



RESEARCH ARTICLE

Trends in influenza coverage rates in five consecutive immunisation seasons in the Local Health Unit of Ferrara (North Italy)

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Keywords

Immunisation • Influenza • Coverage rate • Immunisation season • General practitioner

Summary

Seasonal influenza epidemics yearly affects 5-15% of the world's population, resulting in 3-5 million serious cases and up to 650,000 deaths. Elderly, pregnant women and individuals with underlying conditions are at increased risk of complications. According to the Italian National Immunisation Prevention Plan 2017-2019, these categories benefit from free vaccination but coverage rate in Italy are below desirable levels. The study considered the coverage rate in five consecutive influenza seasons (2010/2011-2014/2015) in Local Health Unit (LHU) of Ferrara (Italy). The amount of delivered vaccinations was not constant, with a decreasing trend. Coverage rose with increasing age, but the 75% target of over-65 years old individuals immunised was never achieved. In addition to age, coverage rates varied also

according to District (the area of residence within the LHU). The District with the lowest vaccination coverage was the Western District. Higher levels of immunisation were observed in South-Eastern District in the pediatric age and in North-Central District in adult age group with a statistically significant difference. In the considered timespan, the percentage of immunisations delivered by the General Practitioners (GPs) increased. The trend in the LHU of Ferrara was similar to regional and national data, conditioned in the 2014/2015 season by the spreading of worrying news, although unfounded, on the safety of the vaccine. The GPs were essential in ensuring vaccine uptake, growing the percentage of delivered doses and achieving as much as possible effective elderly immunisation.

Introduction

Influenza is a common, highly contagious respiratory virus, which infects all age groups. Every year about 5% to 15% of worldwide population experience seasonal influenza, with 3-5 millions severe cases and more than 500,000 deaths [1]. During 2018/2019 influenza season, the cumulative population rate of hospitalization in the United States was 65.3 per 100,000 inhabitants. The majority of hospitalizations observed in over 65 years old people. Similarly to the past, the 93% of adults and 55% of children hospitalized for influenza had underlying medical conditions, and about one third of women of child-bearing age hospitalized for influenza were pregnant [2]. Among infectious diseases, influenza had higher population burden, incidence and mortality in Europe [3]. Influenza accounted for 81.8 DALYs per 100,000 population (95% uncertainty interval: 76.9-86.5) corresponding to the 30% of European total burden of infectious diseases. In the period 2009-2013, the estimated incidence was 5,887 cases per 100,000 population (95% uncertainty interval: 5,544-6,223) and the estimated mortality was 5.89 per 100,000 population (95% uncertainty interval: 5.54-6.22) [3]. On average, the Influenza Like Illnesses (ILI) affected the 9% of Italian population yearly, with a minimum of 4% observed in season 2005/2006 and a peak recorded in season 2017/2018 [4]. High virus circulation and elevated

incidence characterized the 2018/2019 influenza season [5] with about 8,150,000 cases and 812 severe confirmed cases, 205 of them died. Complications are more common in the elderly, specifically in those with chronic underlying conditions, which are at increased risk for hospitalization [6]. The most effective measure to prevent the infection, reduce its morbidity and avoid the complications, including death, is the yearly vaccination [7]. According to the World Health Organization (WHO), the influenza vaccination of the elderly and other people at high risk should reach the 75 % coverage rate [8]. Despite the availability of a safe and effective vaccine and even though the greater part of countries recommended vaccination of the elderly population, immunisation coverage for this group is still low worldwide, also in European countries [9]. The area of the LHU of Ferrara corresponds to the entire territory of the Province of Ferrara (353,481 inhabitants at the 2011 census survey, 23.7% were over 65), located in the east of the Region Emilia-Romagna, North-East of Italy. The area of Local Health Unit of Ferrara is organized in three Districts. About 50% of the population resided in the Center-North District, where the main city Ferrara (132,545 inhabitants at 2011 census survey, about 27.4% were over 65) is located. The Center-North District is the most populated with public hygiene clinics and pediatrics clinics dedicated to immunisations and the University Hospital; the Western District has the smallest area; the South-Eastern

District is the largest and has the lowest population density [10]. The District with the lowest number of inhabitants is the Western District. Healthcare services are supplied by three hospitals and one University hospital, six "Case della salute" and about 250 General Practitioners (GPs). In Italy, influenza immunisation can be obtained in clinics of public National Health System: General Practitioner (GP) or Pediatrician, according to age, in Public Health services or in hospital (mainly for healthcare workers). We assessed the coverage rates for influenza immunisation in five consecutive immunisation seasons from 2010/2011 to 2014/2015 in the area of the LHU of Ferrara in order to evaluate the trend in vaccine uptake, highlight possible conditions of lower immunisation and obtain useful information for the estimation of vaccination campaign compliance.

Methods

ETHICAL ASPECT

The research was approved by Ethics Committee of the Area Vasta Emilia Centro (AVEC) in June 2018.

STUDY POPULATION

This is an observational study. All subjects residing on the territory of the Local Health Unit (LHU) of Ferrara that corresponds with the in the Province of Ferrara, North-East of Italy, in the time span 2010-2015 were considered. Data about residing population according to age, gender and Municipality were obtained from GeoDemo website of Italian Institute of Statistics (ISTAT) [11]. As immunisation season usually lasts from the final months of a year to the first months of the following one, the population resident on the 1st January 2011 for the 2010/2011 immunisation season was evaluated, and as consequence the population resident on the 1st January 2012 for the immunisation season 2011/2012, the population resident on the 1st January 2013 for the immunisation season 2012/2013, the population resident on the 1st January 2014 for the immunisation season 2013/2014, the population resident on the 1st January 2015 for the immunisation season 2014/2015. There were no exclusion criteria. No informed consent was needed as data were processed on a pseudonymised basis.

DATA RETRIEVAL

Data on delivered immunisations were obtained from electronic Registry of Immunisation Service of Public

Health Department of Local Health Unit of Ferrara (Italy). Data on resident population were obtained from GeoDemo.

Data on influenza immunisation

Data about influenza immunisation for five consecutive seasons (from 2011/2012 to 2014/2015) were obtained from the electronic Registry of Immunisation Service of Public Health Department of Local Health Unit of Ferrara. The database included for each administered vaccine doses personal data of the recipient, including age, gender, Municipality and District of residence, place where the vaccination was carried out (Public Health clinic, Community Pediatrics clinic, General Practitioner or Pediatrician's clinic, Hospital clinic, other services). In the LHU of Ferrara, immunisations of at risks children from zero to fourteen years of age were administered in Community Pediatrics or Pediatrician's clinic; from fifteen years of age, the vaccination were administered by the General Practitioner or in Public Health clinic. The healthcare workers (HCW) could obtain the influenza immunisation also in the workplace (Hospital clinic, other services). Data about vaccine uptake were considered in relation to belonging to one of the categories for which vaccination is recommended (over 65 years old or younger with chronic conditions, healthcare workers) according to national and regional guidelines [12].

STATISTICAL ANALYSIS

Coverage rates according to resident population were calculated. The Chi square test was applied to compare coverage rates for influenza immunisation according to gender, age group and District of residence (Western District, Center-North District, South-Eastern District). Statistical analysis was performed with Stata 13.0, the significance was set at 0.05.

Results

The number of influenza vaccinations administered in the LHU of Ferrara in the timespan 2010/2011 to 2014-2015 season showed an irregular trend. In the 2010/2011 immunisation season (Tab. I), 71,166 vaccinations were delivered. The following year, the highest number (88,696) of distributed vaccinations was recorded, afterward the number of delivered immunisations decreased and then increased again. In the 2014/2015 season, the lowest number (68,496) of vaccinations was observed. In all

Tab. I. Number and percentage of doses of influenza vaccine delivered in the Local Health Unit of Ferrara in immunisation seasons from 2010/2011 to 2014/2015.

Immunisation season	2010/2011		2011/2012		2012/2013		2013/2014		2014/2015	
	N	%	N	%	N	%	N	%	N	%
Males	31.025	43.6	39.251	44.3	32.234	44.4	34.102	44.5	30.675	44.8
Females	40.123	56.4	49.431	55.7	40.298	55.6	42.587	55.5	37.821	55.2
n.d.	18	0.03	14	0.02						
Total	71.166		88.696		72.532		76.689		68.496	

considered immunisation seasons, the majority of doses (over 55%) was delivered to females.

As reported in Figure 1A, for females, and in Figure 1B, for males, a minor number of vaccinations, less than a thousand units, has been administered to subjects up to 14 years of age. In the childhood, males were

predominantly immunised but the overall trend was decreasing. In adults (15-64 years old) and in the elderly (over 65 years old), the most relevant part of vaccinations was given to female subjects. Most of the doses were administered to individuals aged 65 or over. As the area of Local Health Unit of Ferrara is organized in three Districts, the percentage of doses distributed according to District of residence was evaluated (Fig. 2). The highest number of vaccinations (over 50%), in all the considered vaccination seasons, was obtained by individuals residing in the Center-North District. About a third of the immunisations was administered to subjects residing in the South-Eastern District and just less than 20% in the Western District.

In all the vaccination seasons considered (Fig. 3), over 95% of the immunisations were carried out at the General Practitioner's clinic. The percentage of vaccinations delivered by GPs showed an increasing trend over the years up to almost 97% in the 2014/2015 vaccination season. About 2-3% of the vaccinations were administered at the clinics of the Hygiene and Public Health Service of the Prevention Department of Ferrara's LHU. A decreasing percentage (from 1.2% in the 2010/2011 season to 0.5% in the 2013/2014 and 2014/2015 seasons) of vaccinations were administered in the outpatient departments of the Community Pediatric Service of the Maternal and Child Department of Ferrara's LHU. A very limited portion of doses was delivered in hospital.

The main motivation for the administration of the vaccine was being older than 64 years, in proportions ranging from 69.7% in the 2010/2011 immunisation season, increasing up to 75.3% in the 2014/2015 season (Tab. II). Other risk conditions were suffering from a chronic disease (respiratory diseases; chronic heart diseases; diabetes and other metabolic diseases, including obesity; malignancies). Only about 5% of influenza immunisations were delivered to healthcare workers. Coverage rates progressively increased with increasing age (Fig. 4) and

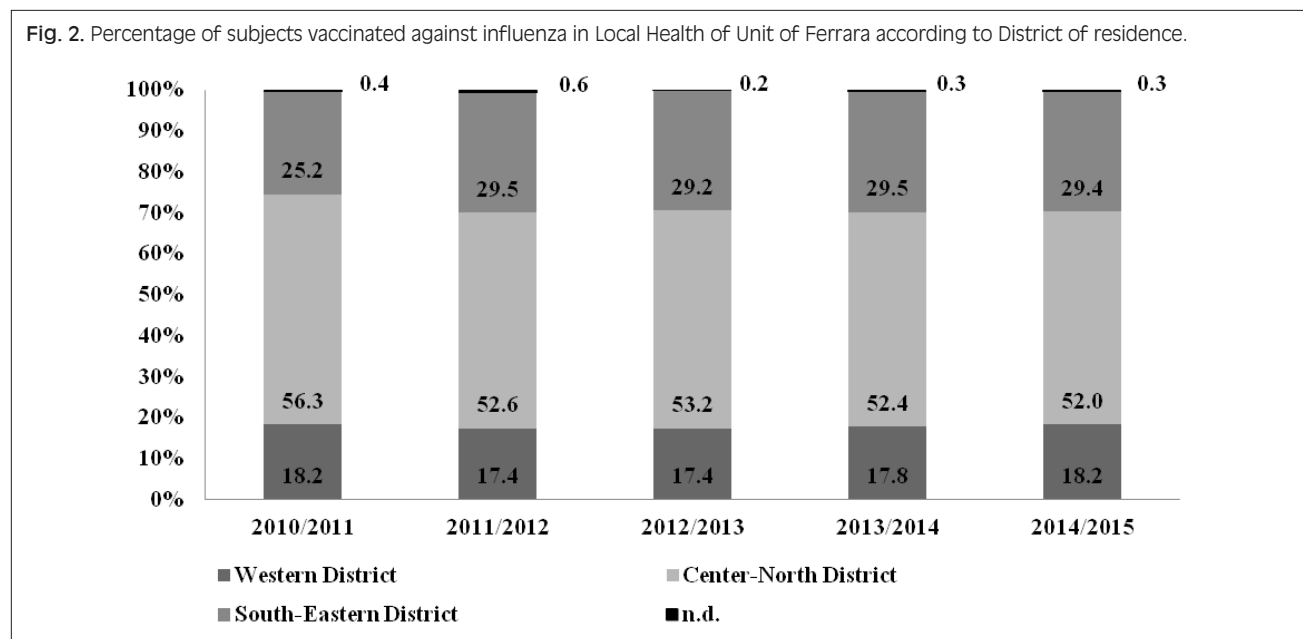
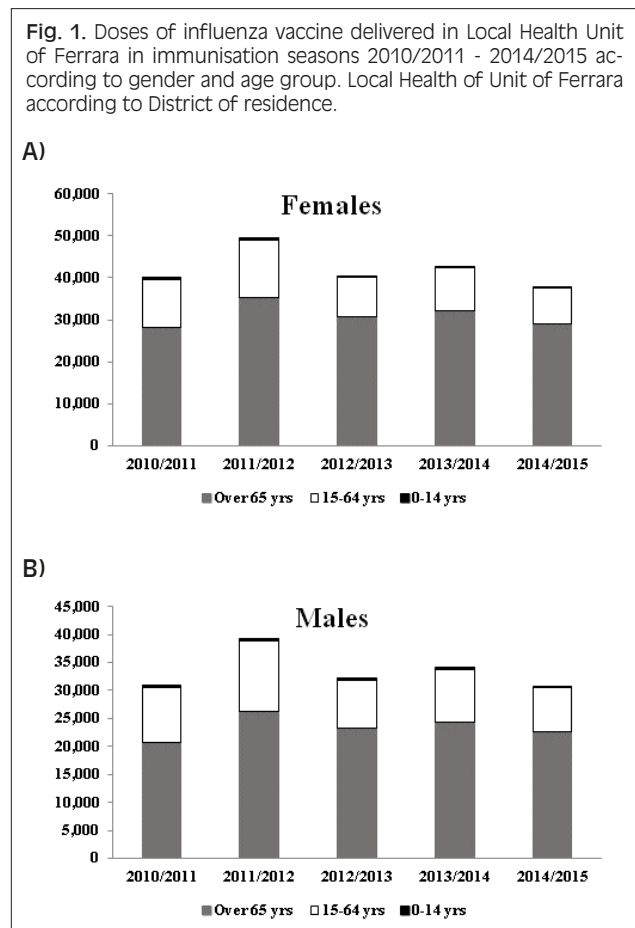
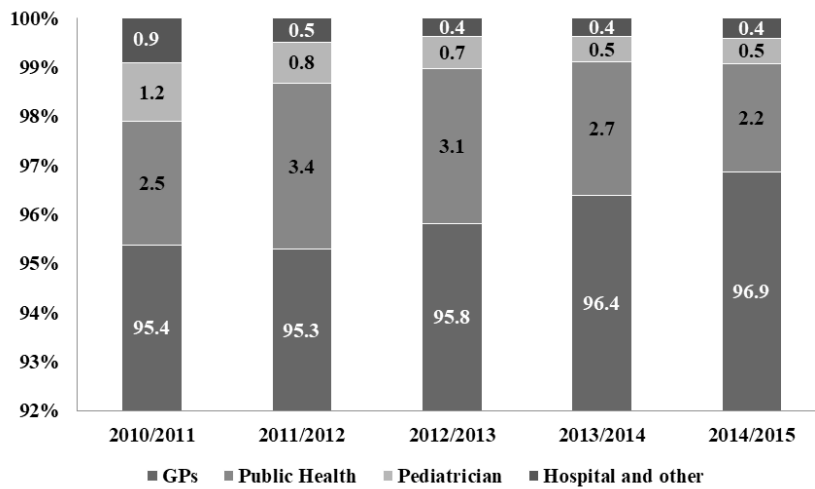


Fig. 3. Percentage of subjects vaccinated against influenza in Local Health of Unit of Ferrara according to place where vaccine was delivered.



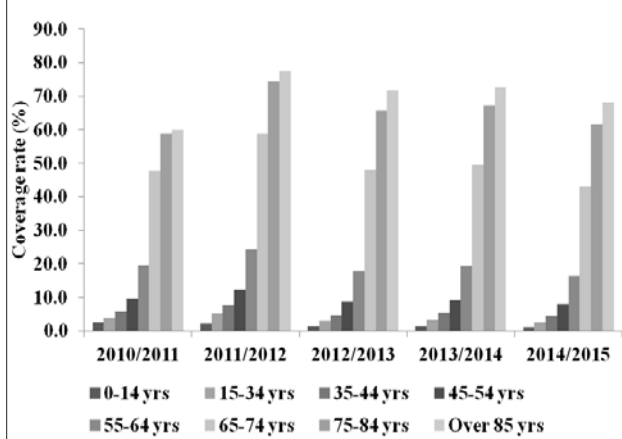
Tab. II. Number and percentage of doses of influenza vaccine delivered in the Local Health Unit of Ferrara in immunisation seasons from 2010/2011 to 2014/2015 according to risk condition.

Immunisation season	2010/2011		2011/2012		2012/2013		2013/2014		2014/2015	
	N	%	N	%	N	%	N	%	N	%
Over 65 yrs	49588	69.7	62605	70.6	54113	74.6	56627	73.8	51600	75.3
Lung diseases	4944	22.9	6572	25.2	4348	23.6	4664	23.2	4208	24.9
Heart diseases	4205	19.5	4791	18.4	3503	19.0	3628	18.1	3079	18.2
Diabetes	2808	13.0	3443	13.2	2622	14.2	2698	13.4	2304	13.6
Malignancies	1452	6.7	1447	5.5	1165	6.3	1443	7.2	1083	6.4
Other risk conditions	1727	8.0	2377	9.1	1877	10.2	2072	10.3	1748	10.3
HCWs	1161	5.4	1301	5.0	888	4.8	918	4.6	802	4.7
Family member and contacts	2066	9.6	2617	10.0	1690	9.2	1958	9.8	1620	9.6
Blood donors and public service workers	1985	9.2	3102	11.9	1896	10.3	2153	10.7	1643	9.7
Pay for vaccine	1230	5.7	441	1.7	430	2.3	528	2.6	409	2.4

HCWs: healthcare workers.

were almost doubled in over 65 compared to adults aged 55-64 years old. Compliance to the influenza vaccination showed a further growing trend in the elderly, reaching the highest values in over 85 subjects. Despite this tendency,

Fig. 4. Coverage rates for influenza vaccination in Local Health of Unit of Ferrara according to age.



the recommended coverage value of 75% was achieved only in subjects aged 85 and only in the 2011/2012 immunisation season.

When considering coverage rates for influenza vaccine according to gender and age (Fig. 5), the target of 75% was never accomplished.

In all immunisation seasons, the coverage rates in over 65 years males were higher than in the females, with an average rate in the period of 59.9% in males and 57.5% in females, with a statistically significant difference ($p < 0.0001$). In 15-64 years age group, the vaccination coverage in females was higher than in the males showing a statistically significant differences ($p < 0.0001$) in all immunisation seasons. The average rate was 9.5% in females and 8.8% in males. In the pediatric age group, male subjects again depicted higher immunisation rates than females with a statistically significant difference ($p < 0.007$). The average rate over the period was 1.9% in males and 1.5% in females.

In Figure 6, coverage rates according the District of residence in different age groups are reported. In all examined immunisation seasons, the higher coverage

rates in pediatric age group were observed in the South-Eastern District, with statistically significant differences compared to the Western District ($p < 0.0001$) and to the Center-North District ($p < 0.014$). In the South-Eastern District coverage rates gradually decreased from 2.9% in the 2010/2011 season to 1.2% in the 2014/2015 immunisation season but the other Districts depicted a similar trend. The lower coverage rates were observed in the residents of Western District (from 2.0% in the 2010/2011 season to 0.8% in the 2014/2015 season), while the Center-North District had intermediate values. The differences between the Western District and the

Center-North District were statistically significant only in the 2012/2013 immunisation season: the Center-North District recorded higher vaccination coverage than the Western District (1.4 vs 1.0%; $p = 0.002$). In the other immunisation seasons, the differences were not statistically significant.

In adults (15-64 years old), the highest levels of coverage rates were recorded in Center-North District (Fig. 6B) in all immunisation seasons. The trend of vaccination rates was inconstant in all districts. The residents in Western District had the lower coverage rates ranging from 9.2% in the 2011/2012 season to 5.8% in the

Fig. 5. Coverage rates for influenza vaccination in Local Health of Unit of Ferrara according to gender and age group.

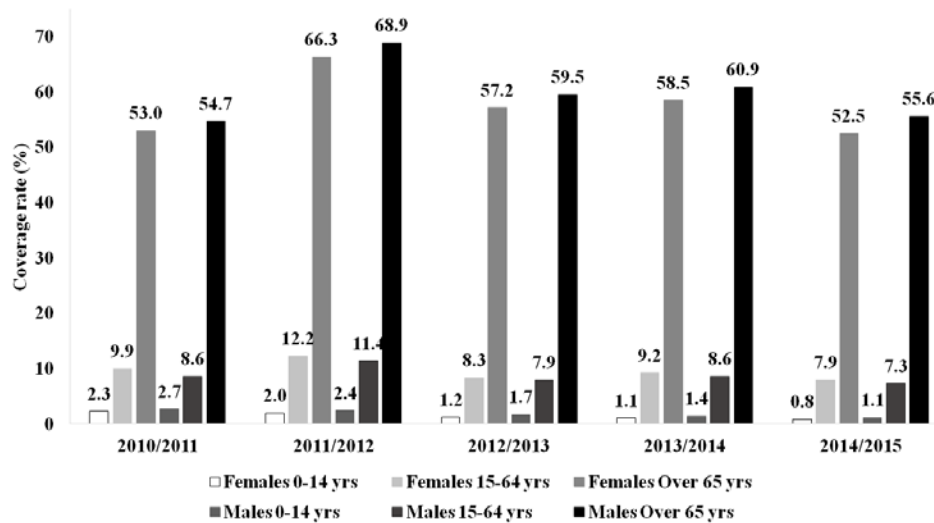
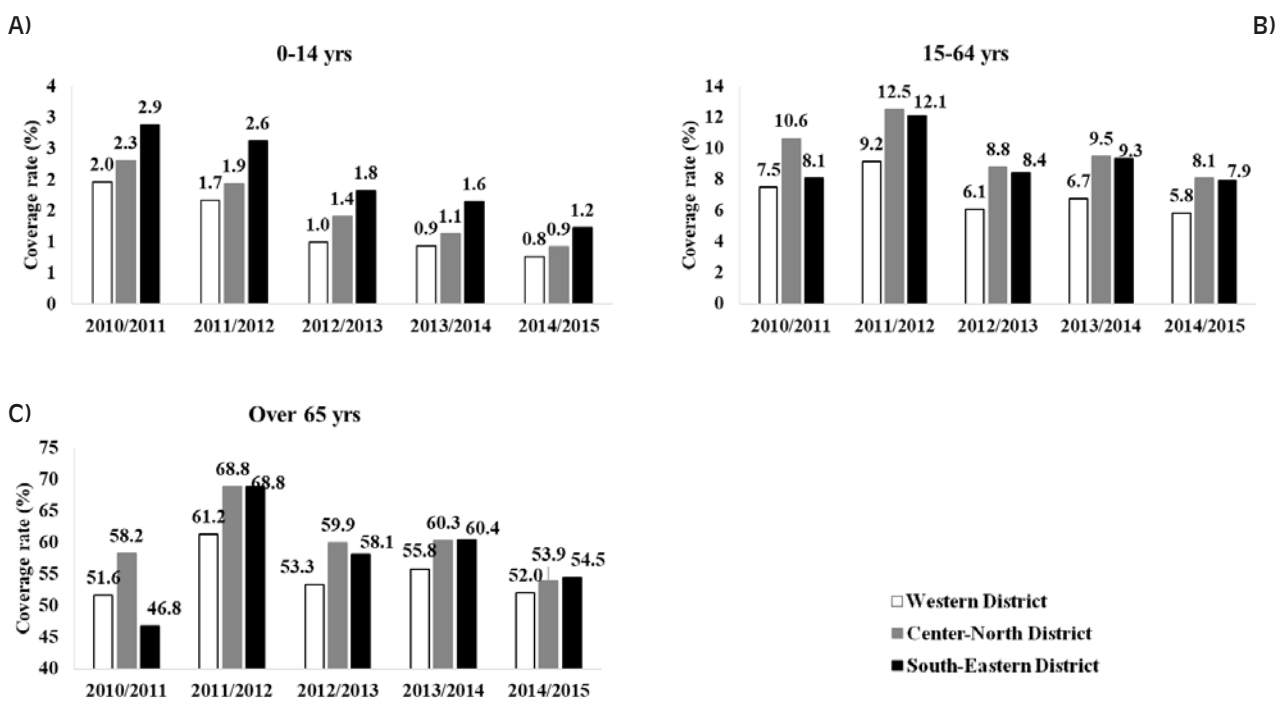


Fig. 6. Coverage rates for influenza vaccination in Local Health of Unit of Ferrara according to age group and District of residence.



2014/2015 season, while in the South-Eastern District values were very similar to those of the residents in the Center-North District, albeit lower and with statistically significant differences only in the first three immunisation seasons (10.6% in the Center-North District vs 8.1% in the South-Eastern District, $p < 0.0001$ in the 2010/2011 season; 12.5% in the Center-North District vs 12.1% in the South-Eastern District, $p = 0.009$ in the 2011/2012 season; 8.8% in the Center-North District vs 8.4% in the South-Eastern District, $p = 0.005$ in the 2012/2013 season). The differences between the Western District and the other two Districts were statistically significant in all immunisation seasons ($p < 0.0001$). The target of 75% of over 65 immunised against influenza was never achieved (Fig. 6C). In 2011/2012 immunisation season the 68.8% of the elderly residing in Center-North District and the South-Eastern District were immunised. In the Western District, coverage rates remained almost unchanged with values slightly above 50%, with the exception of the 2011/2012 season (maximum value of 61.2%). In the vaccination seasons from 2010/2011 to 2012/2013, the coverage rates of residents in the Center-North District were higher than those of residents in the South-Eastern District, while starting from the 2013/2014 season the highest coverage were observed in the residents of the South-Eastern District (60.4% in the 2013/2014 season and 54.5% in the 2014/2015 season). However, the differences between the Center-North and South-Eastern District were statistically significant only in the 2010/2011 season (58.2% in the Center-North District vs 46.8% in the South-Eastern District, $p < 0.0001$) and in the 2012/2013 season (59.9% in the Center-North District vs 58.1% in the South-Eastern District, $p < 0.0001$). The differences between the Western District and the other two Districts were statistically significant in all immunisation seasons ($p < 0.0001$).

Discussion

The study evaluated coverage rates for influenza in the population residing in the area of LHU of Ferrara (Italy) in the immunisation seasons from 2010/2011 to 2014/2015. The percentage of people receiving the flu shot was fluctuant over years, a trend reported also in a meta-analysis on Chinese population [13]. As expected, the influenza vaccination rates showed an increasing trend with increasing age, with a sudden rise from the age of sixty-five. Our results however confirm that despite national and international recommendations for seasonal influenza vaccination for elderly, healthcare workers and those with medical risk conditions, the rates for these groups did not reach the target. Despite data about the prevalence of a chronic condition in people younger than 65 were not available, on the whole it was possible to describe a greater compliance to immunisation in males, in pediatric age, and, in females, in the age group 15-64 years.

In 2009 the Council of the European Union set a target of 75% coverage for annual influenza vaccination among all defined target groups by 2014/15 [14].

Namely, as indicated by the World Health Organization, pregnant women (at any stage of pregnancy), children aged between 6 to 59 months, elderly individuals (aged > 65 years), individuals with chronic medical conditions and healthcare professionals [15]. At present, there is consensus among European countries regarding the routine seasonal influenza vaccination of elderly, however, for children few countries (Austria, Estonia, Finland, Latvia, Malta, Poland, Slovakia, Slovenia and the United Kingdom) have introduced the recommendation of routine influenza vaccination at different age groups and with different reimbursement methods [16]. In the United States, the Advisory Committee on Immunization Practices has recommended the vaccination of all people aged ≥ 6 months without contraindications [17]. Recently, also the Chinese Centre for Disease Prevention and Control published technical guidelines about influenza vaccination to recommend priority populations, which included children (up to 5 years), elderly, pregnant women, and healthcare workers [13]. The Italian National Immunization Prevention Plan 2017-2019 recommendations align with international guidelines [11].

In Europe, the vaccine coverage data referring to the 2014/2015 season showed an average of 45.5% (range from 1.0 to 76.3%) in the elderly, 24% (from 5 to 54.9%) in health care workers, 49.8% (from 21 to 71.8%) in patients with chronic medical conditions, and 23.6% (from 0.3 to 56.1%) in pregnant women. [16]. In our study desirable vaccination coverage levels were obtained only in the most advanced age groups, in particular after the age of eighty-five. Percentages in elderly were very similar to coverage rates reported where compliance in immunisation is higher in Europe (The Netherlands, England and Scotland) in a comparable timespan [18]. Despite the free and active offer of the influenza vaccine, endorsed on the territory by the General Practitioners, among the elderly living in the area of the LHU of Ferrara a decline in coverage rate, comparable to regional [19] and national data [20], was observed. The coverage rates decrease was mainly attributable to a communication crisis on supposed safety issues, later proved to be unfounded. The 2014/2015 immunisation season was marked by a sharp decrease in the coverage rates for influenza vaccination, following the so-called "Fluad case". About a month after the start of the vaccination campaign, two cases of suspected adverse reactions with fatal outcome were reported in Italy after the administration of the Fluad adjuvanted influenza vaccine. Both reports, coming from the same Local Health Unit, occurred on the day of the vaccination, but with different lots. Later a case of meningitis with a fatal outcome and a case of encephalitis occurred with one of the lots already undergoing verification. According to the specific guidelines for vaccines of the European Medicines Agency, the two lots were suspended and investigated. The death events presented various elements of bias; especially advanced age, the presence of co-morbidities and previous therapies able

to explain the adverse reaction but no anomalies able to justify a causal relationship between the reported events and the administration of the vaccine were detected. Unfortunately, the media impact had more serious public health outcomes: a reduction in the number of vaccinated people was observed, with an overall 25-30% decrease in compliance in 2014/2015 immunisation season [21]. The subsequent trend in registered influenza cases may be attributable to the approximately 3 million vaccinations not administered. In all immunisation seasons considered, over 95% of the vaccinations were administered in the clinic of a General Practitioner, with a growing tendency of delivered doses that increased from 95.4% of the 2010/2011 immunisation season to 96.9% in the 2014/2015 immunisation season, despite the general decrease in the compliance to the vaccination proposal. One of the factors favouring the influenza vaccination uptake could be the widespread distribution throughout the territory of General Practitioners. The area of the LHU is composed by three Districts and corresponds with the Province: the most populated Center-North District with public hygiene clinics and pediatrics clinics dedicated to immunisations and the University Hospital; the Western District with the smallest area; the South-Eastern District is the largest and has the lowest population density [10]. Public health and pediatric clinics and one hospital (Cento and Lajosanto respectively) are also located in the Western District and in the South-Eastern District. The inclusion of many Municipalities of the river Po delta area, the shortage of public means of transport would suggest a greater difficulty in achieving good results of vaccination coverage against influenza, in particular in the elderly population, in residents in the South-Eastern District. On the contrary, residents of the South-Eastern District showed levels of vaccination coverage statistically significantly higher than the other Districts, in children in all immunisation seasons and, in the over sixty-five years, in the last two immunisation seasons considered, even in those which showed a general decline in the compliance to the vaccine proposal. The excellent results obtained in the South-Eastern District could suggest that General Practitioners have a crucial role in promoting vaccination compliance in the elderly population, that could face greater difficulties in accessing health services. Italian Healthcare System provides for universal and free influenza immunisation of subjects considered at risk to experience the complication of the infection. In addition, GPs receive a financial incentive for each administered influenza vaccine. The public funding for at-risk groups was shown to be effective in obtaining higher coverage rates [22]. However, the coverage of costs for the older population alone did not seem to be completely successful. Several studies showed that the likelihood of being vaccinated increased significantly with the increasing number of GP visits in the past 12 months [23, 24]. The motivation and the proactive behaviour of the GP remain the main factors able to improve immunisation rates [25-27]. A

recent meta-analysis reported among interventions able to improve influenza immunisation in elderly the health risk appraisal plus an offer of influenza vaccination, the offer of free influenza vaccination, the payment of the GP per vaccination with significant positive effects [28]. These findings suggest that GPs promote the influenza vaccination and that particularly in those patients who frequently visit the GP as they are more likely to receive information; persuading people that they are susceptible to influenza; increase belief that vaccination is effective; and appropriately decrease concern about side effects.

Conclusions

Although not considered by general population a severe disease, influenza is, among infectious diseases, one with the greatest social impact, causing annually millions of cases and thousands of deaths worldwide. In addition to the serious health consequences, influenza has a heavy economic burden, both in terms of loss of productivity due to work absences, and in health costs due to the treatment and hospitalization of those affected by complications. The influenza vaccination, recommended to over 65 and other groups at risk, represents one of the safest and most cost-effective public health interventions. Despite this, immunisation coverage rates are below the minimum optimal threshold of 75%, both in the elderly population and in subjects with chronic diseases. The research on LHU of Ferrara population showed that the levels of immunisation against influenza increased with increasing age. However, the goal of vaccinating at least 75% of people over 65 was not achieved in any of the considered immunisation seasons. The best results were recorded in the 2011/2012 immunisation season, but the target vaccination coverage was only achieved in the over eighty-five-year-old subjects. A possible barrier to influenza immunisation compliance could be represented by the poor perception of the harm of the disease, moreover, the spread of unfounded news on the supposed safety issues of the vaccine in the 2014/2015 immunisation season led to a significant decrease in coverage which is, in following years, gradually and with difficulty recovering. A decline in influenza vaccine uptake was similarly found in the population of LHU of Ferrara, which depicted the same trend observed at regional and national level. As the number of delivered doses and vaccination coverage decreased, a steady increase in the percentage of vaccinations administered by General Practitioners (about 97% of total doses in the 2014/2015 immunisation season) was observed. The gap with respect to the target coverage targets shows the need to take actions aimed at increasing the perception of the safety and efficacy of the influenza vaccination in the general population in order to reach previous coverage levels and further increase the compliance up to the minimum threshold of 75%. The GP's endorsement could be successful in encouraging elderly to be vaccinated.

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Conflict of interest statement

SL, AS, AC, ADT. GC declare no conflict of interest.

Authors' contributions

GG, SL and AS conceptualised and designed the study. AC, ADT, GC provided the data. SL and AS analysed and interpreted the data. AS and SL drafted the manuscript. GG, AC, ADT and GC revised it critically. All authors read and approved the final manuscript.

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