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Influenza vaccination policy-making processes in France and The Netherlands: Framework and determinants

MARIA LAURA SILVA^{A, B, C, ,}, LIONEL PERRIER^{A, C, D,}, JOHN W. PAGET^{E,}, ANNE MOSNIER^{F,}, VALÉRIE BUTHION^{A, G,}, JEAN MARIE COHEN^{F,}, HANS MARTIN SPÄTH^{A, H}

^a University of Lyon, Lyon, France

^b University of Bordeaux; Research Center Bordeaux Population Health U1219 Inserm, Bordeaux, France

^c University Lumière Lyon 2; CNRS, GATELSEUMR 5824, Ecully, France

^d Direction of Clinical Research and Innovation, DRCI, Léon Bérard Cancer Centre, Lyon, France

^e Netherlands Institute For Health Services Research (NIVEL), Utrecht, The Netherlands

^f Open Rome, Paris, France

^g University Lumière Lyon 2 COACTIS, EA 4161, Lyon, France

^h University Claude Bernard Lyon 1, EAM 4128, Lyon, France

ABSTRACT

Objectives: Target groups for seasonal influenza vaccination are nationally defined based on several factors. However, few studies have explored the policy-making processes at the country-level. We investigated key differences in the policy-making process for the development of vaccination recommendations between France (FR) and The Netherlands (NL). This paper presents preliminary results on the evidence used in the decision-making process and focuses on the interactions between the experts and stakeholders.

Methods: A documentary analysis identified the stakeholders of this process as governmental authorities, research institutions, associations, and manufacturers. This qualitative study included at least one expert from each stakeholder group. Thirty-three semi-structured interviews were performed in 2013 (16 FR, 17 NL). We used NVivo10® to perform a thematic content analysis on the data.

Results: National Immunization Technical Advisory Groups (NITAGs) were the key stakeholders in the development of recommendations. There was no systematic standard evaluation of evidence during the decision-making process in both countries. Likewise, voting was not systematic, although it did occur more often in FR. A declaration of interests was obligatory in both countries. Experts with no conflicts of interest were rare because many depend on private funding for their research on influenza vaccination.

Conclusions: The transparency of the NITAGs' procedures for the development of recommendations should be improved. We believe improvements might be achieved by the systematic standard evaluation of evidence, consistent voting, clear declarations of interest, and increased public funding for vaccination research.

1. BACKGROUND

A previous literature review of seasonal influenza vaccination identified three components of the policy-making process [1]: the decision-making process for vaccination recommendations, the implementation of these recommendations, and the funding of the vaccination. The recommendations for influenza vaccination mainly comprise indication of the target groups for free influenza vaccines, type of vaccines to use, and method of their administration. This component of the policy-making process is the principal interest of this paper because the vaccination recommendations serve as the basis for the development of the other components of the process (implementation and funding) [1].

In several countries, the development of recommendations is performed by independent advisory bodies, called National Immunization Technical Advisory Groups (NITAGs) [2], [3] and [4]. The NITAGs often use a systematic and transparent approach for increasing the quality and credibility of their advice, with the goal of contributing to its greater acceptance and broader implementation [5] and [6]. When developing vaccination recommendations, the NITAGs often refer to the international recommendations of the WHO and advice of supranational organisations, such as the ECDC (European Centre for Disease Prevention and Control) [7] and [8]. The ECDC website provides public access to vaccination policies, which can be compared between countries [9]. However, little is known about how NITAGs develop their national recommendations [1] and [10].

The complex interactions between the experts from the NITAGs and stakeholders involved in different levels of the policy-making process (e.g. international level: vaccine recommendations; national level: implementation and funding for influenza vaccinations) have been identified as one of the determinants for the development of national recommendations [8]. However, to the best of our knowledge, the precise interactions between the experts and stakeholders and how they influence recommendations have not been investigated. For this type of analysis, qualitative methods could elucidate both the layperson's and professional's beliefs and explore their thoughts on this subject [11] and [12].

Only a few studies have investigated the seasonal, instead of pandemic, development of influenza recommendations outside of the United States [11], [13], [14] and [15]. France (FR) and The Netherlands (NL) are two countries within the European Union and WHO member states that have high seasonal influenza vaccination coverage rates (72% NL, 52% FR for elderly people ≥ 65 years during the 2013–2014 season) [16] and [17]. Although their target groups for vaccination resemble other WHO member states, there are differences. For example, recommendations regarding pregnant women (FR = yes, NL = no) and the cut-off age for vaccination of the elderly (FR ≥ 65 years, NL ≥ 60 years) differ between the two countries [18] and [19]. We are interested in these countries because of their cultural differences, which could impact the development of recommendations and

interactions between the experts and stakeholders [20], [21] and [22]. In addition, we have collaborations with French and Dutch research teams (see co-author affiliations).

We conducted a qualitative study in FR and NL to compare the key differences in the policy-making process of influenza vaccination. The objective of this project was: (1) to propose a representation of the structure underlying the process, (2) to identify the interactions between the experts and stakeholders, and (3) to investigate the determinants for the development of vaccination recommendations. This paper focuses on the interactions between the experts from NITAGs and stakeholders of the national process and presents preliminary results on the use of evidence in policy-making processes.

2. METHODS

Two complementary techniques for data collection were used: (1) documentary analysis of the procedures, experts, and institutions (stakeholders) and (2) semi-structured interviews to refine the data collected and provide in-depth investigation of the interactions among the experts and stakeholders. Each technique is described below.

2.1. Documentary analysis

The documentary analysis identified the stakeholders engaged in influenza policies in FR and NL, their position in their respective national health systems, and the experts directly and indirectly involved in the formulation of vaccination recommendations. We used a wide electronic search engine (Google[®]) and entered keywords in English, French, and Dutch to search for hits regarding the health systems, influenza vaccination policies, and stakeholders. The search was limited to the last 10 years because policy procedures are constantly evolving, and older documents are probably obsolete. All stakeholder websites that were involved in policy processes were retained. The identified websites were carefully searched using the search strategy presented in Box 1 (additional online material). The documents were screened by two independent researchers based on their titles and abstracts. Documents were included in the study if they provided a description of: the flow of policy decisions, actors participating in counselling committees and advisory boards, and stakeholders supporting the process of vaccination recommendations.

[BOX 1]

2.2. Interviews

Based on the documentary analysis, we placed the stakeholders into four groups: governmental authorities, research institutions, associations, and manufacturers. For each stakeholder (institution/organisation), we identified the experts that were directly or indirectly involved in the development of vaccination recommendations (Table 1). At least one expert from each stakeholder group was approached for an anonymous interview, independent of their background and current job status. An invitation letter was sent by email or post; after two weeks, we phoned those who did not respond to the first invitation. If a face-to-face interview was not possible, we proposed a telephone interview. Some interviews were conducted with two or three people at the same time.

[TABLE 1]

Based on a previous review [1], we developed a unique guide for the semi-structured interviews. It was composed in French and then translated into English; most of the Dutch experts were comfortable with an interview conducted in English. The guide focused on collecting the interviewees' perceptions about policy formulation and the transparency of the process, as well as the interactions between the experts directly and indirectly involved (Annexe 1). Both French and English guides were validated using pilot interviews with influenza experts in both countries. All three pilot interviews (two FR, one NL) were included in the analysis because they provided similar and relevant data; only minor modifications were made to the guide following these interviews.

One interviewer (MLS) conducted the 33 interviews (28 face-to-face and five telephone) in 2013: 16 in FR during the summer and 17 in NL during the autumn (Table 1). Each interview (mean length 59 min) was audio recorded, under oral consent of the interviewee, and then transcribed.

The transcripts were analysed using thematic content analysis, where common themes are identified and grouped into codes. The codes constitute the unit of analysis and are derived from recurring patterns of speech and vocabulary [23]. A first coding scheme was manually developed through identifying verbatim in each transcript the answers that were relevant to the study questions. Transcripts were then coded with the same coding scheme using NVivo10[®]; when new ideas appeared, supplementary free codes were created. Points of difference between the first and second coding were solved by comparing the manual and electronic coding, and a final set of themes was developed. Finally, verbatim codings within all relevant themes were compared and analysed to identify the overall findings, as well as any differences in the interview responses across countries.

2.3. Combining the data from the documents and interviews

Combining the documents retrieved and the interview findings, we analysed the relationships between the experts inside the NITAGs and other stakeholders involved in the policy-making process for influenza vaccination recommendations in FR and NL. Schematic representations of the components of this process (development of vaccination recommendations, implementation, and funding) were developed and validated for each country.

3. RESULTS

The documents analysed generally consisted of official reports (e.g. the national recommendations for influenza vaccination published by the Health Councils), ministerial decrees (e.g. regarding the influenza immunisation program), scientific publications from influenza experts, and grey literature published on the websites of identified stakeholders (Annexe 2).

We obtained a response rate of 70% for the interviews; the non-responders were the healthcare insurance boards in both countries and the French medicines evaluation board (Table 1). Our sample was basically composed of governmental authorities (e.g. politicians, counsellors, and heads of departments), NITAG members, and employees of research institutions, with varied backgrounds (e.g. epidemiology, management, sociology, virology). Sixty percent declared that they were very experienced in the influenza domain. To respect the anonymity of the interviewees, we will not present further details because their identity would be easily recognised.

In the following sections, we present the main results combined from the documentary analysis and interviews.

3.1. Policy-making processes: Recommendations for influenza vaccination, implementation, and funding

3.1.1. The vaccination recommendations process

[FIGURE 1]

In general, the Ministry of Health (MoH) or the Health Directorate triggers the process by questioning their respective Health Council. This question is usually formally sent as a referral. Health Councils transfer the referral to a technical group or advisory board (commonly abbreviated as NITAG) that can appropriately deal with it. NITAGs are composed of experts (permanent or temporary members) who are responsible for selecting, categorising, and judging the evidence over several meetings. NITAGs answer each referral, which is formally written as a report, and send it to the Health Council. The Health Council provides a refined report to the Health Directorate who, together with the MoH, analyses the advice provided. Afterwards, the MoH publishes the final decision.

Participants in FR and NL highlighted the important role of selecting the appropriate evidence for the development of recommendations. In NL, the secretariat of the Health Council (GR) was responsible for the collection and selection of evidence, which they then send to the NITAG. By contrast, in FR, these tasks are executed inside the CTV (French NITAG) by a small group of people who are nominated by the CTV chairman for each decision-making process. French and Dutch participants mentioned the existence of procedures for the evaluation of the selected evidence, but no standard procedure was systematically used.

National research institutes are the primary source of local evidence. Most of the experts that participate in NITAGs are attached to these research institutes. In NL, the RIVM (National Institute for Public Health and the Environment) was largely referred to as a key information provider. According to the participants, there were frequent requests for the RIVM to develop studies for the Dutch NITAG when local information was missing. Similarly, in FR, the InVS (Institute for Public Health Surveillance) was mentioned as the main source of epidemiological information. Other organisations also provide information but do not participate directly in the NITAGs, such as vaccine manufacturers and scientific associations (e.g. French Infectious Diseases Society [SPILF] and Dutch College of General Practitioners [NHG]).

Although the MoH is the final decision-maker, advice provided by the NITAGs is often considered, with minor modifications. Therefore, the NITAGs can be seen as the main stakeholder for the development of vaccination recommendations in both countries.

3.1.2. The implementation of vaccination recommendations and funding

[FIGURE 2]

Numerous stakeholders promote vaccination in FR (Fig. 2). Influenza vaccination recommendations are published in the “National Immunisation Schedule” (along with other recommended or mandatory vaccinations) by the MoH. Recommendations

are further published in medical newspapers and national colleges of healthcare professionals. In addition, an institute attached to the MoH and responsible for health education (French Institution for Prevention and Health Education [INPES]) publishes guides and advertisement materials for healthcare facilities/professionals, the general public, and target groups. Finally, the healthcare insurance board (CNAMTS) has a press conference (together with the MoH) to launch the vaccination campaign, posts newsletters to vaccinators, and sends vouchers to target groups.

By contrast, there is a single program in NL that manages influenza vaccinations (Fig. 2). The National Influenza Prevention Program (SNPG) is directly funded by the MoH and overseen by the RIVM. The SNPG uses an active approach with physicians, the main vaccinators. Physicians are encouraged to order vaccines through the SNPG website and invite their patients who are targeted for vaccination into the clinic. In addition, the NHG (Dutch College of General Practitioners) has a pro-active position and publishes guidelines for vaccination according to the national recommendations. These are sent directly to physicians.

FR and NL both provide free vaccines for target groups. There are financial incentives for the vaccinator in both countries, although there are different processes for vaccine purchases. Fig. 3 provides a representation of the interactions between the stakeholders involved in funding. We observed that in FR, there is another stakeholder (Economic Committee for Medicinal Products [CEPS]) involved in the process that does not exist in NL.

[FIGURE 3]

In FR, the price of the vaccine is negotiated between the CEPS (linked to both Ministries of Health and of Economy) and the manufacturer or distributor, once the vaccine is considered reimbursable by the Health Councils, HCSP/CTV (Technical Vaccination Committee), and HAS/CT (Transparency Committee) [24]. Currently, five brands of flu vaccines (from five manufacturers) are available in community pharmacies, which are responsible for their purchase. Pharmacies provide the vaccines without any charge to the target groups (through a voucher and/or prescription) and are further reimbursed by the CNAMTS. Target groups request vaccine administration by a physician or nurse who is reimbursed for the medical consultation (Fig. 3).

In NL, vaccine procurement is centralised by a national service for vaccine provision and prevention programs (DVP/RIVM). There is no price negotiation; instead, there is a European tender, whose requirements and conditions are publicly available. Currently, there are two brands of flu vaccines (from two manufacturers) that best fit with the tender requirements: the first- and second-choice vaccine. Purchase from the latter is only done when there are shortages of the first-choice vaccine. The DVP works together with the SNPG to deliver the vaccines to physicians' offices. Physicians often invite target groups to receive a flu shot. They receive computer assistance, guidance for ordering the vaccines, and financial compensation for each person vaccinated. Expenses are covered by the SNPG, but vaccine waste over a certain percentage is charged to the physician (Fig. 3).

3.2. Interactions between the experts in NITAGs and other stakeholders

The relationship between the experts inside the NITAGs and their interaction with other stakeholders differed in FR and NL. These interactions and other

characteristics of the NITAGs are further described below. Interviewees from both countries mentioned the influenza pandemic of 2009 as a trigger for changes in the NITAGs' policies; we used this example to illustrate the similarities and differences in the responses to these changes.

3.2.1. Composition of the NITAGs

The two countries have a similar size and composition of NITAGs (around 19 FR and 20 NL), which are composed of a chairman (and a vice-chairman in FR), members, observers, and secretaries (flexible in FR). In both countries, the Health Councils nominate the chairman/vice-chairman who then nominates the other board members. Several types of expertise are required, such as epidemiologists, immunologists, virologists, and clinicians, as well as others less linked to the disease, such as health-economists and ethicists. When expertise is missing, external experts from public or private institutes are temporarily invited to the board. Invited experts usually contribute to the discussions, notably with exhaustive explanations of co-authored studies, but they do not participate in the writing of the final recommendations.

3.2.2. Evidence used during, length and conclusion of the discussion meetings

In general, several meetings are necessary to put forth and evaluate the evidence. Sometimes these discussions are longer, depending on the availability and suitability of the evidence on the subject under discussion. The duration of this process, from the reception of the referral until the delivery of the final report, is slower in FR (6–12 months) than in NL (2–6 months). According to some French interviewees, before the influenza pandemic of 2009, the duration of the process was shorter because the process (described in Section 1.1) was less complex, had fewer steps, and had less people involved.

Participants in both countries equally emphasised the importance of the use of scientific evidence to support NITAG advice. The same evidence, mostly clinical/virological (e.g. vaccine efficacy/effectiveness, safety) and epidemiological studies (e.g. severity, morbidity, and mortality), were mentioned. These studies often come from similar international sources and are interpreted by the NITAGs during the meetings. However, in both countries, there were questions about the quality of the influenza studies and their applicability to national recommendations, although no systematic standard approach for grading and assessment of these studies was cited.

In both countries, the goal of the meetings is to reach a consensus by the end of the discussions. A few interviewees specified that voting was necessary when no consensus was achieved. In NL, voting is seen as a tendency for future meetings, where minor opinions can be stated in the final report. Several French interviewees mentioned that voting was a frequent practice but did not happen systematically. The writing of the final report is done by a writer and co-writer, who describe the discussions and evidence used to justify the advice. Most of the interviewees in both countries mentioned the importance of the writing: in NL, two fixed secretaries are in charge of the writing, whereas in FR, the chairman chooses one or two flexible members of the board to write the report. Only interviewees from NL stated that the report was publicly available in both Dutch and English. They emphasised that this

publication was an important way to show the independence of the advice provided by the NITAG.

3.2.3. Relationship between the experts inside the NITAGs

The majority of interviewees declared that the influenza domain is small and experts had knowledge about each other's work. Therefore, there was a pleasant atmosphere during the meetings. However, some interviewees mentioned that this scenario could be strained when experts with a stronger personality, named 'vocal-people', expressed their opinion in a more enthusiastic manner.

Interviewees had different opinions about 'vocal-people'. Most Dutch interviewees mentioned that experts were eager to express their opinion as part of the scientific debate. Indeed, some interviewees indicated that people were reasonably reliable, wanted to cooperate with each other, and their relationship was based on trust. By contrast, French interviewees mostly stated that 'vocal-people' could influence others in the NITAG, and they perceived this influence as a negative factor for discussions, where the opinions of experts with more subdued personalities could be distorted or ignored. Therefore, the role of the French chairman was emphasised as extremely important to avoid conflicts and enable equilibrium for the discussions. In both countries, experts have their fees reimbursed for participating in the NITAG. In addition, Dutch experts received financial incentives for their participation. In FR, several interviewees complained about the unsatisfactory situation regarding the slowness of the reimbursement system.

Some interviewees, especially in FR, mentioned that the lack of public incentives increased the private funding of experts' research projects (e.g. coming from the pharmaceutical industry), which decreased the independence of the experts and could influence their advice.

3.2.4. Determinants for participation in the discussion meetings

There are different levels of participation in the meetings. The specific conditions for participation are not clearly stated, but only permanent members have the right to vote and participate in the development of the reports; invited experts only provide information under chapters named "experts' advice". Interviewees also mentioned that their "right to vote" was related to their involvement with other stakeholders, for example, the Health Directorate or the MoH (any direct relationship with the final decision-makers prevented voting).

Many interviewees mentioned conflicts of interest that could affect the experts' independence because of their close relationship (lay or professional) with private companies. In NL, several interviewees mentioned that specific conflicts of interest with regards to a specific topic under discussion disabled the participation of the expert in the NITAG (e.g. if the topic under discussion was 'should healthy children be included in target groups', the expert could not be involved with research on 'vaccinating healthy children'). One Dutch interviewee also declared the possibility of 'unconscious influence' from private companies. French interviewees also mentioned that participation as a permanent member in the committee required that the expert must be free of conflicts of interest.

In both countries, interviewees mentioned the difficulty in staying completely disconnected from private companies. Others mentioned that, despite the proximity of the private companies, experts were scientifically independent because they

worked under contract with these companies and when these contracts were over, there were no longer direct links. In NL, more facts related to the independence of experts were mentioned. However, in both countries, there was a unanimous enthusiasm for improving experts' independence using the declaration of interests, which became stricter after the pandemic episode of 2009: before each decision meeting, experts are obliged to provide a public statement of any conflicts of interest or the avoidance of links. People in charge of the organisation of each meeting determine the level of participation in the board (e.g. right to vote or only take part in the discussions). Some French interviewees mentioned that this was a highly individual judgment based on no objective criteria.

After the pandemic episode of 2009, both French and Dutch NITAGs were reformed, adopting stricter rules regarding the experts' relationships with private industry and requiring declarations of interest. Several permanent members became 'invited experts' because of their close relationship with private companies or other stakeholders. People with less experience in influenza vaccination replaced older members. Interviewees had different perceptions of these changes: while some believed that new people with new strategies would improve the transparency of the process (e.g. more independent and more objective decisions), others thought that the process would become mechanistic (e.g. naive grading and evaluation of the evidence to build a decision), without the real-life opinions of experienced people.

4. DISCUSSION

The outcomes presented here contribute to the existing literature about the policy-making process of influenza vaccination. Based on our findings, we were able to identify the interactions between the experts and stakeholders involved in this process. We developed an original schematic framework of this process, which may help policy-makers and researchers develop a holistic perspective that could be used to improve the process. However, further investigation, for instance based on observational studies, is necessary to clarify 'how' the development of recommendations is made in the real world. Using the results presented here and in the literature [22], [25], [26], [27] and [28], we have proposed some hypotheses about the determinants of the policy-making process, which may be helpful for policy-makers searching for improvements.

4.1. Framework of the policy-making process

FR and NL have well-established structures for their influenza vaccination policies, although the experts involved have different roles and interactions. To analyse these differences, we developed schematic flowcharts of the decision-making process for the vaccination recommendations (Fig. 1) and the implementation of these recommendations (Fig. 2). We highlighted two main differences between FR and NL: (1) while actions are nationally centralised in NL through the RIVM, in FR, there are numerous stakeholders and (2) while in FR there are no formal links between vaccinators and other stakeholders, in NL, the vaccinators have an active interaction with other stakeholders and vice versa.

We believe that the nationally centralised Dutch influenza program (SNPG/RIVM) could be one of the determinants of the higher vaccination rates in NL. The SNPG facilitates the implementation of vaccination recommendations, has strong links with stakeholders, and promotes excellent assimilation (by vaccinators) of the specifications of the recommendations [29] and [30]. Many papers have shown the

positive impact that vaccinators, especially general practitioners, have on influenza vaccination rates [31], [32], [33], [34] and [35].

Financial incentives for Dutch vaccinators may also contribute to their higher vaccination rates [36] and [37], although French general practitioners may also receive extra payment for the achievement of pre-established goals on vaccination of target groups (pay-for-performance [38]). Nevertheless, the involvement of the vaccinators in the policy-making process should be emphasised to improve their engagement in passing on the recommendations [39].

4.2. Determinants for the development of national vaccination recommendations

4.2.1. Evaluation of the evidence

The NITAGs from both countries used similar evidence. However, the uncertainty about the quality and relevance of the evidence used for the influenza vaccination recommendations meant that the experts' interpretation was of utmost importance in the process.

The use of the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation) has been widely discussed in recent publications (notably in immunisation policy) [28], [40] and [41]. This approach follows three main steps: the appraisal of the quality of evidence, the judgment between desirable and undesirable effects, and the choice of recommendation strength [42] and [43]. The ability to make considered decisions based on the quality of the evidence independent of coming to sensible conclusions about the strength of the recommendations is a critical and defining feature [28]. Therefore, we believe that the GRADE approach is an important tool that could be systematically used as a standard procedure in both countries to minimise the personal influence of experts and improve the quality and transparency of the decision-making process in FR and NL [5], [44] and [45].

4.2.2. Voting and NITAG coordination

In contrast to the existing literature, we found that voting in the NITAGs did not happen systematically at the end of meetings. Instead, a consensus is often preferred, notably in NL [18], [46] and [47]. Since voting is a democratic method to obtain a fair decision, NITAGs could prioritise this to improve transparency. As emphasised in the literature, this simple method enables the quantitative reporting of pro and con votes and the description of minor disagreements. In addition, experts with a minority opinion can declare their opposition to the advice given [18], [46] and [47]. French interviewees criticised the lack of objective arguments concerning the right to vote and the selection of the writer/co-writer of the report. Improving the confidence between the experts inside the advisory boards could decrease any disagreements that occur (e.g. chairmen, report writers, and invited experts). Confidence could be enhanced by providing a clear definition of the roles of the permanent and invited members and using standard criteria for the right to vote and for the participation in the report writing.

4.2.3. Declaration of interests

The right to vote depends on the experts' declaration of interests. As in most countries where vaccination recommendations are developed by NITAGs [18],

[46] and [47], the public declaration of interests is obligatory for permanent and invited members of the boards [48], [49], [50] and [51]. However, the participants in our survey admitted that it is almost impossible to avoid links with private companies in the influenza scientific and medical communities, which may impede the experts' right to vote, notably in FR [18].

4.2.4. Public funding and independence of the experts

The scarcity of influenza experts with enough expertise to participate in the NITAGs is evident in both countries. In general, experts are involved in influenza vaccination research, which lacks any substantial public investments. This absence of public incentives has necessitated private funding from the pharmaceutical industry, which notably invests in new vaccine technology research or epidemiological follow-ups of laboratory-confirmed influenza cases. Therefore, the involvement of experts with the private sector, especially influenza vaccine manufacturers, is currently inevitable. These links with vaccine manufacturers are historical. In the past, national governments, especially in FR (Sanofi Pasteur) and NL (National Vaccine Institute), had their own non-profit local production and distribution of influenza vaccines. In that time, there were less issues with conflicts of interest because the 'government bought from the government' [52]. However, in our now globalised world, these national companies could not afford the high costs of rigorous production processes and were incorporated into multinational, profit-oriented manufacturers. Therefore, governmental authorities must now interact with multinational manufacturers or distributors of influenza vaccines. These companies have large funds to develop studies for their products, which are often done in partnership with the public sector [52].

4.3. Limitations

The decision-making process for the development of influenza vaccination recommendations by NITAGs is complex. The results presented here could not elucidate the exact development of recommendations. Indeed, we believe that the inscrutability of the process may evoke suspicions about its transparency. All of the participants in this study were attached to the healthcare system: 60% were very experienced with influenza vaccination recommendations and focused on the internal aspects of the NITAG meetings; 40% were less experienced and provided a holistic view of the other components of the policy-making process (e.g. implementation and funding of vaccinations). However, the views of individuals outside the healthcare system were not represented, notably people who are against vaccination. Although this suits the objectives of this study, our findings do not represent this perspective.

The CNAMTS and CVZ (the French and Dutch Healthcare Insurance Boards, respectively) indicated that they were not interested in being interviewed. These organisations execute decisions from the MoH; the CNAMTS is responsible for funding the influenza vaccination policies, although the CVZ is not. The perspective of the CNAMTS would have enriched our outcomes because funding is of utmost importance for implementing the program and may influence the development of recommendations. We were disappointed by the refusal of the French health insurance to accommodate our request and recommend further attempts to obtain their viewpoint about the funding process to contrast with the presented outcomes. In addition, the French Medicines Evaluation Board (ANSM), which is responsible for

influenza vaccine authorisation, did not contribute to our study. This absence could have biased our French results, although experts from other stakeholders provided significant information covering these missing data.

We have only used two methodological techniques to conduct this project: documentary analysis and interviews. The triangulation of these two techniques plus an observational study, for instance, would have enabled a real-world analysis [12]. Although we thought about adding this third technique (the on-site observation of the decision-making process), it has not yet been undertaken. We were afraid that access to the committee meetings in FR and NL would be denied, and direct observation would not be possible. However, there are limitations to this type of data. The potential subjective bias on the part of the observer could have undermined the reliability of the results and the validity of the data gathered. In addition, the observations of the numerous stakeholders identified would simply not be feasible because of limited time and resources.

Our approach to the interviews could produce a declaration bias, where the discourse on a given theme could remain superficial (under-declaration) or excessively intense (over-declaration). We found two instances of this in our study: the under-declaration of the financing of the vaccination programs in both countries, especially in FR, and the over-declaration from French interviewees about personal judgments regarding the conflicts of interest, claiming it was a barrier for participation in the expert committees. Another possible limitation is recall bias; however, this was not relevant to our study because participants were interviewed during or a few weeks after the discussions regarding the update of vaccination recommendations. Finally, affiliation bias was not relevant to our study because our main research group was not associated with the policy-making process.

Language barriers are another limitation of our study: the interviews were carried out and analysed by a sole investigator who did not speak Dutch. We are aware of the issues of accuracy with online translations of Dutch documents; therefore, a Dutch influenza expert validated the data reported in this paper.

Although NVivo10[®] was used to validate the coding of themes, there could have been errors regarding the relevance of the information retained in each of the transcripts analysed. This main limitation of this software could have led to under- or over-estimation of the importance of the citations.

5. CONCLUSIONS

We believe that the implementation of vaccination recommendations could be improved by stronger links between the vaccinators and governmental authorities. Further investigation is underway to evaluate the opinion of general practitioners about which incentives are necessary to improve vaccination rates of target groups. To better understand 'how' national recommendations are developed, we believe that the process must be made more transparent. We think that improvements could be achieved with the following important determinants: the systematic standard evaluation of evidence (e.g. GRADE approach), consistent voting, clear declaration of interests, and increased public funding for vaccination research. Further investigations based on observational studies of these determinants should be done to confirm their impact on the transparency and understanding of the policy-making process.

Competing interests

The authors declare that they have no competing interests.

Author contributions

HMS, JP, AM, and VB designed the survey strategy. MLS performed the documentary analysis, interviews, transcription, and coding. HMS, JP, AM, VB, LP, and MLS participated in the data analysis. HMS, JP, AM, VB, LP, MLS, and JMC prepared the manuscript. All of the authors read and approved the final manuscript.

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Appendix A. Supplementary data

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TABLES AND FIGURES

Box 1 Strategy for online database searches, keywords (English, French, and Dutch), and main sources of material obtained for France and The Netherlands		
(i) demographics and socio-economic context		
Keywords (similar for both countries): <i>health, Gross Domestic Product (GDP), indicators, economy</i>		
Websites (similar for both countries): OECD (http://data.oecd.org/gdp/gross-domestic-product-gdp.htm), WHO (http://data.euro.who.int/healthatlas/CoreIndicatorAP/corenotes.htm)		
(ii) health systems		
Keywords:	<i>Système de santé, réforme, France</i>	<i>Gezondheidszorg, hervorming, Nederland</i>
Websites (similar for both countries): European Observatory on Health Systems and Policies (http://www.euro.who.int/en/about-us/partners/observatory) http://www.cairn.info/revue-les-tribunes-de-la-sante.htm		
(iii) influenza vaccination policies and (iv) stakeholders involved in policies*		
Keywords	<i>Grippe, vaccination, vaccin, remboursement, stratégie vaccinale, recommandation, avis, rapport, conseil</i>	<i>Griep, influenza, vaccinatie, vaccin, vergoeden, vaccinatiestrategie, rapport, advise, recommandatie</i>
Websites		
Ministries of health	http://www.sante.gouv.fr	http://www.rijksoverheid.nl/ministeries/vws
Governmental authorities	http://www.hcsp.fr/explore.cgi http://www.has-sante.fr http://ansm.sante.fr http://www.ameli.fr	http://www.gezondheidsraad.nl http://www.cbg-meb.nl/cbg/nl http://www.zorginstituutnederland.nl http://www.rivm.nl
Laboratories, Surveillance networks	http://grog.org http://www.invs.sante.fr	http://www.nivel.nl http://www.snpng.nl
Associations	http://www.infectiologie.com http://www.grippe-geig.com	https://www.nhg.org
* Dutch websites were automatically translated to English using the Chrome® browser.		

Table 1

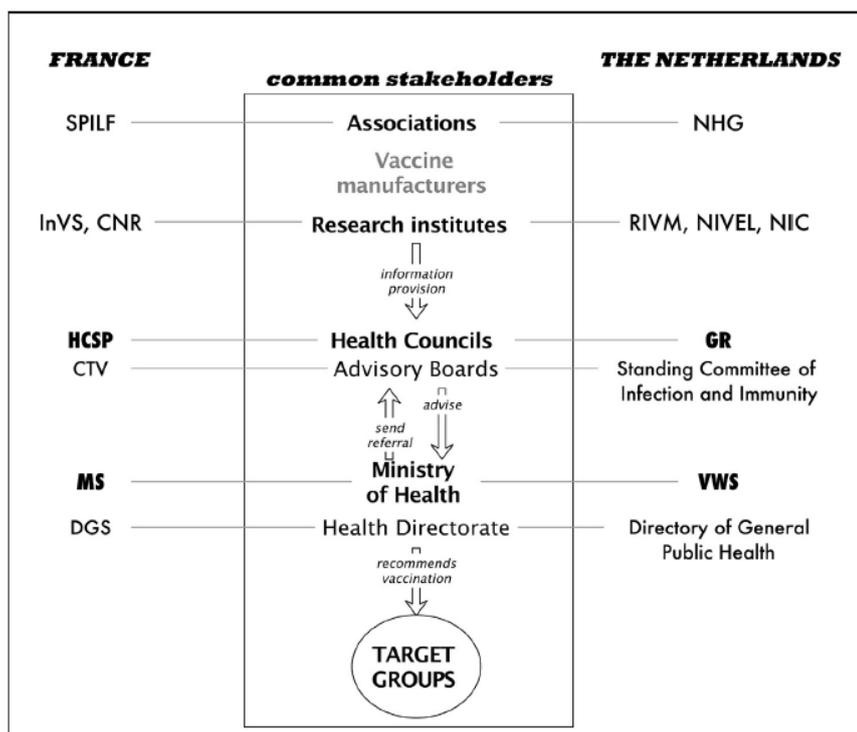
Stakeholders directly or indirectly involved in the decision-making process of influenza vaccination recommendations in France and The Netherlands.

Groups of stake-holders	Stakeholder	France			The Netherlands		
		Stakeholder acronym	Experts interviewed ID	Involvement in the process	Stakeholder acronym	Experts interviewed ID	Involvement in the process
Governmental Authorities	Ministry of Health Health directorate Health Council	MS	Int33*	Direct	VWS	Int19	Direct
		DGS	Int09* Int15**	Direct Direct			
		HCSP/CTV	Int10 Int08 Int12	Direct Direct Direct	GR	Int18 Int21 Int23	Direct Direct Direct
	Medicines Evaluation Board Healthcare insurance board	HAS/CT ANSM	Int06	Indirect	CBG	Int27	Indirect
		CNAMTS	-	Indirect	CVZ	-	Indirect
	Medicines Regulatory/Financial Board	CEPS	Int13	Indirect	RIVM/DVP	Int28**	Indirect
	Research institutions	Influenza surveillance networks National Influenza Centre	GROG	Int02	Indirect	NIVEL	Int16
CNR Paris			Int03 Int05*	Indirect Indirect	NIC	Int26 Int32	Indirect Indirect
Institute of Public Health Research & Monitoring		CNR Lyon	Int01	Indirect	Rotterdam		
		InVS	Int11	Direct	RIVM	Int20 Int22 Int24* Int29* Int30 Int31	Direct Direct Direct Direct Direct
Associations	Society of experts/ College of GPs	SPILF	Int07	Indirect	NHG	Int25	Indirect
Vaccine manufacturers		GSK SPMSD	Int04** Int14	Indirect Indirect	Abbott	Int17	Indirect
Total number of interviews conducted			16		17		

Key: ID- interview identification; MS- Ministère des Affaires sociales et de la Santé; CNAMTS- Caisse nationale de l'assurance maladie des travailleurs salariés; CEPS- Comité Économique des Produits de Santé; DGS- Direction Générale de la Santé; ANSM- Agence National de Sécurité du Médicament; HCSP- Haut Conseil de Santé Publique; CTV- Comité technique des vaccinations; HAS- Haute Autorité de Santé; CT- Commission de la Transparence; SPILF- Société de Pathologie Infectieuse de Langue Française; InVS- Institut de Veille Sanitaire; GROG- Groupes Régionaux d'Observation de la Grippe; CNR- Centre National de Référence; VWS- Ministry of Health, Welfare and Sport; GR- Health Council; CVZ- National Health Care Institute; CBG- Medicines Evaluation Board; RIVM- National Institute of Public Health and Environment; NIVEL- Netherlands institute for health services research; NIC- National Influenza Centre; NHG- Dutch College of General Practitioners; DVP- National service for vaccine provision of prevention programs; GSK- GlaxoSmithKline; SPMSD- Sanofi Pasteur Vaccines.

* No longer at the position during the interview.

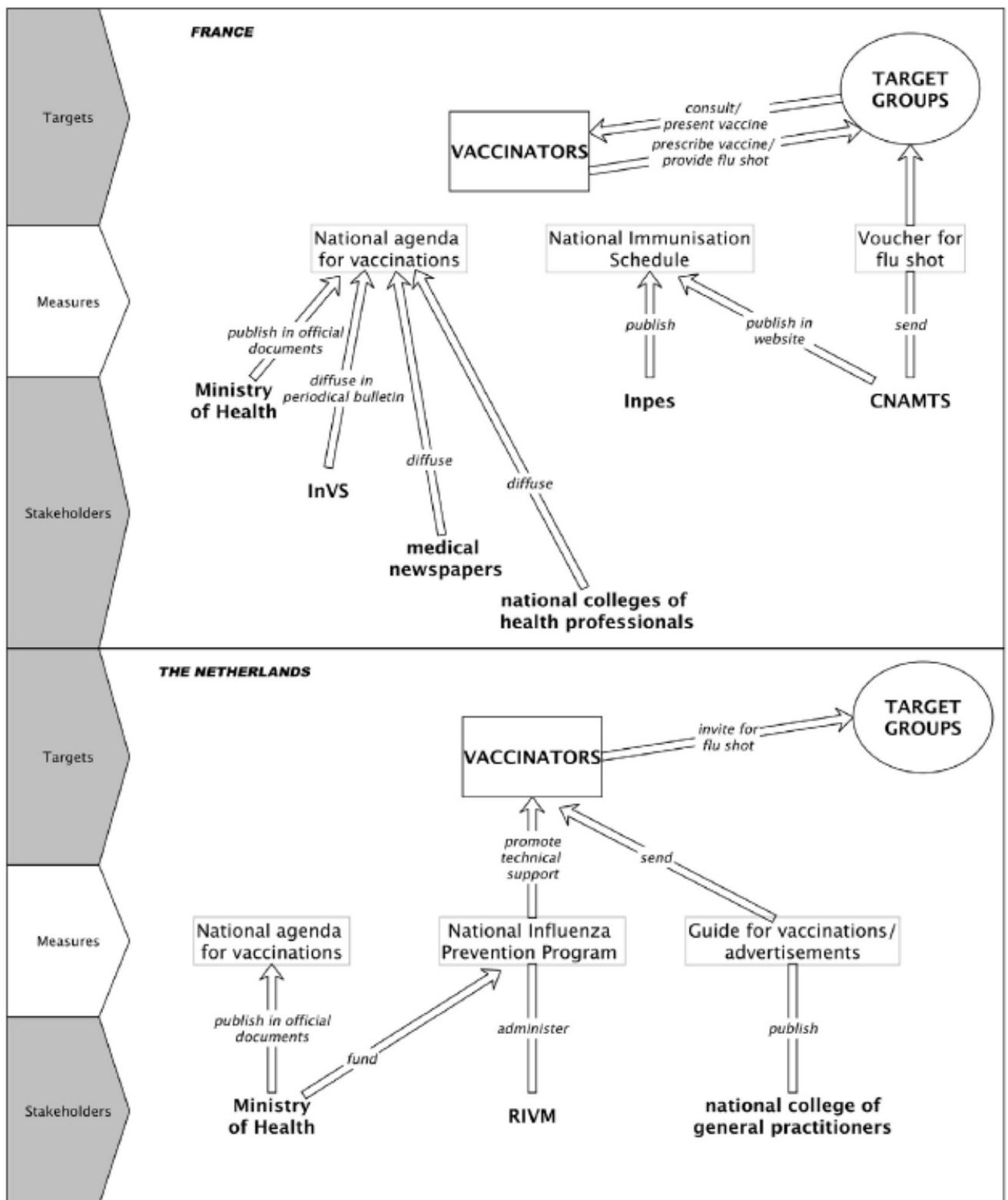
** Face-to-face interview conducted with more than one person, as suggested by the invited expert.



Key for France: MS = Ministry of Social Affairs, Health and Women rights; DGS = Health Directorate General; HCSP = High Council for Public Health; CTV = Technical Vaccination Committee; InVS = Institute for Public Health Surveillance; CNR = National Reference Centre; SPILF = French Infectious Diseases Society

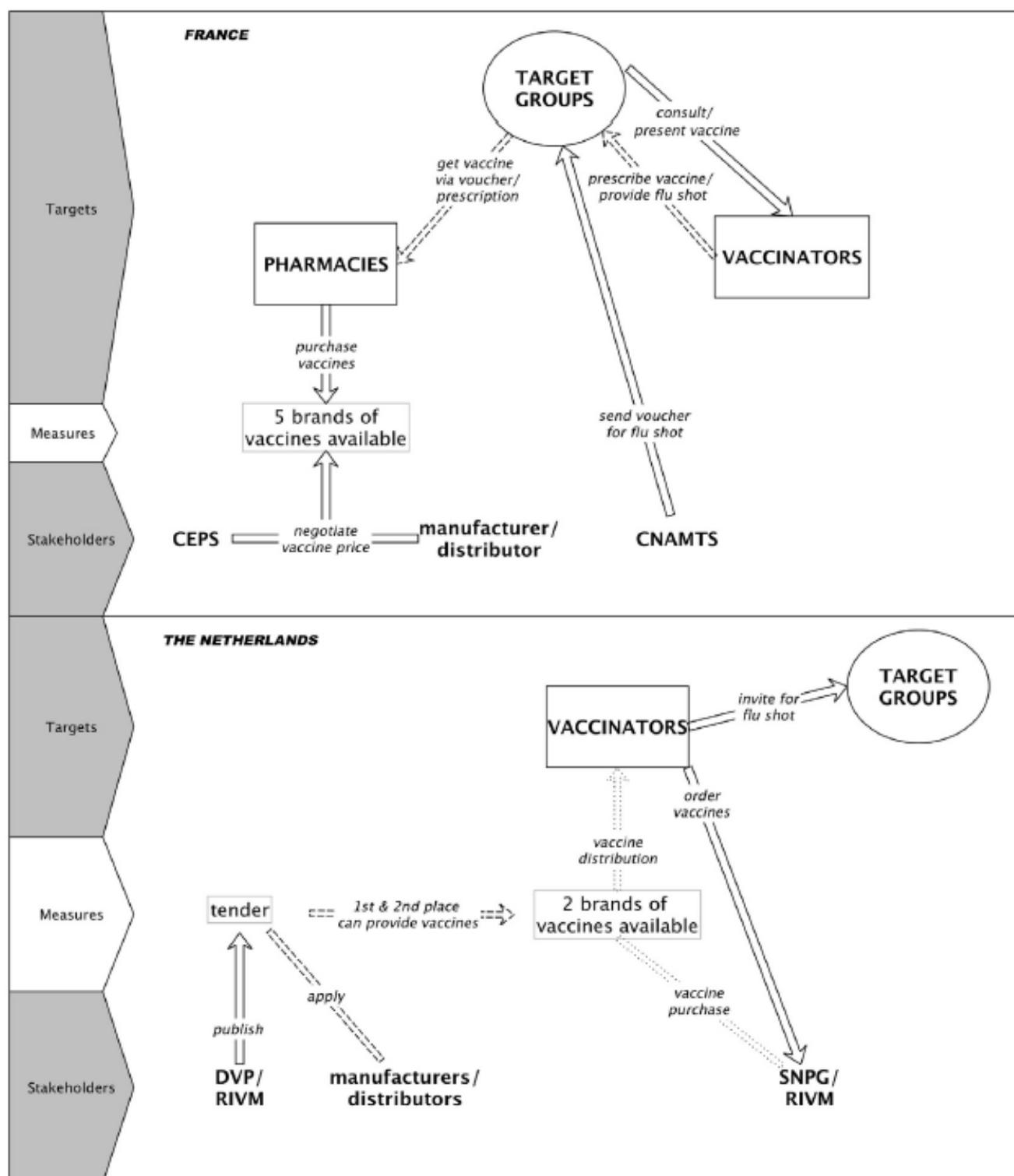
Key for The Netherlands: VWS = Ministry of Health, Welfare and Sport; GR = Health Council; RIVM = National Institute of Public Health and Environment; NIVEL = Netherlands Institute for Health Services Research; NIC = National Influenza Centre; NHG = Dutch College of General Practitioners

Fig. 1. The decision-making process of influenza vaccination recommendations and examples of the stakeholders in France and The Netherlands.



Key: InVS = French Institute for Public Health Surveillance; Inpes = French Institute for Prevention and Health Education; CNAMTS = National Health Insurance Fund; RIVM = National Institute for Public Health and the Environment

Fig. 2. Schematic of the implementation of influenza vaccination recommendations in France and The Netherlands.



Key: CEPS = Economic Committee for Medicinal Products, linked to the Ministry of Health and Ministry of Economy; CNAMTS = National Health Insurance Fund; DVP = National Service for Vaccine Provision of Prevention Programs; SNPG = National Influenza Prevention Program; RIVM = National Institute for Public Health and the Environment

Fig. 3. Schematic of the funding of influenza vaccinations in France and The Netherlands.

Box 1: Strategy for online database searches, keywords (English, French, and Dutch), and main sources of material obtained for France and The Netherlands

(i) demographics and socio-economic context		
Keywords (similar for both countries): <i>health, Gross Domestic Product (GDP), indicators, economy</i>		
Websites (similar for both countries): OECD (http://data.oecd.org/gdp/gross-domestic-product-gdp.htm), WHO (http://data.euro.who.int/healthatlas/CoreIndicatorAP/corenotes.htm)		
(ii) health systems		
Keywords:	<i>Système de santé, réforme, France</i>	<i>Gezondheidszorg, hervorming, Nederland</i>
Websites (similar for both countries): European Observatory on Health Systems and Policies (http://www.euro.who.int/en/about-us/partners/observatory) http://www.cairn.info/revue-les-tribunes-de-la-sante.htm		
(iii) influenza vaccination policies and (iv) stakeholders involved in policies *		
Keywords:	<i>Grippe, vaccination, vaccin, remboursement, stratégie vaccinale, recommandation, avis, rapport, conseil</i>	<i>Griep, influenza, vaccinatie, vaccin, vergoeden, vaccinatiestrategie, rapport, advise, recommandatie</i>
Websites:		
Ministries of health	http://www.sante.gouv.fr	http://www.rijksoverheid.nl/ministeries/vws
Governmental authorities	http://www.hcsp.fr/explore.cgi	http://www.gezondheidsraad.nl
	http://www.has-sante.fr	http://www.cbg-meb.nl/cbg/nl
	http://ansm.sante.fr	http://www.zorginstituutnederland.nl
Laboratories, Surveillance networks	http://www.ameli.fr	http://www.rivm.nl
	http://grog.org	http://www.nivel.nl
Associations	http://www.invs.sante.fr	http://www.snpg.nl
	http://www.infectiologie.com	https://www.nhg.org
	http://www.grippe-geig.com	

*Dutch websites were automatically translated to English using the Chrome® browser

ANNEXE 1: INDIVIDUAL SEMI-STRUCTURED INTERVIEW GUIDE; ENGLISH VERSION FOR THE NETHERLANDS

Before starting the interview, the interviewer will briefly develop the following points:

- Personal and thesis presentation
- State that the interview will be recorded

Opening point

- 1) What do you think about the actual seasonal influenza vaccination strategy in The Netherlands?

The experts and their relationships

- 1) In this field, what is your expertise?
 - a. Currently and in the past three years, for which institutions have you worked?
- 2) Have you been involved (directly or indirectly) in meetings regarding influenza vaccination or vaccine policy (recommendations, campaigns, reimbursements)? When, which one?
 - a. In what level did you participate in this meeting?
 - b. Are the experts the same?
- 3) What do you think about the relationship among experts who participated with you in this meeting?
 - a. Were all “flu expertise” represented? What were the missing skills, according to you?
 - b. Which kind of foreign experts participated? From which institution?
- 4) Could you please talk about the degree of influence among the experts?
 - a. Do you think it is most related to their institution or their skills?
- 5) What is the role of the ECDC and the WHO in the policy-making process?

The policy-making process

- 1) Could you please give more details about the flow or the development of those meetings?
 - a. Is there any written or oral procedure?
 - b. How are the different opinions managed and solved?
- 2) Could you please give further details about the interrelations regarding the following institutions (related to influenza vaccination/vaccines):
 - a. GR: Health Council
 - b. CBG: Medicines Evaluation Board
 - c. CIBG: Central Information for Healthcare Professions
 - d. CVZ and IGZ: Healthcare Insurance Board and Healthcare Inspectorate
 - e. RIVM Cib/CvB: Centre for Infectious Disease Control/Centre for Population Screening

Closing points

- 1) What works well in the process? What could be improved? What possible changes are in progress?
- 2) Is there any additional information or comments would you like to share?
- 3) Can you recommend another person I should talk to get a perspective that complements yours or that is completely different?

ANNEXE 2: MAIN DOCUMENTS ANALYSED DURING THE QUALITATIVE RESEARCH (IN ALPHABETICAL ORDER)

- Bégué P. [Consequences of opposition to vaccination in France and Europe. How to maintain effective vaccine coverage in 2010?]. *Bull Acad Natl Med*. 2010 May;194(4-5):719–32; discussion 732.
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