



Evidence-informed vaccine decision making: The introduction of Human Papilloma Virus (HPV) vaccination in the Netherlands

Ingeborg M. van der Putten^{a,*}, Aggie T.G. Paulus^a, Mickael Hiligsmann^a,
Raymond C.W. Hutubessy^b, Silvia M.A.A. Evers^{a,c}

^a CAPHRI, Care and Public Health Research Institute, Department of Health Services Research, Maastricht University, Maastricht, The Netherlands

^b Initiative for Vaccine Research, World Health Organization, Geneva, Switzerland

^c Trimbos Institute, Netherlands Institute of Mental Health and Addiction, Utrecht, The Netherlands

ARTICLE INFO

Article history:

Received 27 March 2018

Received in revised form 31 August 2018

Accepted 3 September 2018

Keywords:

Policy making

Vaccines

Papillomavirus vaccines

Costs and cost analysis

Immunization programs

Netherlands

ABSTRACT

Little is known about the role of (economic) information or evidence in the different stages of the decision-making process on vaccine introduction. By conducting a document analysis on the public decision-making process of introducing human Papilloma virus (HPV) vaccine into the national vaccination program (NVP) in the Netherlands, we aim to gain insight into which information plays a role during the introduction of a vaccination programme.

A document analysis was performed on the public decision-making process regarding the introduction of HPV vaccine into the NVP in the Netherlands. Information used or asked for by various stakeholders during different stages of the policymaking process was identified. In total, 42 documents were found, analyzed and synthesized, for the period between August 2006 and September 2009. Documents were analyzed using directed content analysis based on eight broad categories of criteria used in decision-making frameworks for introducing a vaccine.

Our analysis demonstrates that a wide variety of stakeholders is involved in the process. Financial or economic issues were stipulated in 64.3% of the documents and information on vaccine characteristics were discussed in 59.5%. Economic information from economic evaluations was discussed most (47.6%). Based on our analysis, it can be concluded that economic information, in particular information from economic evaluations, played an important role in the decision-making process regarding the introduction of HPV-vaccination.

© 2018 Elsevier B.V. All rights reserved.

1. Introduction

Providing vaccination included in the expanded program of immunization to the general public is one of the cornerstones of public health systems [1]. Vaccination schedules are mostly organized through national vaccination programmes (NVP) [2]. In countries with an NVP, generally the Ministry of Health, together with the parliament, decides which vaccines should be included in the country-specific vaccine schedules based on the evidence provided by National Immunization Technical Advisory groups (NITAGS) (if available), or other groups of experts [3]. Not all countries have included the same vaccines in their national vaccination schedules due to differences in the decision-making process, based on cultural differences, the socio-economic context, the health sys-

tems context, epidemiological profiles, and funding mechanisms employed [2]. In addition, due to the rise of expensive vaccines, several initiatives have been initiated to make the process of introducing a vaccine more evidence-informed [4–6].

In the literature the use of information or evidence in decision making and/or policymaking is often researched [7–9]. Some authors talk about evidence-based decision making, in which evidence is a product of research and is seen as facts that can be used as a base for decision making [8,10]. Others argue that decisions have meaning only if evidence is placed in the political and practical context of policymaking. Therefore they suggest using the term ‘evidence-informed policymaking’, defined as ‘the use of different types of information in a variety of forms and from a variety of sources, reflective of, and responsive to the policy and practice context’ [7]. Evidence can be the result of different types of research, and includes knowledge and information such as the results of consultation processes with networks/groups, discussions on internet, published documents/reports, the expressed ideas and interests of individuals, groups and networks, information derived from the

* Corresponding author at: CAPHRI, Care and Public Health Research Institute, Department of Health Services Research, P.O. Box 616, 6200 MD, Maastricht University, Maastricht, The Netherlands.

E-mail address: i.vanderputten@maastrichtuniversity.nl (I.M. van der Putten).

political context, economic information such as the implications for financing and resourcing, economic evaluations and opportunity costs [7,11]. Information is defined as ‘data that has meaning’. During the 65th World Health Assembly in 2012, the importance of evidence-based vaccine decision making was stipulated by endorsing the Global Vaccine Action Plan (GVAP) [12]. This plan [13] states that “National legislation, policies and resource allocation decisions should be informed by credible and current evidence regarding the direct and indirect impact of immunization.” The importance of using economic information in decision making was specifically pinpointed during the 67th World Health Assembly in 2017, by putting it on the agenda of member states.

There is a need for more research exploring when and how often such information is used in the decision-making process and by which stakeholders [14]. Many articles discussed the implementation of the HPV vaccination in countries in general [15,16] or barriers to and facilitators for the uptake of the vaccine [17]. To our knowledge only two studies researched the use of informed decision making on vaccines in the Netherlands and France; these were studies on the annual decision-making process regarding vaccination for seasonal influenza. [18,19]. The findings of the studies suggest that NITAGs played a central role in the decision-making process [19] and used clinical/epidemiological studies and, increasingly, economic models as information, although the overall quality of evidence was regarded as poor [20]. However, the decision-making process regarding influenza vaccines is a repeated process for a new version of a vaccine that is provided outside the NVP [19]. In this research we therefore aim to investigate when different types of information was used or asked for by stakeholders to support their decision-making process. By conducting a document analysis on the public decision-making process of HPV vaccine in the national vaccination program (NVP) in the Netherlands, we aim to gain insight into which information plays a role in the public funding of introducing a vaccine.

The policy process around the decision to introduce HPV vaccination was selected for several reasons. First, it is an example of a vaccine that prevents cancer in the long term, making it difficult to evaluate the effectiveness of the vaccine to determine a cause and effect relationship. Most studies available in 2006–2009 related the effectiveness of the vaccine to HPV infection and not to overcoming cervical cancer, although the rate of HPV infection is regarded as a good proxy [21,22]. Second, prior to its introduction, the HPV vaccine was discussed extensively in the public domain and media, in comparison with the discussion around other vaccines when they were being considered, making it an excellent case study for investigating in detail the use of information in the decision-making process. Last, the government is currently planning to assess whether the HPV vaccination program should be expanded to offer the gender-neutral vaccination. For these reasons, there was a need for rigorous scientific evidence that would support decision-making regarding the introduction of the vaccine [23].

The objective of this research was (1) to map how the decision-making process on the introduction of the HPV vaccine in the Netherlands took place and identify which stakeholders were involved (2) to identify what type of information was used during the decision-making process by the different stakeholders and (3) to identify to what extent economic information did play a role in this decision-making process.

2. Vaccine decision making in the Netherlands

Childhood vaccination is traditionally provided at no charge through the National Vaccination Program (NVP) which is managed by the Dutch National Institute for Public Health and the

Environment (RIVM) [16]. The RIVM works together with 51 youth health services (JGZ) and the service for vaccine provision and prevention programs (DVP) to provide the vaccines to the Dutch population [17]. The total operating costs were € 83.5 million in 2016 [17]. The Dutch NVP was established in 1957 and provides vaccines against 12 antigens including Diphtheria, Pertussis (whooping cough), Tetanus, Polio, Haemophilus influenzae type b, Pneumococcal disease, Hepatitis B, Mumps, Measles, Rubella (German measles), Meningococcal disease and HPV [15].

Vaccines can be 100% reimbursed through the basic national insurance plan, for which the National Healthcare Institute (ZiNL) previously called the Health Care Insurance board (CVZ,) provides advice to the Minister of Health. The decision to include a new vaccine in the NVP is made by the Ministry of Health with input from National Health Council [16,19]. Both ZiNL and the National Health Council use specific lists of criteria to evaluate the appropriateness of implementing a new vaccine [20]. Economic information is part of these frameworks, although at ZiNL the pharmaceutical companies are responsible for providing the economic evaluations, while the National Health Council uses independent researchers to provide the necessary economic analysis [20]. Parliament is also informed on the steps taken and provides input and communicates questions.

3. Methods

A case study design was used to investigate retrospectively the decision-making process of the introduction of HPV vaccination in the Netherlands [24].

3.1. Data selection

To analyse the case we conducted a document analysis to systematically review publicly available documents from August 2006, when the first questions about HPV vaccination were posted in parliament, until September 2009, when the vaccine was officially introduced and became available to the general public. Data was collected from the database of official announcements, ‘Officiële bekendmakingen’, of the Dutch government [25], using the key words HPV and vaccination. All documents published by the government, including the parliament records of the House of Representatives and the senate, can be found in this database [25].

A document analysis was performed to investigate the decision-making process surrounding the vaccine that took place in 2006–2009. Documents are the most effective means of gathering data and information as events can no longer be observed and informants are likely to have forgotten details. Parliament records are the main source of our analysis as these are the official minutes (edited verbatim reports), letters and reports of the process itself, and contain the most accurate information on the events that occurred.

In total 70 documents of parliament records were scanned on the basis of title. Documents that did not discuss the decision-making process on HPV vaccination (24) were deleted, as were those which did not provide new information (11). After these deletions, 35 documents remained. In the parliament records references were made to 7 additional documents of the CVZ and National Health Council. As these organizations play a fundamental role in the decision-making process, these documents were added, making a total of 42 documents in our study pool.

3.2. Data analysis

To provide insight into the decision-making process of introducing HPV vaccine in the Netherlands, a timeline from 2006 to

2009 was developed. Events are included in the timeline if a specific event was mentioned in the documents or the document itself represented a specific event. Nvivo 9.2 software [26] was used to indicate per document the date the document was published, the phase in the decision-making process (Prioritization; Development; Implementation), the kind of stakeholder involved (Parliament; Ministry of Health; National Health Council; CVZ), and the position of the document on implementing the HPV vaccine (Positive; neutral; negative). Furthermore, the stakeholders mentioned and documents cited in the documents were described per document. Based on these three sources, a table was made which provides for every event the date, a short description of the event, the stakeholders involved and the decision phase (See Appendix A). This was translated into a figure providing the most important events in the decision-making process of introducing the HPV vaccine in the Netherlands.

To analyse the information used during the decision-making process of introducing the HPV vaccine in the Netherlands, all selected documents were uploaded to Nvivo 9.2 and analysed by coding the text. Direct content analysis was used for this process; the framework of Burchett was adapted and operationalised per code [27]. This framework gives an overview of information used during the decision-making process regarding the introduction of a vaccine. In total, nine categories are identified in this classification scheme, ranging from financial and economic issues to vaccine characteristics. As the decision-making process itself is one of the categories, this was removed from our analysis, leaving eight categories used.

The role of economic information was researched by including equity and the costs of alternative interventions to the list of information on financial and economic issues (see Table 2). The criterion financial and economic issues included economic evaluation, incremental costs, funding sources, the vaccine price and financial sustainability. To make sure no information was missed we included 'other economic issues' as an extra category.

To pilot our framework, five preselected documents (based on dates) were hand coded by two researchers to see if there were differences in interpretations of the codes. As these only concerned minor differences, the overall structure of coding did not have to be altered. The other documents were further coded by one of these researchers. In case of doubt, classification choices were discussed by the team. Eventually all codes were also checked separately per code to make sure the same themes are covered per code. After that code matrices were made using the explore function of Nvivo categorizing the documents in policy phases and stakeholder categories.

4. Results

4.1. Stakeholders involved

During the decision-making process regarding the introduction of HPV vaccination, different stakeholders were involved, with each playing a different role. In the prioritization phase, the media and members of parliament, and also the RIVM and the National Health Council played important roles in reviewing information on HPV vaccines available on the market and in getting the introduction of the HPV vaccine on the agenda. During the development phase, the different advisory committees, together with the Ministry of Health, played a central role. Furthermore, the members of parliament and pharmaceutical companies were trying to influence the process from the sideline. In the implementation phase, the RIVM and JGZ took over, from the Ministry of Health, the role of implementing the HPV vaccine. During the implementation period the parliament was still discussing the implications of the decisions

made and the progress being made by various institutions, such as the appropriate ways to inform girls and their parents and the independence of the National Health Council.

4.2. The decision-making process

In describing the decision-making process in the Netherlands regarding the uptake of new vaccines it is useful to distinguish between three important phases: the prioritization phase in which the HPV vaccine was put on the agenda, i.e. from August 2006 to March 2007; the development phase in which a policy decision needed to be reached, i.e. from March 2007 to July 2008, and the implementation phase in which the policy decision was planned to be implemented, i.e. from July 2008 to August 2009. A timeline of the most important events can be found in Fig. 1, and a full overview of events can be found in Appendix A.

The *prioritization phase* of the decision-making process for providing HPV vaccination to the Dutch population started when the Labour Party asked questions regarding the usefulness of the vaccine for the Dutch population. These questions were based on a news article that reported the approval of Gardasil (Sanofi Pasteur MSD) for the European Market [28]. The advice was put on the work agenda of the National Health Council for 2007, although an official request for the recommendation was only sent on the 20th of March 2007, after a reminder by the Dutch People's Party for Freedom and Democracy. This delay was due in large part to the fact that the government fell on the 22nd of November 2006 and a new government wasn't formed until the 22nd of February 2007, then with a new Minister of Health. Before this the former Minister of Health had sent, on the 10th of January 2007, a request to the CVZ to ask if the uptake of Gardasil in the basic insurance package was advisable. A spurt of new questions regarding the introduction of the HPV vaccination started 8 December 2007 after a second HPV vaccine, Cervarix (from GlaxoSmithKline), was added to the Dutch market, leading to second request from the Minister of Health to the CVZ, for advice on the uptake of Cervarix in the basic insurance package.

The *development phase* stretches roughly from the moment the official request was given to the National Health Council until the official decision was made to implement the vaccine in the NVP. During this time discussions in parliament were mainly on the possible influence of lobbying by pharmaceutical companies; several attempts were made by the Labour Party to implement the vaccine in the NVP or in the basic insurance package before the official recommendation reports were finished. The official recommendations of the National Health Council were delayed several times. Eventually the advice of the National Health Council was delivered to the parliament on the 31st of March 2008 advising the addition of the HPV vaccine to the schedule for girls of 12 years and doing a catch up campaign for girls 13–16 years old. The CVZ advised for both vaccines separately that they could better not be included in the basic insurance package. They indicated that it was more appropriate to be included in the NVP rather than being made available through insurance. Furthermore, questions were asked about the strength of evidence delivered by the pharmaceutical companies. On the 8th of July 2008 the Minister of health took over the recommendations of the National Health Council to include the HPV vaccine in the NVP and informed the parliament of his decision in a letter.

With the decision by the Minister of Health, the *implementation phase* of the decision-making process for inclusion in NVP started. The planned implementation given in this decision was the first of September 2009, but the actual implementation was delayed by half a year due to the national vaccination campaign for the N1H1 virus. As a response to the letter sent by the minister of health, informing the parliament on the introduction of the HPV vaccine

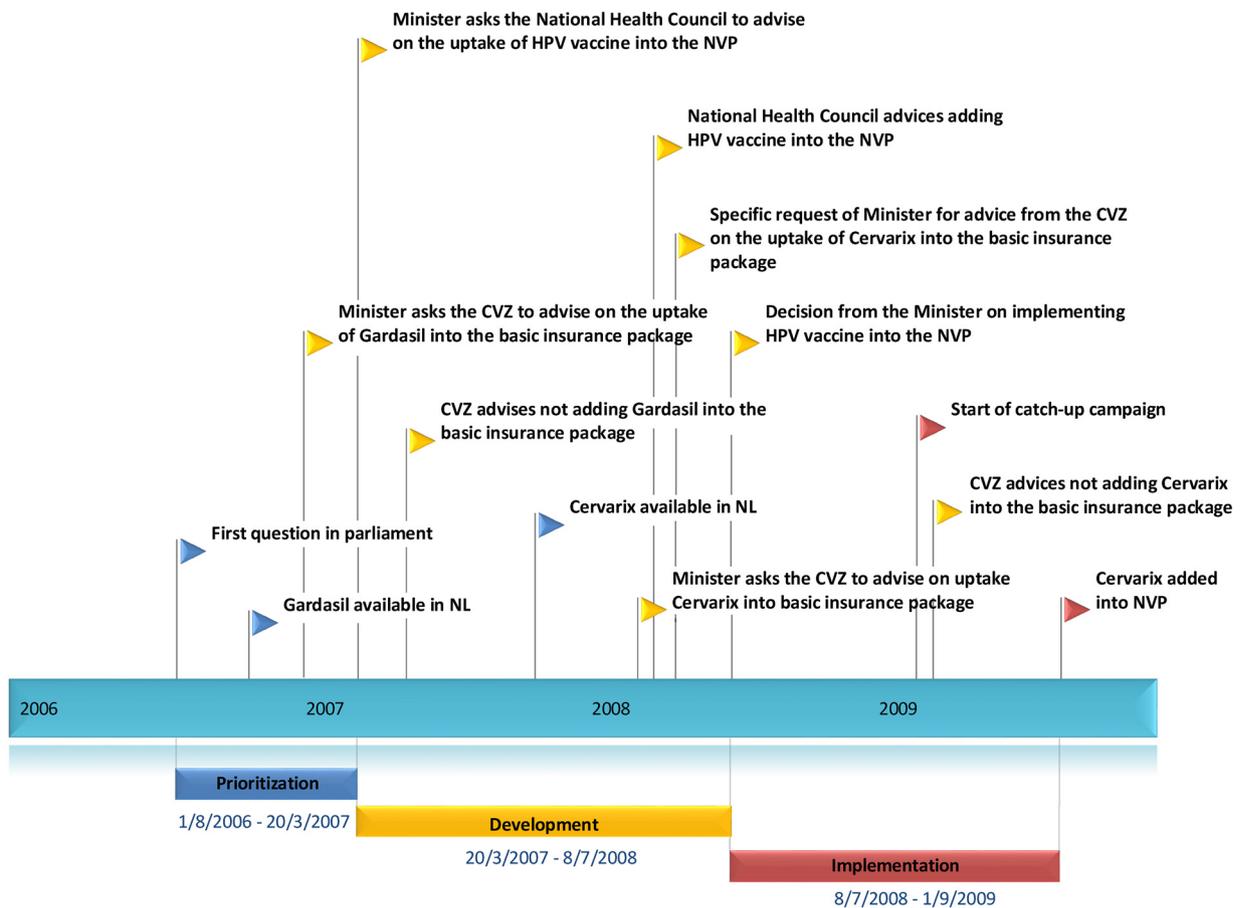


Fig. 1. Timeline for the decision-making process for HPV vaccination.

questions were asked, by parties in the parliament, regarding the decision as made by the Minister of Health. A parliamentary meeting was held to evaluate the decision-making process as members of parliament raised questions regarding the costs of the HPV vaccine, the marketing strategies of the pharmaceutical companies and the reliability of advice given by the National Health Council. Moreover, the choices made by RIVM and the public health institutes (GGDs) during the implementation of the HPV vaccine were questioned. For example, the information included in the information leaflets was considered incomplete and not comprehensive enough and establishing an iPod lottery for girls being vaccinated was considered unethical.

4.3. Use of evidence/information

In Table 1 an overview is given, for each phase and for each stakeholder, of how many documents mention certain categories by providing information or asking for information based on the categories provided by Burchett [14]. Overall it can be said that financial or economic issues (64.3%) are discussed most, closely followed by vaccine characteristics (59.5%). The importance of the health problem, vaccine characteristics and acceptability seem to be more important in the prioritization phase than in the other phases. In the prioritization stage the importance of the health problem was stipulated by using information on the burden of disease of cervical cancer in the Netherlands. For example, facts on prevalence or incidence, mortality rates and also the prognosis of the disease were discussed in parliament. The HPV vaccine was perceived to be important by various parties in parliament, with the Labour Party playing a leading role. Politicians asked for information on

vaccine characteristics as was provided by both the Ministry of Health and the advisory bodies. The efficacy and effectiveness, followed by vaccine safety, was most discussed. Other characteristics, as for example the opportunities for cross protection against other HPV types, were discussed in the Health Council's report. Financial and economic issues, and consideration of alternative interventions were seen as almost equally important in the prioritization and development phases, although there were some differences in the details. In the prioritization phase, economic information was asked for and named as a prerequisite for implementing the HPV vaccine, and in the development phase the outcomes of economic evaluations studies were discussed. When looking at the differences in information used by the different stakeholders it can be seen that the documents of the National Health Council did not take into consideration any programmatic considerations, while CVZ did not take acceptability into account. All categories are discussed in parliamentary and ministerial documents, although some categories are mentioned in only one document from the ministry. The documents also reveal that the quality of evidence was a concern in the reports, although this was related more to the absence of data on the long-term consequences of HPV vaccinations and not to the studies in general.

4.4. Role of economic information

In Table 2 an overview of the economic information (adjusted from Burchett et al. [14]) mentioned in different documents can be found. When looking at economic information, economic evaluations (47.6%) are most referred to in the analysed documents, followed by funding sources (23.8%) and the vaccine price and

Table 1
Overview of information used overall, per policy phase and per stakeholder.

Information on	Overall		Policy phase						Per stakeholder							
			Prioritization		Development		Implementation		Ministry		Parliament		National Health Council		CVZ	
	N = 42	(%)	N = 4	(%)	N = 19	(%)	N = 19	(%)	N = 14	(%)	N = 21	(%)	N = 5	(%)	N = 2	(%)
Importance of the health problem	13	31.0%	3	75.0%	8	42.1%	2	10.5%	3	21.4%	7	33.3%	1	20.0%	2	100%
Vaccine characteristics	25	59.5%	4	100%	13	68.4%	8	42.1%	7	50.0%	12	57.1%	4	80.0%	2	100%
Programmatic considerations	12	28.8%	1	25.0%	7	36.8%	4	21.1%	4	28.6%	6	28.6%	0	0.0%	2	100%
Acceptability	13	30.0%	3	75.0%	5	26.3%	5	26.3%	2	14.3%	8	38.1%	3	60.0%	0	0.0%
Accessibility, equity and ethics	13	30.0%	1	20.0%	7	36.8%	5	26.3%	1	7.1%	10	47.6%	1	20.0%	1	50.0%
Financial or economic issues	27	64.3%	3	75.0%	16	84.2%	8	42.1%	8	57.1%	14	66.7%	3	60.0%	2	100%
Impact of vaccination	11	26.2%	2	50.0%	5	26.3%	1	5.3%	1	7.1%	7	33.3%	1	20.0%	2	100%
Consideration of alternative interventions	15	35.7%	2	50.0%	9	47.4%	3	15.8%	3	21.4%	8	38.1%	2	40.0%	2	100%

Table 2
Overview of economic information used overall, per policy phase and per stakeholder.

Information on	Overall		Policy phase						Per stakeholder							
			Prioritization		Development		Implementation		Ministry		Parliament		National Health Council		CVZ	
	N = 42	(%)	N = 4	(%)	N = 19	(%)	N = 19	(%)	N = 14	(%)	N = 21	(%)	N = 5	(%)	N = 2	(%)
Equity	4	9.5%	1	25.0%	2	10.5%	1	5.3%	0	0.0%	2	9.5%	1	20.0%	1	50.0%
Economic evaluation	20	47.6%	3	75.0%	11	57.6%	6	31.6%	7	50.0%	8	38.1%	3	60.0%	2	100%
Incremental costs	7	16.7%	1	25.0%	4	21.1%	2	10.5%	1	7.1%	4	19.0%	0	0.0%	2	100%
Funding sources	10	23.8%	1	25.0%	7	36.8%	2	10.5%	5	35.7%	5	23.8%	0	0.0%	0	0.0%
Vaccine price	7	16.7%	0	0.0%	4	21.1%	3	15.8%	2	14.3%	3	14.3%	1	20.0%	1	50.0%
Financial sustainability	4	9.5%	0	0.0%	4	21.1%	0	0.0%	0	0.0%	2	9.5%	1	0.0%	1	50.0%
Other economic issues	2	4.8%	0	0.0%	1	5.3%	1	5.3%	0	0.0%	2	9.5%	0	0.0%	0	0.0%
Cost effectiveness of alternative interventions	3	7.1%	0	0.0%	2	10.5%	1	5.3%	0	0.0%	1	4.8%	2	40.0%	0	0.0%

*Terms are based on the framework for the criteria for decision making by Burchett et al. [14].

incremental costs (16.7%). In total four economic modelling studies were performed, of which two were prepared by the pharmaceutical industry for the CVZ and 2 were prepared by independent research institutes for the National Health Council. Economic modelling studies of other countries were also taken into account by the National Health Council. The assumptions used in the different studies differed, leading to different conclusions. This resulted in questions in parliament regarding the interpretation of the results provided in the reports of the CVZ and the National Health Council. In the documents that cover funding sources, the amount of funding needed and the amount of funding to be covered by the Ministry of Health are discussed. The vaccine price was considered to be very expensive and a reason to not implement the vaccine. Almost no other economic issues were named in the documents. In one parliamentary document a policymaker asked why the Dutch are the first to not fund the HPV vaccine in the basic insurance package in Europe. The other parliamentary document raised awareness on the ethical problems of pharmaceutical companies sponsoring educational and promotional activities.

In the prioritization phase, the importance of economic outcomes was stipulated in almost all documents, naming the cost effectiveness of the HPV vaccine as a prerequisite for implementation. During the development phase, in addition to economic

evaluations, attention was also given to funding sources, mostly in regard to organizing the funding needed for implementation of the vaccine. In general, not much attention was given to economic information in the implementation phase, although the positive results of the cost effectiveness studies if the vaccination price was not too high were used as an argument in defence of introducing the HPV vaccine.

Half of the documents provided by the Ministry of Health discussed economic evaluations. Equity, financial sustainability, other economic issues and the cost effectiveness of alternative interventions were not mentioned in these documents. The parliamentary documents covered each criterion at least one time. It is clear that not all categories were taken into account in the advice given by the National Health Council and the CVZ.

5. Discussion

The objective of this research was (1) to map how the decision-making process on the introduction of the HPV vaccine in the Netherlands took place and identify which stakeholders were involved, (2) to identify what type of information was used during the decision-making process by the different stakeholders, and

(3) to identify to what extent economic information played a role in this decision-making process. Looking back at the process, it can be said that the process of decision-making around introducing HPV vaccine in the Netherlands was complex. Many stakeholders were involved, with central roles for the Ministry of Health and parliament, with the National Health Council and the Health Insurance Board (CVZ) as advisory bodies. The media played a more indirect role by initiating many of the questions asked in parliament, through reporting on developments in Dutch society. Financial and economic issues (64.3%), especially economic evaluations (47.6%), played an important role, particularly in the prioritization (75.0%) and development (57.9%) phases of the policy making process.

Due to the difference in focus, the findings of this study are different from the findings of the qualitative study with the same framework conducted by Burchett et al. in 7 low and middle income countries [29]. In contrast to their results, we found that economic evaluations play an important role in the decision-making process. Moreover, typically for low and middle income countries, the decision-making process is heavily influenced by overseas donor agencies such as the GAVI Alliance and the Bill and Melinda Gates Foundation. An analysis of the annual decision-making process for seasonal influenza vaccination in the Netherlands and France found that the evidence used was considered to be of low quality [18]. We also found that the quality of evidence was a concern in the reports, although it was related more to the absence of data on the long-term consequences of HPV vaccinations and not to the studies in general. In addition, Silva et al. found that the advisory process of the National Health Council could be more transparent; this was also debated in parliament regarding the report by the National Health Council on HPV vaccination [19].

This study adds to the body of literature [14–16] on the decision-making process of vaccine introduction by focusing on parliamentary documents, and performs a detailed analysis of the actual use of evidence in decision making. It gives insight into the information used in the different stages of the policymaking process by the different stakeholder groups. Furthermore, this study shows that the framework of Burchett can also be applied to high income countries.

This study has four major limitations that should be discussed. First, we used only written documents for our analysis. Other data, such as interviews or observations, were not possible, making triangulation impossible [24]. As the decision-making process evolved from 2006 to 2009, recall bias would have made interviews an unreliable source; accordingly, documented information is the most reliable source for our analysis. Furthermore, it is important to stress that such documents should not be seen as containing all the information on the decision-making process, but as depicting a part of the events that have occurred. Second, the analysis of the documents was mostly done by one researcher. Although extra checks were performed to improve the analysis and all results were discussed by the research team, some bias may have resulted. Third, search engines covering media and published articles were not incorporated in this analysis. Media articles were used only indirectly in this study, as many of the sources mentioned in the parliamentary records are no longer available. However, articles that impacted the policymaking process were mentioned in the parliamentary records. Research articles were not included as they are already indirectly cited in the reports written by the National Health Council and the CVZ. Fourth, we interpreted ‘evidence’ in a broad sense, whereby the asking for information or mentioning one of the categories, or the citation of findings mentioned in media, reports or publications by politicians were also seen as evidence. We did this as these are all examples of the practical use of evidence in compliance with the broader definition of evidence-informed decision making. If we had used a stricter definition of evidence,

the number of documents discussing evidence would have been lower.

Regarding the different needs per policy phase we recommend remembering the importance of acceptability in the policy process and add it as a criterion for the assessment performed by ZiNL. Furthermore, the different outcomes from the National Health Council and CVZ (now ZiNL) were confusing for the policymakers. Therefore it was wise that the National Health Council and ZiNL started with reevaluating nine vaccines together to explore eligibility for the NVP, the basic insurance package, or whether some vaccines should be made available in the private market in 2015 [21]. Currently advice has been published on three of the vaccines, for Pertussis, shingles, and Rota. Advice on vaccine for pneumococcal disease for the elderly and on HPV vaccine for both girls and boys is expected in 2017, while vaccines for Meningococcal disease, influenza (pregnant ladies) and Varicella still have to be discussed [21]. However, the establishment of one commission working for both organizations will be beneficial for the decision-making process. With regards to research, we would recommend using the Burchett framework as a basis for analysing the decision-making process on vaccine introduction in high income countries as well as in low and middle income countries. Moreover, we would recommend using media search tools such as Coosto and Lexis Nexis to search media, in addition to searching parliamentary records with the database of official announcements as we have done.

6. Conclusion

Based on our analysis, we conclude that economic information, in particular the evidence resulting from economic evaluations, played an important role during the decision-making process for the introduction of HPV-vaccination. Economic evaluations were most used in the first two stages of the policy process, and the advice of the National Health Council and the Health Insurance Board (CVZ) played a crucial role. However, the differences in interpretation of the evidence were confusing for policymakers. Therefore, we recommend establishing one commission working for both organizations to support evidence-informed vaccine decision making.

Authors’ contributions

AP, MH, RH, SE and IvdP conceived the study. IvdP and AP selected the documents and pilot tested the framework used. IvdP analyzed the documents, with input of AP, MH, RH and SE in case of doubt. IvdP wrote the first draft of the manuscript with input from AP, MH, RH and SE. All authors contributed to the writing of the manuscript. All authors read and approved the final manuscript.

Conflict of interest

The author(s) declare(s) that there is *no conflict of interest* regarding the publication of this article. However, RH is a staff member of the World Health Organization. The views expressed is that of the author and do not necessarily represent the views of the World Health Organization.

Acknowledgements

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. This research was presented in earlier forms at the NVTAG abstract symposium and ISPOR 20th Annual European Congress and we thank the audience for their valuable comments. We also thank Alice Abou-Nadar for reviewing an earlier version of the manuscript.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.healthpol.2018.09.001>.

References

- [1] PATH. The cornerstone of public health. Washington: PATH; 2015.
- [2] Arias D, O'Connell M, Cashin C, Bloom D, Saxenian H, Wilson P. Immunization financing: A resource guide for advocates, policymakers, and program managers. Washington D.C: Results for Development; 2017.
- [3] Blau J, Sadr-Azodi N, Clementz M, Abeyasinghe N, Cakmak N, Duclos P, et al. Indicators to assess national immunization technical advisory groups (NITAGs). *Vaccine* 2013;31:2653–7.
- [4] Janusz CB, Jauregui B, Sinha A, Clark AD, Bolaños BM, Resch S, et al. Performing country-led economic evaluations to inform immunization policy: ProVac experiences in Latin America and the Caribbean. *Value in Health Regional Issues* 2012;1:248–53.
- [5] Jauregui B, Sinha A, Clark AD, Bolanos BM, Resch S, Toscano CM, et al. Strengthening the technical capacity at country-level to make informed policy decisions on new vaccine introduction: lessons learned by PAHO's ProVac Initiative. *Vaccine* 2011;29:1099–106.
- [6] Senouci K, Blau J, Nyambat B, Faye PC, Gautier L, Da Silva A, et al. The Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) initiative: a country-driven, multi-partner program to support evidence-based decision making. *Vaccine* 2010;28:A26–30.
- [7] Bowen S, Zwi AB. Pathways to evidence-informed policy and practice: a framework for action. *PLoS Medicine* 2005;2:e166.
- [8] Hanney SR, Gonzalez-Block MA. Evidence-informed health policy: are we beginning to get there at last? *Health Research Policy and Systems* 2009;7:30.
- [9] Lavis JN, Ross SE, Hurley JE, Hohenadel JM, Stoddart GL, Woodward CA, et al. Examining the role of health services research in public policymaking. *The Milbank Quarterly* 2002;80:125–54.
- [10] Hanney SR, Gonzalez-Block MA, Buxton MJ, Kogan M. The utilisation of health research in policy-making: concepts, examples and methods of assessment. *Health Research Policy and Systems* 2003;1:2.
- [11] TC Office. Professional policy-making for the 21st century London. London: Office TC; 1999.
- [12] Jauregui B, Janusz C, Felix G. 4.7 evidence-based policy-making for national immunization programs. In: Family gender and life course. Washington D.C: Pan American Health Organization; 2013.
- [13] World Health Organization. Global vaccine action plan 2011–2020. In: *Global Vaccine Action Plan 2011–2020*; 2013.
- [14] Burchett H, Mounier-Jack S, Griffiths U, Mills A. National decision-making on adopting new vaccines: a systematic review. *Health Policy and Planning* 2012;27:ii62–76.
- [15] Haas M, Ashton T, Blum K, Christiansen T, Conis E, Crivelli L, et al. Drugs, sex, money and power: an HPV vaccine case study. *Health Policy* 2009;92:288–95. <http://dx.doi.org/10.1016/j.healthpol.2009.05.002>. Epub Jun 7.
- [16] Kane MA, Serrano B, de Sanjose S, Wittet S. Implementation of human papillomavirus immunization in the developing world. *Vaccine* 2012;30:F192–200. <http://dx.doi.org/10.1016/j.vaccine.2012.06.075>.
- [17] Ferrer HB, Trotter C, Hickman M, Audrey S. Barriers and facilitators to HPV vaccination of young women in high-income countries: a qualitative systematic review and evidence synthesis. *BMC Public Health* 2014;14(700). <http://dx.doi.org/10.1186/471-2458-14-700>.
- [18] Silva ML, Paget WJ, Mosnier A, Buthion V, Cohen JM, Perrier L, et al. Development of seasonal influenza vaccination recommendations: relevance and influence of the evidence on the decision-making process in France and the Netherlands. *Value in Health : The Journal of the International Society for Pharmacoeconomics and Outcomes Research* 2016;19:670–9.
- [19] Silva ML, Perrier L, Paget JW, Mosnier A, Buthion V, Cohen JM, et al. Influenza vaccination policy-making processes in France and the Netherlands: framework and determinants. *Health Policy* 2016;120:293–305.
- [20] Silva ML, Perrier L, Paget J, Mosnier A, Buthion V, Cohen JM, et al. Information used in the decision-making process regarding influenza vaccination policy: perceptions of stakeholders in France and the Netherlands. *Value in Health : The Journal of the International Society for Pharmacoeconomics and Outcomes Research* 2014;17:A329.
- [21] Munoz N, Castellsagué X, de González AB, Gissmann L. HPV in the etiology of human cancer. *Vaccine* 2006;24:S1–10.
- [22] Schiffman M, Castle PE, Jeronimo J, Rodriguez AC, Wacholder S. Human papillomavirus and cervical cancer. *The Lancet* 2007;370:890–907.
- [23] RIVM. Rijksvaccinatie programma: geschiedenis; 2015.
- [24] Yin RK. Sage publications. In: *Case study research: design and methods*; 2013.
- [25] Overheid.nl. Officiële bekendmakingen. The Hague: Overheid.nl; 2016.
- [26] QSR. What is NVivo; 2016.
- [27] Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qualitative Health Research* 2005;15:1277–88.
- [28] Steenhorst R. Nog dit jaar vaccin cervixkanker. *Telegraaf*; 2006.
- [29] Burchett H, Mounier-Jack S, Griffiths U, Biellik R, Ongolo-Zogo P, Chavez E, et al. New vaccine adoption: qualitative study of national decision-making processes in seven low-and middle-income countries. *Health Policy and Planning* 2012;27:ii5–16.