: a student-centered evaluation. *Pharm. Pract. (Granada)* **2021**, *19*, 2427, doi:10.18549/PharmPract.2021.3.2427.
60. Donohoe, K.L.; Mawyer, T.M.; Stevens, J.T.; Morgan, L.A.; Harpe, S.E. An active-learning laboratory on immunizations. *Am. J. Pharm. Educ.* **2012**, *76*, 198, doi:10.5688/ajpe7610198.
61. Bradley, P. The history of simulation in medical education and possible future directions. *Med. Educ.* **2006**, *40*, 254–262, doi:10.1111/j.1365-2929.2006.02394.x.
62. Korayem, G.B.; Alshaya, O.A.; Kurdi, S.M.; Alnajjar, L.I.; Badr, A.F.; Alfahed, A.; Cluntun, A. Simulation-Based Education Implementation in Pharmacy Curriculum:

A Review of the Current Status. *Adv. Med. Educ. Pract.* **2022**, *13*, 649–660, doi:10.2147/AMEP.S366724.
63. Vyas, D.; Bray, B.S.; Wilson, M.N. Use of simulation-based teaching methodologies in US colleges and schools of pharmacy. *Am. J. Pharm. Educ.* **2013**, *77*, 53, doi:10.5688/ajpe77353.
64. Basak, T.; Unver, V.; Moss, J.; Watts, P.; Gaioso, V. Beginning and advanced students' perceptions of the use of low- and high-fidelity mannequins in nursing simulation. *Nurse Educ. Today* **2016**, *36*, 37–43, doi:10.1016/j.nedt.2015.07.020.
65. Lin, K.; Travlos, D.V.; Wadelin, J.W.; Vlasses, P.H. Simulation and introductory pharmacy practice experiences. *Am. J. Pharm. Educ.* **2011**, *75*, 209, doi:10.5688/ajpe7510209.
66. Yuan, H.B.; Williams, B.A.; Fang, J.B.; Ye, Q.H. A systematic review of selected evidence on improving knowledge and skills through high-fidelity simulation. *Nurse Educ. Today* **2012**, *32*, 294–298, doi:10.1016/j.nedt.2011.07.010.
67. Maran, N.J.; Glavin, R.J. Low- to high-fidelity simulation - a continuum of medical education? *Med. Educ.* **2003**, *37 Suppl 1*, 22–28, doi:10.1046/j.1365-2923.37.s1.9.x.
68. Ziv, A.; Wolpe, P.R.; Small, S.D.; Glick, S. Simulation-based medical education: an ethical imperative. *Acad. Med.* **2003**, *78*, 783–788, doi:10.1097/00001888-200308000-00006.
69. Vyas, D.; McCulloh, R.; Dyer, C.; Gregory, G.; Higbee, D. An interprofessional course using human patient simulation to teach patient safety and teamwork skills. *Am. J. Pharm. Educ.* **2012**, *76*, 71, doi:10.5688/ajpe76471.
70. Aebersold, M. Simulation-Based Learning: No Longer a Novelty in Undergraduate Education. *Online J Issues Nurs* **2018**, *23*, doi:10.3912/OJIN.Vol23No02PPT39.
71. Kneebone, R. Simulation in surgical training: educational issues and practical implications. *Med. Educ.* **2003**, *37*, 267–277, doi:10.1046/j.1365-2923.2003.01440.x.
72. Bundesverband der Pharmziestudierenden in Deutschland e.V. Positionspapier Impfen. Available online: https://mcusercontent.com/1d757dbd1c4635939d0393cbe/files/c3102c86-54c2-49d1-86cb-828e805edd1b/BPhD_PosPap_Impfen_20200216.pdf (accessed on 5 March 2024).
73. International Pharmaceutical Federation. Supporting life-course immunisation through pharmacy-based vaccination: enabling equity, access and sustainability: A toolkit for pharmacist. Available online: https://www.fip.org/file/5588 (accessed on 26 October 2023).
74. Vaccines work. *Nat. Commun.* **2018**, *9*, 1666, doi:10.1038/s41467-018-04085-z.
75. Leidner, A.J.; Murthy, N.; Chesson, H.W.; Biggerstaff, M.; Stoecker, C.; Harris, A.M.; Acosta, A.; Dooling, K.; Bridges, C.B. Cost-effectiveness of adult vaccinations: A systematic review. *Vaccine* **2019**, *37*, 226–234, doi:10.1016/j.vaccine.2018.11.056.
76. Ehreth, J. The global value of vaccination. *Vaccine* **2003**, *21*, 596–600, doi:10.1016/S0264-410X(02)00623-0.
77. Bärnighausen, T.; Bloom, D.E.; Cafiero-Fonseca, E.T.; O'Brien, J.C. Valuing vaccination. *Proc. Natl. Acad. Sci. U. S. A.* **2014**, *111*, 12313–12319, doi:10.1073/pnas.1400475111.

78. Arsenault, C.; Harper, S.; Nandi, A. Effect of vaccination on children's learning achievements: findings from the India Human Development Survey. *J. Epidemiol. Community Health* **2020**, *74*, 778–784, doi:10.1136/jech-2019-213483.
79. Dye, C. The benefits of large scale covid-19 vaccination. *BMJ* **2022**, *377*, o867, doi:10.1136/bmj.o867.
80. Paudyal, V.; Fialová, D.; Henman, M.C.; Hazen, A.; Okuyan, B.; Lutters, M.; Cadogan, C.; da Costa, F.A.; Galfrascoli, E.; Pudritz, Y.M.; et al. Pharmacists' involvement in COVID-19 vaccination across Europe: a situational analysis of current practice and policy. *Int. J. Clin. Pharm.* **2021**, *43*, 1139–1148, doi:10.1007/s11096-021-01301-7.
81. *Infection Protection Act*: *IfSG*, 2001.
82. World Health Organization. Seasonal influenza vaccines: an overview for decision-makers. Available online: https://apps.who.int/iris/bitstream/handle/10665/336951/9789240010154-eng.pdf (accessed on 30 August 2022).
83. *Health care use;* OECD, 2017.
84. The Pharmaceutical Society of Ireland. *Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacy 2014/2015*, 2015. Available online: https://www.thepsi.ie/Libraries/Pharmacy_Practice/PSI_2014_15_Report_on_Seasonal_Influenza_Vaccination_Service.sflb.ashx (accessed on 18 August 2022).
85. Steyer, T.E.; Ragucci, K.R.; Pearson, W.S.; Mainous, A.G. The role of pharmacists in the delivery of influenza vaccinations. *Vaccine* **2004**, *22*, 1001–1006, doi:10.1016/j.vaccine.2003.08.045.
86. Bushell, M.-J.A.; Yee, K.C.; Ball, P.A. Case for Pharmacist Administered Vaccinations in Australia. *Journal of Pharmacy Practice and Research* **2013**, *43*, 292–296, doi:10.1002/j.2055-2335.2013.tb00278.x.
87. Prescott, W.A.; Bernhardi, C. Immunization Education in US Pharmacy Colleges and Schools. *Am. J. Pharm. Educ.* **2019**, *83*, 6765, doi:10.5688/ajpe6765.
88. Eickhoff, C.; Griese-Mammen, N.; Müeller, U.; Said, A.; Schulz, M. Primary healthcare policy and vision for community pharmacy and pharmacists in Germany. *Pharm. Pract. (Granada)* **2021**, *19*, 2248, doi:10.18549/PharmPract.2021.1.2248.
89. Morris, A.; Young, G.; Roller, L.; Li, F.; Takamoto, P.; Baumgartner, L. High-fidelity simulation increases pharmacy resident perceived competence during medical emergencies. *Curr. Pharm. Teach. Learn.* **2019**, *11*, 1016–1021, doi:10.1016/j.cptl.2019.06.008.
90. Vyas, D.; Wombwell, E.; Russell, E.; Caligiuri, F. High-fidelity patient simulation series to supplement introductory pharmacy practice experiences. *Am. J. Pharm. Educ.* **2010**, *74*, 169, doi:10.5688/aj7409169.
91. Bingham, A.L.; Sen, S.; Finn, L.A.; Cawley, M.J. Retention of advanced cardiac life support knowledge and skills following high-fidelity mannequin simulation training. *Am. J. Pharm. Educ.* **2015**, *79*, 12, doi:10.5688/ajpe79112.
92. Awaisu, A.; Abd Rahman, N.S.; Nik Mohamed, M.H.; Bux Rahman Bux, S.H.; Mohamed Nazar, N.I. Malaysian pharmacy students' assessment of an objective structured clinical examination (OSCE). *Am. J. Pharm. Educ.* **2010**, *74*, 34, doi:10.5688/aj740234.

93. Harden, R.M. Revisiting 'Assessment of clinical competence using an objective structured clinical examination (OSCE)'. *Med. Educ.* **2016**, *50*, 376–379, doi:10.1111/medu.12801.
94. HARDEN, R.M.; GLEESON, F.A. Assessment of clinical competence using an objective structured clinical examination (OSCE). *Med. Educ.* **1979**, *13*, 39–54, doi:10.1111/j.1365-2923.1979.tb00918.x.
95. R Core Team. *A language and environment for statistical computing.;* Vienna, Austria.
96. Sharkas, A. Vaccination training project using high-fidelity simulation for pharmacy undergraduates. Master thesis; Heinrich-Heine-University, Martin-Luther-University, Düsseldorf, Halle-Wittenberg, 2021.
97. Bundesapothekerkammer. Durchführung von Grippeschutzimpfungen in öffentlichen Apotheken. Available online: https://www.abda.de/fuer-apotheker/qualitaetssicherung/leitlinien/leitlinien-und-arbeitshilfen/ (accessed on 20 September 2022).
98. Microsoft Corporation. *Microsoft Excel 2019;* Redmond,WA, USA, 2019.
99. OriginLab Corporation. *Origin(Pro);* Northampton, MA, USA, 2021.
100. 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 (Basel)* **2020**, *8*, doi:10.3390/pharmacy8030151.
101. Skoy, E.T.; Eukel, H.N.; Frenzel, J.E. Comparison of Low- and Higher-Fidelity Simulation to Train and Assess Pharmacy Students' Injection Technique. *Am. J. Pharm. Educ.* **2013**, *77*, doi:10.5688/ajpe77233.
102. Carroll, P.R.; Hanrahan, J. Development and evaluation of an interprofessional student-led influenza vaccination clinic for medical, nursing and pharmacy students. *Pharm. Pract. (Granada)* **2021**, *19*, 2449, doi:10.18549/PharmPract.2021.4.2449.
103. Lau, E.T.L.; Rochin, M.E.; DelDot, M.; Glass, B.D.; Nissen, L.M. “There's No Touching in Pharmacy”: Training Pharmacists for Australia's First Pharmacist Immunization Pilot. *Can. J. Hosp. Pharm.* **2017**, *70*, 281–287.
104. Abajas-Bustillo, R.; Amo-Setién, F.; Aparicio, M.; Ruiz-Pellón, N.; Fernández-Peña, R.; Silio-García, T.; Leal-Costa, C.; Ortego-Mate, C. Using High-Fidelity Simulation to Introduce Communication Skills about End-of-Life to Novice Nursing Students. *Healthcare (Basel)* **2020**, *8*, doi:10.3390/healthcare8030238.
105. Tokunaga, J.; Takamura, N.; Ogata, K.; Yoshida, H.; Setoguchi, N.; Matsuoka, T.; Hirokane, T.; Yamaoka, A.; Sato, K. Vital sign monitoring using human patient simulators at pharmacy schools in Japan. *Am. J. Pharm. Educ.* **2010**, *74*, 132, doi:10.5688/aj7407132.
106. Massoth, C.; Röder, H.; Ohlenburg, H.; Hessler, M.; Zarbock, A.; Pöpping, D.M.; Wenk, M. High-fidelity is not superior to low-fidelity simulation but leads to overconfidence in medical students. *BMC Med. Educ.* **2019**, *19*, 29, doi:10.1186/s12909-019-1464-7.
107. La Cerra, C.; Dante, A.; Caponnetto, V.; Franconi, I.; Gaxhja, E.; Petrucci, C.; Alfes, C.M.; Lancia, L. Effects of high-fidelity simulation based on life-threatening clinical condition scenarios on learning outcomes of undergraduate and postgraduate nursing students: a systematic review and meta-analysis. *BMJ Open* **2019**, *9*, e025306, doi:10.1136/bmjopen-2018-025306.

108. Alinier, G.; Hunt, B.; Gordon, R.; Harwood, C. Effectiveness of intermediate-fidelity simulation training technology in undergraduate nursing education. *J. Adv. Nurs.* **2006**, *54*, 359–369, doi:10.1111/j.1365-2648.2006.03810.x.
109. McCoy, C.E.; Rahman, A.; Rendon, J.C.; Anderson, C.L.; Langdorf, M.I.; Lotfipour, S.; Chakravarthy, B. Randomized Controlled Trial of Simulation vs. Standard Training for Teaching Medical Students High-quality Cardiopulmonary Resuscitation. *West. J. Emerg. Med.* **2019**, *20*, 15–22, doi:10.5811/westjem.2018.11.39040.
110. Branch, C. Pharmacy Students' Learning and Satisfaction With High-Fidelity Simulation to Teach Drug-Induced Dyspepsia. *Am. J. Pharm. Educ.* **2013**, *77*, doi:10.5688/ajpe77230.
111. Gilliland, I.; Frei, B.L.; McNeill, J.; Stovall, J. Use of high-fidelity simulation to teach end-of-life care to pharmacy students in an interdisciplinary course. *Am. J. Pharm. Educ.* **2012**, *76*, 66, doi:10.5688/ajpe76466.
112. Lee Chin, K.; Ling Yap, Y.; Leng Lee, W.; Chang Soh, Y. Comparing effectiveness of high-fidelity human patient simulation vs case-based learning in pharmacy education. *Am. J. Pharm. Educ.* **2014**, *78*, 153, doi:10.5688/ajpe788153.
113. Yang, C.-W.; Ku, S.-C.; Ma, M.H.-M.; Chu, T.-S.; Chang, S.-C. Application of high-fidelity simulation in critical care residency training as an effective learning, assessment, and prediction tool for clinical performance. *J. Formos. Med. Assoc.* **2019**, *118*, 1347–1355, doi:10.1016/j.jfma.2018.12.003.
114. Zamami, Y.; Imai, T.; Imanishi, M.; Takechi, K.; Shiraishi, N.; Koyama, T.; Sagara, H.; Shiino, Y.; Sendo, T.; Ishizawa, K. Evaluation of pharmaceutical lifesaving skills training oriented pharmaceutical intervention. *J. Pharm. Health Care Sci.* **2016**, *2*, 21, doi:10.1186/s40780-016-0054-7.
115. ABDA. Grippeschutzimpfungen. Available online: https://www.abda.de/themen/grippeschutzimpfungen/ (accessed on 22 August 2023).
116. *Infection Protection Act*: *IfSG*, 2000.
117. International Pharmaceutical Federation. An overview of current pharmacy impact on immunisation: a global report. Available online: https://www.fip.org/files/fip/publications/FIP_report_on_Immunisation.pdf (accessed on 16 August 2022).
118. World Health Organization. Seasonal influenza vaccines: an overview for decision-makers. Available online: https://apps.who.int/iris/bitstream/handle/10665/336951/9789240010154-eng.pdf (accessed on 30 August 2022).
119. Community Pharmacy England. Flu Vaccination - Statistics. Available online: https://cpe.org.uk/national-pharmacy-services/advanced-services/flu-vaccination-service/flu-vaccination-statistics/ (accessed on 22 August 2023).
120. Nuffield Trust. Adult flu vaccination coverage. Available online: https://www.nuffieldtrust.org.uk/resource/adult-flu-vaccination-coverage (accessed on 22 August 2023).
121. The Pharmaceutical Society of Ireland. *Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacy 2014/2015*, 2015. Available online:

https://www.thepsi.ie/Libraries/Pharmacy_Practice/PSI_2014_15_Report_on_Seasonal_Influenza_Vaccination_Service.sflb.ashx (accessed on 18 August 2022).
122. Eurostat. Flu vaccinations at age 65 and over. Available online: https://ec.europa.eu/eurostat/databrowser/view/HLTH_PS_IMMU/bookmark/table?lang=de&bookmarkId=8b35002c-47c2-4ac3-8a01-7dc03aa42d05.
123. ABDA. APOTHEKENDICHTE IM EUROPÄISCHEN VERGLEICH (PHARMACY DENSITY IN EUROPEAN COMPARISON). Available online: https://www.abda.de/fileadmin/user_upload/assets/ZDF/ZDF21/ZDF_21_86_Apothekendichte_im_europaeischen_Vergleich.pdf (accessed on 27 December 2023).
124. International Pharmaceutical Federation. Community pharmacy at a glance: Regulation, scope of practice, remuneration, and distribution of medicines through community pharmacy premises and other outlets. Available online: https://www.fip.org/file/5015 (accessed on 27 December 2023).
125. How vaccination training for pharmacy students can help solve the current NHS workforce crisis. *Pharmaceutical Journal* **2022**, doi:10.1211/PJ.2022.1.156547.
126. Thomas Benkert. Symposium "Vaccination in Pharmacies", March 21, 2023.
127. Sayyed, S.A.; Sharkas, A.R.; Ali Sherazi, B.; Dabidian, A.; Schwender, H.; Laeer, S. Development and Assessment of Innovative High-Fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy Undergraduates-A Randomized Controlled Study. *Vaccines (Basel)* **2023**, *11*, doi:10.3390/vaccines11020324.
128. Qualtrics. *Qualtrics;* Provo, Utah, USA.
129. Marcum, Z.A.; Maffeo, C.M.; Kalsekar, I. The impact of an immunization training certificate program on the perceived knowledge, skills and attitudes of pharmacy students toward pharmacy-based immunizations. *Pharm. Pract. (Granada)* **2010**, *8*, 103–108, doi:10.4321/s1886-36552010000200004.
130. Jessee, J.K.; Miller, A.; Ebied, A.M. Beyond the Classroom: An Observational Study to Assess Student Pharmacists' Confidence and Perception of a High-Fidelity Manikin Chemotherapy Infusion Reaction Simulation. *J. Pharm. Technol.* **2022**, *38*, 135–141, doi:10.1177/87551225211073570.
131. Thompson Bastin, M.L.; Cook, A.M.; Flannery, A.H. Use of simulation training to prepare pharmacy residents for medical emergencies. *Am. J. Health Syst. Pharm.* **2017**, *74*, 424–429, doi:10.2146/ajhp160129.
132. ABDA. Schutzimpfungen in Apotheken (Vaccination in pharmacies). Available online: https://www.abda.de/fuer-apotheker/schutzimpfungen/schutzimpfungen-in-apotheken/ (accessed on 27 December 2023).
133. Carroll, P.R.; Chen, Y.; Vicheth, P.; Webber, P.; Hanrahan, J.R. Evaluation of a vaccination training program for pharmacy graduands in Australia. *Curr. Pharm. Teach. Learn.* **2020**, *12*, 850–857, doi:10.1016/j.cptl.2020.02.016.
134. Au, M.L.; Tong, L.K.; Li, Y.Y.; Ng, W.I.; Wang, S.C. Impact of scenario validity and group size on learning outcomes in high-fidelity simulation: A systematics review and meta-analysis. *Nurse Educ. Today* **2023**, *121*, 105705, doi:10.1016/j.nedt.2022.105705.
135. Sayyed, S.A.; Kinny, F.A.; Sharkas, A.R.; Schwender, H.; Woltersdorf, R.; Ritter, C.; Laeer, S. Vaccination Training for Pharmacy Undergraduates as a Compulsory

Part of the Curriculum?-A Multicentric Observation. *Pharmacy (Basel)* **2024**, *12*, doi:10.3390/pharmacy12010012.

# 8. Appendix

## Appendix 1: OCSE-Checklist of the RCT; station 1-3

| **Station 1: Anamnesis (9 Points)** | | | fulfilled | Not fulfilled |
|---|---|---|---|---|
| 1.1 | *Medical history: The examinee asks about acute and chronic diseases and excludes contraindications* | acute diseases/infection | | |
| | | chronic diseases | | |
| | | pregnancy (only for female patients) | | |
| | | planned surgery in the next 3 days | | |
| | | fever (>38.5°C) | | |
| 1.2 | *Medication history: the examinee asks about all medications taken.* | previous/current medication (Rx, OTC, NEM) | | |
| | | taking blood thinners | | |
| 1.3 | *Allergy: examinee asks about previous and current allergies* | known allergies | | |
| | | allergic to vaccines/components (previous vaccination reaction) | | |

| Station 2: Patient Information/Counseling (12 Points) | | | | |
|---|---|---|---|---|
| 2.1 | *Influenza Infection & Treatment Options: The examinee educates the patient generally and about possible risks of influenza infection* | Symptoms of influenza infection | | |
| | | Routes of infection | | |
| | | Risk group(s) | | |
| | | Season | | |
| 2.2 | *Vaccination: The examinee educates the patient about the benefits and administration of vaccination.* | Benefits | | |
| | | UAW/Complications | | |
| | | Vaccination administration process | | |
| | | complete vaccination protection | | |
| 2.3 | *Other: The examinee....* | clarifies open questions | | |
| | | hands out information leaflet | | |
| | | has consent and privacy statement signed | | |
| | | points out OTC medications | | |

| Station 3: Vaccination administration (13 Points) | | | | |
|---|---|---|---|---|
| 3.1 | *Preparation: The examinee makes all preparations for the administration of the vaccination.* | Area preparation (e.g. disinfection)/provision of materials | | |
| | | Preparation of own person (e.g. washing hands, gloves) | | |
| | | Vaccination (tempering, shaking, testing the syringe) | | |
| | | Patient preparation (position, selection of the arm) | | |
| 3.2 | *Execution: The examinee administers the vaccination in the correct manner.* | Disinfection of the injection site | | |
| | | Technique (3-finger rule, 90° injection) | | |
| | | rapid and complete injection | | |
| | | Formation of a skin fold and care of the injection site (plaster) | | |
| | | Disposal | | |
| 3.3 | *Instructions & documentation: The examinee gives the patient the correct instructions and performs the relevant documentation* | 15 min waiting/observation time | | |
| | | Vaccination certificate (for the patient) | | |
| | | Vaccination documentation (for the pharmacy) | | |

*(In the study, the German version was used)*

## Appendix 2: OSCE-Checklist of the RCT; Station 4; Case 1-5

| **Station 4: Scenario 1- Anaphylactic reaction (7 Points)** | | | | |
|---|---|---|---|---|
| 4.1 | *Subjective: The examinee first addresses the patient's complaints* | Checks responsiveness/responds to the patient | | |
| | | asks about symptoms/complaints | | |
| 4.2 | *Objective: The examinee collects relevant parameters* | recognizes itching/urticaria in the patient | | |
| | | takes blood pressure/heart rate | | |
| 4.3 | *Assessment: the examinee correctly classifies the emergency situation* | detects allergic reaction (low grade) | | |
| 4.4 | *Plan: The examinee initiates the necessary measures* | makes emergency call | | |
| | | First aid measures (change position, provide fresh air, keep calm, attend to patient) | | |

| Station 4: Scenario 2 - vasovagal syncope (7 Points) | | | | |
|---|---|---|---|---|
| 4.1 | *Subjective: The examinee first addresses the patient's complaints* | Checks responsiveness/responds to the patient | | |
| | | Asks about symptoms/complaints | | |
| 4.2 | *Objective: The examinee collects relevant parameters* | obtains blood pressure/heart rate | | |
| 4.3 | *Assessment: the examinee correctly classifies the emergency situation* | recognizes vasovagal syncope | | |
| 4.4 | *Plan: The examinee initiates the necessary measures* | makes emergency call | | |
| | | first aid measures (change of position, fresh air supply, keep calm, care) | | |
| | | puts the patient's legs up | | |

| Station 4: Scenario 3 - Angina pectoris (7 Points) | | | | |
|---|---|---|---|---|
| 4.1 | *Subjective: The examinee first addresses the patient's complaints* | Checks responsiveness/responds to the patient | | |
| | | Asks about symptoms/complaints | | |
| 4.2 | *Objective: The examinee collects relevant parameters* | Takes blood pressure/heart rate | | |
| 4.3 | *Assessment: the examinee correctly classifies the emergency situation* | recognizes angina pectoris attack | | |
| 4.4 | *Plan: The examinee initiates the necessary measures* | makes emergency call | | |
| | | first aid measures (change of position, fresh air supply, keep calm, care) | | |
| | | advises use of nitro spray | | |

| Station 4: Scenario 4 - Asthma attack (7 Points) | | | | |
|---|---|---|---|---|
| 4.1 | *Subjective: The examinee first addresses the patient's complaints* | Checks responsiveness/responds to the patient | | |
| | | Asks about symptoms/complaints | | |
| 4.2 | *Objective: The examinee collects relevant parameters* | takes blood pressure/heart rate | | |
| 4.3 | *Assessment: the examinee correctly classifies the emergency situation* | recognizes asthma attack | | |
| 4.4 | *Plan: The examinee initiates the necessary measures* | makes emergency call | | |
| | | first aid measures (change of position, fresh air supply, keep calm, care) | | |
| | | advises use of asthma spray | | |

| Station 4: Scenario 5 - Hypoglycemia (7 Points) | | | | |
|---|---|---|---|---|
| 4.1 | *Subjective: The examinee first addresses the patient's complaints* | checks responsiveness/responds to the patient | | |
| | | Asks for symptoms/discomforts (feeling warm, headache) | | |
| 4.2 | *Objective: The examinee collects relevant parameters* | takes blood pressure/heart rate | | |
| 4.3 | *Assessment: the examinee correctly classifies the emergency situation* | recognizes hypoglycemia | | |
| 4.4 | *Plan: The examinee initiates the necessary measures* | makes emergency call | | |
| | | First aid measures (change position, provide fresh air, keep calm, attend to patient) | | |
| | | provides glucose | | |

*(In the study, the German version was used)*

# Appendix 3: Short case description

***Scenario 1:*** Anaphylactic reaction

| | |
|---|---|
| Age | 30 years |
| Profession | Teacher |
| Diseases | Allergic asthma |
| Medication | Salbutamol, Cetirizine |
| Contraindication | None |
| Additional information | Smokes sometimes, BMI: 23 kg/m² |
| Questions/Statements | How tolerable is the vaccination? |
| adverse reaction | Itching on the body, headache, feeling of heat, sweating<br>Question: What is wrong with me? What happened to me?<br>Respiratory rate: 25/min; Heart rate: 120/min; Blood pressure: 90/60 mmHG |

**Medikationsplan**

Seite __ von __

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

für: ____ geb. am: ____

ausgedruckt von:

(Stempel)

ausgedruckt am: ____

| Wirkstoff | Handelsname | Stärke | Form | Mo | Mi | Ab | zN | Einheit | Hinweise | Grund |
|---|---|---|---|---|---|---|---|---|---|---|
| Salbutamol | Salbuhexal | 100µg | SUS | | | | | | if needed | |
| Cetirizin | Cetirizin ADGC | 10mg | TAB | | | 1 | | | | |
| | | | | | | | | | | |

***Scenario 2:*** <u>vasovagal Syncope</u>

| | |
|---|---|
| Age | 65 years |
| Profession | Cab driver |
| Diseases | Hypertension, diabetes, mild heart failure |
| Medication | Bisoprolol, metformin, ramipril, simvastatin |
| Contraindication | None |
| Additional information | Smokes more often, BMI: 26 kg/m² |
| Questions/Statements | I am afraid of injections. |
| adverse reaction | Dizziness, blackness in front of eyes, eyelids closing, speaks indistinctly, almost falls off the chair/ about to fall over<br>Question: What is wrong with me? What happened to me?<br>Respiratory rate: 30/min; Heart rate: 45/min; Blood pressure: 100/70 mmHG |

**Medikationsplan**

Seite __ von __

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

für: geb. am:

ausgedruckt von:

(Stempel) ausgedruckt am:

| Wirkstoff | Handelsname | Stärke | Form | Mo | Mi | Ab | zN | Einheit | Hinweise | Grund |
|---|---|---|---|---|---|---|---|---|---|---|
| Bisoprolol | BisoLich | 5mg | TAB | 1 | | | | | | |
| Ramipril | RamiLich | 5mg | TAB | 1 | | | | | | |
| Simvastatin | SimvaHexal | 40mg | TAB | | | 1 | | | | |
| Metformin | Metformin Heumann | 850mg | | 1 | | 1 | | | | |
| | | | | | | | | | | |

***Scenario 3:*** Angina pectoris

| | |
|---|---|
| Age | 45 years |
| Profession | Factory worker |
| Diseases | CHD, hypercholesterolemia, hypertension, |
| Medication | ramipril, bisoprolol, simvastatin, nitrospray |
| Contraindication | None |
| Additional information | BMI: 28 kg/m² |
| Questions/Statements | Vaccination recommended by the doctor |
| adverse reaction | Stinging/pressure in chest (grabs chest), shortness of breath, gagging feeling in throat, nausea.<br>Question: What is wrong with me? What has happened to me?<br>Breathing rate: 30/min; Heart rate: 90/min; Blood pressure: 150/95 mmHG |

**Medikationsplan** für: geb. am:

Seite __ von __ ausgedruckt von:

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

(Stempel) ausgedruckt am:

| Wirkstoff | Handelsname | Stärke | Form | Mo | Mi | Ab | zN | Einheit | Hinweise | Grund |
|---|---|---|---|---|---|---|---|---|---|---|
| Bisoprolol | BisoLich | 5mg | TAB | 1 | | | | | | |
| Ramipril | RamiLich | 5mg | TAB | 1 | | | | | | |
| Simvastatin | SimvaHexal | 40mg | TAB | | | 1 | | | | |
| Glycerolnitrat | Nitrolingual akut | 0,4mg | SPR | | | | | | in emergency | |
| | | | | | | | | | | |

The highlighted medication was the emergency medication the standardized patient carried with them.

***Scenario 4:*** Asthma attack

| | |
|---|---|
| Age | 25 years |
| Profession | Student |
| Diseases | Asthma |
| Medication | Salbutamol, fluticasone spray |
| Contraindication | None |
| Additional information | BMI: 21 kg/m² |
| Questions/Statements | Why should you get a flu shot? |
| adverse reaction | Difficulty exhaling (sounds when breathing out), dry cough, tightness in the chest.<br>Question: What is wrong with me? What has happened to me?<br>Respiratory rate: 23/min<br>Heart rate: 100/min; Blood pressure: 95/65 mmHG |

**Medikationsplan**

Seite __ von __

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

für: ____ geb. am: ____

ausgedruckt von:

(Stempel)

ausgedruckt am: ____

| Wirkstoff | Handelsname | Stärke | Form | Mo | Mi | Ab | zN | Einheit | Hinweise | Grund |
|---|---|---|---|---|---|---|---|---|---|---|
| Salbutamol | Salbuhexal | 100µg | SUS | | | | | | if needed | |
| Beclometason/ Formoterol | Foster 100/6 | 10mg | INH | 1 | | 1 | | | | |
| | | | | | | | | | | |

The highlighted medication was the emergency medication the standardized patient carried with them.

***Scenario 5:*** Hypoglycemia

| | |
|---|---|
| Age | 80 years |
| Profession | Retired |
| Diseases | Hypertension, osteoarthritis, diabetes (type II) |
| Medication | Insulin (short, long), bisoprolol, ibuprofen, zopiclone |
| Contraindication | None |
| Additional information | BMI: 28 kg/m² |
| Questions/Statements | Has not been able to eat much today due to excitement. |
| adverse reaction | Confused, trembling, visual disturbance, decreased responsiveness, short unclear answers.<br>Question: what's wrong with me? What happened to me?<br>Respiratory rate: 10/min; Heart rate: 80/min; Blood pressure: 90/60 mmHG |

**Medikationsplan**

Seite __ von __

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

für: ____________ geb. am: ______

ausgedruckt von:

(Stempel)

ausgedruckt am: ______

| Wirkstoff | Handelsname | Stärke | Form | Mo | Mi | Ab | zN | Einheit | Hinweise | Grund |
|---|---|---|---|---|---|---|---|---|---|---|
| Bisoprolol | BisoLich | 5mg | TAB | 1 | | | | | | |
| Ibuprofen | Ibuflam | 600mg | TAB | 1 | 1 | 1 | | | | |
| Zopiclon | Zopiclon AbZ | 7,5mg | TAB | | | 1 | | | | |
| Insulin (kurz) | Actrapid | 40 IE | INJ | | | | | | according to plan | |
| Insulin (lang) | Lantus | 500 IE | INJ | | | | | | according to plan | |
| | | | | | | | | | | |

(*All cases were used in both studies and in German language)*

## Appendix 4: Knowledge quiz

*Pre-training*

1.) Which statement about the vaccination process is true?
(A) The vaccine must be administered quickly after taking it out of the refrigerator, because the vaccine becomes ineffective due to stability problems.
(B) The needle should be injected at a 45° angle to avoid damaging lower skin layers.
(C) The injection should proceed rapidly.
(D) After injection, pressure should not be applied to the injection site, as this may inhibit distribution of the vaccine.

2.) Which statement about possible vaccination reactions is true?
(A) Systemic symptoms such as fever or headache can be treated with traditional OTC medications.
(B) Side effects or vaccine adverse reactions do not occur with administration of a dead-vaccine because no viable pathogens are contained.
(C) Typical symptoms of syncope include increased blood pressure and rapid pulse.
(D) An allergic reaction may be manifested only by redness at the injection site.

3.) Which statement about vaccination and vaccines is correct?
(A) Vaccination against influenza provides protection for at least 3 years.
(B) The maximum protective effect of influenza vaccination is reached after only 5 days.
(C) Influenza vaccines available on the market are exclusively administered intramuscularly.
(D) Vaccines are usually added adjuvants, so-called effect enhancers.

4.) Which statement about rules and regulations of vaccinations is true?
(A) The documentation for the administration of an influenza vaccination must be archived in the pharmacy for 3 years.
(B) The Robert Koch Institute is responsible for approving vaccines.
(C) Physician specialists may administer a vaccination regardless of the limits of their professional practice as a specialist.
(D) The permanent vaccination commission is composed by new experts at each scheduled meeting.

5.) Which statement about influenza/illness and influenza vaccination in the pharmacy is true?
(A) Neuraminidase inhibitors are also useful for prevention against influenza infection.
(B) Antigenic drift requires multiple infection of the host cell.
(C) Influenza vaccine is produced only via cell culture.
(D) Taking blood thinners (e.g., Marcumar) is not an contraindication to administering vaccination at the pharmacy.

*Post-training*

1.) Which statement about the vaccination process is true?
- (A) The left arm should preferably be used to administer a vaccination.
- (B) Age is not a factor in the selection of influenza vaccine.
- (C) The injection cylinder should not be shaken before use, otherwise the vaccine may denature.
- (D) Before vaccination, the surfaces which are used should be disinfected.

2.) Which statement about possible vaccination reactions is true?
- (A) Headache and/or myalgia are very common side effects in people over 60 years of age.
- (B) Anaphylactic reactions are classified into five grades.
- (C) In case of syncope, the patient should be kept in an upright position to prevent a possible fall.
- (D) After 15 minutes of waiting, there is no longer a risk of vaccine reactions occurring in the patient.

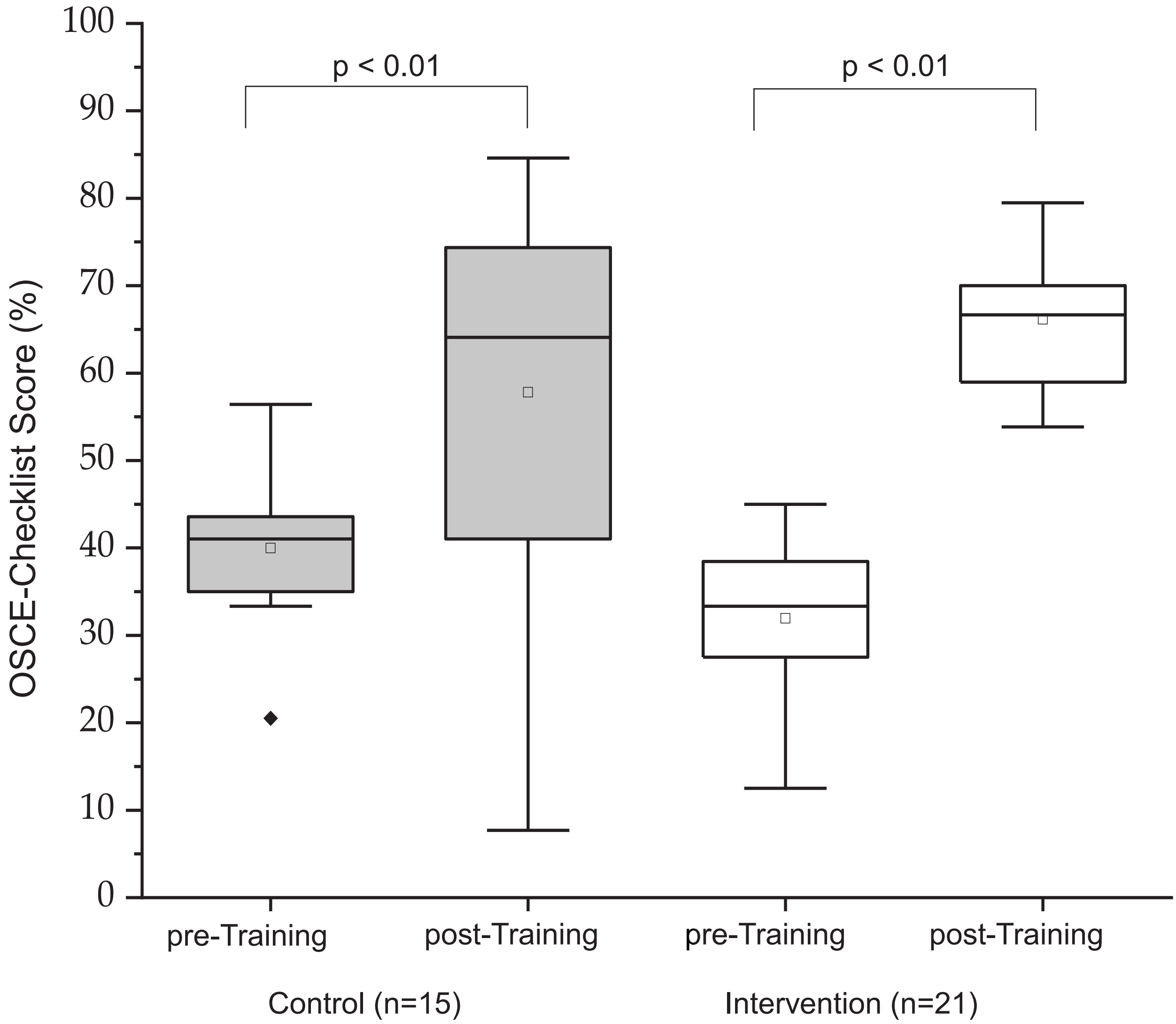
3.) Which statement about vaccination and vaccines is correct?
- (A) Subunit or split vaccines are types of Live vaccines.
- (B) Multiple doses of vaccine can be obtained from one chicken egg.
- (C) Vaccines against two or more diseases should not be applied at the same time.
- (D) The purpose of a vaccination is to produce immunoglobulins against pathogens in the body.

4.) Which statement about rules and regulations of vaccinations is true?
- (A) There must be a 2-week interval between an influenza vaccination and Covid-19 vaccination.
- (B) Reports of ADRs after receiving a vaccination are received by the Robert Koch Institute.
- (C) The Infection Control Act should establish uniform regulations for the prevention of communicable diseases.
- (D) The European target for vaccination coverage among at-risk groups is set at 65%.

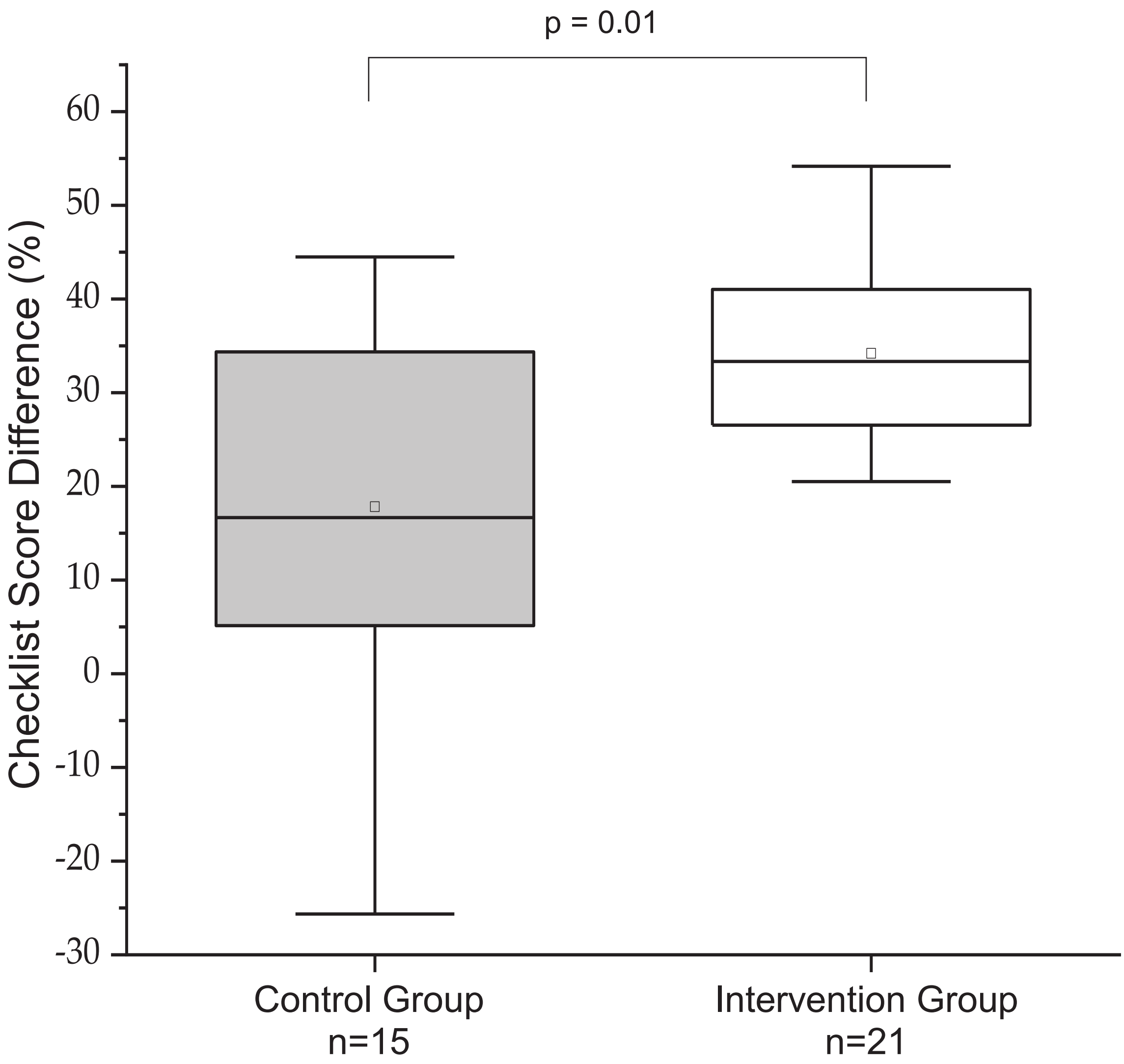
5.) Which statement about influenza/illness and influenza vaccination in the pharmacy is true?
- (A) For anxious patients, it is best to give the vaccination standing up.
- (B) New influenza subtypes may emerge due to antigenic shift.
- (C) Only inactivated influenza vaccines are available on the German market.
- (D) The membrane protein neuraminidase initiates endocytosis of the virus into the host cell.

*(In the study, the German version was used.)*

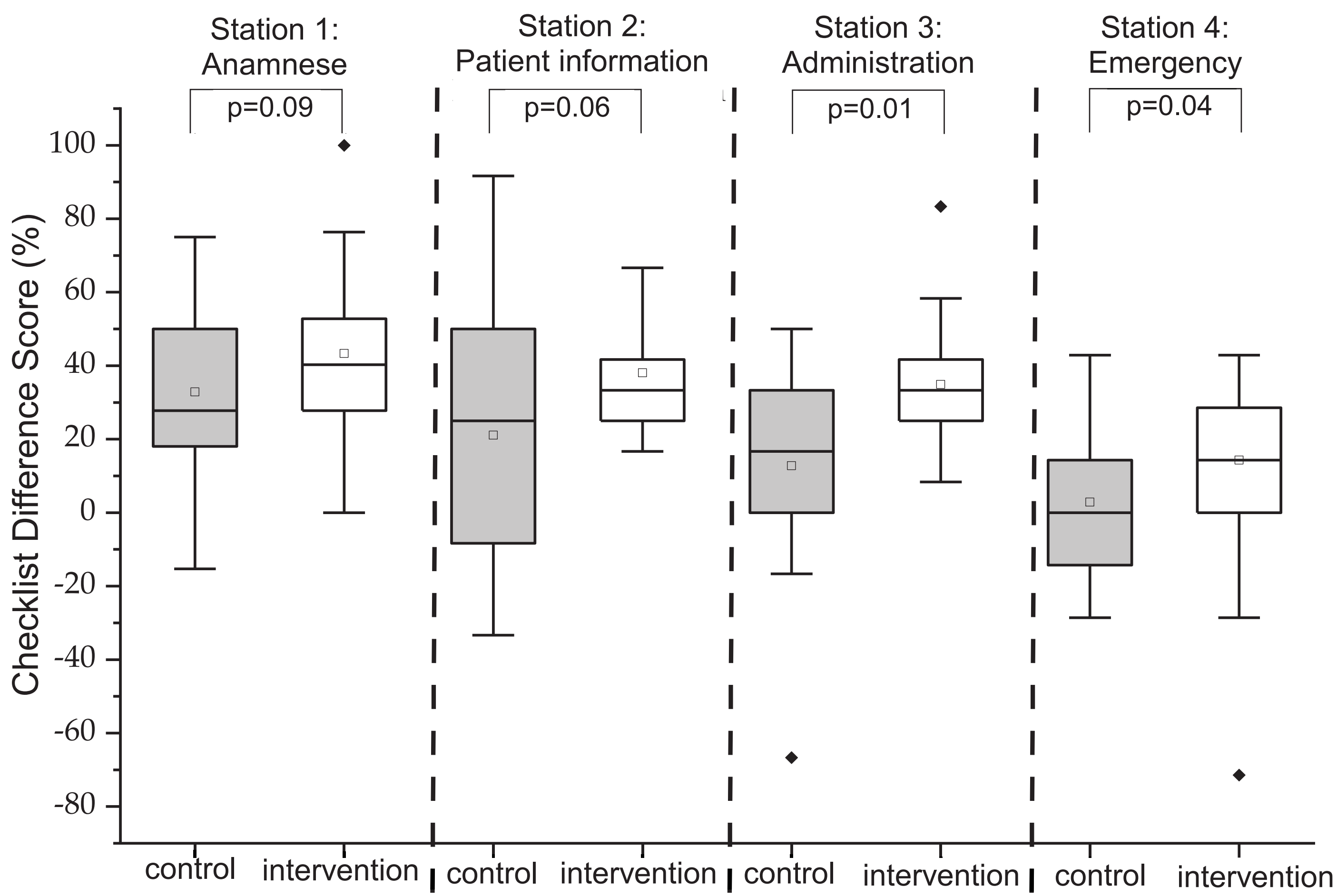
## Appendix 5: Sensitivity analysis of the RCT




**Appendix 5-1:**
Box-Plots of analytical Checklist scores between pre-Training and post-Training OSCEs. The black diamonds (♦) indicates the outliers. A one-sided paired Wilcoxon signed-rank test with a significance level of alpha=0.05 was used.



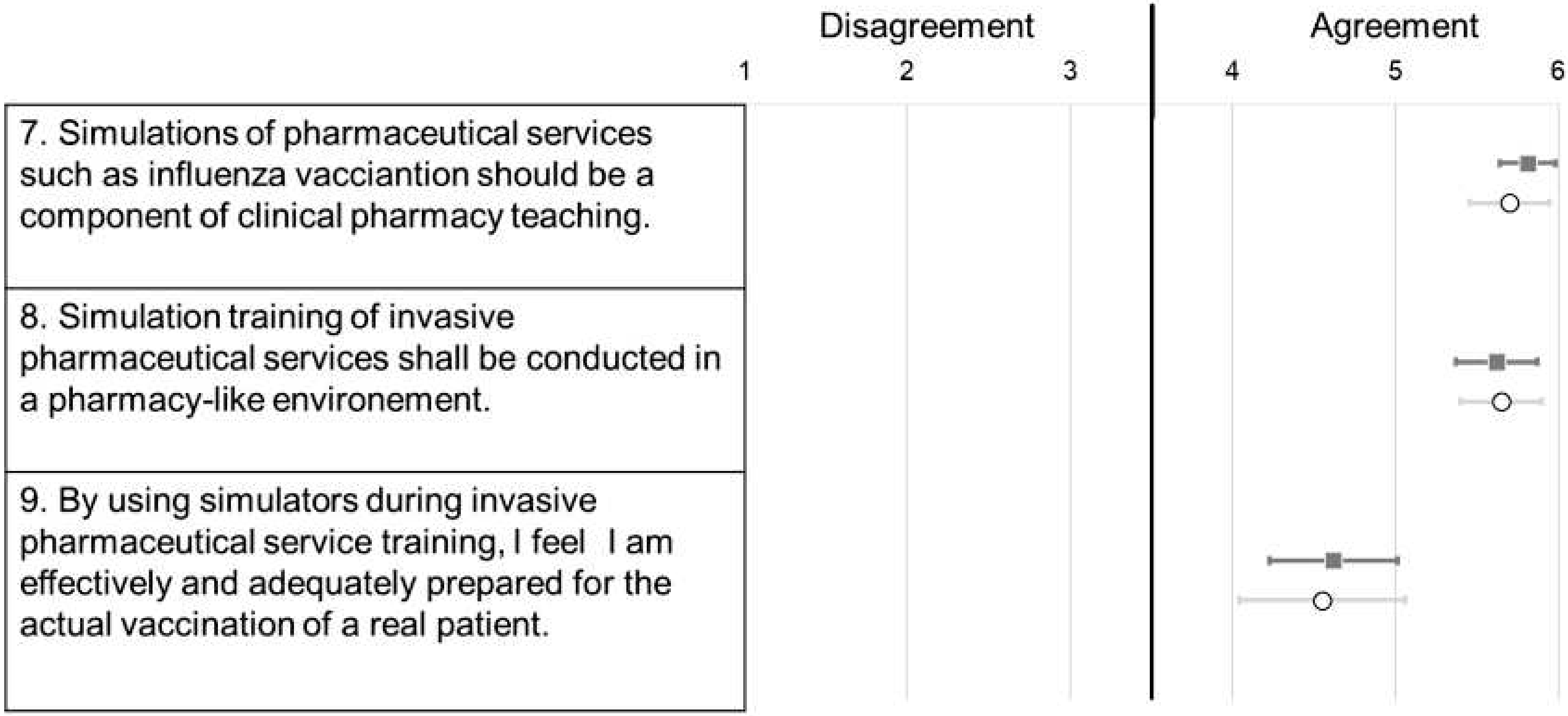

**Appendix 5-2:**
Box-Plots of analytical checklist score difference between pre-training and post-Training OSCE. A one-sided Mann-Whitney test with a significance level of alpha=0.05 was use




**Appendix 5-3:**
Box-Plots of analytical Checklist score differences for each station between pre-training and post-training OSCE for respective groups. the black diamonds (♦) indicate the outliers. A one-sided Mann-Whitney test with a significance level of alpha=0.05 was used.

**Appendix 6:** Achieved scores by intervention and control group in pre- and post- training self-Assessment of the RCT.

| **Group** | **Pre-Training** | **Post-Training** | ***p*-Value (intragroup)** |
|---|---|---|---|
| | Mean (CI) | Mean (CI) | |
| Intervention | 32.45<br>3.10 | 41.60<br>2.77 | $p < 0.01$ |
| Control | 33.92<br>2.96 | 41.33<br>2.10 | $p < 0.01$ |
| *p*-Value (intergroup) | $p = 0.505$ | $p = 0.568$ | |




**Appendix 6-1:**
Forest Plot of mean values with 95%-confidence interval of self-assessment scores for question 7 to 9 in post-Training (6-point Likert scale). White dots (○) = intervention group (n=20); grey square (▪) = control group (n=21).

# 9. List of own Publications

Some parts of this dissertation were previously published in international peer-reviewed journals or were presented at conferences beforehand:

**Original Publications in Peer-Reviewed Journals**

1. Sayyed SA, Sharkas AR, Ali Sherazi B, Dabidian A, Schwender H, Laeer S. Development and Assessment of Innovative High-Fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy Undergraduates-A Randomized Controlled Study. Vaccines (Basel). 2023 Jan 31;11(2):324. doi: 10.3390/vaccines11020324

2. Sayyed SA, Kinny FA, Sharkas AR, Schwender H, Woltersdorf R, Ritter C, Laeer S. Vaccination Training for Pharmacy Undergraduates as a Compulsory Part of the Curriculum? - A Multicentric Observation. Pharmacy (Basel). 2024 Jan 11;12(1):12. doi: 10.3390/pharmacy12010012

3. Sharkas AR, Ali Sherazi B, Sayyed SA, Kinny FA, Steichert M, Schwender H, Laeer S. Development and Evaluation of Interprofessional High-Fidelity Simulation Course on Medication Therapy Consultation for German Pharmacy and Medical Students - A Randomized Controlled Study. Pharmacy (Basel). 2024 July (Manuscript submitted for publication)

4. Ali Sherazi B, Sayyed SA, Moellenhoff K, Laeer S. Telepharmacy versus Face-to-Face Approach in Providing Inhaler Technique Training Service: A Non-inferiority Assessment Among Final Year Pharmacy Students. Integrated Pharmacy Research and Practice. 2024 May (Manuscript submitted for publication)

**Conference contribution**

Sayyed S, Reda Sharkas A, Ali Sherazi B, et al “Innovative high-fidelity simulation for vaccination training of pharmacist including emergency cases - a randomised controlled study” Archives of Disease in Childhood 2023;108:A13. 19th European Society for Developmental, Perinatal and Paediatric Pharmacology (ESDPPP) congress (June, 2022), Liverpool, United Kingdom