

# Effect of mass media on influenza vaccine coverage in the season 2014/2015: a regional survey in Lazio, Italy

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## Key words

Mass media • Vaccine coverage • Anti-flu vaccine

## Summary

**Introduction.** Adherence to vaccination program for Influenza virus is an important issue of Public Health in presence of many no-vaccine tendencies. The media event about some deaths, occurring after MF59 adjuvanted vaccine administration, has characterized the season 2014/15 vaccination program in Italy. Aim of the study is vaccination adherence assessment of the current season with regards to local health units (LHU) coordinators' perceptions in Lazio Region (IT).

**Methods.** LHU coordinators' perceptions were collected from a questionnaire that was sent via email to the all 12 LHU coordinators. The questionnaire was built with 4 questions concerning the impression about the vaccination adherence of elderly people in the current season. Data from questionnaire was compared with the official coverage rate obtained by the Regional Authority. Severe adverse events were collected by 1 LHU.

**Results.** All the 12 LHU coordinators answered to our questionnaire: 7/12 (50%) predicted a coverage rate of at least 50%; 3/12 (25%) referred a coverage rate around 40-45%; 2/12 (17%) predicted a reduction of 5-10% less than the previous season. Indeed, a mean 49.1% vaccination coverage in the elderly has been reported by the Regional Authority highlighting a reduction of 10% less than the 2013/14 season coverage. No severe adverse events were observed.

**Discussion.** In our survey an important effect of media event on anti-flu vaccination program adherence has been evidenced, with a failure in communication and joint management of Public Health Institutions in Italy about efficacy and safety information of flu vaccine.

## Introduction

Influenza viruses are the etiological agents for flu illness, an important cause of morbidity and mortality worldwide. Flu easily spreads through the population and is present year round in the tropics or during winter in the temperate regions. Influenza affects globally 5-10% of adults and 20-30% of children each year. Cases of severe illness are estimated about 3 to 5 millions, with a mortality around 250 to 500 thousands [1-4]. In Europe about 10% of the population presents symptoms of flu with hundred million hospitalizations yearly [5]. In Italy, flu illness affects an average 8% of the population [6] and causes more than 8,000 deaths per year due to fatal consequences [7]. The clinical manifestations of the disease are not typical, and the term Influenza-Like-Illness (ILI) is used, which includes acute self-limited febrile respiratory symptoms with muscular pain, asthenia, headache and malaise [8]. Case definition of ILI has been recently updated from European Centre for Disease Prevention and Control (ECDC), and it is defined as the sudden onset of fever, malaise, headache or myalgia, associated with at least one of respiratory symptoms such as cough, sore throat or shortness of breath [9]. Course of illness is generally mild; however, in some groups (elderly peo-

ple, infants, pregnant women and patients with chronic diseases such as diabetes, cardiovascular disorders, asthma, BPCO or immunodeficiency) important consequences can be experienced. These complications include: primary influenza viral pneumonia [10], chronic illness exacerbation, secondary bacterial pneumonia, sinusitis, otitis media, coinfections with other viral or bacterial pathogens [7, 11, 12].

To prevent these complications an adequate vaccination program is important to be planned. The importance of preventing influenza is mainly for the above-mentioned groups with an increased risk to develop flu complications. In particular, vaccination is important in the elderly (people with an age  $\geq 65$  years), as they present a reduced immunological response to microbial agents [13, 14]. As influenza viruses are highly mutant, vaccine is built from the new circulating viral components; consequently, annually vaccine formulation made by a global surveillance coordinated by World Health Organization (WHO) is required [15]. Once vaccine is produced, Public Health Institutions coordinate each year vaccine campaigns for influenza prevention. In Italy, official recommendation for flu prevention program is published each year by Ministero della Salute (MdS). Recommendation indicates risk groups to whom vaccine has to be offered and the formulations

appropriate for each age groups. Vaccine campaign is performed from October to December [16].

In Italy during 2014/15 flu season, vaccination campaign has been characterized by an important media event, which negatively influenced the coverage. Four deaths occurred from 1 hour to 5 days after MF59 adjuvanted vaccine administration in the period 7-24 November 2014. Then in November 27, two batches of the MF59 adjuvanted vaccine were precautionarily withdrawn by the Agenzia Italiana del Farmaco (AIFA), and exhaustive analyses about their safety were performed [17]. Lazio Region decided to suspend the distribution of all batches of MF59 adjuvanted vaccine, after 2 additional suspected deaths were reported in the Region [18, 19].

In December 3, the European Medicine Agency (EMA) established the absence of relationship between deaths and vaccine administration [20]. To this date, an overall 19 deaths after MF59 adjuvanted vaccine administration were reported to AIFA. In December 24, after Istituto Superiore della Sanità (ISS) had verified vaccine safety with laboratory tests [21], AIFA removed the block of the two batches [22]. After obtaining the positive advice of MdS, Lazio Region extended flu vaccination campaign up to January 31, 2015 [23].

In this situation, the emphasis of mass media on reporting these news determined an increasing fear about flu vaccine and vaccination that spread through the Italian population.

Aim of the study is to assess the vaccination adherence following the media event in more than 1,200,000 people aged  $\geq 65$  years, resident in Lazio Region, Italy.

## Methods

A questionnaire was built with the following four topics: flu vaccine distribution, adherence at campaign startup, media event effects, coverage projection in  $\geq 65$  years population. In January 26, 2015, the questionnaires were sent via email to coordinators of the influenza campaign or vaccinations for the 12 local health units (LHU) in Lazio. Results of questionnaire were collect via email or telephone from January 27 to February 17. Moreover, data of severe adverse events after vaccine administration were collected from one LHU.

Adverse events were investigated in subjects aged  $\geq 65$  years immunized with MF59 adjuvanted vaccine, through a 7-days monitoring (namely active surveillance) or through a questionnaire sent to all general practitioners in that LHU (i.e. passive surveillance).

The distribution of available vaccines in the different LHU and the 2013/14 and 2014/15 vaccine coverages at the end of November and at the end of the campaign were obtained from the Regional Authority.

Descriptive analyses were made based on the answers to 4 questions. The results of these analyses were subsequently compared with data of vaccine coverage.

## Results

The responses to the questionnaire were collected from 12/12 coordinators of LHU. MF59 adjuvanted vaccine was available in 12/12 LHU, 10/12 (83%) coordinators specified the use in  $\geq 65$  years people for whom the vaccine is licensed.

One or both suspected batches were present in 7/12 (58%) LHU.

Almost all the LHU coordinators (11/12) reported a startup campaign better or similar to that of the previous year; only 1/12 (8%) referred a low initial adherence to vaccination program (Fig. 1).

A personal opinion was asked about the impact of the media events on the vaccination campaign as Figure 2.

Fig. 1. LHU coordinators' perception on flu vaccination campaign startup adherence.

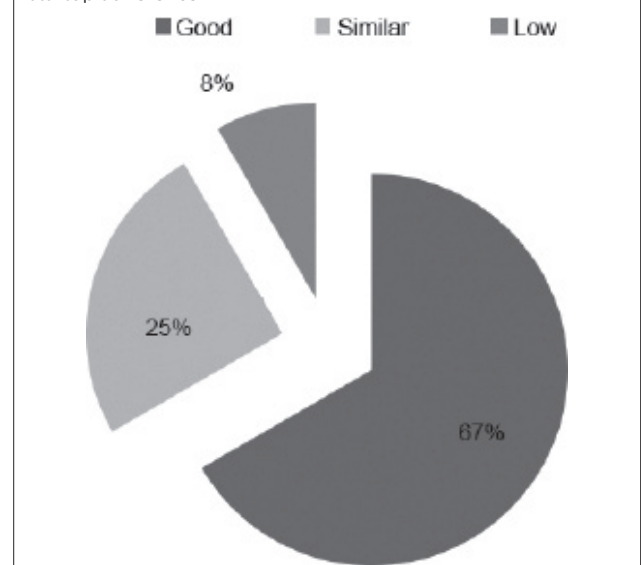
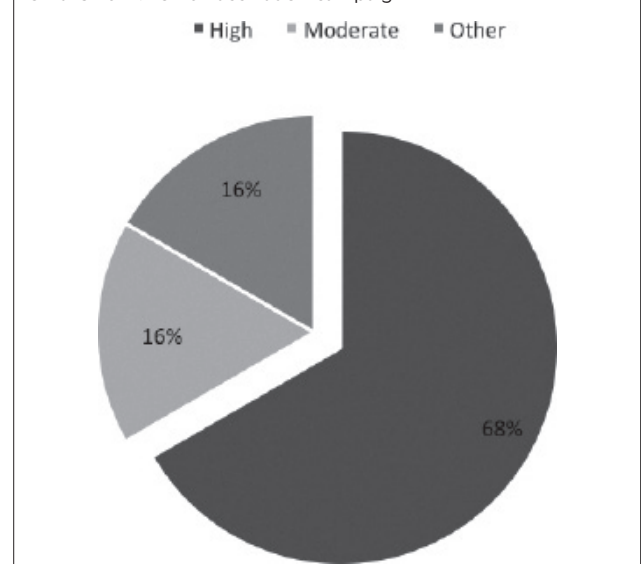


Fig. 2. LHU coordinators' judgement about media event impact on the 2014/15 flu vaccination campaign.



**Tab. I.** Coverage rate of vaccination among elderly in flu season 2013/14 and 2014/15.

LHU	Elderly resident in Lazio 2013/14*	Influenza Season 2013/14		Estimated LHU Projections	Elderly resident in Lazio 2014/15**	Influenza Season 2014/15	
		Vaccinated	Coverage Rate (%)	Coverage Rate (%)		Vaccinated	Coverage Rate (%)
LHU 1	124163	55207	44.5	45.0	127033	47529	37.4
LHU 2	139543	76522	54.8	50.0	142323	70863	49.8
LHU 3	133991	67743	50.6	46.0	136907	62710	45.8
LHU 4	123031	67609	55.0	50.0	125495	63572	50.7
LHU 5	122856	56880	46.3	46.0	125504	51530	41.1
LHU 6	56564	32354	57.2	45.0	57692	29740	51.5
LHU 7	86500	51279	59.3	50.0	88251	47223	53.5
LHU 8	97343	52874	54.3	53.0	99273	49882	50.2
LHU 9	71759	41299	57.6	50.0	73292	37873	51.7
LHU 10	38539	21904	56.8	55.0	39381	18385	46.7
LHU 11	103017	66567	64.6	59.0	105104	62740	59.7
LHU 12	104187	63357	60.8	50.0	106431	60586	56.9
TOT	1201495	653595	54.4	49.7 <sup>a</sup>	1226686	602633	49.1

LHU: Local Health Unit

\* Data from ISTAT 01/01/2014

\*\* Data from ISTAT 01/01/2015, central hypothesis

<sup>a</sup> Adjusted by ISTAT 01/01/2014

In particular: a very negative impact of media event was generally perceived by 8/12 (68%) LHU, sometimes describing a real refusal of flu vaccination with subsequent important adherence lowering; 2/12 (16%) specified a moderate reduction of the vaccination adherence; 2/12 (16%) coordinators quantified an hypothetical percentage of adherence reduction around 10-15%.

The LHU coordinators gave their personal projections regards to vaccination coverage in the  $\geq 65$  years population: 7/12 (58%) predicted at least 50% coverage; 3/12 (25%) estimated a coverage less than 50%, included in a 40-45% range; 2/12 (17%) answered in terms of coverage reduction, reporting a 5-10% decrease compared with the previous influenza vaccine campaign.

Using these data, a weighted mean 49.7% vaccination coverage in people  $\geq 65$  years was expected, with an estimated reduction around 10% compared to the previous seasonal coverage data (54.4%), shown in Table I.

Coverage data from Regional Authority showed a mean rate among the 12 LHU of 54.4% and 49.1% for season 2013/14 and 2014/15 respectively (Tab. I), with a decrease in all LHU ranging from 6 to 18%. In particular, 3/7 (43%) coordinators of LHU with the suspected batches gave an overestimation of effective coverage in elderly, 4/7 (57%) gave the same or a quite lower estimation than the real coverage data. Despite that, 4/5 (80%) of the LHU without the suspected batches gave an estimate of reduced coverage caused by the media impact similar to the value reported by the Regional Authority. Interestingly, 4/12 (33%) coordinators had overestimated as well as 4/12 (33%) had underestimated the coverage reduction, without any correlation with the presence of the suspected batches.

Moreover, a reduced adherence (around 7%) in the first 2 months of 2014/15 season for elderly has been evidenced when compared with the previous seasonal adherence at startup.

No evidence of severe adverse events were identified from both active and passive surveillances. Active surveillance was performed in 95 subjects, of whom 68/95 received the suspected batches of MF59 adjuvanted vaccine. Among general practitioners, 97/456 answered to the questionnaire reporting 9,483 subjects immunized with MF59 adjuvanted vaccines, of whom 5,916 subjects received the batches under investigation.

## Discussion

Vaccination adherence is an important issue about which Public Health Institutions debate for several years. Vaccination programs have surely reduced in the last years the burden of many infectious diseases with regard to incidence, morbidity and mortality. As a consequence of this success, general population looks mostly at the adverse events to vaccines and underrate their beneficial preventive effects. Due to a supposed low utility, a disputable feeling for vaccine is recently organized, enhanced and conducted into several no-vaccine tendencies, which strengthen the fear about vaccine utilization also with publishing no scientific papers [24]. In particular, one of the main object of the debate for these no-vaccine tendencies is anti-flu vaccine, caused by its annual program planning, production and distribution. Moreover, general population don't think that anti-flu vaccine is necessary, as influenza is a disease with a good prognosis.

These considerations cause a low amount of people to which vaccine is annually administered, that is often lesser than the minimal coverage target built on a 75% of people  $\geq 65$  years by Public Health Institutions [25]. This point is well evidenced in Italy, where a mean flu-vaccine coverage around 60% (range 54.2-68.3%) is observed in the last 10 years. In particular, in Lazio Region a progressive low decline in anti-influenza vaccine coverage has been observed in the last years, after a peak of 74.1% registered in 2006/07 [26]. In 2013/14 season the declining trend seemed to get a stop and a lot of work had been planned to increase coverage.

In the matter of question, season 2014/15 was characterized by an important reduction in terms of adherence to vaccination for elderly people, caused by the obsessive fear after the media event of suspected deaths related to MF59 adjuvanted vaccine administration. The perception of LHU coordinators is that this fear for flu-vaccine was induced and not well managed by the different Italian Public Health Institutions, as they did not take in consideration the media impact for deaths, did not pay the right attention to better transmit the vaccine safety to general population and, most important, they did not act univocally.

The media event occurred in Italy highlighted the problem of adverse events management following immunization. According to WHO recommendations, serious adverse events (e.g. deaths) have to be evaluated in order to determine the causal or only temporal association [27].

In this survey, the LHU coordinator's perception in Lazio Region has been that the vaccine coverage in elderly was about 10% less than 2013/14 season, although they felt campaign starting better than the previous one. This perception has been already confirmed for the reduced low adherence of elderly decreasing from 54.4% of the previous season to 49.7% of 2014/15 season in all LHU, without a correlation between perception and real decrease rate. This lack of correlation could be explained by the fact that around 99% of people  $\geq 65$  years resident in Lazio has been vaccinated by the general practitioners (GP) and not by physician of LHU, with a GP/LHU ratio of 122:1. Therefore, LHU coordinators did not receive a real-time information about vaccination coverage in the elderly.

Moreover, we have pointed out that the media event has determined an important flu vaccination coverage reduction in the LHU using the suspected batches. The decrease was, however, detected also in the LHU not having these batches, in those using only a small amount of MF59 adjuvanted vaccine and even where both active and passive surveillance did not recognize any severe adverse event.

However, this low adherence was already observed at startup of vaccination program, because a coverage of about 7-9% less than the previous season is reported from official data by Regional Authority. In fact, a 42.5% mean coverage in elderly has been reported at the end of November 2014 in respect to the 46.6% reported in November 2013.

These considerations highlight an extreme precaution for Italian Public Health Institutions in dealing the effects of media event [28], in particular for Lazio Region with the suspension of all MF59 adjuvanted vaccine batches. In fact, after the vaccine was available again the Region proposed to prolong the campaign up to the end of January; however, there was a delayed final approval from MdS and some LHU coordinators referred a late official communication press, which took place after several general practitioners had already given back to LHU all vaccines.

## Conclusions

The media event about the suspected deaths related to MF59 adjuvanted vaccine administration has highlighted a failure in communication and cooperation of Public Health Institutions in Italy. A good management of vaccine planning, as well as improving health workers knowledge for vaccine safety and effectiveness, are needed to ensure the right level of vaccination coverage and increase the acceptance of immunization by the target population.

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## References

- [1] Harper SA, Bradley JS, Englund JA, et al.; Expert Panel of the Infectious Diseases Society of America. *Seasonal influenza in adults and children - diagnosis, treatment, chemoprophylaxis, and institutional outbreak management: clinical practice guidelines of the Infectious Diseases Society of America*. Clin Infect Dis 2009;48:1003-32.
- [2] Thompson WW, Shay DK, Weintraub E, et al. *Influenza-associated hospitalizations in the United States*. JAMA 2004;292:1333-40.
- [3] Centers for Disease Control and Prevention (CDC). *Study Shows Flu Vaccination Prevents Hospitalizations in Older Adults*. Available at: <http://www.cdc.gov/flu/spotlights/flu-vaccination-older-adults.htm> Accessed 02/07/2015.
- [4] Thompson WW, Shay DK, Weintraub E, et al. *Mortality associated with influenza and respiratory syncytial virus in the United States*. JAMA 2003;289:179-86.
- [5] World Health Organization (WHO). *Influenza (Seasonal)*. Available at: <http://www.who.int/mediacentre/factsheets/fs211/en/> Accessed 02/07/2015.
- [6] Epicentro. *Influenza*. Available at: <http://www.epicentro.iss.it/problemi/influenza/influenza.asp> Accessed 02/07/2015.
- [7] Agenzia Italiana del Farmaco (AIFA). *Vaccino FLUAD*. L'AIFA fa il punto della situazione. Available at: <http://www.agenziafarmaco.gov.it/it/content/vaccino-fluad-laifa-fa-il-punto-della-situazione-0> Accessed 02/07/2015.
- [8] Nicholson KG. *Clinical features of influenza*. Semin Respir Infect. 1992;7:26-37.
- [9] European Centre for Disease Prevention and Control (ECDC). *Influenza cases definition*. Available at: <http://ecdc.europa.eu/>



- en/activities/surveillance/eisn/surveillance/pages/influenza\_case\_definitions.aspx Accessed 02/07/2015.
- [10] Ho YC, Wang JL, Wang JT, et al. *Prognostic factors for fatal adult influenza pneumonia*. J Infect 2009;58:439-45.
  - [11] Writing Committee of the WHO Consultation on Clinical Aspects of Pandemic [H1N1] 2009 Influenza. *Clinical aspects of pandemic 2009 influenza A [H1N1] virus infection*. N Engl J Med 2010;362:1708-19.
  - [12] Fiore AE, Fry A, Shay D, et al.; Centers for Disease Control and Prevention [CDC]. *Antiviral agents for the treatment and chemoprophylaxis of influenza - recommendations of the Advisory Committee on Immunization Practices [ACIP]*. MMWR Recomm Rep. 2011;60:1-24.
  - [13] McElhaney JE, Dutz JP. *Better influenza vaccines for older people: what will it take?* J Infect Dis 2008;198:632-4.
  - [14] Goodwin K, Viboud C, Simonsen L. *Antibody response to influenza vaccination in the elderly: a quantitative review*. Vaccine 2006;24:1159-69.
  - [15] Centers for Disease Control and Prevention (CDC). *Prevention and control of seasonal influenza with vaccines. Recommendations of the Advisory Committee on Immunization Practices - United States, 2013-2014*. MMWR Recomm Rep. 2013;62:1-43.
  - [16] Ministero della Salute. *Dipartimento della prevenzione e dell'innovazione. Prevenzione e controllo dell'Influenza: raccomandazioni per la stagione 2014/2015*. Available at: [http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?jsessionId=1uXoYPAYNa59k+MzXMCu6g\\_\\_sgc3-prd-sal?anno=0&codLeg=49871&parte=1%20&serie=](http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?jsessionId=1uXoYPAYNa59k+MzXMCu6g__sgc3-prd-sal?anno=0&codLeg=49871&parte=1%20&serie=) Accessed 02/07/2015.
  - [17] Agenzia Italiana del Farmaco (AIFA). *AIFA dispone il divieto di utilizzo per due lotti del vaccino antinfluenzale FLUAD*. Available at: <http://www.agenziafarmaco.gov.it/it/content/aifa-dispone-il-divieto-di-utilizzo-due-lotti-del-vaccino-antinfluenzale-fluad-0> Accessed 02/07/2015.
  - [18] Conferenza delle Regioni e delle Province autonome. *Vaccini: Regione Lazio, sospensione totale FLUAD*. Available at: <http://www.regioni.it/dalleregioni/2014/11/28/vaccini-regione-lazio-sospensione-totale-fluad-379080/> Accessed 02/07/2015.
  - [19] Regione Lazio. *Direzione regionale salute e integrazione socio sanitaria area politica del farmaco. Ritiro cautelativo vaccino antinfluenzale FLUAD*. Available at: [http://www.aslromab.it/campagna\\_promozione\\_salute\\_roma/docs/FLUR2014-2015/Nota\\_Prot\\_\\_n\\_\\_664796\\_28nov14.pdf](http://www.aslromab.it/campagna_promozione_salute_roma/docs/FLUR2014-2015/Nota_Prot__n__664796_28nov14.pdf) Accessed 02/07/2015.
  - [20] European Medicines Agency (EMA). *No evidence that FLUAD vaccine caused deaths in Italy*. Available at: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2014/12/news\\_detail\\_002228.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/12/news_detail_002228.jsp&mid=WC0b01ac058004d5c1) Accessed 02/07/2015.
  - [21] Agenzia Italiana del Farmaco (AIFA). *Vaccino FLUAD: negative le prime analisi ISS su lotti bloccati dall'AIFA*. Available at: <http://www.agenziafarmaco.gov.it/it/content/vaccino-fluad-negative-prime-analisi-iss-su-lotti-bloccati-dall%E2%80%99aifa> Accessed 02/07/2015.
  - [22] Istituto Superiore di Sanità (ISS). *Vaccino FLUAD: Favorevole esito finale analisi ISS. AIFA annuncia sblocco Lotti*. Available at: <http://www.iss.it/pres/?lang=1&id=1482&tipo=6> Accessed 02/07/2015.
  - [23] Regione Lazio. *Decreto del Commissario ad Acta. Prolungamento del periodo di svolgimento e disapplicazione della penalizzazione inerente la non utilizzazione dei vaccini da parte del medico partecipante*. Available at: [http://www.regione.lazio.it/binary/rl\\_sanita/tbl\\_normativa/DCA\\_U00042\\_03\\_02\\_2015\\_Campagna\\_di\\_vaccinazione\\_antinfluenza\\_Prolungamento\\_del\\_periodo\\_di\\_svolgimento.pdf](http://www.regione.lazio.it/binary/rl_sanita/tbl_normativa/DCA_U00042_03_02_2015_Campagna_di_vaccinazione_antinfluenza_Prolungamento_del_periodo_di_svolgimento.pdf) Accessed 02/07/2015.
  - [24] VaccinarSi. *Il valore di vaccinarsi*. Available at: <http://www.vaccinarsi.org/il-valore-di-vaccinarsi.html> Accessed 02/07/2015.
  - [25] Ministero della Salute. *Piano Nazionale Prevenzione Vaccinale 2012/2014*. Available at: [http://www.salute.gov.it/imgs/c\\_17\\_publicazioni\\_1721\\_allegato.pdf](http://www.salute.gov.it/imgs/c_17_publicazioni_1721_allegato.pdf) Accessed 02/07/2015.
  - [26] Ministero della Salute. *Vaccinazione antinfluenzale: coperture vaccinali*. Available at: [http://www.salute.gov.it/imgs/C\\_17\\_pagineAree\\_679\\_listaFile\\_itemName\\_6\\_file.pdf](http://www.salute.gov.it/imgs/C_17_pagineAree_679_listaFile_itemName_6_file.pdf) Accessed 02/07/2015.
  - [27] World Health Organization (WHO). *Global manual on surveillance of adverse events following immunization*. Available at: [http://www.who.int/vaccine\\_safety/publications/aefi\\_surveillance/en/](http://www.who.int/vaccine_safety/publications/aefi_surveillance/en/) Accessed 02/07/2015.
  - [28] Signorelli C, Odone A, Conversano M, et al. *Deaths after Fluad flu vaccine and the epidemic of panic in Italy*. BMJ 2015;350:h116.

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