

Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacy 2012-2013.

Executive Summary

In October 2011, legislation was introduced which enabled pharmacists to participate in the annual seasonal influenza vaccination campaign for the first time. Following the underdosing of some patients by certain pharmacists during the 2011/2012 season, an independent risk review group was established to examine and report on the cause of the error. The report of this review focussed on learning from what occurred and on the changes that may be required.

The PSI Council committed therefore to undertaking an evaluation of the 2012/2013 influenza vaccination service in pharmacies to provide on-going assurance regarding the provision of this still relatively new service in pharmacy, and following on from the risk review that took place in 2012.

The evaluation included engagement with patients, pharmacists and other key stakeholders. As a result of this engagement and the information gathered, a number of findings have been made:

- The seasonal influenza vaccination service provided in pharmacies is operating effectively and no quality or safety concerns were identified. Pharmacists were more fully integrated into the national immunisation campaign in 2012.
- The number of patients accessing vaccinations through pharmacies increased significantly in 2012/2013. Patients expressed satisfaction with the service provided.
- There was also a significant uptake of influenza vaccination by pharmacy staff leading to potential public health benefits.
- Pharmacists reported that they were satisfied with the training received in 2012 and provided further feedback on how training might be further improved and developed in the coming season(s). The evaluation has provided valuable feedback to inform Council's decisions regarding training and continuing professional development needs for the 2013/2014 season and into the future.

- It is recommended that a “Vaccinating Pharmacists Special Interest Group” should be established through the Irish Institute of Pharmacy to facilitate peer support and the maintenance of vaccination competence.
- Pharmacist feedback highlighted difficulties in the 2012/2013 season regarding the requirements relating to adrenaline (for the emergency treatment of anaphylaxis) for the provision of vaccination services. Following consultation and a review of international practice, the *PSI Guidance on the Provision of Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses* has been amended.
- Pharmacists expressed a wish to develop and expand on the vaccination and other clinical services provided in pharmacies, and patients interviewed expressed their support for these initiatives.

Introduction

In 2011 the Minister for Health introduced legislation which provided pharmacists with the authority to supply and administer the seasonal influenza vaccine to patients without the requirement for a prescription. This enabled pharmacists to participate in the annual vaccination campaign for the first time for the 2011/2012 seasonal influenza season.

Following the underdosing of some patients by certain pharmacists during the 2011/2012 influenza season, an independent risk review group was established to examine and report on the cause of the error. The report of this review focussed on learning and on the changes that may be required, and made a number of recommendations in that regard. The recommendations of the risk review group were reflected in the review of the *PSI Guidance on the Provision of Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses* in 2012, the review of the *PSI Interim Accreditation Standards for Seasonal Influenza Vaccination Training Programmes for Pharmacists* in 2012 and the training requirements for 2012/2013 approved by the PSI Council in line with the legislation.

For the 2012/2013 seasonal influenza season, the Health Service Executive (HSE) expanded the patient groups for which community pharmacists were eligible to claim for reimbursement for vaccination and/or who could be given vaccine supplied free of charge by the HSE (see Appendix VI). The stated aim of this extension was to increase the vaccine uptake in these high risk groups and to reduce morbidity, mortality and the burden to the health service, particularly in primary care, associated with seasonal influenza.

The PSI Council committed to undertaking an evaluation of the 2012/2013 seasonal influenza vaccination service in pharmacies to provide ongoing assurance regarding the provision of the service, given that it is a very new initiative and following on from the risk review that took place in 2012. This evaluation is intended to inform the Council's decisions regarding training for the 2013/2014 season and future policy developments in respect of this type of service provision by pharmacists.

Methodology

In undertaking the evaluation, the PSI sought to engage with patients, pharmacists and key stakeholders regarding their experience of and views on the service, pharmacist training, PSI guidance, service expansion etc.

This involved:

- Meetings with key stakeholders such as:
 - The ‘Pharmacy Working Group’, established by the PSI in 2011, comprising representatives from the Irish Pharmacy Union (IPU), Boots, Unicare/Doc Morris and Uniphar Retail Services.
 - The HSE National Immunisation Office (NIO)
 - The HSE Primary Care Reimbursement Service (PCRS)
 - Training Providers: Hibernian Healthcare and Boots
- Facilitating focus groups and interviews with patients and pharmacists regarding their experiences of the services provided.
- Gathering additional information on the delivery of the service in pharmacies.
- Considering international experience, from other countries providing pharmacy vaccination services, in the provision of such services in pharmacy and in pharmacist training and continuing professional development (CPD).
- An internal PSI evaluation of pertinent issues which arose through inspection or complaints procedures.

Qualitative Consultation

Mary Culliton, former Director of Advocacy with the Quality and Patient Safety Directorate of the HSE, a member of the risk review group and a member of the PSI Pharmacy Practice Development Committee, was engaged to assist the evaluation. This assistance included qualitative interactions with pharmacists and patients (recruited with the assistance of the “pharmacy working group”).

Eight patients attended a focus group, one patient was interviewed in person and five patients were interviewed by phone. Focus groups were held in both Dublin and Mullingar ensuring an urban- rural mix. The patients interviewed reflected the age groups of patients vaccinated in the 2012/2013 season. The qualitative consultation with pharmacists incorporated two individual face to face interviews with pharmacists, one telephone interview with a pharmacist and nine pharmacists attending a focus group. The format of the focus groups and interviews was relatively unstructured allowing participants to debate and discuss issues of relevance while keeping the purpose of the evaluation in focus. (See Appendices I-V)

Findings

Information gathered from all elements of the evaluation was collated and is examined under the following headings:

Implementation of a Vaccination Service

Feedback received through the 'Pharmacy Working Group' indicates that approximately 19,000 patients were vaccinated in pharmacies this season (this figure has yet to be validated by PCRS). If so this would equate to an approximate doubling of the number of patients vaccinated in the 2011-2012 season.

The IPU reported that an estimated 27% of patients attending pharmacies of their members reported that they had not been vaccinated before and 80% of these previously unvaccinated patients were in an at risk category. 58% of pharmacists who provided feedback to the IPU had vaccinated their own staff. (Frontline healthcare professionals' vaccine uptake levels are generally very low and this is an important step in protecting staff and patients from influenza infection¹.) Similarly high levels of pharmacy staff uptake were reported by the pharmacy chains.

Pharmacists

Pharmacists reported that they were satisfied with the training they received in 2012. They also highlighted that for many pharmacies the service is provided primarily as a public health service and that all of the costs associated with delivering the service are not necessarily covered. Some pharmacists expressed the view that there is scope for developing efficiencies in the IT infrastructure to simplify the administration of the service.

There were mixed views among pharmacists about whether they were influenced by the potential reaction of other stakeholders (e.g. general practitioners) in the decision whether or not to provide this service to patients.

Patients

Patients interviewed about pharmacy vaccination reported that they were very satisfied with the service provided in pharmacies and were impressed with both the service delivery and how they were treated by pharmacists. Patients described the experience as being very thorough. They appreciated the fact that, in the course of this service, the pharmacists performed good history taking, that they explained the procedure and the risks and that they ensured that the patient was informed in giving consent. Many patients also said that they were reassured by being asked to wait in the pharmacy in case of an adverse reaction. All patients reported that the benefits they

¹ NIAC National Immunisation Guidelines for Ireland 2012

perceived in terms of accessibility, flexibility and cost of the service in pharmacies made this option very attractive to them. For some patients it was important to have their vaccination done by “their own pharmacist” but others were quite happy to use a pharmacy previously unfamiliar to them. Some patients reported receiving a reminder from their pharmacist about the influenza vaccine and these patients found it very helpful.

Premises and Facilities

Patients generally described the use of the consultation room as appropriate and providing comfort and privacy. In cases where space was felt by patients to be restricted, this was noted by patients. (Note: Where PSI authorised officers identify patient consultation areas, during inspections, that do not meet the minimum requirements outlined in the PSI vaccination guidance, they advise that vaccination should not take place in the pharmacy pending rectification of any noted deficiencies.)

Management of Adverse Events

The IMB (Irish Medicines Board) received 39 reports of adverse reactions following the administration of the seasonal influenza vaccine during the period 1st January 2012 to 15th May 2013. Of those reports, 8 were from a pharmacist (however it is unclear which healthcare professional had administered the vaccines in these cases). The majority of reports were reactions expected of a vaccine (injection site reactions, swellings, fever etc.). There were no reports of anaphylaxis.

In the feedback received from pharmacists, difficulties were reported in obtaining supplies of adrenaline injection (for the emergency treatment of anaphylaxis) for the 2012-2013 season. These difficulties were compounded by the cost and short shelf-life of the available products. The current (2012/2013) PSI Guidance states “adequate stock of adrenaline injections, designated for vaccination service use only, must be maintained in the pharmacy at all times. There must be sufficient stock of adrenaline injections for administration to a minimum of two patients available at all times.”

Following a review of international practice and a consultation with Dr. Kevin Connolly of the National Immunisation Advisory Committee an amendment to the PSI guidance has been approved by the PSI Council. This amendment requires that where pharmacists ensure that a time interval of at least 20 minutes elapses between the administration of a vaccine to patients, the pharmacy must have sufficient stock of epinephrine (adrenaline) injections for administration to one patient (per vaccinating pharmacist). In all other circumstances, there must be sufficient stock of epinephrine (adrenaline) injections for administration to a minimum of two patients available at all times. This amendment is designed to facilitate pharmacist participation in influenza vaccination without

compromising patient safety. Pharmacists consulted about this approach welcomed the proposed amendment.

HSE Registration and Notification

A meeting was held with the HSE Primary Care Reimbursement Service (PCRS) Chief Pharmacist regarding the HSE's perspective on the service provided in pharmacy. The HSE received very few queries from pharmacists and reported that the registering of pharmacies with the HSE was a smoother process this year. The notification website has worked well. Pharmacists have some minor issues regarding the information required (e.g. GP data field), however given the novelty of this process there were few difficulties experienced by all parties. The expansion of the use of the PCRS website to capture the vaccination of patients in all settings would be welcomed by all parties and would facilitate better surveillance of public health.

National Immunisation Office (NIO)

The NIO reported a high level of satisfaction with the service provided through pharmacies and that pharmacies had easily integrated into their existing system.

This year the NIO noted a 45% increase in the number of vaccines distributed to pharmacies. From the NIO's perspective, pharmacists appeared to be planning their service provision well with many pharmacies placing an initial vaccine order sufficient to last well into the influenza season. Pharmacists expressed a preference for the availability of more frequent deliveries from the HSE National Cold Chain Service.

The NIO received few queries from pharmacists. The PSI facilitated the dissemination of information to pharmacists in response to one query received. The NIO saw potential benefits from increasing the uptake of influenza vaccination delivered by pharmacists.

Pharmacists and patients were asked in the focus groups about the national seasonal influenza information campaign. The vast majority of pharmacists felt the campaign was very good and all emphasised the importance of the information specifically mentioning pharmacists as providers of the service. Some patients had heard about vaccinations being available in pharmacies from the HSE media campaigns but most relied on information provided in their pharmacy.

Pharmacist Training and Continuing Professional Development (CPD)

Training was provided by Hibernian Healthcare Ltd (in conjunction with the IPU) to 757 pharmacists and by Boots Ireland Ltd to 187 pharmacists.

Pharmacists were satisfied with the training provided this year. Some reported that they felt that the training may have been “overly thorough” which they acknowledged may have been as a result of the error in the previous year. They made constructive suggestions about how the training might be improved e.g. reduction in the duplication of the reading required before and during the training.

Training providers highlighted the difficulties caused by the short timescales involved in designing the training programmes and successfully completing the accreditation process ahead of the start of the vaccination season. Some suggested that the PSI interim accreditation standards be amended to further improve the process.

It is important to pharmacists that their training is completed in time to ensure that they are ready to vaccinate at the beginning of the season. They believe that this would greatly enhance pharmacists’ contribution to national immunisation uptake.

Regarding the development of training and CPD requirements, pharmacists have different levels of experience and they believe that training needs to be flexible enough to reflect these differences. The new CPD system for pharmacists in Ireland is amenable to such an approach.

The consensus among the vaccinating pharmacists who participated in the evaluation was that ‘live’ training was necessary for the first two years as a vaccinator, particularly for the building of competence and confidence. Following the first two years, the consensus opinion was that face-to-face skills retraining every five years should be adequate. There was agreement that this should be combined with self-assessment of one’s own needs, centred on competence and confidence levels, with annual online updates available for all vaccinating pharmacists.

It was also identified by a number of stakeholders that the cost of on-going training should ensure the best value use of public funds.

Service Expansion and Development

When consulted on the potential for service expansion and development, pharmacists expressed interest in providing other vaccines; specifically pneumococcal polysaccharide (linked to influenza ‘at-risk’ patients) and particularly where they provide services (methadone/needle exchange) which require staff to be protected, Hepatitis B. Pharmacists have expressed a general acceptance that vaccinating children under 18 was not yet appropriate. Notwithstanding that opinion, pharmacists were interested in joining other national immunisation campaigns such as cervical cancer/childhood vaccines and related ‘catch up’ vaccines. Interest in the provision of travel vaccine services was also expressed. Some pharmacists who attend nursing homes expressed regret that they could not

vaccinate in the nursing home due to legislative restrictions. Nursing home staff were encouraged by some pharmacists to come to the pharmacy for vaccination.

Pharmacists also described readiness to contribute more to integrated primary care service delivery, including health screening, minor injuries, sexual health services, medication reviews etc.

During focus group discussions with patients when these issues were raised, patients said they would welcome the expansion of pharmacist-delivered clinical services including additional vaccines, other services as per the *Pharmacy Ireland 2020* initiative and being able to access more (prescription-only) medicines and treatments directly from pharmacists.

Conclusions and Recommendations

The seasonal influenza vaccination service provided in pharmacies is operating effectively and no quality or safety concerns were identified. Pharmacists were more fully integrated into the national immunisation campaign in 2012.

The number of patients accessing vaccinations through pharmacies increased significantly in 2012/2013. Patients expressed satisfaction with the service provided. There was also a significant uptake of influenza vaccination by pharmacy staff leading to potential public health benefits.

Pharmacists reported that they were satisfied with the training received in 2012 and provided further feedback on how training might be further improved and developed in the coming season(s). The evaluation has provided valuable feedback to inform Council's decisions regarding training and continuing professional development needs for the 2013/2014 season and into the future.

It is recommended that a "Vaccinating Pharmacists Special Interest Group" should be established through the Irish Institute of Pharmacy to facilitate peer support and the maintenance of vaccination competence.

Pharmacists expressed a wish to develop and expand on the vaccination and other clinical services provided in pharmacies, and patients interviewed expressed their support for these initiatives.

Through *Pharmacy Ireland 2020*, the PSI should continue to examine how services could be expanded in pharmacies, to further enable and support pharmacists to contribute to public health.

Acknowledgements

The PSI would like to extend its gratitude to the members of the pharmacy working group, the HSE and various national bodies who gave of their time and expertise through correspondence and meetings with the PSI, as part of this evaluation. Particular thanks are also due to the patients and pharmacists who attended focus groups. All of those who participated approached the evaluation with openness, generosity and honesty.

APPENDIX I – Focus Group Invitation to Pharmacists

17/03/2013

Dear Pharmacist,

I would like to invite you to participate in a review of the immunisation service provided in Pharmacies in 2012/2013 season.

The PSI is currently evaluating the vaccination service provided to patients in 2012-2013. As part of that evaluation the experience of Pharmacists is central. To that end the PSI has committed to run a number of focus groups with the purpose of hearing the views and suggestions of Pharmacists on the entire process of vaccination in the 2012-2013 seasons. The PSI is interested in all issues relating to your experience and your suggestions for the development of the vaccination service both in terms of cohorts of patients and the introduction of other vaccines. The further development of the Pharmacist's contribution to Public Health will be explored and whether current guidance and training is adequate and appropriate. The PSI welcomes suggestions for quality improvement in service administration e.g. how vaccine stocks are acquired, how well the PCRS (HSE) notification website functioned etc.

It is important to establish whether pharmacists will participate again in the vaccination programme and the reasons why/why not. Pharmacists may have suggestions regarding supports desired for future developments.

In order to ensure independence of the information from the group discussion the PSI made the decision to have an independent person facilitate and report on the discussions. As a Healthcare Consultant I have significant experience in working with professionals, patients and advocacy groups and I very much look forward to meeting pharmacists in the course of this work.

Each focus group will comprise 8 (max) people and will be informal but clearly focused on the topic. Each group discussion will take 1hour-90mins (max). Comments will not be attributed to individuals and a report outlining the general comments will be submitted as part of the PSI report to its Council.

If you are willing to participate in this very important evaluation I would appreciate if you could contact ... before Friday March 22nd 2013. I hope you will join me for these discussions

Yours faithfully

Mary Culliton

Healthcare Consultant

APPENDIX II- Focus Group Invitation to Patients

17/03/13

Dear

I would like to invite you to help in a review of the vaccination service provided in Pharmacies in 2012/2013 season. Reviewing services such as this helps to continuously improve the quality of the service to patients.

The Pharmaceutical Society of Ireland (PSI) regulates Pharmacists and Pharmacies in Ireland. The role of the Pharmacist in healthcare is expanding in Europe and in 2011 the Irish Government introduced legislation supporting Pharmacists to administer the flu vaccine in their Pharmacies. Many patients chose to have their vaccination in a pharmacy in 2012/2013.

As part of its work the PSI monitors new services - keeping patients safe and supporting Pharmacists in their practice. As the vaccination of patients in Pharmacies is a new service the PSI is currently evaluating the vaccination service provided to patients in 2012-2013. As part of that evaluation the experience of patients is central. To that end a number of focus groups with patients who were vaccinated in Pharmacies in the 2012-2013 'flu season will be run in the next couple of weeks.

The PSI is keen to make sure that this process is impartial and consequently made the decision to have an independent person facilitate and report on the discussions. I am not a Pharmacist and as a Healthcare Consultant I have significant experience in working with patients and advocacy groups and I very much look forward to meeting patients in the course of this work.

Each focus group will comprise 8 (max) people and will be informal but clearly focused on the topic. Each group discussion will take 1hour-90mins (max). You will have the opportunity to tell about your experience of the 'flu vaccine and to suggest any improvements you would like to see. Comments will not be attributed to individuals and a report outlining the general comments will be submitted as part of the PSI report to its Council.

If you are willing to participate in this very important evaluation I would appreciate if you could contact ... before Friday March 22nd 2013 to agree the time and date of the focus group that suits you best. I hope you will join me for these discussions and I very much look forward to meeting you.

Yours faithfully

Mary Culliton

Healthcare Consultant

APPENDIX III – Focus Group Objectives

Focus Groups for Patients

The overall purpose of the focus groups with patients was to gain a sense of the experience of patients who were vaccinated in pharmacies in 2012/2013. The objectives were:

- To invite patients to describe their experience of vaccination in the 2012-2013 season.
- To explore the reasons why patients used their pharmacy for vaccination.
- To invite patients to give suggestions for quality improvement.
- To explore whether patients would use pharmacy again for vaccination and the reasons why/why not.
- To examine if patients had been vaccinated before and why they chose to be vaccinated e.g. did they hear a radio advert, did their pharmacist or a pharmacy staff member encourage them or is this something they do every year?
- For those patients who had been vaccinated before (whether in pharmacy or another setting), how did this year's vaccination compare to their previous experience?

Focus Groups for Pharmacists

The purpose of the focus group and interviews with pharmacists was:

- To invite pharmacists to describe their experience of vaccinating patients in the 2012-2013 season.
- To invite pharmacists to give suggestions for quality improvement in the process including training, PSI guidance, national immunisation campaigns etc.
- To explore whether pharmacists would participate again in the vaccination programme and the reasons why/why not.
- To invite suggestions for quality improvements in service administration e.g. how vaccine stocks are acquired, how well the PCRS notification website functioned etc.
- To explore if there are any new cohorts of patients that they would like to vaccinate or vaccinations that they would like to administer.
- To examine why they chose to participate or not participate in vaccinating this year.
- To examine whether their local GPs influence their decisions regarding service participation, service promotion, patient selection etc.

APPENDIX IV – Prompts Used for Patient Focus Groups

Examples of prompts used by the facilitator to promote discussion with patients:

- Did you have the flu vaccination before?
- If so where did you have your flu injection last year?
- How did you hear about pharmacists providing the 'flu vaccine'?
- Why did you choose pharmacy?
- Describe the experience for you.
- Do you feel you were provided with enough information by your pharmacist?
- Would you go back to a pharmacist for vaccination?
- Is the fact that you know your pharmacist important to you?
- Did you experience any difficulties or have any reaction?
- Were the facilities adequate in terms of comfort and privacy?
- Were you asked to remain for a few minutes and provided with an information leaflet to take away?
- Are there other services that you think pharmacists could or should provide?

Note: Not all prompts were required at each session.

APPENDIX V – Prompts Used for Pharmacist Focus Groups

Examples of prompts used by the facilitator to promote discussion with pharmacists:

- Describe your experience of vaccinating patients in the 2012-2013 season.
- What are your views of the training - timeliness, quality etc?
- What recommendations do you have for future training of pharmacists – regularity, face-to-face, podcast etc?
- Would you participate in the vaccination programme again?
- Did you have any issues in terms of the following;
 - Information
 - Delivery of vaccines
 - PCRS
- The expansion of the role of pharmacists - what new services/new cohorts of patients would you consider appropriate?
- Taking consent - did you have any difficulties?
- Service costs and feasibility?

Note: Not all prompts were required at each session.

APPENDIX VI –At Risk Groups

HSE SEASONAL INFLUENZA VACCINATION PROGRAMME 2012/2013

At Risk Groups eligible to be vaccinated by pharmacists at the premises of a retail pharmacy business

- all those aged 65 years and older
- those aged 18 years and older
 - o with any of the following
 - chronic illness requiring regular follow up (e.g. chronic respiratory disease including cystic fibrosis, moderate or severe asthma, chronic heart disease, chronic renal disease, diabetes mellitus, haemoglobinopathies, chronic liver disease, chronic neurological disease including multiple sclerosis, hereditary and degenerative disorders of the central nervous system etc)
 - those who are immunosuppressed due to disease or treatment including those with missing or non-functioning spleens
 - morbid obesity i.e. Body Mass Index over 40
 - o all pregnant women (at any stage of pregnancy)
 - o residents of nursing homes and other long stay facilities
 - o healthcare workers
 - o carers
 - o people who have close, regular contact with pigs, poultry or water fowl

Groups in red are new for 2012/2013