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Manuscript Concise Title:

Community pharmacists at the heart of public health: A longitudinal evaluation of the Community Pharmacy Influenza Vaccination Service

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ABSTRACT (max 300 words)

Background

Influenza (“flu”) is a contagious viral infection causing approximately 600 deaths/year in the United Kingdom. Annual vaccination is the most effective prevention strategy with a target of 75% uptake in ‘at-risk’ patient groups. Before 2012, immunisation was conducted in General Practice (GP), but uptake was below target. NHS Wales therefore introduced a programme allowing community pharmacists to administer the vaccine to certain patient groups:

Objectives

This study aimed to evaluate the community pharmacy (CP) flu Vaccination Programme in Wales.

Methods

A longitudinal study was undertaken by secondary data analysis on data related to all NHS funded flu vaccinations administered in CP between 2012-2018 (n=103941). Data were analysed using IBM SPSS® and Excel®. Pearson’s correlation and independent sample t-test were conducted to compare the number of vaccines administered in CP vs overall numbers and those under 65 years and in the ‘at risk’ category in CP and GP respectively. Ethical approval was not required.

Results

In total, pharmacists administered 103941 vaccinations. Vaccination numbers increased each season from 1568 in 2012/13 to 36238 in 2017/18. The main risk group was those aged 65 and over (59.9% of vaccinations). The proportion of those vaccinated who were aged <65 years and in an ‘at risk’ category was significantly higher in CP than GP ($p<0.01$). There was a shift in balance between vaccinations administered by GPs and CPs in which CPs increased their share of all vaccinations in the flu programme from 0.3% in 2012-13 to 5.7% in 2017-18. A strong positive correlation was observed between increasing CP vaccinations and total vaccination numbers ($R=0.9316$, $p<0.01$).

Conclusions

Community pharmacists are providing increasing numbers of flu vaccinations in Wales, benefitting patients in all at-risk groups and reinforcing the valuable role of pharmacists at the heart of their communities, in terms of public choice and accessibility.

INTRODUCTION

Influenza ('flu') is a contagious acute respiratory infection caused by the influenza virus, most prominent between October and April in the United Kingdom (UK). It can cause sudden fever, congestion and severe fatigue.¹ These symptoms are usually self-limiting in healthy individuals, typically lasting 7-14 days; however, flu can have a severe effect on specific 'at risk' groups, such as those with diabetes, and the elderly.² Complications associated with flu result in approximately 600 deaths in the UK every year, while it is estimated that annual epidemics lead to 290000 to 650000 deaths and up to 5 million cases of severe illness globally.³

The World Health Organization³ (WHO) recommends annual vaccination as the most effective prevention method to protect individuals who are most 'at-risk' of serious illness or death if they contract flu, to reduce transmission of the virus between individuals and ultimately to protect vulnerable patients with weakened immune systems.⁴ Flu vaccination is most advantageous if administered before flu begins to circulate (November in the Northern Hemisphere) although can be beneficial at any point in a flu season.⁵ The WHO recommends that 75% of patients in 'at risk' groups should be vaccinated.⁶ Patients are currently eligible for free NHS flu vaccination in the UK if they are over the age of 65, pregnant, have certain medical conditions, reside in a long stay home or care facility or are a carer or healthcare professional.⁷

Prior to 2012, General Practice (GP) surgeries were the predominant provider of NHS flu vaccination and the only provider in primary care. Annual uptake rates have repeatedly fallen short of the WHO target.⁸ In order to improve vaccination uptake, in 2012, Community Pharmacies (CPs) in Wales were commissioned to administer NHS vaccinations to eligible patients through the introduction of the NHS Seasonal Flu Vaccination Programme (the CP flu programme). This was the first national immunisation scheme in the UK in which eligible individuals receive their flu vaccine free of charge from a pharmacy, on the NHS via a Patient Group Direction (PGD).^{9,10} Whilst moves to involve pharmacies in the provision of flu vaccination have been welcomed by pharmacy representatives¹¹ they have been controversial, with GP leaders asserting that far from increasing uptake, pharmacy vaccination would undermine GPs, reduce GP income and leave practices with vaccines that had been "paid for but cannot be administered".^{12,13}

In the UK, prior to the introduction of the CP flu programme, CPs had been providing flu vaccinations for many years, vaccinating customers privately.¹⁴ Prior to 2015, Wales was the only country within the UK to have a national CP influenza programme, although a similar programme has since been implemented in England.¹⁵ Most research into UK pharmacy vaccination programmes has been limited to analyses of the results of single seasons.^{15,16,17} We are unaware of any previous research conducted to longitudinally evaluate any CP flu vaccination programmes.

The aim of this study was to evaluate changes in a CP delivered flu vaccination programme, over the first six years in Wales (2012-2018). This study is unique in that it utilises data from six full flu seasons and includes data on all vaccines administered by pharmacists since the inception of the NHS CP flu vaccination service in Wales.

METHODS

A longitudinal study was undertaken by secondary data analysis of data related to all NHS funded flu vaccinations administered in CPs between 4 October 2012 and 31 March 2018 (n = 103941).

Data on NHS flu vaccinations administered by both pharmacies and GPs, were obtained from the NHS Wales Shared Services Partnership. An assumption was made that the number of vaccines delivered by other sources, such as private clinics, would consistently be of minimal impact on numbers and were therefore not included. Data were derived from claims submitted by CPs for reimbursement (Figure 1). Data were fully anonymised, as such, the study did not require ethical approval.

The outcome measures were the number of flu vaccinations administered over time, the proportion of vaccines administered by CPs, patient age and gender, eligibility criteria and reasons for utilising the service. A vaccination season was defined as vaccinations taking place in the period September of one year to April of the next.

Data were coded in Microsoft Excel in order to convert pre-defined text responses (input by pharmacist from drop down menus relevant to questions in the consultation record) to numeric data that could be descriptively analysed. Data were exported to IBM SPSS® v23; a 10% validation check was conducted independently by two researchers for quality assurance of the data transfer process. Secondary data analysis was carried out using Microsoft Excel® and IBM SPSS® v23 to obtain descriptive statistics. No statistical trend analysis was performed due to the limited number of time points available to the researchers. An independent samples t-test was undertaken to compare the proportion of vaccines administered to those under 65 and in 'at-risk' groups by GPs and CPs. The relationship between the number of CP vaccinations and overall vaccination numbers was carried out using a scatter plot and two tailed Pearson's correlation.

RESULTS

A total of 103941 flu vaccinations were administered in CP in Wales during the six flu seasons covered by the study period (see Table 1 for data related to vaccines administered in CPs, by GPs and as a whole in Wales).

Numbers and timing of CP NHS flu vaccinations

The total number of patients vaccinated in CPs increased in each flu season; Figure 2 shows the cumulative uptake of the NHS CP flu vaccination in Wales by season. Most patients were vaccinated in October (66.4%, n = 68972); with the proportion of patients vaccinated in the month increasing in each year from 46.0% in 2012/13 to 65.9% in 2017/18. November vaccinations accounted for just under a quarter of the total vaccinations (22.5% n = 23491). Only around 1 in 10 vaccinations were administered late in the season, between December and April (10.5% n = 10936).

Characteristics of service users (Table 2)

Gender data were available for 103846 consultations. The majority of service users were female (57.6% n = 59801).

Age data were available for 103880 consultations. The median age of individuals vaccinated was 68 years (IQR 54-74). The median age of service users increased after 2012/13 and remained stable in each of the subsequent flu seasons. Over half of service users were aged 65 or over and there was an increase in the proportion of patients aged 65 or over vaccinated over the study period (from 30.0% to 59.9%) as a whole. Whilst there was a corresponding decrease in the proportion of those vaccinated who met eligibility criteria for those under 65 years, the overall increase in vaccination numbers in each year meant the number of individuals vaccinated in CPs from the largest 'at-risk' groups, increased in absolute terms in each year of the service.

The proportion of those vaccinated who were aged <65 years and in a clinical 'at-risk' group was significantly higher in CP than GP (Table 1) (mean proportion of vaccinations which were <65 years and in a clinical 'at-risk' group: 47.5% v 28.6%; difference 19.0%; 95% CI 8.6 to 29.3; $p < 0.01$).

Reason for accessing flu vaccination from a CP

Service users were asked whether at the time of vaccination, they had been offered an appointment for flu vaccination by their GP practice. Data were available for all vaccinations undertaken by pharmacies from 2013-14 up to and including the 2017-18 season ($n = 102373$). Overall just under a third of pharmacy service users reported having been offered an appointment with their GP before attending the pharmacy ($n = 31828$, 30.6%). Of these 19145 (60.1%) reported they had been unable to attend the appointment with their GP (Table 3). There was a decrease in pharmacy users reporting being offered a GP appointment over time with a small increase in those unable to attend their appointment. Pharmacy users' stated reasons for using the pharmacy vaccination service are shown in Table 3.

Impact on vaccination rates

Data regarding whether or not each service user had been vaccinated in the previous flu season were available from 2013-14 ($n = 102373$). The proportion of service users reporting not having been vaccinated in the previous season declined after 2013-14. An increase in the proportion of service users returning to CPs, having been vaccinated there previously, meant the proportion of service users reporting having been vaccinated by their GP in the previous season, declined in each year of the service (Table 2).

There was a shift in balance between vaccinations administered by GPs and CPs over the study period in which CPs increased their share of all vaccinations in the seasonal flu programme from 0.3% in 2012-13 to 5.7% in 2017-18. Despite a decrease in the proportion of vaccinations administered by GPs, the number of GP vaccinations increased by 48,334 (8.8%) by the end of the study period, albeit with a reduction between the 2014-15 and 2015-16 seasons (Table 1). A strong positive correlation was observed between increasing CP vaccinations and total vaccination numbers ($R = 0.9316$, $p < 0.01$).

DISCUSSION

Main finding of this study

A total of 103941 flu vaccinations were administered in CPs in Wales, between September 2012 and April 2018; an over 20-fold increase in CP vaccinations was observed from 1568 in the 2012-13 to 36225 in the 2017-18 season with the smallest annual increase observed at 35% (between 2016-17 and 2017-18).

Despite apparent rapid growth in the number of vaccinations they administered, CPs made only a small contribution to overall vaccination numbers, providing at its highest, just 5.7% of all flu vaccinations in any flu season. Whilst CPs have made an increasing contribution to vaccination numbers and increased their market share over time, this has not resulted in a reduction in vaccinations provided by GPs. The decrease in vaccination numbers between 2014-15 and 2015-16 was consistent with the decrease observed in other parts of the UK, including those without a CP flu service⁴ suggesting this was unrelated to the involvement of CPs. GP vaccination numbers increased over the study period. Despite concerns^{12,13} that GPs, in the face of increased competition from CPs, would reduce orders for vaccines, leading to interruption to supply for some patients the data shows GPs are administering more vaccines than ever before. Whilst it was not possible to obtain reliable data in relation to wasted vaccines, the data suggests that, if GPs have reduced orders, waste must have reduced as a consequence. Conversely, if waste has remained the same or increased it is because, contrary to concerns, GPs are placing larger orders regardless of increased competition from CPs.

There was no difference in overall rates of vaccination over the study period, increasing pharmacy numbers did not increase overall vaccine coverage, contrary to the stated objectives of the service.¹⁸ However, our data suggest that by the 2017-18 season, in addition to the 48334 extra vaccinations they provided relative to 2012-13 (an increase of 8.8%), GPs would have had to administer a further 36238 vaccinations (a further 6.6%) simply to maintain vaccination rates. Given the current concerns regarding workload pressures in general practice,¹⁹ it is at least feasible that GPs would have been unable to absorb the vaccinations undertaken by CPs and numbers and vaccination rates in Wales could have fallen.

We found pharmacies administer the majority of vaccines early in the flu season, in line with recommendations by the Centers for Disease Control and Prevention in the United States.⁵ Our data indicate the majority of patients accessing the service were aged 65 or over, confirming findings of previous studies.^{15,16,20} This increased year on year which might be expected given the demographics of the population who are eligible for vaccination, with those aged 65 or over outnumbering those under 65 and 'at risk' by a factor of 1.73.⁸ Importantly we found CPs were more likely than GPs to vaccinate those under 65 and 'at risk', a group in which flu vaccination rates are generally lower.¹⁵ This is also the group identified as the primary focus for the CP service.¹⁸ We found that people's preference for using a pharmacy was mainly due to not needing to book an appointment; which has been previously highlighted.²⁰

We also found over 18,000 vaccinations were administered by CPs to individuals not vaccinated in the previous season. However, data support concerns that CPs would 'poach',²¹ individuals previously vaccinated at their GP surgery, confirming a large proportion of those vaccinated by CPs attended their GP surgery in the previous season. That said, the proportion moving from GP to CP vaccination decreased in each year of the service with the proportion of individuals vaccinated in CPs reporting returning to the CP for vaccination, increasing. Whilst the anonymized nature of our data does not allow us to confirm this definitively, the data imply there is a growing cohort of individuals who now routinely use CPs, rather than their GP, for their annual flu vaccination.

Previous studies have demonstrated a range of factors influence take up of flu vaccination and not simply the wider availability of vaccinations.²² Our findings suggest whilst not contributing to an overall increase in vaccination rates, CP provision does contribute to an increase in capacity, an increase in vaccination numbers; and may help offset potential reductions in vaccination coverage.

What is already known on this topic

To our knowledge this is the first study to longitudinally investigate a CP flu vaccination programme. Private vaccination has been in place for some time both in the UK and other countries, with mixed findings on impact.¹⁴ An evaluation of the NHS England pilot programme found reduced vaccination uptake was documented in relation to the introduction of a CP immunisation programme¹⁷ while Isenor et al. found increased uptake when pharmacists were included in any area of an immunisation service (education, administration or facilitation).²³

What this study adds

This first longitudinal evaluation of CP flu-vaccination gives a unique insight into the development of the CP flu programme since its introduction in 2012. The large sample included data of over six full flu seasons covering every CP provided NHS flu vaccination; this enabled longitudinal interpretation of results over time. The increasing uptake through CPs is in line with a year on year increase in the overall total number of people receiving a flu vaccination. Despite the increase in overall numbers, immunisation targets²⁴ are still not being met.⁸

Studies in the United States²⁵ and China²⁶ have shown the highest uptake of flu vaccination to be amongst those aged 65 or over, however, an evaluation of the 2013-14 CP flu programme in Wales found that the CP reached the 'at-risk' under 65 population with their uptake being greater than in the vaccination programme as a whole.¹⁵ Our findings confirm this effect is sustained over the longer term which highlights the valuable role that CP may have in providing equitable access to the population as a whole.

Chronic respiratory disease, diabetes and carers were the main 'at risk' groups accessing CP flu vaccination. Around 17% of deaths each year from flu, are amongst those with chronic respiratory diseases.²⁷ The reason for high uptake in group using CPs has been attributed to the numerous visits they make to the pharmacy.²⁸ Whilst diabetes was one of the highest groups, it only accounted for 7.6% of CP vaccinations, despite being the highest eligibility category across all Flu vaccinations in Wales.⁸

This study has shown that obtaining flu vaccination from a CP is an increasingly popular choice amongst patients. The findings that the proportion of patients returning to a CP for vaccination is increasing and that thousands of previously unvaccinated patients continue to present at CPs each season supports the view that CP vaccination services are acceptable and meet service user needs.^{16,29}

Our findings suggest patients are making an active decision to attend their CP based on a range of factors, the main one being not needing to book an appointment, in line with other research.^{20,30} Moreover, accessibility of CPs was an important determinant of CP vaccination particularly for those whose CP was located close to their homes. This is consistent with previous studies.^{16,17,20}

Limitations

The main limitation of this study is the use of secondary data. This means there was no control by the researchers over the data entry and choice of variables. As such, it is not possible to check the accuracy of data entry or investigate the reasons behind any anomalies. Nevertheless, the data included information on all CP NHS vaccinations which have been provided in Wales and is to our knowledge the most comprehensive source of information related to CP flu services. Occasional errors in data entry would be unlikely to have a large impact on a dataset of this size.

CONCLUSIONS

This study reaffirms a view that Wales' CP flu service consistently engages with a statistically significant proportion of under vaccinated groups (those under 65 and 'at risk') more effectively than the GP programme in Wales, without reducing the number of GP vaccinations. Since its introduction in 2012, year on year increases in CP flu vaccination have been observed. There is clear indication that CPs provide convenient access to flu vaccination for many 'at risk' individuals with increasing numbers of patients choosing to visit and revisit the CP in preference to the GP. Importantly this shift does not reduce GP vaccination numbers which have grown over the study period driven both by policy changes to offer vaccination to additional 'at-risk' groups and by increasing numbers of individuals in existing eligible cohorts. CP vaccination is associated with increasing vaccination numbers although not vaccination rates. We believe this support a view that CP-led immunisation programmes are of value albeit for different reasons to those initially envisaged.³¹ There is opportunity for greater collaboration between GPs and CPs to increase overall uptake. Our results reinforce the valuable public health role of pharmacists at the heart of their communities.

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Gender
 Age
 Eligibility criteria for NHS flu vaccination
 Date of vaccination
 Flu vaccination status in previous season
 Location of flu vaccination in previous season
 Whether offered a GP appointment for vaccination
 Whether able to attend GP appointment for vaccination
 Reasons for attending pharmacy for vaccination

Figure 1: Patient reported data available from CP flu vaccination records

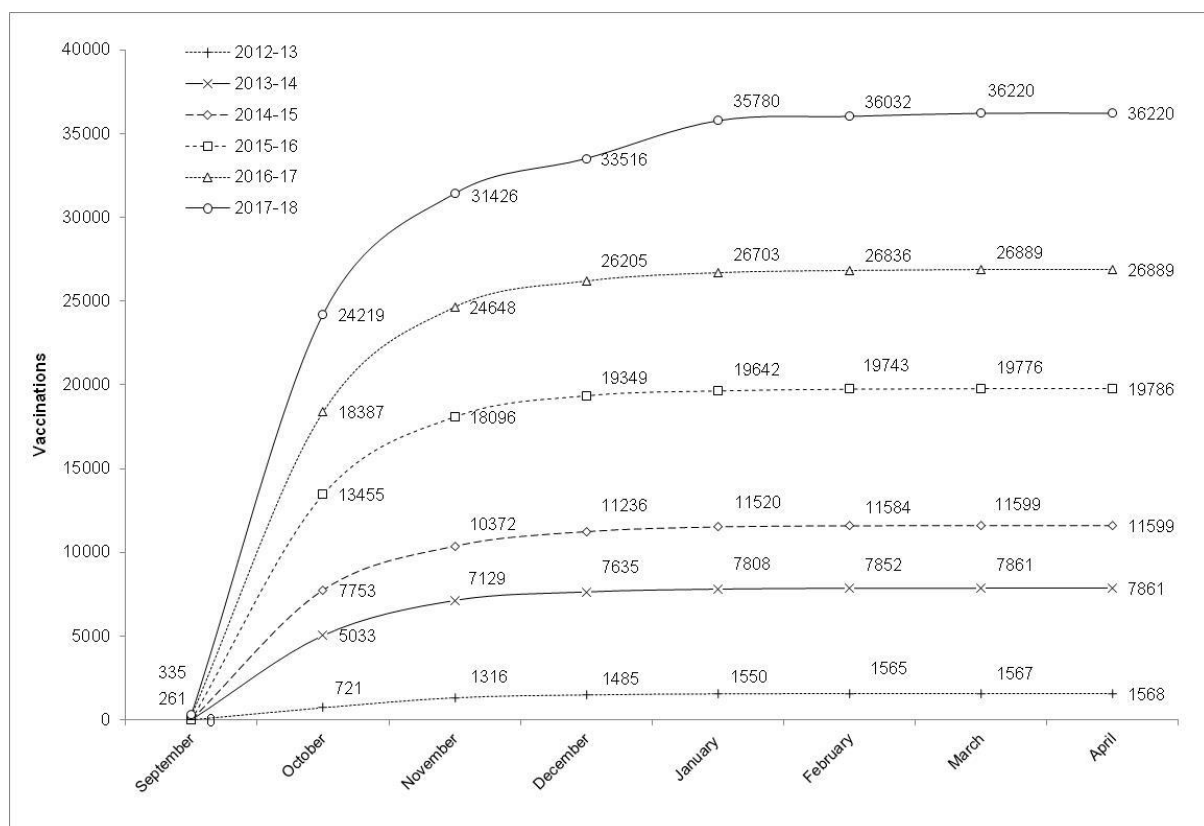


Figure 2. Cumulative number (percentage of seasonal total) NHS Flu vaccinations administered in CPs in Wales (September 2012-April 2018) n=103941)

Table 1: Flu vaccinations and uptake by flu season 2009-10 to 2017-18

	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	Total	Total since 2012-13
Under 65 and at risk											
Total vaccinations	122803	150790	160915	160915	163377	175871	171162	174997	184055	1464885	1030377
Pharmacy vaccinations				1098	3778	5078	8328	11084	14536	43902	
GP vaccinations	122803	150790	160915	159796	159443	170507	162834	163890	169532	1420510	986002
Pharmacy as % of total	0	0	0	0.68	2.31	2.89	4.87	6.33	7.90		
Vaccine uptake %	49.1	48.5	50	50	51.1	49.3	46.9	46.9	48.5		
65 and over											
Total vaccinations	322593	369480	392051	392051	401456	425552	423110	431791	451902	3609986	2525862
Pharmacy vaccinations				470	4083	6521	11458	15805	21702	60039	
GP vaccinations	322593	369480	392051	391602	397529	419317	411652	416009	430200	3550433	2466309
Pharmacy as % of total	0	0	0	0.12	1.02	1.53	2.71	3.66	4.80		
Vaccine uptake %	63.5	65.7	67.1	67.8	68.3	68	66.6	66.7	68.8		
All vaccinations											
Total vaccinations	445396	520270	552966	552966	564833	601423	594272	606788	635957	5074871	3556239
Pharmacy vaccinations				1568	7861	11599	19786	26889	36238	103941	
GP vaccinations	445396	520270	552966	551398	556972	589824	574486	579899	599732	4970943	3452311
Pharmacy as % of total	0	0	0	0.28	1.39	1.93	3.33	4.43	5.70		
Vaccine uptake %	57.2	59.6	61.4	61.7	62.2	61.2	59.4	59.4	61.4		

Table 2: Selected characteristics of individuals receiving flu vaccination at a CP by season and overall

	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	Overall
Gender (n =103,846)							
Female (%)	876 (55.9)	4533 (57.7)	6727 (58.1)	11325 (57.3)	15471 (57.6)	20869 (57.6)	59801 (57.6)
Male (%)	691 (44.1)	3321 (42.3)	4860 (41.9)	8432 (42.7)	11399 (42.4)	15342 (42.4)	44045 (42.4)
Median Age (IQR) (n=103,880)							
	55 (40-66)	65 (50-72)	66 (52-73)	66 (53-73)	67 (55-74)	67 (55-74)	68 (54 -74)
Age group (n = 103,941)							
Under 65 and at risk (%)	1098 (70.0)	3778 (48.0)	5078 (43.7)	8328 (42.1)	11084 (41.2)	14536 (40.1)	43902 (42.2)
65 and over (%)	470 (30.0)	4083 (52.0)	6521 (56.3)	11458 (57.9)	15805 (58.8)	21702 (59.9)	60039 (57.8)
Main at risk groups (n = 43,902)							
Chronic Respiratory Disease (%)	498 (31.8)	1562 (19.9)	2139 (18.4)	3337 (16.9)	4585 (17.1)	5888 (16.2)	18009 (17.3)
Diabetes (%)	210 (13.4)	639 (8.1)	893 (7.7)	1520 (7.7)	2073 (7.7)	2501 (6.9)	7836 (7.5)
Carer (%)	106 (6.8)	571 (7.3)	728 (6.3)	1177 (5.9)	1316 (4.9)	1856 (5.1)	5754 (5.5)
Chronic Heart Disease (%)	86 (5.5)	280 (3.6)	369 (3.2)	619 (3.1)	894 (3.3)	1219 (3.4)	3467 (3.3)
Immuno-suppressed (%)	58 (3.7)	174 (2.2)	265 (2.3)	471 (2.4)	635 (2.4)	870 (2.4)	2473 (2.4)
All other (%)	140 (8.9)	552 (7.0)	684 (5.9)	1204 (6.1)	1581 (5.9)	2202 (6.1)	6363 (6.1)
Referral (n = 103,941)							
Self (%)	1341 (85.5)	7367 (93.7)	11186 (96.4)	18805 (95.0)	25947 (96.5)	34977 (96.5)	99623 (95.8)
GP (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	309 (1.2)	662 (1.8)	971 (0.9)
Other (%)	227 (14.5)	494 (6.3)	413 (3.6)	981 (5.0)	633 (2.3)	599 (1.7)	3347 (3.3)
Vaccination in previous flu season (n = 102,373)							
Not vaccinated (%)	-	1960 (24.9)	1990 (17.2)	3366 (17.0)	4132 (15.4)	7096 (19.6)	18544 (18.1)
GP Practice (%)	-	5035 (64.1)	6191 (53.4)	10643 (53.8)	12711 (47.3)	14884 (41.1)	49464 (48.3)
CP - NHS (%)	-	485 (6.2)	2941 (25.4)	4968 (25.1)	9096 (33.8)	13081 (36.1)	30571 (29.9)
CP - paid for (%)	-	225 (2.9)	244 (2.1)	378 (1.9)	406 (1.5)	437 (1.2)	1690 (1.7)
Other (%)	-	156 (2.0)	233 (2.0)	431 (2.2)	544 (2.0)	740 (2.0)	536 (2.1)

Table 3: Factors influencing decision to attend CP for flu vaccination

	2013-14	2014-15	2015-16	2016-17	2017-18	Overall
Offered GP appointment (n = 102,373)						
Yes (%)	3555 (45.2)	4249 (36.6)	6901 (34.9)	9635 (35.8)	7488 (20.7)	31828 (30.6)
No (%)	4306 (54.8)	7350 (63.4)	12885 (65.1)	17254 (64.2)	28750 (79.3)	70545 (69.4)
Unable to attend GP appointment (n = 31,828)						
Yes (%)	2138 (60.1)	2409 (56.7)	4071 (59.0)	5767 (59.9)	4760 (63.6)	19145 (60.2)
No (%)	1417 (39.9)	1840 (43.3)	2830 (41.0)	3868 (40.1)	2728 (36.4)	12683 (39.8)
Did not need an appointment	4593 (58.4)	5631 (48.5)	9417 (47.6)	10787 (41.2)	16373 (40.1)	46801 (42.2)
Pharmacy is near home	1793 (22.8)	2524 (21.8)	4638 (23.4)	7267 (27.0)	8608 (23.8)	24830 (24.3)
Visiting pharmacy for another reason	2133 (27.1)	2838 (24.5)	5423 (27.4)	6482 (24.1)	6526 (18.0)	23402 (22.9)
Pharmacy is near place of work	465 (5.9)	687 (5.9)	1053 (5.3)	1164 (4.3)	1634 (4.5)	5003 (4.9)
Other reason (not stated)	1085 (13.8)	1830 (15.8)	2885 (14.6)	2900 (10.8)	3651 (10.1)	12351 (12.1)
Open at time when could not get appointment	-	-	-	2621 (9.8)	3256 (9.0)	5877 (9.3)