Seasonal Influenza Vaccination Programme in Pharmacies – Evidence Base and Framework

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Overview:
Influenza is a highly infectious acute respiratory illness. In most adults it is a self-limiting illness with most people recovering in 2-7 days. However, in specific patients the effects of influenza can be severe and can cause serious illness and death, especially in the very young and in the elderly. In such patients, serious respiratory complications can develop, including pneumonia and bronchitis which require hospital treatment and a number of patients die from influenza each winter. The Irish national estimate of the number of deaths annually from influenza and its complications is 300-400 deaths per year the majority of deaths occurring in those over the age of 65.

It is widely accepted that influenza immunisation remains the most effective way to prevent influenza and reduce complications. It also reduces hospital admissions as a result of influenza by as much as 60% and morbidity by 40%.

Experience and evidence base for pharmacy vaccination services
Pharmacy vaccination services have been successfully implemented in many other jurisdictions. This extensive experience provides the evidence base for the safe provision and delivery of vaccination services through pharmacies.

USA
Across the USA, there is extensive experience in the administration of vaccines through pharmacies. In California pharmacy vaccination services have been in place since the mid-1990s and since 2009, pharmacists have been authorised to administer vaccinations in all 50 US States in accordance with state-specific prescribing arrangements such as written or verbal prescriptions, standing orders, protocols or collaborative agreements. More than 150,000 pharmacists are now trained to administer vaccinations and immunisation training for pharmacists is provided by both the American Pharmacists Association (APhA) and the universities.

In the 2010-2011 influenza season the Centres for Disease Control and Prevention estimated that almost 20% of adult vaccination doses nationwide were delivered by pharmacists and the CEO of the
APhA, at the annual congress of the International Pharmaceutical Federation (FIP) in September 2011, stated the APhA estimate this to be approximately 5 million doses. He also stated that anaphylactic reactions following the administration of vaccines are very rare and that no anaphylactic reactions have been reported following their administration in pharmacies the last 12 years. In addition, for the period July 2004 to June 2005 (as population-level projections based on 17 states) it is reported that 30.4% of the influenza vaccines administered, were administered in pharmacies.

In 2002 the American College of Physicians and the American Society of Internal Medicine issued a position paper in which they support the use of the pharmacist as an immunisation information source, host of immunisation sites, and immuniser, as appropriate and allowed by state law, and in which they state they will work with pharmacy organisations to increase immunisation awareness. They noted that because of the extensive state legislation that already existed, in 2002, allowing pharmacists to administer immunisations, the potential benefit of non-physician immunisation of patients was widely recognised. Pharmacists provide increased access to immunisation through extended business hours and locations and increased access to immunisation by trained pharmacy professionals will help to increase adult immunisation.

Public Health Officials also recognise the role of pharmacists in immunisation campaigns, the Association of State and Territorial Public Health Officials stated, in 2009, that pharmacies are in a unique position to reach mass numbers of people. There are more than 56,000 community retail pharmacy outlets in the United States and these offer the public convenience, accessibility, and extended hours of operation.

One study undertaken by the Medical University of South Carolina, prior to all states providing vaccination services, indicated that individuals aged 65 years and older who live in states where pharmacists can provide vaccines had significantly higher influenza vaccine rates than individuals of this age who reside in states where pharmacists didn't provide vaccines.

**UK**

Since 2002, UK pharmacists have been authorised to administer certain vaccines, including the influenza vaccine, through a Patient Group Direction (PGD) without the requirement for a patient specific prescription written by a medical practitioner.

To improve uptake of influenza vaccination, City and Hackney Primary Care Trust in London introduced an enhanced pharmacy service allowing pharmacists to administer the influenza vaccine. Following provision of this service through pharmacies, the uptake increased from 59% in 2005 to 76% in 2008, for patients over 65 years. In a survey carried out in Scotland, patient satisfaction with the provision of influenza vaccination was high, almost all patients surveyed thought the vaccination was well administered (98%) and the pharmacist was professional (96%).

In 2010, the NHS in Wales carried out an extensive review of the experience available on the delivery of vaccination services through pharmacies. The review provides background information on the provision of pharmacy vaccination services in different countries, including the UK and USA. It focuses on the provision of the seasonal influenza vaccination through pharmacies and demonstrates the service has increased vaccination uptake and is well received by patients. The report concludes that pharmacies are well placed to complement vaccination services offered by traditional providers.
Portugal
Following a change in legislation in 2007 a training programme, based on the APhA (USA) certified training programme, on immunisation delivery was developed for pharmacists to provide a vaccination service through pharmacies. The first national Pharmacy-Based Influenza Immunisation Campaign in Portugal was held in October 2008 and data was collected for the entire influenza season (October 2008 – March 2009) with 1588 pharmacies participating. It was estimated that nearly a quarter of all influenza vaccines dispensed in Portugal in this time period were administered in pharmacies.\(^{13}\)

The reported rates of patient satisfaction with pharmacy vaccination services were high, specifically 99.5% satisfaction with the immunisation provider; 98.2% with the waiting time; 98.0% with the privacy. Importantly, it was reported that 13.1% of people were first time recipients of the influenza vaccine, demonstrating the role of pharmacy in improving access to the population and increasing vaccination uptake. The convenience and accessibility were favourable, 91.4% did not require an appointment and the mean waiting time was 5.1 minutes. Overall 98% of patients stated that pharmacy was their preferred location for the service and that they would choose to be vaccinated the following year in pharmacy.\(^{13}\)

At FIP’s international congress 2011, the Associacao Nacional das Farmacias, the Portuguese pharmacist representative association, stated 59.7% of community pharmacies participated in the immunisation programme during the 2009-2010 influenza season and no anaphylactic reactions were reported in the three years of vaccines being administered through pharmacies. The uptake of pharmacy vaccinations is high, for example, in 2009-2010 26.8% of the influenza vaccines administered were administered through pharmacies and pharmacies were where the highest proportion of patients were vaccinated.\(^{12}\)

Canada
Canada is another jurisdiction which currently provides immunisation services through pharmacies. Trained pharmacists in British Columbia, Alberta and New Brunswick are able to administer vaccinations and provide the related education and counselling. To ensure competence, registered pharmacists in British Columbia must complete training from a College of Pharmacists approved accredited training program and possess current certification in CPR and first-aid from a recognized provider, prior to administering injections. Pharmacists who receive authorisation to administer immunizations must then follow the Standards, Limits and Conditions established by the College of Pharmacists of British Columbia.\(^{14}\)

Australia
The Pharmaceutical Society of Australia have stated they support vaccination as a public health program and will lead the development of immunisation administration training, credentialling for pharmacists and accreditation of sites.\(^{15}\) In anticipation of this role for pharmacists certain universities, e.g. Charles Sturt University in New South Wales, began training their pharmacy students to vaccinate in 2010.

Ireland
The delivery of vaccination services through community pharmacies is line with the PSI’s Pharmacy Ireland 2020\(^{16}\) initiative which recommends developing a strategy for maximising access to vaccines to improve patient outcomes, by utilising the community pharmacy network. It has also been identified as a priority by the National Pharmacy Reference Group (NPRG).\(^{17}\)

In autumn-winter 2010, trained pharmacists were involved in the national immunisation programme, which involved 120 pharmacists administering approximately 7,000 doses of the
influenza vaccine. No incidences of anaphylaxis were encountered. Patient records were required to be maintained and all patient vaccination details were collated and provided to the Health Protection Surveillance Centre (HPSC) audit as part of the HSE programme to monitor vaccination coverage. Immunisation training for pre-registration pharmacists is now also included in the learning programme of the national MPharm degree which fulfills academic requirements for professional registration.

Anaphylactic reactions following the administration of the seasonal influenza vaccine are very rare (the Irish Medicines Board have received three reports of anaphylaxis since 2000\(^{18}\)). All pharmacists administering the vaccine will nevertheless be required to undergo comprehensive training in this area.

**Safe and appropriate regulatory and professional framework**

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. The PSI is accountable for the effective regulation of pharmacy services, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies. The Pharmacy Act 2007 introduced a robust legal framework for the regulation of pharmacy services including the accreditation of educational programmes for the pharmacy profession, the quality assurance of standards, the development of pharmacy practice, the inspection and registration of pharmacies and handling complaints and disciplinary matters. It is within this framework that the PSI fully supports the the broadening of health services delivery within the community and the recent proposal by the Minister for Health to improve public accessibility to the annual influenza vaccination through pharmacies.

All pharmacists providing an immunisation programme will be required to undergo a specific, comprehensive and appropriate training programme to achieve and maintain competency. This immunisation training programme will include robust quality assurance in relation to vaccination technique as well as the management of anaphylaxis and resuscitation. National standards and protocols for the delivery of such a service through community pharmacies, including the exclusion and inclusion criteria for patients, are currently under development and will be issued in advance of any vaccination service provision through pharmacies. Pharmacists will be required to practice in accordance with the PSI guidance and protocols and all superintendent pharmacists will be required to notify the PSI that they are providing the influenza vaccination service and the names of all trained participating pharmacists.

The Pharmacy Act 2007 also introduced within each registered pharmacy a robust system of clinical governance and accountability. A named superintendent pharmacist is now responsible and accountable within each pharmacy for ensuring the safe management and administration of the sale and supply of medicinal products. Each superintendent pharmacist will be required to have the necessary clinical governance systems, including robust policies and procedures, in place. These procedures and protocols will include specific referral procedures to ensure continuity and integration of patient care.

Superintendent pharmacists will also be responsible for ensuring that the premises, including the required patient consultation area, equipment and facilities are of an appropriate standard to provide the influenza vaccination service and that the provision of the service, is covered by appropriate professional indemnity arrangements. All participating pharmacists will be required to maintain appropriately detailed patient records; the requirements in relation to this will be detailed in PSI guidance.
The PSI is aware the legal issues associated with the administration of seasonal influenza vaccines by pharmacists are being examined.

Conclusion
The compelling international evidence base demonstrates the benefits to public health of vaccination services being delivered through pharmacies while the robust Irish regulatory framework ensures the maintenance of patient safety throughout this process. The pharmacist has the most frequent contact of any healthcare professional in Ireland with the population as a whole and the international evidence base shows increasing access to vaccinations through pharmacies improves public health by maximising vaccination uptake and awareness in both the general public and at-risk groups. The PSI fully supports the recent proposal by the Minister for Health to improve public accessibility to the seasonal influenza vaccination by incorporating pharmacists into the national immunisation strategy.

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