REVIEW

VACCINATION IN COMMUNITY PHARMACIES – A GLOBAL REVIEW AND THE ROMANIAN OPPORTUNITY

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Abstract

Vaccination represents a very important global health concern, at this time being the most effective method of immunization. Growing the vaccination rate has become a target in many countries because over the years the statistical data showed a significant decrease in the number of preventable deaths through vaccination. In developing countries, vaccination is a form of public health protection against more than 20 infectious diseases. Medical science is in continuing development and new vaccines continue to appear, the most recent being against rotavirus and papillomavirus. The techniques of achieving this target are different from country to country, but a trend that extends the role of community pharmacies in vaccination is attracting more states. Argentina, South Africa, the United States of America, the United Kingdom, Portugal, Ireland, Australia, Switzerland and France offer community pharmacists the possibility to administrate vaccines under certain conditions. Although in Romania vaccination in pharmacies is regulated by the modified and republished Pharmacy Law 266/2008, in practice this is not yet possible due to the lack of implementing regulations. Good practice examples from all these states show that such measure possible. Expanding the role of Romanian community pharmacies in vaccination could raise the vaccination rates. In the last years, Romania has experienced a significant decrease in the number of vaccinated people that has led to an increase in epidemics in the country. In order to accomplish the objectives of The Global Vaccine Action Plan (GVAP) initiated by WHO, Romania should follow the example of all these states and implement vaccination in community pharmacies, because this will increase the number of providers of vaccination services, therefore population enjoying access to fair information and vaccination programs.

Rezumat

Vaccinarea reprezintă un motiv important de îngrijorare în privința sănătății la nivel global, la ora actuală reprezentând cea mai eficientă metodă de imunizare. Creșterea ratelor de vaccinare a devenit o țintă pentru multe țări deoarece de-a lungul anilor datele statistice au arătat o scădere considerabilă a numărului de decese prevenite prin vaccinare. În țările în curs de dezvoltare, vaccinarea reprezintă o formă de protecție de sănătății populației împotriva a mai mult de 20 de boli infecțioase. Știința medicală este în continuă dezvoltare și noi vaccinuri continuă să apară, cele mai recente fiind împotriva rotavirus și papilomavirus. Modalitățile de atingere ale acestui obiectiv diferă de la țară la țară, dar un *trend* care extinde rolul farmaciilor comunitare în vaccinare atrage tot mai multe state. Argentina, Africa de Sud, Statele Unite ale Americii, Regatul Unit al Marii Britanii, Portugalia, Irlanda, Australia, Elveția si Franța oferă farmaciștilor comunitari posibilitatea de a administra vaccinuri în anumite condiții. Deși în România vaccinarea în farmacii este reglementată în Legea Farmaciei 266/2008 modificată și republicată, în practică nu este încă posibilă din cauza lipsei normelor de aplicare ale legii. Bunele exemple de practică din aceste state arată că o asemenea măsură este posibilă. Extinderea rolului farmaciilor comunitare românești în vaccinare ar putea crește rata vaccinării. În ultimii ani, România s-a confruntat cu o scădere semnificativă a numărului de persoane vaccinate care a condus la o creștere a epidemiilor la nivelul țării. Pentru îndeplinirea obiectivelor Planului Global de Acțiune al Vaccinării inițiat de OMS, România ar trebui să urmeze exemplul acestor state și să implementeze vaccinarea în farmaciile comunitare, deoarece în acest fel va crește numărul furnizorilor de servicii medicale de vaccinare, populația beneficiind de un acces echitabil la informații și programe de vaccinare.

Keywords: vaccination, community pharmacy

Introduction

Increasing access to vaccination, medical and pharmacological services can save millions of lives annually [41, 42], and the community pharmacy occupies an important role in contributing to public health through accessibility, distribution and medical expertise. Pharmacists are professionals trusted by

the population that can increase the appropriate communication regarding medical information and products quality. They can provide patients with fair information about how important vaccination is, also they can warn people in the risk category by helping them to understand why it is important to be vaccinated, thus playing an important role in promoting vaccination.

In 2012, The Global Vaccine Action Plan (GVAP) initiated by the WHO was endorsed by 194 Member States of the World Health Assembly in order to stimulate the universal access to immunisation [41]. As WHO mentions in The Global Vaccine Action Plan, it aims to prevent millions of deaths through more equitable access to vaccines. Possibility of administering vaccines by pharmacists may be a good start for Romania to move closer towards the goals proposed by WHO through increasing the number of vaccine providers that helps to consolidate the immunization process. In recent years, community pharmacies have become increasingly populated. The pharmacist is the first health specialist to be addressed by the patients when faced with a health problem, which demonstrates the trust given by patients.

This paper represents a review of the international experience regarding vaccination in community pharmacies and a presentation of the necessary steps in order to implement this measure in Romania.

Influenza vaccination in Romania

Analysing the Romanian data on influenza vaccination rate between 2008 - 2016, it can be noted that it dramatically decreased. In this situation the experiences found in several countries may be a good solution to increase influenza vaccine coverage in line with WHO recommendations.

WHO position paper on influenza estimates that this infection occurs globally with an annual attack rate estimated at 5% - 10% in adults and 20% -30% in children. Morbidity and mortality is underestimated in many countries [43].

Percentage of vaccinated people which are part of risk-groups of contracting disease (healthcare workers) or those at risk to develop complication or severe infection (pregnant women, the elderly over 65, individuals with underlying health conditions such as HIV/AIDS and chronic heart or lung diseases, children aged <5 years) is currently low in Romania.

The recommendations of WHO for an influenza vaccine coverage of 75% of elderly and those with chronic conditions is far to be attaint in Romania. Since 2008 the number of doses distributed freely by the Romanian Ministry of Health through general practitioners to risk categories sharply decreased. Additionally 0.1 million doses sold on free market should be added yearly to figures of the Figure 1.

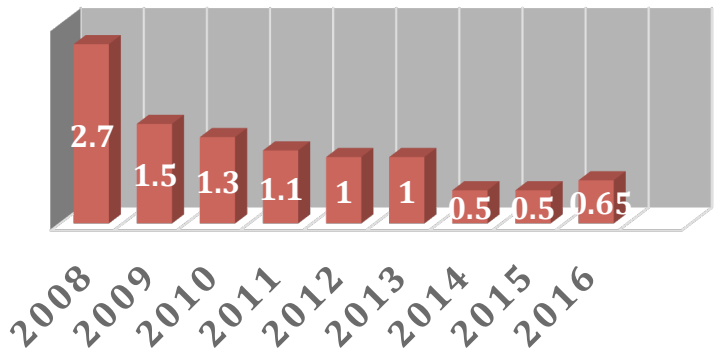

Figure 1.
Millions of doses distributed yearly by the Romanian Ministry of Health

During 2016 - 2017 vaccination season only 2.5 of the general population was vaccinated against influenza, one of the lowest rates registered in Europe (Table I).

These data should be analysed in critical conjunction with the influenza cases reported in the last 10 years, as depicted in Figure 2.

Table I

Romania - Influenza vaccine coverage for the season 2016-2017*

General population	Elderly > 65 years	Healthcare workers	Pregnant women	Chronic conditions patients
2.5%	8.1%	47.5%	2.9%	17.8%

* Source: National Institute of Public Health, National Centre for Surveillance and Control of Communicable diseases

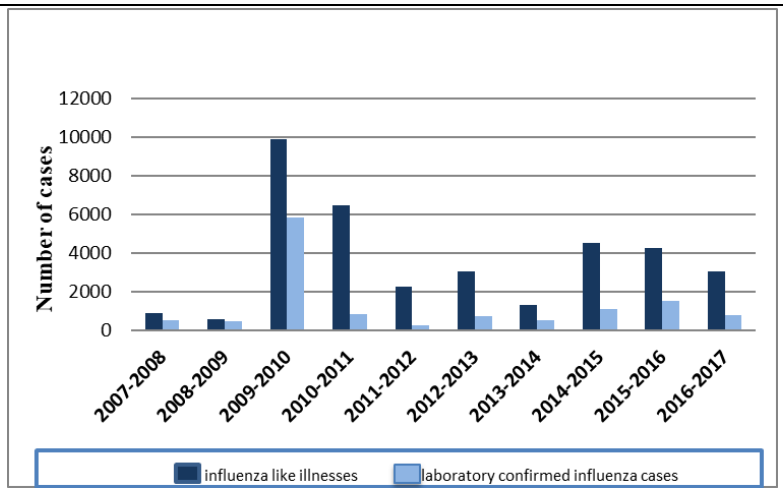

Figure 2.
Romania- Influenza cases: 2007-2017 (National Institute of Public Health, National Centre for Surveillance and Control of Communicable Diseases)

Vaccination in community pharmacies

Vaccination in community pharmacies is a common practice among many countries that should also be applied in Romania to increase the vaccination rate.

In **Argentina**, one of the first countries to implement such strategy, pharmacists were authorised to administer intramuscular and subcutaneous injections under medical indication since 1958, and a law specifically stated vaccination in pharmacies based on a prescription since 1983, but only in 2011 the regulations included intradermal injections in pharmacies with the specific purpose of vaccination [17, 18, 37].

Regarding **South Africa**, pharmacists were never forbidden to administrate vaccines if trained and experienced. There is a list of vaccines that can be sold without prescription, the Department of Health aiming to reduce child mortality through a National Expanded Programme for Immunization (EPI) that outlines guidelines, instructions and requirements for vaccination. The South African Pharmacy Council (SAPC) set the rules of Good Pharmacy Practice (GPP) with the Minimum Standards for Immunization Services that outline the activities, procedures, equipment and facilities, training, documentation and records, waste management, etc. Pharmacists must have the skills and knowledge to administer vaccinations including the schedules for immunisation of different age groups and travellers and how to deal with anaphylaxis. Cardio-pulmonary resuscitation abilities are also required [8, 9, 38, 40].

In the **United States of America** pharmacists are allowed to administrate vaccinations. The first immunisation training began in 1994 in Seattle, but later on, in 1996, it was followed by the American Pharmacists Association's (APhA's) Pharmacy-Based Immunization Delivery Certificate Training Program (CTP), recognised by the Centres for Disease Control and Prevention (CDC). The APhA provides resources, guidelines, and materials available online. Immunisation schedules, patient hand-outs, videos, resources that address religious concerns, etc. are available through the Immunization Action Coalition (IAC) [4, 36, 39].
Pharmacies promote immunisation through incentive programmes, by rewarding patients with monetary and nonmonetary rewards such as vouchers, gift cards, prizes, products, in order to enhance patients' access. The Academy of Managed Care Pharmacy reported that the pharmacist led immunisation programmes increased the number of patients seeking vaccination both in pharmacies and from their physicians. Pharmacists were awarded by the APhA since 2008 [1, 31].

In the **United Kingdom** pharmacies promote immunisation through posters, flyers and leaflets and pharmacists collaborate with general practitioners (GPs) to promote seasonal flu campaigns. Pharmacists can also administrate vaccines. In 2013/2014 pharmacies were commissioned to provide NHS flu immunisation services alongside GPs, but all pharmacies were included in the national flu campaign for the first time in 2015 [2, 34].
Flu vaccination is considered an Advanced Service that can be provided only in certain conditions like the existence of a consultation room and pharmacists with appropriate training, qualified to administrate vaccines. The range of available vaccines in pharmacies has extended to hepatitis B, human papilloma virus, travel vaccines, etc. However, pharmacists must notify general practitioners on the same or the next working day after administrating a vaccine [2, 6, 11].
The biggest challenge was the opposition of general practitioners whose income lowered. Furthermore, a 2003 survey conducted by the Patients Association

revealed that patients were concerned about pharmacists' expertise, confidentiality and privacy, but since then the public image has improved due to extended opening hours and higher accessibility [19, 23, 24].

Regarding immunisation services in **Portugal**, pharmacists can also administrate vaccines since the Governmental Decree (Portaria) 1429/2007; 2nd November extended pharmacies services to screening activities, administration of medicines and vaccines, information campaigns and health education programmes. The Deliberation 139/CD/2010 of the National Authority of Medicines and Health Products (INFARMED), as amended by the Deliberation 145/CD/2010, makes the pharmacy manager responsible for vaccination and attributes the administration of vaccines to a trained pharmacist or a nurse hired for this purpose and states the requirements for private room, materials, equipment and waste management. The Portuguese Pharmaceutical Society (PPS) is responsible for the accreditation of pharmacists training regarding the administration of injectable medicines and vaccines. The National Association of Pharmacies (ANF) and the PPS provide recommendations and professional tools for pharmacies and a PPS book, considered a good practice guideline is freely distributed to pharmacists [7, 12-14, 22, 35].
The Centre for Health Evaluation and Research vaccination data for 2014/2015 estimated that almost 49% of all flu vaccines were administered in community pharmacies [5].

In **Ireland** pharmacists are authorised to administrate flu vaccines in registered pharmacies without a prescription since 2011, and the list of vaccines was extended in 2015 to the pneumococcal and herpes zoster vaccines. Pharmacists training consists of theoretical and practical components approved by the Council of the Pharmaceutical Society of Ireland (PSI) and accredited by the Irish Institute of Pharmacy (IIOP). The PSI also issued the Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses [20, 21, 27].
According to the PSI reports on the evaluation of seasonal influenza vaccination service in pharmacy, a high percentage of the pharmacy vaccinated patients were never vaccinated before: 27% in 2012/2013, 24% in 2013/2014, 23% in 2014/2015 [28-30].

In **Australia**, the administration of vaccines started in 2014, with the Queensland Pharmacist Pilot (QPIP). In 2016, amendments were made to the Poisons Regulations to allow trained pharmacists to administrate influenza vaccines in Tasmania (TAS), Australian Capital Territory (ACT) and Victoria (VIC). However, the legislative requirements are different between States and Territories. The pharmacists that administrate the vaccine are legally accountable for the service. Furthermore, first aid and cardio pulmonary resuscitation trained pharmacists must observe the patients for 15 minutes after the administration of the vaccine. The standards are outlined in the Australian Immunisation Handbook and there are requirements regarding the consultation room, cold chain management and record management [3, 25, 26].

In **Switzerland** the authorisation for pharmacists to administrate vaccines is under the control of each of the 26 Cantons. First Cantons were granted vaccination rights in 2015, but since then the list has been extended. Currently vaccine administration in pharmacies without prescription is authorised in 18 Cantons, with prescription in Tessin Canton and the other 7 Cantons offer only counselling regarding vaccination. Pharmacists must obtain a Certificate from pharmaSuisse, accredited by the independent authority Foederatio Pharmaceutica Helvetiae (FPH) validation committee. The Federal Office of Public Health provides leaflets and factsheets [10, 32, 33].

France is the last country where, since May 2017 vaccination in community pharmacies became possible in two regions, Auvergne-Rhone-Alpes and Nouvelle-Aquitaine as part of a pilot project. The Ministry of Social Affairs and Health gave pharmacists the authorisation to administrate flu vaccines under certain conditions. A consent form must be signed by the patient and the pharmacist must inform the patient's physician. Pharmacists must follow a vaccination guideline and their services are paid for each vaccine administration if there is a medical prescription. Each community pharmacy receives a payment for each pharmacist that administrated at least 5 vaccinations. Payments are received only if the pharmacists report their vaccination activities. It is estimated that until October 2017, 26,958 patients over 65 years old were vaccinated by almost 3 000 pharmacists in 2 562 pharmacies [8].

In **Romania** administrating vaccines in community pharmacies is regulated by the modified and republished Pharmacy Law 266/2008 [15], article 2, point g that attributes vaccination to the list of community pharmacy activities, under the conditions stipulated by the order of the Minister of Health. In practice, administrating vaccines in pharmacies is not yet possible due to the lack of implementing regulations. However, good practice examples from all these states show that such measure could be useful for Romania in order to grow the vaccination rates.
Every year, millions of deaths are prevented by vaccination, however the population's anxiety about vaccine is more and more common which hinders

the development of this public health measure. In recent years, there has been a continuing decline in vaccine coverage across the country, for all types of vaccines included in national and optional schedules, which has led to national epidemics. Reported data by the National Institute of Public Health, National Centre for Surveillance and Control of Communicable diseases until 07.04.2017 confirmed a number of 4090 cases of measles, and the influenza vaccination coverage for the season 2016-2017 in Romania being: 2.5% for the general population, 8.1% for the elderly (> 65 years old), 2.9% for pregnant women and 17.8% for the chronic patients. These numbers demonstrate a significant decrease in vaccination in Romania. Disinformation in the social media, lack of health care staff, all led to hesitation in vaccination.

To allow vaccination in community pharmacies, certain implementing regulations laws are necessary. If pharmacists and patients are open to this, measures should be taken into consideration through public debate before taking the necessary steps in this direction. Pharmacists would have to attend training and obtain a diploma in order to administrate vaccinations. The National Family Medicine Society together with the College of Pharmacists and the College of Physicians should have a major role in training pharmacists. After obtaining the diploma attesting the right to administer vaccines, pharmacists must be registered in the National Electronic Vaccination Register. Another aspect that should be taken into consideration in community pharmacies is the access to the National Electronic Vaccination Register so that pharmacists can check the history of a patient's vaccination and be able to successfully complete the administration of a vaccine.

Otherwise, an important role in training pharmacists for the administration of vaccines may be attributed to vaccine producing companies who can provide more information and instructions on vaccine conditioning, route of administration, information about adverse reactions observed during clinical trials, so that pharmacists can provide complete and accurate product information as possible.

Vaccination programs have had a strong impact on society, helping to reduce the number of infectious disseases such as diphtheria, tetanus, measles, yellow fever. Vaccination in community pharmacies could raise the vaccination rates for risk groups and general population because campaigns to promote vaccination can be organized, patients may have access to flyers with information about possible epidemics in the country, and their personal vulnerability profile. At the same time, the pharmacist is always present to answer their questions and to help patients understand the importance of vaccination. Pharmacists can approach patients from the risk group (pregnant woman, elderly people, parents with children) who are attending their pharmacy, informing about the importance of vaccination for them. Among the benefits of administering vaccines to community pharmacies we can identify the increasing patient compliance because the number of providers of vaccination services will be increased and the number of patient in the medical cabinets will be reduced.

The correct administration of vaccines involves monitoring several important factors, including the administration in the correct anatomical area, the correct injection technique and maintaining in the perfect temperature conditions.

Romania could begin adopting the vaccination strategy in community pharmacies with the flu vaccine, which was the first vaccine to be administered in pharmacies in most of the states mentioned above and it is also one of the most commonly used vaccines. In the upcoming period we should adopt the strategy of Ireland which approved the administration of pneumococcal and herpes zoster vaccines in community pharmacies.

The level of involvement from the College of Physicians should be debated with all the involved partners. Another aspect that should be taken into consideration is the reimbursement for influenza vaccines by the health insurance houses, in order to increase the free access to vaccines.

Administration of vaccines in community pharmacies would also have beneficial effects for improving pharmacovigilance, primarily by the pharmacist of the first adverse reactions that may occur in first 30 minutes after administration, and reporting later occurring adverse effects, much easier by the patient at the time he returns to the pharmacy.

Conclusions

Vaccination in community pharmacies represents a common practice in many states in order to grow the vaccination rates. Argentina, South Africa, the United States of America, the United Kingdom, Portugal, Ireland, Australia, Switzerland and France offer community pharmacists the possibility to administrate vaccinations under certain conditions. In Romania immunisation in pharmacies is regulated by the Pharmacy Law, although in practice this is not yet possible due to the lack of implementing regulations.

Considering the benefits and advantages of administering vaccines in the community pharmacies, it can be strongly argued that adopting changes to existing legislation can bring benefits to the vaccination system in Romania.

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Conflicts of interest

The authors declare that they have no conflict of interest.

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