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# **LITERATURE REVIEW OF THE DECISION MAKING DETERMINANTS RELATED TO THE INFLUENZA VACCINATION POLICY**

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## **ABSTRACT**

**Background:** Seasonal influenza concerns the worldwide population every year, whilst pandemic influenza is an unpredictable threat. Due to an important socioeconomic impact, mitigation measures must be specified. Governments elaborate vaccination policy based on scientific evidence. However, this process is, in general, not transparent.

**Objectives:** To study the decision-making process related to the influenza vaccination policy, identifying the actors involved, the decisions made and describing the information used by type and level of importance.

**Methods:** Six major databases were searched in seven languages, without time limit, using keywords related to influenza vaccination, decision-making and health policy. Titles and abstracts were screened according to three established criteria. Selected articles were analysed and compared against a checklist for context, stakeholders and evidence.

**Results:** 111 articles were retrieved since the 1990s, most of them (40%) were conducted in the USA. The decision-making process mainly concerned vaccination strategies (53%) and pandemic preparedness (28%). Stakeholders were identified at an institutional, production and consumer level. Evidence used by policy-makers was similar (e.g. logistics of vaccines), but the factors influencing were different (e.g. social conditions).

**Conclusion:** Considering the imminent risk of socio-economic disruption and media pressure, the pandemic threat needs to be integrated into an analysis of decision making processes regarding seasonal influenza vaccination.

**KEYWORDS:** decision-making, influenza vaccination, public health policy

**JEL CLASSIFICATION:** I18

## INTRODUCTION

In annual influenza epidemics, 5-15% of the world population is affected with acute respiratory infection. Most people with the illness recover quickly, but children, elderly and those with chronic medical conditions are at higher risk for complications and sometimes death (OECD, 2011). According to the World Health Organization (WHO) these annual epidemics result in 3-5 million cases of severe illness and 250-500 thousand deaths worldwide. In terms of costs of healthcare, lost days of work and education, and social disruption are between USD 1 million and USD 6 million per 100,000 inhabitants yearly in industrialized countries (WHO, 2009). In the case of influenza pandemic, this impact could be increased by a high order of magnitude (Chick et al., 2008).

Policy-makers at all levels are usually interested in the socioeconomic impact of influenza, in order to better allocate resources for strategies of prevention and control, such as vaccines (Jefferson and Demicheli, 1998). Although vaccines could be considered effective (Germann et al., 2006; Osterholm et al., 2012) and cost-effective (Nichol et al., 1994), their suboptimal allocations can be attributed to misaligned incentives of policy-makers (Chick et al., 2008). Nevertheless, there is a lack of studies evaluating the decision-making process regarding the supply chain of vaccines and vaccination strategies during seasonal or pandemic contexts. This situation leads to the main question of our research: which kind of evidence do policy-makers use when facing decisions concerning influenza?

The objective of this literature review is to emerge studies evaluating the decision-making process related to the influenza vaccination policy. The secondary objectives are to identify the actors involved and their role in the process, to describe the information used in decision making for vaccination policy, to group by type of information, to classify by level of importance, to describe the decisions made.

## **METHODS**

### **Search definitions**

Keywords were chosen based on the terms of the Medical Subject Heading (MeSH). They were combined according to the main objective of this literature review: study the decision making process of influenza vaccination policy:

- Influenza vaccines
- Vaccinations AND Influenza
- Decision support techniques OR decision making
- Policy OR public health OR public health administration OR health policy OR public policy OR Management

No limits of period or location delimitation were applied.

Main electronic databases were use:

- Web of Science (consists on seven multidisciplinary databases containing information gathered from scholarly journals, books, reports, conferences coverage in the sciences, social sciences, arts and humanities)
- Google Scholar (includes most peer-reviewed online journals of Europe and America's largest scholarly publishers, plus scholarly books and other non-peer reviewed journals)
- Pubmed (includes citations for biomedical articles from MEDLINE and life science journals)
- EconLit (contains abstracts of the international economic literature and related fields: economy, growth, development and technological change, demography, econometrics, finance and money, mathematical and quantitative methods, natural resources)
- Euronheed (network built on the foundations of two databases: 1-NHS EED: UK's National Health System Economic Evaluation Database and 2-CODECS: Connaissances et Décision en Économie de la Santé French database of Knowledge and Decision in Health Economics; it is also composed by other five European databases of economic evaluation: Germany, Italy, Netherlands, Nordic, Spain)
- Cochrane (collection of databases in medicine and other healthcare specialties; database of systematic reviews and meta-analyses, which summarize and interpret the results of medical research)

References without abstracts and which full text was written in other language different from English, French, Spanish, German, Italian and Portuguese were excluded.

Specific databases such as the Centers for Disease Control and Prevention's (CDC) reports or the World Health Organization (WHO) Bulletins were also searched.

### **Criteria for inclusion and exclusion**

The articles retrieved had titles and abstracts screening according to criteria of inclusion and exclusion established.

#### *Inclusion criteria*

- Presence of macro<sup>1</sup> level decision-making (at local, regional, national or international levels) regarding influenza vaccination programs (target groups, reimbursement...) and vaccines (formulation, stockpile, distribution, production, management...),
- Description of the actors involved in this decision,
- Description of the information used during the decision making process assessed.

#### *Exclusion criteria*

- Decisions made in meso or micro<sup>2</sup> levels only, such as in hospitals, clinics or medical offices (relation between physicians and patients),
- Assessments of the willingness of people (general population, health care professionals, parents of children...) to get vaccinated or to accept recommendations or requirements about getting vaccinated,
- Modeling studies concerning past vaccination strategies adopted, or proposition of new strategies (optimal vaccination strategies),
- Economic evaluations (cost-benefit, cost-effectiveness, cost-of-illness, economic burden...) about vaccine efficacy/effectiveness and vaccination rate.

### **Checklist for full text reading**

Articles selected to full text reading were checked according to the following list:

- What is the current context (influenza pandemic or seasonal, health system, politics, socio-demographic, economics)?
- Which decisions are under discussion (vaccination strategies and vaccines)?

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<sup>1</sup> From an organization perspective, the macro level refers to the actors and institutions within which the general organizational, regulatory frameworks and public health interventions of the broad health system are established and delivered, beyond national borders or not.

<sup>2</sup> From an organization perspective, the meso level refers to medium-sized units of service provision such as primary healthcare units or hospitals, and the micro level refers to interactions between individual patients and healthcare professionals.



- who are the stakeholders (agencies providing recommendations about vaccines formulation and vaccination practices, policy-makers, manufacturers, healthcare professionals, patients -associations of high risk groups, anti-vaccine leagues-)?
- Which information influence decision-making (clinical evidence, burden of disease and epidemiological studies, economic evaluations)?
- Is there other factors influencing in decisions (experts opinions, pressure of groups target for vaccination, the media)?
- What is the relation between different stakeholders?
- What is decided?

Aiming to facilitate the analysis we classified each of the points highlighted in the checklist. This classification is based in the common characteristics of stakeholders and the impact of the information in the decision made.

## **RESULTS**

### **Articles inclusion**

Electronic databases search retrieved 4743 references. Based on the titles and abstracts, we excluded: 465 articles that did not have an abstract, 348 repeat texts and 3588 that did not meet the inclusion criteria. 342 articles were selected for full text reading. After a detailed reading of those, 231 (68%) were excluded because they actually didn't match the inclusion criteria. Finally, we consider for analysis 111 articles (Annex 1).

Most of the articles excluded concerned local decision-making process (meso/micro level). They were mainly related to the personal choice of being vaccinated, especially target people such as children, elderly, immunosuppressed, patients with chronic diseases and healthcare professionals. Other articles excluded concerned decisions related to the influenza vaccines: composition, virus strains selection (virology and immunology assays), vaccine efficacy/effectiveness (randomized clinical trial, economic evaluations and modeling), adverse events of vaccines and vaccination rates. Decisions regarding solely antivirals policy were also excluded.

## **Period of publication**

Publication of articles ranged from year 1994 to 2012. Peaks of publication happened in the years with a remarkable event, such as a pandemic, vaccine disruption and ethical issues. Fifty seven percent (n=63) of the articles included were published in the last three years (from 2009 to 2012). The possible reason is the pandemic human influenza (H1N1pdm09) happened in the year of 2009. Twenty five percent (n=28) of the articles were published in 2005 and 2006. In this case, a shortage of vaccine supply in 2005 seasonal influenza in the US was in the spotlights together with ethical issues of equitable access, distribution and allocation of existing vaccine resources. Four publications related to epizootic pandemic influenza H5N1 of 2003 were included from 2003 and 2004

## **Location**

The United States was the most common local chosen by authors in local, state or federal levels<sup>3</sup> (n=44, 40%). The comparison between vaccination policies in the US and European countries, Canada, or Latin America was the object of other 7 studies.

Eight studies conducted in Canada mostly evaluated pandemic preparedness plan and compared national influenza vaccine strategies to other countries around the world.

Twenty six percent of the studies (n=29) did not focus on a particular location for the analysis, but made a global comparison about vaccination policies and pandemic preparedness plan. European countries (France, Germany, Italy, Israel, Netherlands) were selected for twelve studies and one comparison with Canada and US.

Representing the east side of the globe, Australia (n=7), India (n=2) and Hong Kong (n=1) evaluated their vaccination strategy and pandemic preparedness plan. Table 1 details the location where the studies were conducted.

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<sup>3</sup> The US government is responsible for the buying and distribution of influenza vaccines in the US. This work is largely carried out by the Centers for Disease Control and Prevention. As a result, there are many US publications in the public domain regarding this issue which appear every year. For example, the CDC gives a regular update on vaccine supplies each winter. However, this is not comparable to other countries where other procedures are at work and supply is often left more to the private market.

*Table 1: Location where studies were conducted*

Location	Decisions made	Nb of studies	#
Australia	Vaccine prioritization, purchasing Pandemic preparedness plan	7	25, 26, 37, 48, 78, 85, 132
Canada	Vaccine production, prioritization, purchasing Pandemic preparedness plan	6	11, 69, 97, 102, 108, 125
Canada and others (Australia, France, Mexico, Sweden, US, UK)	Vaccination strategy Pandemic preparedness plan	2	41, 131
China/ Hong Kong	Pandemic preparedness plan	1	70
EU	Vaccine virus selection, prioritization Vaccination strategy Pandemic preparedness plan	8	2, 31, 34, 59, 74, 100, 117
EU, Canada, US	Vaccine production, prioritization, distribution	1	33
France	Vaccination strategy	1	38
Germany	Pandemic preparedness plan	1	115
India	Pandemic preparedness plan	2	42, 66
Israel	Vaccine purchasing	1	14
Italy	Vaccine prioritization	1	23
Netherlands	Pandemic preparedness plan	1	109
USA	Vaccine virus selection, development, production, prioritization, purchasing, supply Vaccination strategy Pandemic preparedness plan	51	1, 8, 12, 15, 16, 18, 19, 20, 22, 30, 36, 39, 45, 46, 47, 49, 50, 51, 52, 55, 57, 58, 61, 63, 67, 68, 72, 73, 76, 77, 80, 82, 83, 84, 86, 87, 88, 89, 91, 98, 99, 113, 114, 121
USA and others (Canada, EU, UK, Latin America)	Vaccination strategy Pandemic preparedness plan	7	93, 103, 54, 101, 44, 104, 124
Global (no country specified)	Vaccine virus selection, development, production, prioritization, purchasing, supply Pandemic preparedness plan	29	9, 90, 92, 94, 110, 119, 3, 4, 5, 6, 7, 10, 13, 17, 24, 28, 29, 32, 53, 56, 60, 62, 64, 71, 75, 81, 96, 105, 107

## Current context

In order to classify the articles found, we use the assumptions driven by the virus-centric thinking which leads to dichotomizing influenza into “pandemic” and “seasonal”, according to the genetic mutations of the flu virus (Doshi, 2011). On this basis, we found that 81 articles were related to pandemic and 24 to seasonal flu. Some articles (n=6) discussed how seasonal influenza surveillance systems could be used in pandemic situations, giving emphasis on both seasonal and pandemic contexts. Half of the 111 articles included, target the preparedness plan for influenza pandemic, before, during and after the occurrence of a pandemic. Ancient and recent pandemics (1918, 1957, 1968, 2009) are taken as examples of what has been learned and what was improved meanwhile.

## **Stakeholders**

The noun “stakeholder” receives different definitions according to the environment in where it is used. In our research, we adopted the business concept retrieved at the Collins Dictionary online (Collins, 2012) which defines stakeholder as: “a person, group, organization, member or system that affects or can be affected by a project or event”.

Stakeholder can also be used as an adjective that matches with our study: “of or relating to policies intended to allow people to participate in and benefit from decisions made by enterprises which they have a stake”. Stakeholders, related to influenza vaccination policy, who participate in and benefit from decisions made by health organizations which they have a stake were identified and classified in the following groups:

- Institutional level:
  - International organizations: WHO, World Bank,  
Regional departments: EuroWHO, Pan American Health Organization (PAHO), (European Center for Disease Prevention and Control (ECDC),
  - National institutes: Advisory Committee on Immunization Practices (ACIP), Food and Drug Administration (FDA), CDC, Australian Health Protection Committee (AHCPR),
  - Governments (Ministry of Health, Health department),  
National/federal, Province/state/territory, local,
- Production level (market forces):
  - Manufacturers of vaccines,
  - Healthcare providers: insurance companies, clinics, hospitals,
  - Healthcare workers, professionals: nurses, pharmacists, physicians,
- Consumers level:
  - General public.

## **Information influencing decisions and other factors of impact**

Main information and factors influencing decisions were identified in the articles selected. Fourteen categories were established and ranked in Table 2 according to its impact on the decision.

*Table 2: Main information and factors influencing the decision making process regarding influenza vaccination policy*

<b>Main information, number of articles related</b>	<b>Information detailed</b>	<b>#</b>
Logistics of vaccines n=46	Virus selection/composition Development Production/manufacturing Industrial capacity Prioritization/rationing Purchase/order/demand Distribution/supply/allocation Delivery Social acceptance Recommendation Mandatory Mass campaign Programmatic administration	2, 4, 6, 8, 9, 10, 11, 13, 14, 16, 17, 20, 30, 33, 38, 39, 45, 50, 51, 53, 57, 58, 62, 63, 64, 68, 71, 72, 73, 74, 76, 77, 81, 83, 89, 91, 94, 97, 98, 103, 105, 107, 108, 114, 115, 125
Influenza surveillance data n=41	Flu activity Transmissibility Geographic distribution Time course of <u>pandemic</u>	6, 7, 8, 11, 13, 17, 20, 22, 23, 24, 26, 29, 32, 36, 37, 44, 51, 55, 56, 63, 66, 70, 71, 72, 73, 76, 82, 83, 84, 86, 90, 93, 97, 98, 107, 109, 113, 114, 115, 119, 126
Vaccines scientific studies n=37	Randomized clinical trials: vaccine efficacy effectiveness safety clinical evidence, scientific, observational studies immunization	1, 4, 11, 13, 14, 28, 30, 31, 32, 33, 34, 36, 37, 38, 44, 45, 46, 53, 56, 58, 59, 61, 67, 69, 73, 75, 78, 81, 85, 86, 93, 99, 100, 101, 102, 104, 105
Local status, social conditions n=26	Logistics for pandemic response Education Politics (political willingness) Economy Media Transparency	18, 28, 39, 41, 42, 44, 45, 50, 53, 54, 61, 80, 85, 87, 88, 89, 90, 91, 97, 99, 107, 113, 115, 117, 121, 125
Epidemiology n=25	Morbidity Mortality Severity	3, 8, 10, 11, 13, 15, 18, 23, 24, 30, 33, 36, 41, 49, 54, 56, 71, 73, 74, 81, 84, 92, 109, 115, 132
Ethics n=24	Professional judgments Cultural requirements Willingness to be vaccinated Legal/juridical approaches Philosophy grounds	5, 11, 16, 19, 42, 46, 48, 51, 58, 67, 69, 70, 76, 78, 81, 87, 89, 92, 93, 99, 101, 102, 103, 121
Guidelines n=24	Reviews, reports, records, publications, website docs Protocols, checklist Recommendation	3, 19, 25, 26, 30, 31, 34, 41, 47, 50, 54, 55, 58, 66, 68, 75, 85, 97, 102, 110, 111, 112, 124, 131
Virological diagnosis n=19	Serological Antigenic strains Laboratory capacity	6, 13, 23, 28, 29, 38, 44, 53, 57, 64, 66, 71, 93, 96, 100, 104, 114, 119, 126

Main information, number of articles related	Information detailed	#
Financial resources n=18	Funding Budget	10, 14, 25, 29, 49, 51, 62, 64, 74, 77, 97, 98, 100, 101, 102, 104, 114, 119
Registries n=16	Past pandemic information History Lessons learned	8, 11, 12, 13, 15, 26, 60, 62, 63, 68, 86, 93, 99, 108, 110, 132
Models n=14	Mathematical Decision policy analysis	6, 7, 11, 12, 15, 16, 20, 24, 38, 51, 52, 96, 108, 109
Experts advices n=13	Advisory groups Scientific committees	2, 5, 14, 30, 47, 55, 58, 60, 61, 77, 99, 109, 121
Economic studies n=13	Burden of influenza Cost-benefit analysis Cost-effectiveness analysis Risk analysis Uncertainty	9, 11, 15, 33, 54, 59, 81, 93, 100, 105, 109, 117, 121
Demographics n=5	Population size and age	19, 68, 91, 108, 125

## Decisions made

Two main categories of decisions were established: (1) vaccination strategy and (2) pandemic preparedness plan. Vaccination strategy is analyzed in both pandemic and seasonal contexts. Although vaccination strategy can be part of a pandemic preparedness plan, it is here analyzed separately (Annex 2).

### 1) Vaccine strategy (n=70, 53%)<sup>4</sup>

the steps of a vaccination strategy do not depend on the context (pandemic or seasonal), and it corresponds to the pharmaceutical cycle of the vaccine, from its conception, through logistics of distribution until consumption. Decisions are specific to each stage of this cycle and regards the main choices described below:

#### a) Virus selection, composition or formulation of the vaccine:

*influenza strains to include, trivalent vs. quadrivalent, pandemic...*

#### b) Development of the biological product (requires R&D<sup>5</sup>)

*use of adjuvants, eggs vs. cell culture, age restrictions...*

<sup>4</sup> See annex 2.

<sup>5</sup> The term R&D or research and development refers to a specific group responsible for develop new products;

- c) Production, manufacturing (requires approval by regulatory institutes)  
*quantity to produce, consider reimbursement*
- d) Purchase, ordering  
*amount to purchase, prioritization of groups target (age, medical condition...),  
allocation of resources, mandatory vaccination (healthcare workers, military...)*
- e) Distribution from manufacturer to the purchaser or from centralized to decentralized levels  
*logistics of delivery, transportation of thermosensitive biologicals*
- f) Vaccine intake  
*incitation for vaccination (universal free vaccine, reimbursement, mandate),  
allocation of healthcare expenditures.*

This final step will not be analyzed once it concerns a lower level of decision (patient level, social acceptance of getting vaccines), and we are interested in higher levels (policy level).

## 2) Pandemic Preparedness Plan (n=37, 28%)<sup>6</sup>

Generally, when policy makers elaborate an influenza pandemic preparedness plan, a vaccination strategy is included as one of the measures for containing pandemic virus spread. Other measures for control are also included in the plan, such as social distance and isolation (closing schools, quarantine), disinfection, antivirals promotion. Although these measures are usually adopted together with a vaccination strategy, we are only focusing on the latter. The most important difference between vaccination strategies during seasonal or pandemic context is the situation of risk faced by policy makers. Concepts of uncertainty, risk management and emergency actions are usually adopted.

Information used in decisions made in the contexts of seasonal or pandemic influenza is similar, but the factors influencing were very different. A routine situation of annual influenza policy in the case of a seasonal flu becomes an uncertainty context of risk management when a pandemic is declared.

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<sup>6</sup> See annex 2.

## DISCUSSION

This literature review identified the contexts where influenza policy is done and the information used. Most of the publications referred to decisions made in the context of pandemic influenza, due to the imminent risk of socio-economic disruption and media pressure. The other articles analyze if measures adopted for seasonal influenza can be used in case of pandemic. Main factors influencing or information used when elaborating plans for control measures against influenza seasonal or pandemic are described below.

### *Population target for vaccination*

The first issue to be considered when planning for a seasonal or pandemic influenza is the target population for vaccination. This is based on assumptions of the group that might get most benefit from vaccination. Studies assessing vaccine effectiveness, economic evaluations, type of influenza epidemiology (morbi-mortality) and data about vaccination rates are useful to justify choices made (Lee et al., 2012; Lipsitch et al., 2011).

### *Vaccines formulation and production*

WHO recommends annually the virus composition of seasonal influenza vaccine for both northern and southern hemispheres. These recommendations are based on surveillance data from sentinel influenza networks worldwide and antigenic virological information provided during the whole year by the National Influenza Centres responsible for virus identification, subtyping and characterization. For pandemic vaccines, once the virus is isolated, recommendations about the antigenic characteristics are provided. Manufacturers have then some months before the winter season, where influenza is epidemic, to make available a sufficient amount of vaccines for supplying the world demand. Commercial interest associated with studies of vaccine effectiveness in different age groups and antigenic match (between the circulating virus and the current vaccine composition) encourage manufacturers to promote new types of vaccines. These vaccines can present different formulations from the ones recommended by WHO, target a specific age group, or can be available by nasal administration, for instance (Kamradt-Scott, 2012; Yaesoubi and Cohen, 2011).

### *Communication*

Communication between stakeholders involved in the decision making process was seen to be very important for the success of the vaccination policy. Collaboration between different levels of governance (federal, state/regional, local), health institutes, experts and



manufacturers enable robustness of information produced and evidence used in the policy. Transparency when involving health care professionals and patients in the process of policy elaboration is essential to guarantee compliance. The media should be seen as an alliance, so information given must also be transparent and retrieved from confident sources (Gazmararian et al., 2006; Ringel et al., 2009).

### *Ethics*

Policy implementation is certainly enhanced when decision makers are perceived to act in a responsible and ethical manner. Healthcare professionals have rights and obligations that must be taken into account, but during a pandemic the individual rights are questionable in the benefit of the society. This polemic statement is discussed in some of the articles included, and contradictory opinions are given (Dupras and Williams-Jones, 2012; Monto et al., 2011).

### *Implications*

This literature review did not retrieve any publication conducted in France that evaluated the decision process regarding influenza policy with policy makers involved. Few studies conducted in the US and Canada reported findings obtained after surveys or workshops promoted with the objective of improving the seasonal influenza plan and the preparedness plan for pandemic influenza. According to these studies, feedbacks of the workshops were positive and changes were successfully approved and adopted by local vaccination policies. However, studies surveying patients and healthcare professional against vaccination were not found (Doxtator et al., 2004; Neudorf et al., 2003; Oxford et al., 2005; Stroud et al., 2011).

## **CONCLUSION**

Articles included in this literature review were retrieved since the 1990s until 2012. Most of them were conducted in the North America (59%) and Europe (11%). Stakeholders were identified as institutional, production and consumers levels. Decisions were made in both seasonal and pandemic context regarding several levels of the vaccine lifecycle chain. Each step of this chain required specific decisions, which were based on similar evidence in different countries. However, no standard process among locations was observed. External factors, such as the health system, economic context and the resources allocated influenced on the decision making process.

Further studies based on this literature review will consist on the elaboration of questionnaires and a semi-structured interview. These could be applied to the stakeholders involved in the vaccination policy here identified, for example by comparing different locations or levels of decisions, and groups pro and against vaccination. Evidences and information used may be stated to the respondents, for verifying the existence of standard procedures or justifying such a position regarding vaccination. Local peculiarities of French health system, the political and economic context and in case of a pandemic or not must be taken into account. After validation and data collection in France a second phase is planned.

Questionnaires and the interview could be adapted to stakeholders located in the Netherlands. Local details would be considered. Data collected in France would be compared with Dutch data. Vaccination policies and the opinions of different stakeholders within and between countries would be analyzed. Future findings could be used as another source of information for changes and improvement of the existing vaccination policy in both countries.

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### Annex 1 – List of articles included by date of publication

#	Authors	Period of publica-ion	Country	Context
1	Phillips	2012	USA	seasonal flu
2	Mereckiene	2012	EU	pandemic flu
3	Lee	2012	not specified	pandemic flu
4	Kamradt-Scott	2012	not specified	pandemic flu
5	Dupras	2012	not specified	pandemic flu
6	Ampofo	2012	not specified	seasonal flu
7	Yaesoubi	2011	not specified	pandemic flu
8	Stroud	2011	USA	pandemic flu
9	Ng	2011	many in the world	both
10	Monto	2011	not specified	pandemic flu
11	Moghadas	2011	Canada	pandemic flu
12	Maciejewski	2011	USA	pandemic flu
13	Lipsitch	2011	not specified	pandemic flu
14	Levine	2011	Israel	pandemic flu
15	Lee	2011	USA	pandemic flu
16	Lee	2011	USA	pandemic flu
17	Kamradt-Scott	2011	not specified	pandemic flu
18	Hollingsworth	2011	USA	pandemic flu
19	French	2011	USA	pandemic flu
20	Chao	2011	USA	pandemic flu
22	Burke	2011	USA	pandemic flu
23	Ajelli	2011	Italy	pandemic flu
24	Abellin	2011	not specified	pandemic flu
131	Lam	2011	Canada and others (Australia, Mexico, US, UK)	pandemic flu
132	Kelly	2011	Australia	pandemic flu
25	Weeramantheri	2010	Australia	pandemic flu
26	Spokes	2010	Australia	pandemic flu
28	Rosner	2010	not specified	seasonal flu
29	Richard	2010	not specified	seasonal flu
30	Rambhia	2010	USA	pandemic flu
31	Nicoll	2010	EU	pandemic flu
32	Morens	2010	not specified	pandemic flu
33	Monto	2010	EU, Canada, USA	seasonal flu
34	Mereckiene	2010	EU	seasonal flu
36	Lee	2010	USA	pandemic flu
37	Leask	2010	Australia	seasonal flu
38	Labro	2010	France	both
39	Kuehnert	2010	USA	pandemic flu
41	Kendal	2010	Canada and others (Australia, England, France, Sweden, US)	pandemic flu
42	Kakkar	2010	India	pandemic flu
44	Dehner	2010	USA, Europe	pandemic flu
45	Cho	2010	USA	seasonal flu
46	Bernstein	2010	USA	seasonal flu
47	Berman	2010	USA	seasonal flu
48	Bennett	2010	Australia	pandemic flu
49	Alenzi	2010	USA	pandemic flu
50	Zigmond	2009	USA	pandemic flu
51	Schwartz	2009	USA	pandemic flu
52	Savoia	2009	USA	pandemic flu
53	Sahni	2009	not specified	pandemic flu

#	Authors	Period of publica-ion	Country	Context
54	Ropero-Alvarez	2009	USA, Canada and Latin America	seasonal flu
55	Ringel	2009	USA	both
56	O'Neil	2009	not specified	pandemic flu
57	Mazanec	2009	USA	pandemic flu
58	Kinlaw	2009	USA	pandemic flu
59	Johansen	2009	EU	pandemic flu
60	Hollenbeck	2009	not specified	pandemic flu
61	Gallaher	2009	USA	pandemic flu
62	Friede	2009	not specified	pandemic flu
63	French	2009	USA	pandemic flu
64	Flyborg	2009	not specified	pandemic flu
66	Chawla	2009	India	pandemic flu
67	Barnett	2009	USA	pandemic flu
68	Orenstein	2008	USA	both
69	Mah	2008	Canada	seasonal flu
70	Lam	2008	China	pandemic flu
71	Jennings	2008	not specified	pandemic flu
72	Gotham	2008	USA	pandemic flu
73	Fineberg	2008	USA	pandemic flu
74	Esposito	2008	EU	seasonal flu
75	Dutta	2008	not specified	pandemic flu
76	Wynia	2006	USA	pandemic flu
77	Whitley	2006	USA	pandemic flu
78	Torda	2006	Australia	pandemic flu
80	Sencer	2006	USA	pandemic flu
81	Schuklenk	2006	not specified	pandemic flu
82	Roddy	2006	USA	seasonal flu
83	Ransom	2006	USA	pandemic flu
84	Lewis	2006	USA	pandemic flu
85	Letts	2006	Australia	pandemic flu
86	Krause	2006	USA	pandemic flu
87	Kayman	2006	USA	pandemic flu
88	Iton	2006	USA	both
89	Hodge	2006	USA	pandemic flu
90	Gronvall	2006	many in the world	pandemic flu
91	Gazmararian	2006	USA	seasonal flu
92	Garcia-Garcia	2006	many in the world	both
93	Ferguson	2006	USA UK	pandemic flu
94	Fedson	2006	many in the world	seasonal flu
96	Wu	2006	not specified	seasonal flu
97	Tam	2005	Canada	pandemic flu
98	Seiguer	2005	USA	seasonal flu
99	Schoch-Spana	2005	USA	seasonal flu
100	Oxford	2005	EU, others	pandemic flu
101	Kotalik	2005	USA, Canada, UK	pandemic flu
102	Kort	2005	Canada	pandemic flu
103	Hadler	2005	USA, Canada	pandemic flu
104	Fedson	2005	USA, Europe	pandemic flu
105	Daems	2005	not specified	pandemic flu
107	Gostin	2004	not specified	pandemic flu
108	Doxtator	2004	Canada	pandemic flu
109	Van Genugten	2003	Netherlands	pandemic flu
110	Van Essen	2003	many in the world	seasonal flu
113	Strikas	2002	USA	pandemic flu
114	Gensheimer	2002	USA	pandemic flu
115	Fock	2002	Germany	pandemic flu
117	McDaid	2001	EU	seasonal flu
119	Wunderli	1997	many in the world	seasonal flu
121	Hinman	1997	USA	seasonal flu
124	Nicholson	1995	USA, Europe	seasonal flu
125	Tamblyn	1994	Canada	pandemic flu

## Annex 2 – Categories of decisions established, main actors and information used

Decision	Actors	Current Context	Information influencing	Other factors influencing decisions	#
VACCINE STRATEGY  Vaccine virus selection and composition (adjuvants...)	WHO, GIRS, manufacturers, health authorities, virological labs, veterinarian	Seasonal	-antigenic history of strains, frequency and type -pathogenicity of variants -serological studies	-virus sharing between countries -influenza surveillance	6, 96, 45, 119, 29
=	=	Pandemic	-antigenic characteristics of pandemic virus	-logistics -financial	64, 59
VACCINE STRATEGY  Vaccine development	Health authorities, manufacturers, EMEA, FDA	Seasonal	x *  *no “seasonal” articles regarding vaccine development	x	x
=	=	Pandemic	-influenza activity -severity -virological information -economic studies	-influenza surveillance - logistics - regulatory agencies approval -financial	22, 17, 64, 56, 83, 105, 90, 15, 104
VACCINE STRATEGY  Vaccine production manufacturing	CDC, manufacturers, health authorities	Seasonal	-vaccine clinical studies -demographics	-logistics - authorities recommendations	45, 39, 33
=	=	Pandemic	-standard operating procedures -batch process records	-historical records -influenza surveillance -financial -skilled personnel -timeline of pandemics -validation procedures	62, 68-both, 90, 86, 105, 125

Decision	Actors	Current Context	Information influencing	Other factors influencing decisions	#
VACCINE STRATEGY  Vaccine prioritization, rationing (definition of priority groups) Mandatory vaccination (HCW)	ECDC, EMA, WHO, HSC, MS, healthcare providers	Seasonal	-epidemiology data -vaccine clinical studies -ethics, philosophy and cultural grounds	-logistics -economic studies -political willingness -local status (public and stakeholders opinion)	1, 33, 117, 46, 37, 69, 9-both, 99, 124
=	=	Pandemic	-epidemiology data -vaccine clinical studies -models -ethics, law, jurisdictions -severity -demographics of pandemics -virological data	-logistics -influenza surveillance -authorities recommendations -experts -financial -local status (public and stakeholders opinion) -skilled personnel	3, 4, 51, 71, 89, 102, 114, 125, 53, 87, 23, 76
VACCINE STRATEGY  Vaccine purchasing, ordering	WHO, SAGE, health authorities, manufacturers,	Seasonal	-demographics -history of previous years demand	-authorities recommendations	82, 68 -both
=	=	Pandemic	-prescription pad orders -severity -epidemiology -economic studies -vaccine clinical studies -ethics, law -demographics	-influenza surveillance -local status (public and stakeholders opinion) -experts -regulatory approval -financial -timeline of pandemics -guidelines	72, 14, 11, 10, 25, 74, 89, 125
VACCINE STRATEGY  Vaccine distribution, supply, allocation	WHO, health authorities, manufacturers, healthcare providers	Seasonal	-historical records of purchase -logistics -epidemiology -vaccine clinical studies	-local status (public and stakeholders opinion) -financial -economic studies	45, 98, 33, 94

<b>Decision</b>	<b>Actors</b>	<b>Current Context</b>	<b>Information influencing</b>	<b>Other factors influencing decisions</b>	<b>#</b>
=	=	Pandemic	-vaccine clinical studies -epidemiology -models -ethics, law (willingness to be vaccinated)	-influenza surveillance -logistics -economic studies -historical records -authorities recommendations -local status (public and stakeholders opinion) -guidelines	15, 16, 24, 51, 83, 100, 89, 87, 83, 105, 103, 100, 18
VACCINE STRATEGY  Vaccination policy implementation or management	WHO, ECDC, health authorities, healthcare providers, virological labs, veterinarian	Seasonal	-vaccine clinical studies	-epidemiology -economic studies -logistics	33, 47, 38-both, 34, 54, 110, 28, 88, 91, 121
= (mass vaccination campaign)	=	Pandemic	-vaccine clinical studies -influenza surveillance -severity	-epidemiology -historical records -experts -local status (public and stakeholders opinion) -financial -models	2, 8, 22, 32, 86, 51, 44, 41, 36, 30, 73, 15, 80, 97
Pandemic Preparedness Plan		Pandemic			5, 7, 12, 13, 19, 20, 26, 31, 42, 48, 49, 50, 52, 55, 57, 58, 60, 61, 63, 66, 67, 70, 75, 77, 78, 81, 84, 85, 92, 93, 101, 107, 108, 109, 113, 115, 131, 132