

Flu: An Epidemic of Misconceptions

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Abstract

Influenza is a viral disease; it spreads during the winter season in the form of epidemics or even pandemics. Its clinical and social importance is highly amplified by International and National (mainly in Italy) Health Authorities in order to promote and justify the vaccination campaigns. This aim is achieved by providing distorted or fake information to the public. These distortions mainly concern 4 aspects: 1) the real diffusion of influenza viruses; 2) the death rate relative to this disease; 3) vaccine effectiveness; 4) the presence of new viruses in new vaccines. Each of these points will be analysed. Real data, reviews of the literature and arguments will be shown for comparison. The conclusion is that: 1) the spread of the disease is about 10 times lower to the declared one; 2) mortality is very modest, questionable and anyway far less than what was declared; 3) vaccine effectiveness has always been proved as being far low than what had previously been declared, and it has often produced unpredictable and capricious results; 4) vaccines contain antigens of viruses circulating in the 2 - 10 previous years, therefore they certainly cannot be new. Vaccines composition is decided with a sort of bet, which is made by WHO experts more than a year before their use.

Therefore, in case of influenza, the social alarm is the basis of health policy. The fear leads to adopting the offered solution that is an increasingly widespread vaccination. After analysing real data, the rationale of this preventive measure proves to be a failure.

Keywords Epidemic; Flu; Flu-like syndromes; Mortality; Pandemic; Vaccine; Effectiveness

Introduction

Every year in the autumn season, Italian health authorities describe the flu epidemics that are about to arrive with great alarm. In the past, they have even made predictions of imminent plagues, as in the cases of the avian and swine flu pandemics that have then duly not occurred. In the past two decades, the data provided to the public have always been particularly worrying. The ones related to 2016-2017 winter season allegedly concerned 5 million cases of flu and "at least 18,000 deaths". The solution advocated and strongly promoted by the Italian Health Authorities is to vaccinate ever-widening layers of the population. This is in line with the international strategies on the issue.

It is important to understand how these figures are obtained and which limits the proposed prophylaxis has. The suggested thesis is that the figures given to the public do not match reality and originate from four high effect "misconceptions". The main ones concern the real diffusion of the disease, the mortality data, vaccine effectiveness and the composition of the vaccine. Each one of them is duly analysed below.

Examples of mediatic announcements of dreadful looming epidemics without any base of sound data or serious scientific justifications

Avian flu

"The chicken virus is at the door". La Repubblica (national newspaper), September 13, 2005. La Valletta (Malta)- «It will happen, it's unavoidable. When? Nobody can say». Professor Pietro Crovari, university professor in Genoa and Coordinator of the Ministerial Commission on Flu says calmly, but with no doubt. "The countdown has started already; it's only a matter of time. With projections for Italy that speak of 16 million infected individuals, 2 million hospitalizations and 150 thousand victims, the next flu pandemic could be one of the most devastating of the century".

Swine flu

Prof. Fabrizio Pregliasco, a renowned Italian Virologist: "In Italy maybe 12 thousand victims". Il Messaggero. September 19, 2009. "The morbidity and the number of cases expected in Italy", claims Pregliasco, «will be proportional to the virus infection strength. This means that if the virus is highly infectious there will be from 12.6 million to 23 million cases, equal to 38.7% of the population." All those forecasts, revealed themselves to be a non-occurrence that allowed a supplementary purchase of two dozens of millions of vaccine doses in Italy (and in other European Nations alike). The inspiration for such alarms comes from WHO experts [1].

Misconception no. 1: 'flu' versus 'flu syndromes'

Every year health authorities consciously perpetrate the misconception of the name, by labeling all 'flu syndromes' as 'flu' or "influenza". It is not a linguistic nuance but it is totally incorrect as flu-

like symptomatology could be caused by a multitude of germs and viruses and in most cases its origin remains unknown.

In fact, only about one eleventh of flu syndromes are caused by ‘flu viruses’.

‘Flu syndrome’ and “flu” definitions according to the Italian Superior Institute of Health (ISS):

Definition of a case of ‘flu-syndrome’

a patient who has a temperature $\geq 38^{\circ}\text{C}$,

and at least one of the following respiratory symptoms:

cough, sore throat and rhinorrhoea

plus at least one of the following:

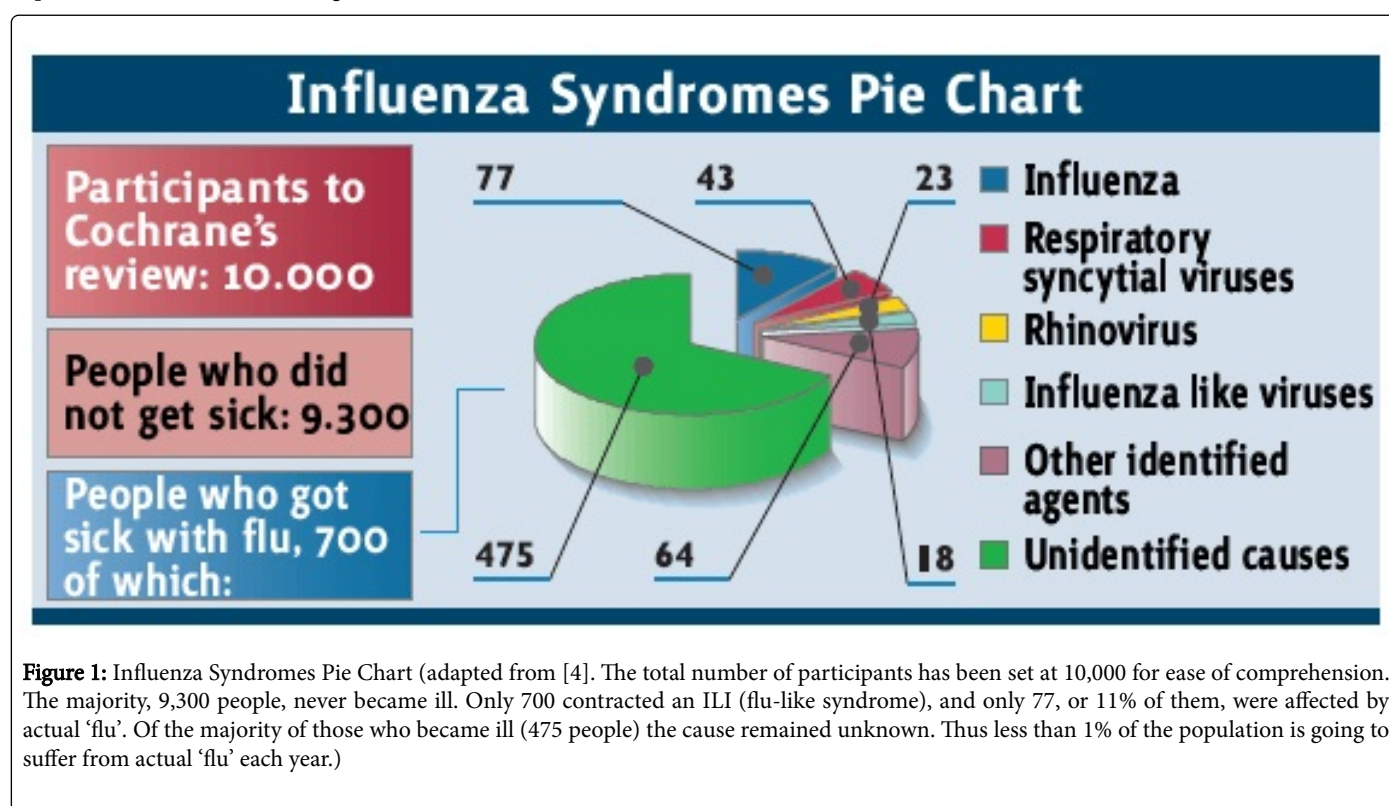
headache, malaise and asthenia.

Definition of a case of ‘flu’:

An individual with ‘flu syndrome’ symptoms and a throat swab, taken within 7 days from the beginning of the symptoms, positive for whatever flu virus circulating (type A with subtypes H1N1 e H3N2, and type B, all circulating for many decades). Adapted from Rapporti ISTISAN 16/36 [2].

In English they are called: ILI and ARI (or SARI in case of hospitalization) [3].

On the basis of a maxi-review provided by the Cochrane Collaboration of the published studies (and on millions of observations), the epidemiology of ‘flu syndromes’ and ‘flu’ can be described by Figure 1.



The same was confirmed also by the following graph adapted from EuroFlu [5]. It shows how the situation changes week by week with the

real prevalence of flu viruses compared to other causative agents (Figure 2 and 3).

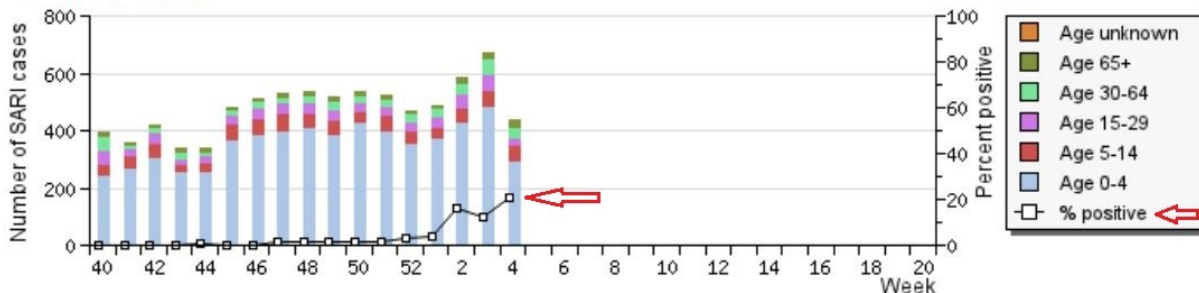


Figure 2: SARI (Severe Acute Respiratory Infections): percentage of specimens positive for influenza at sentinel hospitals (The bars represent numbers of cases of ‘flu syndromes’ in people admitted to hospital (SARI), while the line connecting the small squares represents the percentage of their positivity to flu viruses. This percentage, as can be seen, is close to 0 up to the last weeks of the year. Only then it goes up to reach about 20% at the end of January (year 2012). These charts cannot be equivocated, unfortunately they are no longer published in EuroFlu updates. Arrows added to the original figure (Figure 2) [5].)

Elsewhere the charts are mostly constructed in such a way as to mislead people into believing that all ‘flu syndromes’ are due to strains of two virus subtypes (A and B):

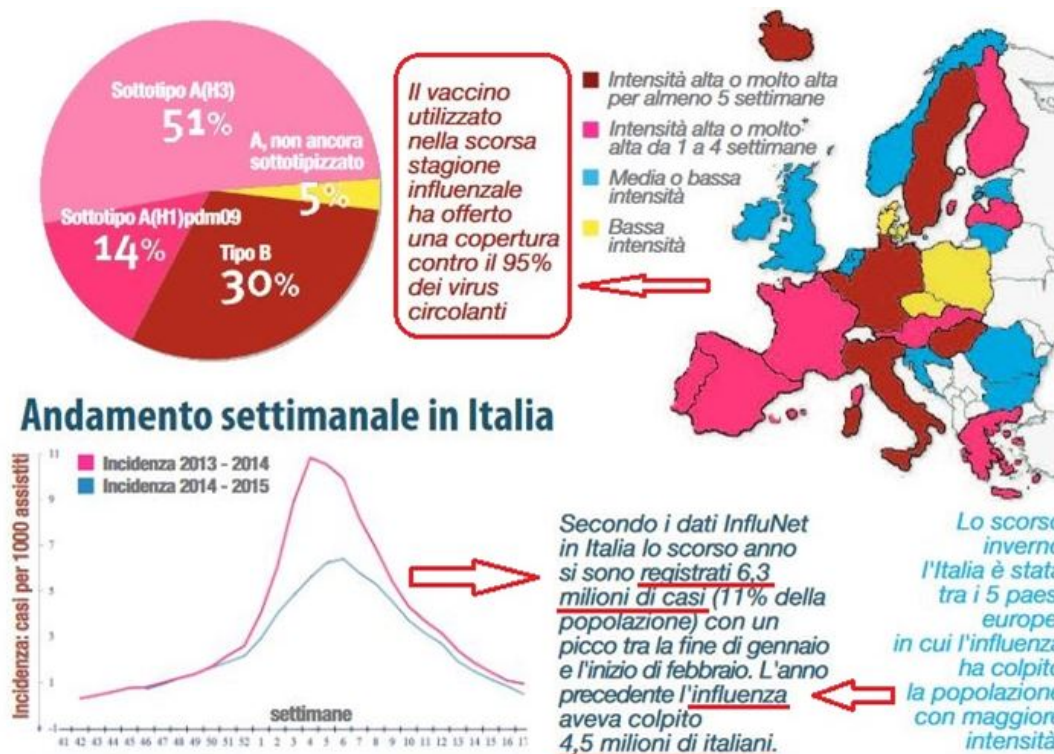


Figure 3: FNOmCeO Poster: ambiguous and false data offered to the public (Taken from 2015 FNOmCeO Poster, intended for medical outpatient clinics for the season 2015/16 [6]. In the following year, 2016, a similar poster was published. This is an example of a typical intentional equivocation. It lets the reader believe that 4,5-6 millions of flu-syndromes (ILI) were real “flu”, that all circulating viruses were “influenza viruses” and that the vaccine efficacy was very high (95%) (Figure 3). Arrows added to the original figure.)

Therefore, an average of 11% of seasonal ‘flu syndromes’ are actual ‘flu’ cases [4]. In Table 1, the second column shows annual cases of flu syndrome; the third column shows the cases of actual ‘flu’, assuming as valid the upper estimate of Cochrane’s report. The clarification is important because the vaccine is effective in theory to prevent ‘flu’ but not the remaining ‘flu syndromes’. It should be underlined that these are estimates; also the figures regarding ‘flu syndromes’ are estimates based on samples collected from data deriving from all the country.

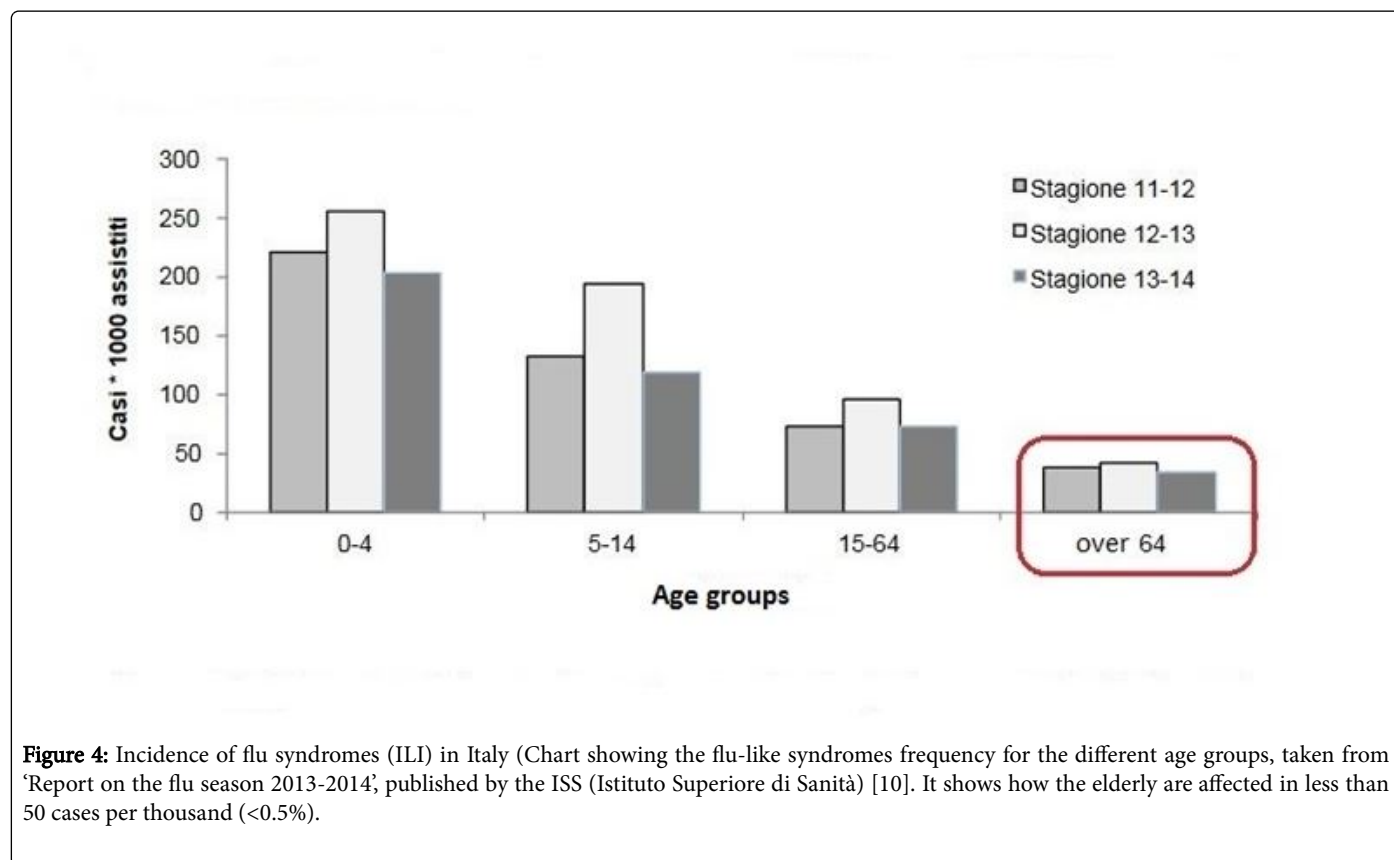
If we want to consider national data, the percentage of real flu diseases was sometimes much lower, as it happened in Italy in the 2005-2006 season (“As for virological surveillance, during the 2005-2006 season, only 4% of the clinical samples collected and analyzed by the ISS, were positive for influenza”) [7]. Paradoxically that was the season of the purported “avian flu pandemic” (Table 1).

Italy (national data)	No. of ‘flu syndromes’ cases ^a	No. of ‘flu’ cases for each season: 11% of total ^c
2016-17	5,031,000	553,410
2015-16	4,900,000	539,000
2014-15	6,300,000	693,000
2013-14	4,500,000	495,000
2012-13	6,013,000	661,430
2011-12	4,763,586	523,994

The number of cases of actual ‘flu’ is estimated at about 11% of the flu syndromes
^aEstimates by Istituto Superiore di Sanità (ISS) (Superior Institute of Health)
^cData calculated on estimates, assuming as a benchmark the ratio between flu and flu-like syndromes as reported in the Cochrane Reviews [8].

Table 1: Estimates of the number of “flu-syndrome” cases and “flu” cases in Italy.

The least affected age group is that of people older than 64 years, as shown in the ISS chart (Figure 4) [9].



Italy	Italian population aged >65 ^a	% Population aged >64 years who contracted the 'flu-like syndrome' ^b	No. of 'flu-like syndromes' in people aged >64 years	No. of 'flus' in people aged >64: 11% of 'flu-like syndromes' ^c
2016/17	13,369,754	4.51	602,976	66,000
2015/16	13,219,074	2.9	374,100	41,000
2014/15	13,014,942	4.7	611,702	67,000
2013/14	12,639,829	3.13	395,627	44,000
2012/13	12,370,822	3.8	470,091	52,000

The number of cases actually affected by 'influenza' is calculated annually.
^aStat data referring to 1st January of each year.
^bSource of percentages ISS data [9-16]
^cRounded to the thousands

Table 2: Estimates of the number of flu-syndrome cases and real flu cases in Italy in the older age group.

In Table 2 the number of cases of 'flu' affecting people over the age of 64 every year is calculated (these are estimates: the focus is on the order of magnitude). They are tens of thousands and not millions.

Misconception no. 2: mortality data

The reported and registered mortality rate ranges from a few dozen cases to less than two hundred per year. More than 90% of these deaths refer to elderly people and/or to people affected by other chronic diseases [17] or immunosuppression. Therefore, in most cases, they could be regarded as complications. This was stated a few years ago also by Silvio Garattini, President of the Pharmacological Institute, Mario Negri [18].

Incidentally, one Eurostat report of 2015 [19], lists the death causes related to respiratory diseases recorded in 2012 in EU Countries, of

which only 0.3% were due to flu viruses, that is a total of 2,286 people in a population of (more than) half a billion. However, ECDC provided also very different figures (Figure 5). For instance, in a press release, estimated casualties (for influenza, in the European Union) have been at least 40.000 [20] every year, and in another press release of the same day, provided again by ECDC, they have varied from 40.000 to 220.000 ("ECDC estimates that seasonal influenza is responsible for between 40,000 and 220,000 excess deaths in Europe each year, depending upon the severity of the influenza season.") [21]. This assertion is backed by a bibliographic reference that no longer exists [22].

In parallel in Italy, Health Authorities have started to consider extensively such additional thousands of deaths as being caused by 'complications' (Table 3).

Italy (national data)	No. of 'flu' cases: 11% of 'flu-like syndromes'	No. of deaths with initial cause 'flu' (cod. J10) ^a	No. of deaths (alleged, without evidence) for 'flu' complications ^b
2016-17	553,410	53 (0.01%)	18,000
2015-16	539,000	32 (0.01%)	9,000
2014-15	693,000	163 (0.02%)	8,000
2013-14	495,000	16 (0,003%)	8,000
2012-13	661,430	53 (0.01%)	8,000
2011-12	523,994	(not received)	8,000
Average in the last 5 years	582,425	63 (0.01%)	8,200

Notes: ^aSource ISS-Health Ministry, referring to the solar year; ^bInstitutional sources, including the President of ISS, Walter Ricciardi, for 2017 and previous years [23-27].

The last column shows the (alleged) mortality rate due to complications. This data is offered by Italian health authorities to the national media without any documental support, and without citing any sources. In the INFLUNET and Flunews bulletins of ISS, at most the mortality rate is reported as due to flu as the initial cause [26]. It should also be noted that, although the mortality data are reported on an annual basis and those of morbidity are deferred [or anticipated?] by a quarter, the order of magnitude of cases of mortality in cases of morbidity from flu can still be determined, and the ratio is in the order of 1/10,000 (0.01%; in the order of 1/100,000 referring to 2013-14). Note also that mortality due to influenza complications, as claimed by the President of the ISS, Walter Ricciardi, doubled in the current season compared with the previous one, and was 220% above the average mortality rate for the same cause in the last 5 years, despite the number of cases of "flu syndrome" and thus of influenza, in 2016/2017, it is estimated to be 5% lower than the average of the last five years. All this demonstrates the improbability of the statement by the President of the ISS himself regarding the number of annual cases of deaths from influenza and its exaggeration of some order of magnitude.

Table 3: Mortality rate due to flu: registered cases and alleged cases

In 2009-2010 Report on Health, a comprehensive ministerial document, it was reported that “in Italy it is estimated that each year seasonal flu causes about 8,000 deaths in excess, of which 1,000 due to pneumonia and flu, and a further 7,000 due to other causes” [28] without quoting any source or publication.

In 2012, the future ISS President, Walter Ricciardi declared that ‘flu’ had caused several thousand deaths in Europe and several hundred in Italy” [29].

In the Health Report related to the season 2012-2013 [30]: “230 cases of serious and confirmed forms of flu complications have been reported, including 53 deaths”.

In short, they jumped from a few dozen, to a few hundred, to several thousand cases, without any prove, without citing any scientific source.

A few doubts have emerged even from the Director of the Infective Diseases Department of the Superior Institute of Health (ISS), Giovanni Rezza. In an interview in 2014 [31] he answered as follows to the Italian journalist Gioia Locati on the topic:

G. Locati: “Would you confirm that there are 8,000 deaths per year due to flu complications?”

G. Rezza: “These are ISTAT data: the estimation refers to deaths related to cardio-respiratory diseases during the flu season.”

G.L.: “Therefore, in total, there are also heart patients who didn’t get any flu.”

G. R.: “Exactly.”

G.L.: “And, in total, there are also people that had been vaccinated but died of heart failure.”

G. R.: “Exactly”.

It is essential to understand how these huge numbers have been reached.

First operation to get data ‘replenishment’, the ‘influenza’ and pneumonia deaths were pooled, as shown in the chart given as an example. This chart refers to Italy statistics in the year 2012, and was published in 2014 [32]. Bacterial bronchitis and pneumonia are

actually possible complications of the disease, especially in debilitated people, but most of the times they are treatable with antibiotics. Surely not all pneumonia deaths are complications caused by a flu [33] !

In Austria where the flu vaccine coverage is less than half of the Italian one [34,35], flu and pneumonia death rate [36] is by far lower too. This comparison is revealing and could be considered as the single decisive argument, sufficient to judge on this preventive measure.

Second operation: EuroMOMO (European Agency specifically dedicated to finding correlations between flu and excess mortality rates) [37].

The inconceivable idea of willing to merge flu with all pneumonia types has led to finding a better solution. From statistical calculations, a line of ‘expected mortality rates’ was drawn by Euromomo. During the winter season when ‘flu’ spreads, if a mortality rate higher than the expected one is recorded, this excess (for all causes) is then related to seasonal disease. The concomitance of both events triggers the automatic attribution of causal association!

Such speculations at first sight seem to be justified.

From a less superficial analysis, one can realize how they are forced. In some cases researchers themselves admit this. In a publication of ECDC (European Centre for Disease Control) in 2015 on mortality rate excess among the elderly [38], the authors write:

“The increase in unspecified excess mortality coincides with an increased proportion of ‘flu’ in Europe. [...] “But factors other than influenza, which include other respiratory tract infections or environmental conditions, can also play an important contributing role.”

They clearly admit [38] that in Sweden and especially in Finland, the alleged cause of the excess mortality (flu virus circulation) occurred, but this did not produce any purported effect (no mortality excess). The opposite also happened: there was some time an excess of mortality rates without it being preceded or accompanied by the alleged cause (spread of ‘flu’). As it can be seen in the Figure 5 [38], where we highlighted several abnormal situations.

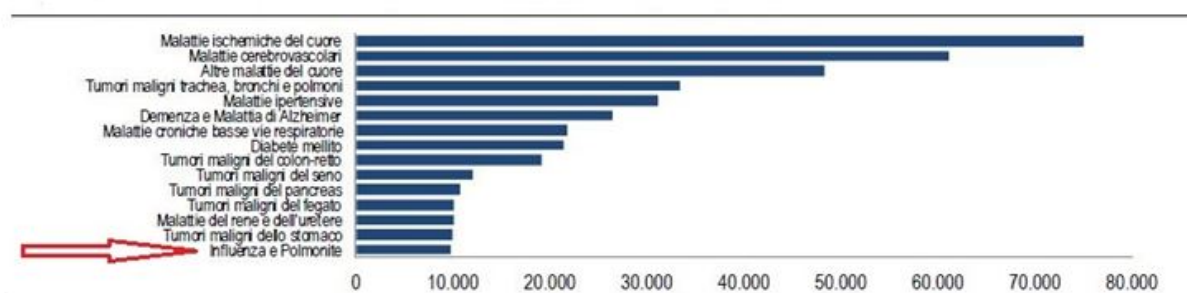


Figure 5: The 15 leading causes of death in Italy, year 2012 (‘Influenza’ has been included among the first 15 causes of death ‘on the strong back’ of all types of pneumonia [32]. By itself, with a few dozen cases per year (up to a maximum of a few hundreds), it would have disappeared from sight and attention [33]).

Since in some countries the expected chronological association between these two phenomena does not exist and since it is not

possible to conceive that flu viruses behave so differently from one nation to another, the exclusive causal correlation is simply unfounded. Italy in this ranking was absent.

Moreover, during one winter season in 2013/14, “no significant excess of mortality was seen in Europe. In fact, EuroMomo [39]

network data show that mortality was below the expected level of deaths” “Among the elderly aged 65 and over, the number of deaths was 5,607 below the expected baseline.” That is 5,600 fewer deaths! (Figure 6 and 7).

Excess mortality ≥ 2 z-scores over baseline among individuals aged ≥ 65 years and assessment of transmission intensity of influenza-like-illness in EuroMOMO countries, by week, week 49, 2014–week 9, 2015* (n=16 countries)

Country	Year - Week												
	2014				2015								
	49	50	51	52	1	2	3	4	5	6	7	8	9
Belgium	Low	Low	Low	Low	Low	Low	Medium	High	High	High	High	High	Medium
Denmark	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Estonia	Low	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium
Finland	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	High	High
France	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	Medium	High	High	Medium
Greece ^b	Low	Low	Low	Low	Low	Medium	Medium	High	Medium	Medium	Medium		
Hungary	Low	Low	Low	Low	Low	Low	Low	Medium	High	High	High	High	High
The Netherlands	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
Portugal	Low	Low	Low	Low	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium	Low
Spain	Low	Low	Low	Low	Low	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium
Sweden	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	High	High	High	High
Switzerland	Low	Low	Low	Low	Low	Medium	Medium	Medium	High	High	High	High	High
UK-England	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Low	Low	Low	Low
UK-Northern Ireland	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
UK-Scotland	Low	Low	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
UK-Wales	Low	Low	Low	Low	Low	No info	Low	Low	Low	No info	Low	No info	No info

Excess mortality (≥ 2 z-scores over baseline) among individuals aged ≥ 65 years

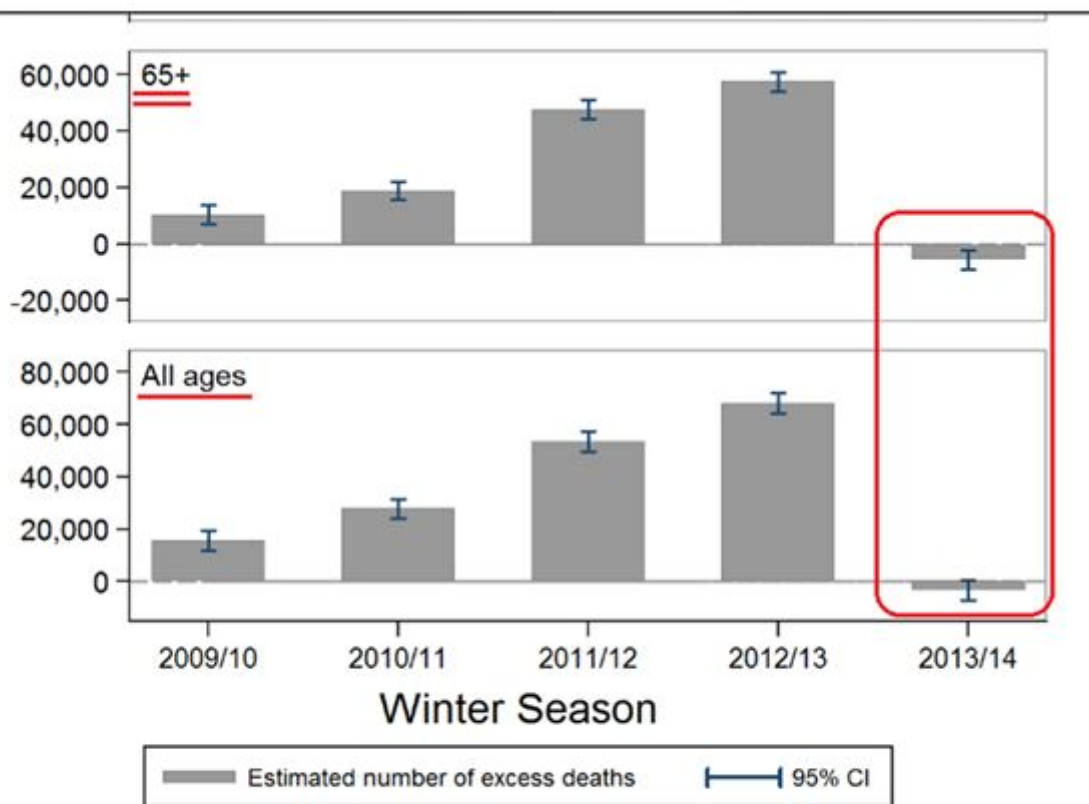
EuroMOMO: European monitoring of excess mortality for public health action; UK: United Kingdom; z-score: standardised deviation from the baseline.

The terms high, medium and low in the cells of the table refer to the intensity of influenza-like illness transmission.

* Corresponding to 1 December 2014–1 March 2015.

^b Mortality data is missing in week 8 and 9, 2015. Mortality data is derived from municipalities of Athens, Keratsini-Drapetsona and Pireas as well as prefectures of Magnisia, Sporades, Kerkira, Achaia, Kavala and Thasos.

Figure 6: Excess mortality: correlation and inverse correlation with high virus circulation (Inconsistencies (see text) are circled in red and grey (low flu virus diffusion and high mortality: circled in grey; high viral circulation and low mortality: circled in red, added to the original table) (Table 3) [38].



Estimated number of excess deaths by age group for winter seasons 2009/10 to 2013/14

Figure 7: Estimated number of excess deaths (Euro MOMO) by age group for winter season 2009/10 to 2013/14 (The grey columns above the baseline represent an excess of mortality, the ones below the baseline (and encircled) a decrease compared to the expected mortality [39]).

Therefore, if that winter during the epidemic there were fewer deaths, it would be consistent to argue that the ‘flu’ was then protective and prevented thousands of deaths in Europe. This is clearly absurd but it demonstrates the extent to which these algorithms are unreliable.

It should be noted that in Italy, in the same season (2013-2014) (Figure 7), the “usual” 8,000 deaths in excess were reported, as in the previous and following years. The fact that in Italy the excess of mortality rate, allegedly due to ‘flu’, has remained constant between 2009 and 2016 (8,000 cases), it would appear to be an unequivocal indication that such numbers are fabricated.

The validity of the association between the excess of winter mortality and flu viruses has been carefully analyzed by Lone Simonsen in a study published in 2005 (and quoted more extensively later) [40]: “Excess of mortality among the elderly was investigated in the United States from 1968 to 2001, both for pneumonia and for all mortality causes, for 33 consecutive seasons”. They concluded that, “less than 10% of all winter deaths were attributable to flu in each of the 33 seasons examined”.

The excess of mortality can be due to several factors, besides flu syndromes.

Misconception no. 3: on vaccine effectiveness (Cochrane Review, Australian flu, vaccine on the elderly)

The reviews of all the published studies on the effects of flu vaccine on different populations, carried out by the Cochrane Collaboration, independent institute, authoritative body among the research community, reveal a scarce benefit, if at all, of vaccination. Such reviews have not been scientifically confuted, but confirmed by others [41].

1) In the case of vaccines to prevent ‘flu’ in healthy children, the authors therefore conclude: “The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies. The content and conclusions of this review should be interpreted in the light of this finding.”

“No safety comparisons could be carried out, emphasizing the need for standardization of methods and presentation of vaccine safety data in future studies. In specific cases, influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions. It was surprising to find only one study of inactivated vaccine in children under two years, given current recommendations to vaccinate healthy

children from six months of age in the USA, Canada, parts of Europe and Australia” [42].

2) In case of healthy adults, the authors’ conclusion is: “Influenza vaccines have a very modest effect in reducing influenza symptoms and working days lost in the general population, including pregnant women. No evidence of association between influenza vaccination and serious adverse events was found in the comparative studies considered in the review. This review includes 90 studies, 24 of which (26.7%) were funded totally or partially by industry. Out of the 48 RCTs, 17 were industry-funded (35.4%.” [43].

3) In case of people with cystic fibrosis, the authors attest: “There is currently no evidence from randomized trials that the flu vaccine given to people with cystic fibrosis is beneficial to them. There remains a need for a well-established clinical study that evaluates the effectiveness of flu vaccinations on important clinical outcome measures” [44].

4) In the elderly: “The available evidence is of poor quality and provides no guidance regarding the safety or effectiveness of flu vaccines for people aged 65 years or older. In order to solve the uncertainty, a randomized, placebo-controlled multi-seasonal, publicly funded study, with adequate demonstrative power, should be undertaken” [45].

5) In immunosuppressant adults with malignancies, “observational data suggest a lower mortality with flu vaccine. Outbreaks related to infections were fewer than or similar to those with flu vaccination. The strength of evidences is limited by the small number of studies and by the fact that only one was an RCT. The flu vaccine is safe, and evidence, although weak, is in favor of vaccination of adult cancer chemotherapy patients” [46].

6) In patients with cardiovascular disease, “flu vaccine can reduce cardiovascular mortality and combined cardiovascular events. Nevertheless, these studies have shown an increased risk of confusion,

and results have not always been consistent, so evidence of better quality is needed to confirm these results. There was not enough evidence available to determine whether the flu vaccine had a role to play in primary prevention of cardiovascular diseases or not.” [47].

Flu Epidemics in Australia

For geographical reasons the cold season and the flu epidemic in Australia anticipate the European (and Italian one) by six months. The vaccine distributed in the Southern hemisphere is the same as for the Northern hemisphere (Italy included) [48] and the composition is established one year in advance. Data are collected in the Australian bulletins which gives information that we do not partially find in Italian publications. On “Australian Influenza Surveillance Report” of October 2016 the authors report that symptoms and absences from work have been recorded roughly in equal measure among the vaccinated and unvaccinated individuals:

For example, in the week ending 15 October 2017, “Across Australia, fever and cough was reported by 1.2% of vaccinated participants and 1.1% of unvaccinated participants. Fever, cough and absence from normal duties was reported by 0.9% of vaccinated participants and 0.7% of unvaccinated participants.” About 63% of the participants had received the seasonal vaccine [49].

At the end of the season, in 2016, 92 deaths associated to influenza were reported by the Australian Health Service (NNDSS). The median age of death was 80 years (range between zero and 99 years) [50]. In 2017, 598 influenza associated deaths have been notified to the NNDSS. The majority of deaths were due to influenza A (78%, n=466). The median age of deaths notified was 85 years (range 0 to 107 years)” [51]. Incidentally, the vaccine had a very poor effect on virus A subtypes [52], especially on the elder. Similar data have been reported in earlier reports. In 2017 the results of the whole season are represented in Figure 8.

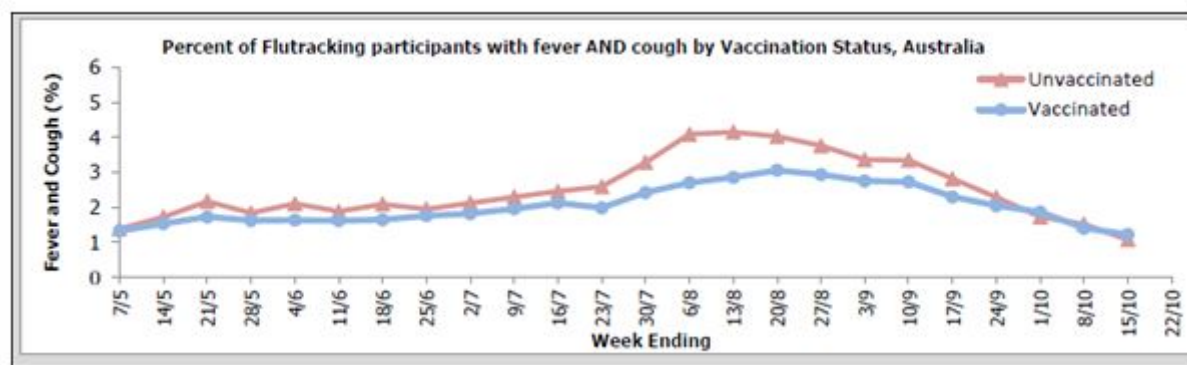


Figure 8: Slight differences among vaccinated and unvaccinated subjects in Australia (2017) (Vaccinated (blue line) and unvaccinated (red line) contract ILI (“influenza syndromes”): he difference is slight [49]).

Similar findings have been made in Canada [53] in long term care institution both among residents (VE: 7.9%) and staff (negative VE: -52%).

In Italy a case-control study [2] was carried out to evaluate the vaccine effectiveness (VE) against flu. In the season 2010-2011, it was

found to be 52.1% (CI95%: 39,6 - 61,9). In the season 2011-2012, VE was 4.5% (CI95%: -17.6 - 22.5). It is interesting to note that in 2011-2012 VE was strongly negative in subjects aged ≤ 65 years (-178,2) with CI95%: -246 - 123,7, thus confirming the unreliability of vaccine effects.

Simonsen's Study

Based on the observation that the practice of vaccination had progressively increased in the USA, a group of researchers wanted to determine whether it had reduced mortality rates among the elderly in 33 consecutive winter seasons from 1968 to 2001 [40]. Some key steps are reported:

"Influenza vaccination coverage among elderly persons (65 years) in the United States increased from between 15% and 20% before 1980 to 65% in 2001."

"The sharp decline in influenza-related deaths among people aged 65 to 74 years in the years immediately after A(H3N2) viruses emerged in the 1968 pandemic was most likely due to the acquisition of natural immunity to these viruses. Because of this strong natural immunization effect, by 1980, relatively few deaths in this age group (about 5000 per year) were left to prevent. We found a similar pattern in influenza-related mortality rates among persons aged 45 to 64 years (Figure 4), an age group with substantially lower vaccine coverage."

"Our finding that influenza-related mortality among the very elderly did not decline after 1980 might be explained by this group's failure to respond vigorously to the vaccine. This possibility is supported by an immunologic study that found that antibody responses following influenza vaccination decline sharply after age 65 years and a clinical trial involving subjects 60 years or older that found that the efficacy of influenza vaccine in preventing influenza illness was lower in people older than 70 years."

"If vaccination reduces influenza-related mortality by 70% to 80%, then the 50-percentage-point increase in vaccination coverage among the elderly after 1980 should have reduced both excess P&I (Pneumonia and Influenza) and excess all-cause mortality by about 35% to 40%. We found no evidence to indicate that such a reduction had occurred in excess P&I or excess all-cause mortality in any elderly age group."

The researchers thus concluded:

We could not correlate increasing vaccination coverage after 1980 with declining mortality rates in any age group.

In a review published later [54] in which the actual antibody response to the flu vaccination in the elderly was sought, the authors found "consistent evidence that the immune response to vaccination declined substantially with age". However, researchers from all over the world did not adequately address such a problem until then: "We were surprised to find that only 3 out of 31 studies had shown results for age groups for older participants. Therefore, in order to characterize the probable dependence of vaccine response by age, we suggest that future studies should report the vaccine response in the elderly with ten or five year increments."

The Simonsen's findings have been confirmed by Peter Doshi, who found that mortality did not change much even during the fearsome pandemics of the past (i.e. those of 1957-1958 and that of 1968-1969 winter season) [55].

Misconception no. 4: Vaccine composition with "new viruses".

It is generally thought that vaccines contain the most recent viruses, those that have appeared and are destined to spread for the first time. However, this is not the case. Vaccine preparation has to start at least 6

months before it reaches the pharmacy shelves: this is the time needed to decide what vaccine, preparation, production and distribution are needed. The Australian vaccine has to be ready 6 months before ours, in April. Curiously, its composition is always the same as the European one, every year [48]. Therefore, it is clear that only viruses which have circulated in the past and that the experts speculate will be the protagonists of the next cold seasons could be present in the vaccine. In the current year (2017-2018), the most recent viral isolate is from 2015. The composition, with the year of the first isolation is given below [56]:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus;
- an A/Hong Kong/4801/2014 (H3N2)-like virus; and
- a B/Brisbane/60/2008-like virus.

(It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Phuket/3073/2013-like virus.)

Therefore, in the vaccines there are antigens of one virus isolated in 2008, one in 2014, and one in 2015 (and the forth in 2013).

As it happened in the previous years, WHO experts anticipated in September 2016 that the flu epidemic (to be) in Australian winter season (April – September) 2017, would have involved exactly these strains. Then the WHO experts anticipated, in March 2017, that the same strains would have transferred themselves to the northern hemisphere to spread during 2017-2018 winter season.

If those WHO prediction are going to be respected, also the vaccine would obtain the same effectiveness in Europe as it did in Australia. We know now that the effectiveness of it was low, as much as 33% (95% CI 17-46) [52]. Remarkably, the effectiveness among the chief target group (people aged >65 years old) was -0.3%, which means that not even one disease (ILI) has been spared for the elderly who got the flu shot.

Similar observations were made by Anthony Fauci, director of National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA. About VE vaccine effectiveness in 2017, in Australia, he wrote: "Interim reports suggest that the 10% vaccine effectiveness against A (H3N2) influenza A (H3N2) viruses was not primarily attributable to antigenic mismatch between the vaccine strain and circulating viruses" [57]. Moreover, "Given that ... the composition of the 2017-2018 Northern Hemisphere vaccine is identical to that used in Australia, it is possible that we will experience low vaccine effectiveness against influenza A (H3N2) viruses ...".

Discussion

The equivocal terminology used for flu epidemics and pandemics is useful to Italian health authorities in order to amplify a minor health issue and depict it as a public threat. The same strategy is led by WHO experts and is pursued in all continents [1]. The definition of pandemic has been modified by WHO in 2009, thus allowing a higher phase of alarm (phase 5 or even 6, the maximum) which was tailored for flu [58]. The unequivocal aim is to promote an ever widening vaccination strategy based on false premises [59], i.e. on vaccine performance (VE of 80%) which has never been achieved in the past [57], on obligatoriness [59], and on creating fear [60]. Phase 6 of WHO alarm provides the opportunity to decide for compulsory vaccination of entire populations.

Elderly people are the main annual target of the flu vaccine.

It should be considered that vaccination is less effective if performed: a) every year, b) at a late age, and c) in cases where other chronic conditions are present. Unfortunately, effectiveness is lower where it would be more necessary. On the other hand, every year the elderly population is affected by flu illness in minimum percentages, from 0.33 to 0.52% (Table 2). One reason lies most likely in the fact that they are already protected against viruses which were circulating in the past (i.e. with minor antigenic drifts), and that there are no 'new' viruses (i.e. with major antigenic shifts) since many decades. Obviously aging inevitably affects health (in Italy there are around 18,000 centenarians) [61] and therefore any problem, including flu, could aggravate their situation. Nevertheless, in this context the main causal factor is given by basic health conditions and by the very senescence (*senectus ipse morbus*). Senescence affects also the immune system, which becomes less responsive, even to vaccines. In such situation, the best solution is the timely use of antibiotics for bacterial complications.

It is worth remembering the results of the already mentioned [2] Italian study which adds a further insight on the matter. Researchers found a modest performance for older people (+50%) and very negative results for people aged 64 or younger (-178%). This figure was obtained for the same season, against the same circulating viruses and with the same vaccines. This wide difference allows concluding that this preventive measure is totally unpredictable: how could this wide range of results be otherwise explained?

In the present review, we have not considered the possible adverse effects of flu vaccination, which have emerged in the past years and which also weigh negatively in the overall assessment of the preventive measures too.

Perhaps the reasons of this health policy are at least partially due to private interests of many decision makers.

Vaccination proponents who hold important public roles should not have conflicts of interest. On the contrary, even the president of the Italian Superior Health Institute (ISS), Walter Ricciardi, director of Osservatorio Salute, is sponsored by pharmaceuticals companies [62], and his conflicts are duly reported in his own declaration [63]. Pasqualino Rossi has represented Italy at the European Agency of Medicines (EMA) since 2015, despite having been caught with a bribe in hand, while serving as AIFA president, in 2008 [64]. Dr. Enrica Alteri has been appointed EMA Head of safety and efficacy at in 2012, where she is playing a key role at introducing pharmacovigilance legislation, notwithstanding she was working for pharmaceutical industries and her husband is a contract counsellor for Merck-Serono [65].

Conclusion

The spread of misleading data provided to the press without critical filtering supports the alert for flu epidemics. The flu epidemic is amplified by a factor of 10 or more. The number of elderly people affected every year ranges approximately from 40,000 to 66,000 in a population of more than 13 million people (age>64). Therefore, only a very small number of old people are affected by "flu" every year (in percentages ranging from 0.33% to 0.52% in the last years). Relative mortality is limited to a few dozen cases, mostly in people aged over 65 years old with chronic pathologies [66]. Any primary evidence does not support the alleged thousands of deaths due to flu complications and the available data are in contrast with the reliability of such

estimates. The paradigmatic example is given by the Austrian situation, where their vaccine coverage is half than that of Italy. In spite of this fact they show a reduced mortality both for influenza and pneumonia.

Vaccine effectiveness is poor, as demonstrated by Cochrane reviews, Australian epidemic reports, Italian data, Austrian data and Simonsen's study, which detailed this issue analysing 33 consecutive influenza seasons in the United States. The flu vaccine (which could only contain non-recent viruses) is especially recommended to the elderly. But the more advanced the age, the more often it is repeated, the less effective it is. This is confirmed by the recent winter season (2017) in Australia, where the vaccine performance has been very disappointing [52,57]. From 9 to 11.4 million flu vaccine doses are administered every year in Italy, of which about 7 million to the elderly [66], that is considered the chief target. The stated goal of Italian Health Authorities is to extend the vaccination to at least 75% of elderly people (and other categories) [67], which in Italy correspond to about 10 million vaccines only for this age group. Upon these figures, this means that around 400 vaccines would be needed to spare one disease for people aged 65 or over, of whom very few are usually affected (and supposing a very unrealistic high effectiveness of 50%). Actually vaccine effectiveness has proved to be far lower, for example it was less than 0 (-0.3%) for elderly people in Australia in 2017. There they used the same vaccine destined to Europeans for the 2017-2018 winter season.

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