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► **To cite this version:**

Jeremy K Ward, Florian Cafiero, Raphael Fretigny, James Colgrove, Valérie Seror. France's citizen consultation on vaccination and the challenges of participatory democracy in health. *Social science & medicine*, 2019, 220, pp.73-80. 10.1016/j.socscimed.2018.10.032 . hal-01959783

HAL Id: hal-01959783

<https://hal.science/hal-01959783>

Submitted on 19 Dec 2018

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France's citizen consultation on vaccination and the challenges of participatory democracy in Health

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Pre-print version of: Ward J.K., Cafiero F., Fretigny R., Colgrove J., Seror V., France's citizen consultation on vaccination and the challenges of participatory democracy in Health, *Social Science & Medicine*, 220 (1), 2019, pp. 73-80, DOI: [10.1016/j.socscimed.2018.10.032](https://doi.org/10.1016/j.socscimed.2018.10.032)

Abstract

Background: Confronted with a rise in vaccine hesitancy, public health officials increasingly try to involve the public in the policy decision-making process to foster consensus and public acceptability. In public debates and citizen consultations tensions can arise between the principles of science and of democracy. To illustrate this, we analyzed the 2016 citizen consultation on vaccination organized in France. This consultation led to the decision to extend mandatory vaccination.

Methods: The analysis combines qualitative and quantitative methods. We analyze the organization of the consultation and its reception using the documents provided by its organizing committee, articles of newsmedia and the contents of 299 vaccine-critical websites. Using methods from computational linguistics, we analyze the 10542 public comments posted to the consultation's official website.

Results: The combination of a narrow framing of debates (how to restore trust in vaccination and raise vaccination coverages) and a specific organization (latitude was given to the orientation committee with a majority of medical experts) was successful in avoiding legitimizing vaccine critical arguments. But these choices have been at the expense of a real reflection on the acceptability of mandatory vaccination and it did not quell vaccine-critical mobilizations.

Conclusions: Public health officials must be aware that when trying to increase democratic participation into their decision-making process, how they balance inputs from the various actors and how they frame the discussion determine whether this initiative will provide meaningful information and democratic legitimacy.

Keywords

Vaccination, participation, controversies, legal mandates, ethics, policy

Manuscript

1. Introduction

In the past decade, public health authorities from a great number of countries have been confronted to a multiplication of vaccine-related controversies and a rise in “vaccine hesitancy” (Larson et al., 2016). France has been particularly hit by this trend. Vaccine-related controversies have emerged at the end of the 1990s with a first vaccine scare surrounding an alleged link between the hepatitis B vaccine and multiple sclerosis. They have multiplied since 2009 and the pandemic flu vaccination campaign, with debates surrounding the use of aluminum-based adjuvants, the recommendation of the human papillomaviruses vaccines and the availability of vaccines only containing the three strains covered by French legal mandates (Diphtheria, Tetanus and Polio) and not other strains such as Hepatitis B (Anonymous 2018). They have been accompanied by a sharp rise in vaccine hesitancy, to the point that France is today among the countries with the largest proportion of the population doubting the efficacy or safety of at least one vaccine (Larson et al., 2016; Peretti-Watel et al., 2014).

In reaction to this alarming trend, French authorities have decided to extend mandatory vaccination to eight more childhood vaccines since January 1, 2018, bringing the total to 11. This decision has sparked a heated debate in the international public health community over whether legal mandates are the best way to raise vaccination coverages and whether they are likely to polarize attitudes towards vaccination rather than alleviate doubt (Nature, 2018; Ward et al., 2017; Plotkin et al., 2018; Ward et al., 2018). The disagreement surrounding this decision may seem surprising given that the French government had organized a “citizen consultation” on vaccination between January and October 2016 to involve the wider public in policymaking and foster public acceptability. This citizen consultation was crucial in pushing forward the idea that mandates are a solution to France’s contemporary crisis with vaccines (Anonymous, 2018). Why has this effort to open up the decision-making process not prevented such a debate from arising? Drawing lessons from this precedent is crucial in a context where public health authorities across the world struggle to find the solution to contemporary vaccine hesitancy (Larson et al., 2016).

Drawing lessons from this precedent is also necessary beyond the case of vaccination. In the past 30 years, the way national and international public health authorities have devised their policies has been accused of being technocratic and of prioritizing political and economic interests over those

of the public (Callon et al., 2011). In response, decision-makers have sought to improve transparency and to increasingly turn to the tools of participatory democracy to foster public acceptability for a wide variety of their policies. This turn towards public participation has affected vaccination policies beyond the borders of France. For instance, the National Vaccine Advisory Committee of the U.S. Centers for Disease Control has tried to involve the public in policy-making since 2009 and the European Commission launched in December 2017 a three-months long public consultation on vaccination (European Commission, 2017; National Vaccine Advisory Committee, 2016)

However, shifting control away from experts and closer to public opinion carries the risk of giving prominence to unfounded beliefs and special interests. This is especially the case in a context where the Internet provides a relatively unregulated ground for motivated minorities to mobilize and, sometimes, spread refuted arguments (Vosoughi et al., 2018). The tension between scientific and democratic principles has been the impetus behind the continuous search by authorities and political scientists for new ways to involve the public while maintaining a high standard of rational discussion (Callon et al., 2011; Fishkin, 2009). These methods include citizen consultations, general assemblies, citizen conferences, citizens' juries, and deliberative polls (Bourg and Boy, 2005; Callon et al., 2011; Fishkin, 2009). Each of these experiments can help us move toward a more democratic public health system if we analyze closely whether and how they provided decision-makers with crucial information and a democratic mandate for their policies. The French citizen consultation on vaccination organized in 2016 highlights the temptations faced by decision-makers when they try to foster public debate while preserving an existing scientific consensus.

The purpose of this article is to present how this citizen consultation was organized and analyze the tensions at its core between the democratic and scientific principles. With this case study, we aim to further the understanding of how the concrete organization of a participatory device determines the contents of deliberations, the quality of the information gathered and how much democratic legitimacy authorities can gain in the process. We underline the importance of the formulation of the question to be debated – i.e. the framing of the debate - and how the organizational setup gave different weights to the various contributions to the debate. We show how this choice of setup affected discussions on crucial issues such as vaccine safety and legal mandates. These choices were effective to avoid legitimizing vaccine critical arguments and sparking even further debate on the safety of vaccines. But we also show that they ran counter to some essential principles of participatory

devices. Because of this, it is unclear exactly what made this citizen consultation informative or efficient in comparison to more traditional forms of expertise, especially when it came to the discussion of mandatory vaccination. To facilitate readability and to highlight the implication of our case study, we will present our results and their discussion together (section 3).

2. Data and methods

We draw on data pertaining to the setup in itself. But to analyze any participatory setup, it is necessary to set it in its wider political context. We therefore also turn to data relative to how this consultation was received by major stakeholders (media coverage and documents produced by vaccine critics). The analysis is based on a mix of qualitative methods commonly used in political science and of quantitative methods developed in the field of computational linguistics. To interpret our results, we drew on our previous work on French vaccine-related controversies and policy-making (Anonymous, 2015, 2016, 2018).

Our main focus will be on the two datasets that concern the setup in itself: the documents describing its organization and the public's comments posted on its website.

The organizers of the consultation were particularly transparent and gave the public access to documents detailing the workings of this consultation (see the annex to the final report available on the consultation's website: <http://concertation-vaccination.fr/la-restitution>). Two of the authors applied thematic content analysis to these documents with a coding scheme centered in particular on the presence of vaccine critics, the way the general public and civil society were integrated at the various stages of the consultation and how the recommendations coming from them were presented in the final report. This coding framework was formulated both deductively (through pre-established concepts guiding the research questions), and inductively (on the basis of salient and recurrent themes identified in the data) (Braun & Clarke, 2014).

The database of all contributions published on the consultations' internet platform was provided by Santé Publique France, a public agency under the supervision of the French Minister for Health in charge of monitoring the French population's health and promoting health-inducing behaviors. This agency was in charge of the logistics of the citizen consultation including the construction and administration of the consultation's website. They were therefore responsible for

guaranteeing that the contributions posted in the comments section of the website complied with French legal and ethical standards regarding internet publication (anonymization, filtering of violent and libelous discourse, etc.). This led them to delete 1404 contributions and to authorize the publication of a total number of 10 435 contributions. A deontologist was also responsible for insuring that all aspects of the consultation complied with ethical standards (see here: <http://concertation-vaccination.fr/page-d-exemple/le-comite-dorientation/la-deontologue-anne-fagot-largeault/>).

These contributions could not be analyzed using a qualitative coding scheme because of their great number. We therefore turned to quantitative tools developed in the field of computational linguistics. Two of the authors annotated manually a sample of a little more than 10% of the 10 435 contributions (1054) chosen at random, encoding two variables: does the text criticize at least one recommended vaccine? (yes/no); does the text praise mandatory vaccination, criticize it, or is it silent on the subject? These two themes were chosen because they are central to current vaccine-related controversies in France as they have been elsewhere (Colgrove, 2006; Blume, 2017)(Anonymous, 2016). This choice of themes also reflects the fact that we were already aware before launching the study that this consultation led to the decision to extend mandatory vaccination and that it was criticized for not taking on the issue of the safety of adjuvants. Assessing the proportion of comments that took on these issues and the opinion they expressed was therefore crucial in the analysis of how the public's opinion was integrated in this participatory setup.

Using the software WEKA (Eibe et al., 2016), one of the authors trained an artificial intelligence to recognize texts according to those variables, with our sample as training corpus. To that end, he implemented two models based on multinomial logistic regression with Tikhonov regularization (Le Cessie and Van Houwelingen, 1992)based on n-grams (4-grams to 7-grams) of characters. Punctuation marks were retained as they proved to be meaningful for the categorization of the texts. For instance, in our corpus, the use of exclamation marks is significantly associated with vaccine-critical texts. The texts have not been lemmatized as this would have concealed important information. Speaking of one « vaccine » and not of « vaccines », of one's « doctor » and not of « doctors » in general etc. is significant in the context of our study. Outcomes of the model were generated with an acceptable precision for the first question (0.71, superior to the acceptability threshold of 0.68 defined by Bradley (Bradley, 1997), as well as for the second question (0.82).

Relevant lexical entities were isolated using CQL requests with the software TXM (Heiden et al., 2010).

To set the results from the previous analyses in context, we will also occasionally draw on the qualitative content analysis of two datasets that concern the reception of the consultation in the media and by vaccine critics. This was meant to assess whether this consultation favored consensus-building and acceptability of its recommendations and whether it favored the wide dissemination of vaccine-critical arguments in the media. We gathered all articles pertaining to the consultation published in 7 of France's most prominent national newspapers (Libération, Le Parisien-Aujourd'hui en France, Le Monde, Le Figaro, La Croix, L'Humanité, Les Echos). These newspapers were accessed through the database Europresse which allows keywords searches (see www.europresse.com). We selected all articles containing the fragment "débat" or "Concertation" and the fragment "vacc" published between June 1st, 2015 and February 1st, 2017. The search generated 48 articles (after exclusion of duplicates and errors). Two of the authors applied a coding scheme focused on identifying critics and defenders of the consultation and their arguments.

To analyze the reception of the consultation among vaccine critics we turned to a database of the contents 299 French-speaking vaccine-critical websites. This sample comprises all prominent French vaccine-critical organizations and activists who had a website or a blog at the time. It was crawled using the software Hyphe, developed by the Medialab at Sciences Po Paris. We analyzed through close-reading all the pages of these websites that evoked this citizen consultation using the same keywords searches as for the media articles. Analysis was performed by two of the authors and the coding scheme focused on identifying the arguments for and against this consultation and the chronology of their appearance.

Since all the data used in this article are public, this research did not require the approval of an ethics committee in France.

3. Findings

3.1 Participatory democracy in France and the surge of vaccine hesitancy

Since the 1970s, social scientists have drawn attention to the growing distrust towards public officials and their institutions in most developed countries (Inglehart and Welzel, 2005). This phenomenon and the multiplication of scandals involving public administrations has prompted political theorists and activists to draw attention to the limits of “representative democracy” or “opinion democracy” (Fung and Wright, 2003; Rosanvallon, 2006). They underline the fact that the tools of representative democracy, such as elections, do not provide enough control over elected officials. In articulation with elections, opinion polls and public debates in the media are supposed to compel officials to take into consideration the will of the people. However, analysts have shown that media contents do not reflect public opinion’s point of view on a number of subjects and that neither do opinion polls because of a wide range of biases in their methodology and misuses by politicians (Bourdieu, 1993; Ginsberg, 1986). The consequence of these shortcomings is that public interest is often trumped by political, economic or personal interests.

A number of institutional tools have been designed to overcome these limits by including the public at various stages of institutional decision-making processes (Blatrix, 2009; Fishkin, 2009). Since the 1980s, officials in a great number of countries have increasingly turned to these tools of “participatory democracy” to deal with issues pertaining to science and technology, urban planning, health and medicine, the environment, etc. A first set of these tools are based on an understanding of democracy as participation of all the stakeholders on a given issue. In this approach to participatory democracy, the primary aim is avoiding cases where the interests of a minority are favored to the expense of the majority. This has led to a focus on integrating social movements and civil society more generally in decision-making processes. This is done either by including actors who represent civil society in these processes – for instance by putting the president of an NGO in an advisory board – or by setting up open spaces for anyone to give their opinion on a given subject – for instance by organizing neighborhood meetings or open internet websites (Fung and Wright, 2003; Rose, 1999; Shane, 2004). A second set of tools focuses on democracy as an overcoming of individual interests through rational collective deliberation (Elster, 1998; Manin, 1987). In this approach, the primary aim is to build consensus and reach a decision that satisfies all the stakeholders’ interests. This is done by choosing settings that favor the exchange of arguments rather than the successive expression of interests – for instance by favoring deliberative juries rather than polls and hearings – and by actively working to improve the participants’ knowledge of the issues in order for them to express a better-

informed opinion. This has led to the modification of some traditional tools of public opinion analysis, for instance deliberative polls and training courses for members of the public included in “citizen juries” (a variation on focus groups) before they deliberate (Fishkin, 2009).

In France, these new institutional devices were introduced at the turn of the 1990s mainly in the domain of urban policies (Joly et al., 2003; Nez, 2015). Participation was progressively institutionalized within state administrations, in the opinion polling industry and in think tanks during the 1990s and 2000s (Blatrix et al., 2007). Such devices were later imported in the domain of health with the organization of general assemblies on bioethics and nanotechnology in 2009, of 150 local debates on the national health strategy in 2013-2014 and of a citizen consultation on mammary cancer in 2015-2016). In most cases, authorities opted for a set up that mixed several of types of participatory tools and articulated them with more traditional expert and politician-focused processes (Bourg and Boy, 2005; Callon et al., 2011).

These experiments with participatory democracy in health coincided with the turbulent period for vaccination in France we described in the introduction. The idea that a public debate could be the solution to vaccine hesitancy emerged in this context. Following the hepatitis B vaccine scare, the second half of the 2000s was a period of intense reflection on the ways to improve France’s vaccination policies (Comité pour l’amélioration de la politique vaccinale, 2011). But recourse to participatory devices was not part of these debates. It only came to the fore after the traumatic experience of the 2009 pandemic flu vaccination campaign. The French government planned on spending around one billion euros in the fight against this disease and hoped to vaccinate around 70% of the population. Because it eventually appeared that this flu was not as lethal as expected, the government came under heavy criticism and the campaign was labelled a fiasco. As a consequence, two parliamentary enquiries were set up in the first half of 2010 to identify what went wrong and improve governmental preparedness to pandemic crises (Assemblée Nationale, 2010; Sénat, 2010). The enquiry led by deputies from the National Assembly (lower house, where legislation is debated and voted) endorsed the idea that a lack of openness to public debate and public opinion was part of the issue with this campaign. They came to the conclusion that a “public debate” on vaccination in pandemic situations and a “General Assembly” on vaccination should be organized (Assemblée Nationale, 2010). This suggestion that more public participation and debate were necessary became very influential in public health circles. In the following years, several prominent institutions and

expert circles put in charge of finding a solution to French vaccine hesitancy endorsed this recommendation (Assemblée Nationale, 2012; Conférence Nationale de Santé, 2012; Haut Conseil de la Santé Publique, 2014). So, when in summer 2015 then Minister for Health Marisol Touraine decided to take on the subject of vaccination, a public debate had already been primed as a necessary step in the policy-making process.

Interestingly, these various expert advices also stress the risks that such a public debate could constitute a platform for vaccine-critical movements. This is not surprising or specific to the subject of vaccination. The possible conflict between democratic principles and the requirements of a rational debate based on facts and informed by science has been highlighted not only by public health experts, but also by some prominent thinkers of participatory democracy (Bourg and Boy, 2005; Callon et al., 2011).

3.2 The imperium of science: setting boundaries to public discussion of vaccines

The will to preserve vaccines while gathering as much information as possible on the societal aspects of vaccination is manifest in the setup eventually chosen by the French minister for Health in January of 2016. The goal set by the minister for the consultation was to restore trust in vaccination as part of the renewal of France's vaccination policy (Hurel, 2016; Ollivier-Yaniv, 2017). The organization of the consultation reflected this goal.

The consultation was conducted under the supervision of an ad hoc board of 16 people (the "orientation committee") composed of medical experts, representatives of state institutions, member of civil society, and social scientists. They translated this framing into a set of questions meant to guide the debates and organized the various settings which composed the consultation. The setup aimed to include the lay public in five ways: 1) a comment section on the consultation's website opened between September 14th and October 14th 2016 to gather the comments of the public (which ultimately numbered 10 435 comments), 2) a citizen jury composed of 22 laypeople randomly selected by a polling agency, 3) a jury of 16 medical professionals selected in the same way, 4) a qualitative study consisting of focus groups and interviews with laypeople and medical professionals, and 5) a quantitative study of vaccine-related perceptions (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016a). It also integrated members of civil society at various stages and levels of the process. The organization committee comprised 5 members of civil society one of which co-

chaired the committee with a pediatrician. Others were auditioned by the orientation committee and by the two juries, including some vaccine critics. Each jury auditioned a variety of experts and stakeholders, then deliberated and transmitted their recommendation to the orientation committee. The orientation committee wrote the final report using information gathered through all these various pathways (juries, auditions, website and qualitative study).

Several elements of this setup mark the will to preserve the imperium of scientific facts in this consultation. Firstly, the orientation committee was given the latitude to select among the proposals and arguments formulated during debates to compose the final report. Doctors and medical experts made up half of this committee (8 out of 16 members). The committee did not include vaccine critics and comprised several people known for their public defense of vaccination. Secondly, the juries were trained in the basics of vaccine science before deliberating on the subject. The third element is the most important one and consists in the framing of the debate. The orientation committee was intent on keeping the debates within the boundaries set by the minister's mission statement. The consultation was to answer the question of how to restore trust in vaccination and therefore raise vaccination coverage. This framing implies that the current vaccination strategy and the safety and efficacy of any of the recommended vaccines should be pushed to the margins of the debate if not outside. This is made clear in the set of six questions the orientation committee gave to both juries to help them focus their reflections and exchanges. Four of them focus on the public's behavior and how to have an effect on it: 1. what are French people's perception of vaccines, 2. how can we facilitate vaccination, 3. in which conditions can mandatory vaccination be acceptable, 4. what do you expect of research on vaccines, 5. what are your recommendations to improve trust in vaccines, and 6. what are your recommendations to improve vaccine coverages? The comments section of the consultation's website was even more focused, with internet users posting their answers to one of three questions: questions 5 and 6 and an open question on vaccination.

3.3 How vaccine criticism emerged in the consultation

This does not mean that this setup excluded other types of questioning.

It is important to note that vaccine critics were included in the list of people automatically auditioned by both juries. Those who reject vaccination in itself (antivaccinationists) were represented in this list by a spokesperson for France's oldest antivaccine group: La Ligue Nationale Pour la Liberté

des Vaccinations (National League for Freedom in Vaccination). But this list also included a member of Entraide aux Malades de la Myofasciite à Macrophages (Support Group for People Suffering from Macrophagus Myofasciite, or E3M), a group of purported victims of aluminum-based adjuvants. In France, the use of these substances has become publicly contested since 2010. This patient group has three aims: recognition for the particular chronic fatigue syndrome they claim to suffer from, recognition by the medical community that aluminum-based adjuvants are the cause of this disease and financial compensation. The head of the research team they work with was also auditioned by the orientation committee and was requested by both juries for their second round of auditions.

Also, among the six guiding questions, the ones pertaining to vaccine research and legal mandates were seized by the jury as opportunities to raise questions outside the box. The citizen jury, when responding to the former, raised the issues of conflicts of interest and transparency in the institutional processes that lead to a vaccine being put on the market, and recommended that research should be conducted to help replace aluminum-based adjuvants or produce non-adjuvanted vaccines; and, when responding to the latter, raised the issues of compensation for vaccine-related injuries and of multivalent vaccines. The jury of medical professionals advocated for more research on the long term adverse effects of vaccines and their genetic determinants.

The comment section of the consultation's website was unsurprisingly a space for the free expression of opinions regardless of the framing proposed by the organizers. Nurses and pharmacists took this opportunity to push forward the idea that they should be given a greater role in vaccination campaigns (with 936 contributions evoking the former and 584 the latter), following calls to flood the consultation's website by prominent professional organizations (Conseil de l'Ordre Infirmier de Paris, 2016; Infirmiers.com, 2016; SNIIL, 2016; SNPI, 2016). More importantly, the theme of the safety of some or all vaccines barged in through this open window (60% of the contributions criticized at least one vaccination recommendation), with aluminum first among them (evoked in more than 20% of the contributions). This critique was often intertwined with issues of mandatory vaccination and transparency as is illustrated in the following contributions:

Vaccination has been a major leap forward for health. It has saved a number of lives. However, for many reasons, vaccination has a bad press in France: - the vaccination calendar, vaccination of newborns: why vaccinate babies so early when we know that their brain is still too vulnerable, notably to aluminium, and that they can be protected by their mother's antibodies? - Mandatory

vaccines and combined vaccines: why force parents to vaccinate their children with combined vaccines that lump together compulsory valences and others who are optional, when some vaccines are out of stock? When will we have vaccines with only the compulsory strains? And without aluminium, since it is possible? – side effects: nobody wants the side effects of a preventative product. Why don't public authorities want to be transparent about the known side effects of some vaccines? Why is there no open discussion on the risk/benefit ratio of vaccines? – Adjuvants: it is now proven that some adjuvants are a risk for health. Why deny it? Why not undertake actions on the short, middle and long term with manufacturers to encourage them (force them?) to find other means to improve the immune response to a vaccine? The decrease in vaccine coverage for some diseases is a risk we should not take lightly. Which actions will the government undertake to restore trust among the French without infantilising them? It is a pity that the dialog is not more open on this societal and public health issue, that patients and doctors from all sides are not being heard. This citizen consultation is a first step. Vaccination is up for debate!

Contribution 11716, October 13th, 2016, posted as an answer to question 1: Express your opinion on vaccination in general

Hello, My baby will have her first vaccines with aluminium next Monday and my spouse and myself are going there with fear in my belly, hands tied by the law and our desire to protect our daughter from serious diseases. Why leave this accursed aluminium in these injections? For pharmaceutical companies' money. Why put a baby's life in danger? Why will my daughter receive 5 vaccines on the same day? For pharmaceutical companies' money again. I wish and I even want safe and transparent vaccination!

Contribution 5972, September 30th, 2016, posted as an answer to question 3: What would be your recommendations to improve vaccination coverage?

The great number of contributions evoking aluminum reflects in some way the fact that it has become one of the crucial motives for vaccine hesitancy in France (Bulletin d'épidémiologie hebdomadaire, 2017). But it is also very likely that it is the effect of a great mobilization of vaccine critical activists. For instance, within the month the platform was open, E3M prompted their supporters to comment on the platform on three separate occasions through their website and Facebook page.

With a relative consensus in the French vaccinology community on the lack of evidence to support the theory that aluminum-based adjuvants cause serious long-term effects (Académie

Nationale de Médecine, 2012; Académie Nationale de Pharmacie, 2016), the emergence of this theme constitutes exactly what the public health milieu tends to fear about participatory devices.

The latitude given to the orientation committee in drafting the final recommendations allowed them to push aside these doubts and avoid legitimizing them. This can be seen in two different sections of the final report: in its introduction (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016a) p9) ...:

The analysis of all the available studies does not enable, in the current state of scientific knowledge, to establish a causal link:

- between the administration of vaccines containing aluminium-based adjuvants and auto-immune or inflammatory diseases such as macropagus myofasciitis,
- between vaccination against hepatitis B and multiple lateral sclerosis,
- between hpv vaccination and auto-immune diseases, only one study having observed a very low and still to be confirmed risk of Guillain-Barré syndrome,
- between measles vaccination and autism

... and in the section presenting recommendations for future research in vaccinology (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016a) , p25):

Adjuvants are necessary to the efficacy of non-living vaccines. Live vaccines (measles, rubella, mumps, varicella, etc.) contain enough activating signals adjuvants of the immune system. Adjuvants are therefore essential to many protein vaccines (such as diphtheria, tetanus, whooping cough, polio, hepatitis B, HPV, etc.) as substitutes to natural substances of infectious agents which stimulate the production of antibodies as well as cellular immunity. Recourse to non-adjuvanted protein vaccines, as suggested by the citizen jury cannot therefore be considered. Current research does not have the objective of replacing aluminium salts whose efficacy and safe use have been demonstrated in existing vaccines (...)

Finally, it is important to note that the time necessary for operational development of a new adjuvant (which implies safety and efficacy tests) to replace aluminium salts is of around ten years. As for the safety, data should then be compared with that for aluminium salts for the use of which there is hindsight of almost 100 years.

The choice of framing also meant that it was very difficult for the issues of vaccine safety and of the list of recommended vaccines to become central in debates. More generally, this choice of setup seems to have been effective in preventing this consultation from sparking an even larger debate over

the science of vaccines – the period of the consultation was marked by very little media coverage of vaccine-critical mobilizations. Even the announcement of the committee’s recommendations at the end of November 2016 elicited little debate in the media. Among these recommendations were: making all these vaccines free of charge and more easily available; allowing pharmacists to vaccinate; increasing transparency, especially by facilitating access to the data of clinical trials; putting more effort in communication towards the public and training of medical professionals; and developing research on a variety of aspects of vaccination. But the most important and eye-catching recommendation was to extend mandatory vaccination to all childhood vaccines temporarily in order to abrogate all mandates once vaccination rates become satisfactory. The orientation committee also suggested that conscientious exemptions should be included in the law.

3.4 A missed opportunity to gather information on the acceptability of vaccine mandates

This combination of a narrow framing and a specific organization was successful in maintaining the imperium of scientific consensus, such as in the case of aluminium-based adjuvants. But these constraints have run counter to some essential principles of participatory devices. Because of this, it is unclear exactly what made this citizen consultation informative or efficient in comparison to more traditional forms of expertise.

1. Firstly, participatory devices can help deflate controversies by helping find common grounds with critical actors from social movements (Callon et al., 2011; Fishkin, 2009; Neveu, 2011; Topçu, 2013). This was not the case here. Many prominent vaccine critics applauded the initiative at first. Michèle Rivasi, a member of the European Parliament, posted as soon as November 2015 her 7 propositions to restore trust in vaccination in anticipation of the citizen consultation. The Institut pour la Protection de la Santé Naturelle (the Institute for the Protection of Natural Health, or IPSN) – the group that launched the petition against the use of aluminum that reached a million signatures and prompted the minister to call for this citizen consultation – promised at the beginning of January 2016 that they would “play the game” and placed great hope in this debate (E3M, 2016; IPSN, 2016; Rivasi, 2015). But the choices of framing and setup, announced in February 2016, antagonized them and also part of the participatory democracy milieu (Collectif, 2016; Formindep, 2016; Joyeux, 2016; Le Monde, 2016; Le quotidien du médecin, 2016). The deputy director of the Conférence Nationale de

Santé, one of the most prominent public institutions in charge of organizing public debates on health related issues, resigned resoundingly in reaction to the announcement of this setup. His protest was followed by Formindep, a prominent nonprofit which lobbies against the intervention of pharmaceutical companies' in the training of medical professionals. Commenting on the orientation committee's recommendations in December of 2016, they described the consultation in the following terms (Formindep, 2016) :

The consultation on vaccines, whose objective was to raise the level of trust in vaccines and vaccination coverage, is a total failure. The final report is an example of intellectual mediocrity, of loose deontology, of dubious transparency and its writing is the negation of a democratic exercise. With defenders like that, vaccination does not need, alas, any enemies.

The recommendations' legitimacy was called into question - with some press coverage (Le Monde, 2016; Libération, 2016) - and mobilizations have not slackened since (En Marche Pour La Liberte Vaccinale, 2017; Le Monde, 2017; Rivasi, 2017).

2. Secondly, it is necessary to reflect on the democratic legitimacy the consultation's process has given to the orientation committee's recommendations with regards to involving the wider public. What makes this consultation a "citizen" consultation? The citizen jury and the web platform were supposed to be the two main pathways to this involvement. But the committee had to go beyond or against the information gathered through these means for two of their essential recommendations: the extension of vaccine mandates and maintaining aluminum-based adjuvants. The citizen jury could not reach a conclusion on the first issue and recommended that aluminum adjuvants should be abandoned since a great proportion of the population feared them (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016b). Comments on the website contradicted these recommendations both on aluminium as mentioned previously, but also more clearly on mandatory vaccination. Indeed, only 20% of contributions evoked this issue, 87% of which opposed this measure. This does not mean that these opinions are representative of the wider public, but it does mean that both recommendations must find their legitimacy somewhere else, in the more expert-oriented aspects of this setup. Regarding mandates for instance, the committee relied more on the traditional tools associated with "opinion democracy". They focused on the result of an opinion poll suggesting that around 20% of the population would not get any vaccine if they

weren't mandatory (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016a).

3. Our third concern relates to how the framing of a public debate affects the quality of the information it generates for decision-makers. In these devices meant to involve the wider public, individuals are first and foremost apprehended as citizens i.e. as capable of prioritizing competing social goals (Callon et al., 2011). It is implied that they can do so because there is some kind of civic education in society, because they have a local or practical expertise on these subjects but also because however informed their judgment, it is legitimate because they endure the consequences of public policies (Callon, 1998; Fishkin, 2009; Sintomer, 2010). Reciprocally, members of the public take an interest in these debates for the same reasons. By focusing the reflection on ways to elicit a certain attitude in the public, this consultation asked citizens not to express their own point of view and values but to engage in the type of strategic thinking expected of political consultants or sociologists rather than of citizens. It is therefore not surprising that many commentators on the internet website shunted the two main questions put forward by the organizers: a majority of the were answers to the open question on vaccination (61%) rather than to the questions more in line with the framing of the consultation (how to restore trust and how to reach high vaccination rates, 19% and 20% respectively). Most members of the public wanted to debate of other aspects of vaccination and not just of the best ways to have everyone vaccinated. The issue of the framing of the debate was often explicitly addressed in comments such as these:

The debate is biased: this question shows that this is not an open debate on vaccination, but that the goal is to sell always more vaccines, whatever the cost...

Contribution 4430, September 21, 2016, posted as an answer to question 3: What would be your recommendations to improve vaccination coverage?

How could we not see that this consultation is biased? It's a "mug's game"? What kind of deontology is behind it? How about the 2nd and 3rd questions! Don't they imply the premise that "vaccination is not up for debate! (Mme the Minister)?

Contribution 6989, September 30, 2016, posted as an answer to question 1: Express your opinion on vaccination in general

The emergence of a debate about what the debate should be about is not unusual in participatory setups (Blatrix et al., 2007). They reflect the fact that organizers are never completely open to questioning every aspect of the policy or issue under scrutiny and try to frame debates in a way that they deem “constructive”, i.e. in a way that does not completely call into question their own intervention on the issue, past and future. For instance, public health officials want debates that generate ideas that they can use in their public health policies and not debates about the legitimacy of the institutions they represent or of the principle of public health. But in this case, this inevitable framing work is problematic even if we adopt the point of view of French public health officials.

Indeed, if we ask citizens to fill the shoes of experts of public opinion, the question necessarily arises of the quality of their judgments. The feeling that they were not experts of public opinion can explain why the citizen jury was unsure and divided on the subject of vaccine mandates. Their disagreement was not on matters of principle (individual autonomy vs state control for instance) but on whether the abrogation of mandates would effectively raise or lower vaccination coverages (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016b). But even if they had agreed on their assessment of the social impact of vaccine mandates, why would the committee give any credence to this assessment compared to that of the various social scientists they auditioned and to the data gathered through the traditional tools of opinion politics such as methodologically-sound opinion polls? Not only did the orientation committee and the Minister for Health confuse participation with public opinion analysis, they also fell prey to some classical biases in public opinion research. They asked the public 1. a different type of question than the ones they were likely to be interested in or have an opinion about and 2. to analyze itself rather than produce the judgments necessary for the analysis (Bourdieu, 1979).

4. Finally and consequently, this consultation constitutes a missed opportunity to gather precise information on the acceptability of mandatory vaccination in a given national context. This precedent could have provided the international public health community with a framework and a model for ethical decision-making on this sensitive issue.

The question of when compulsory vaccination is acceptable has been discussed for more than a century and ethicists have not reached a definitive answer (Omer et al., 2009; Salmon et al., 2015). This is not surprising; such discussions are inseparable from the inextricably political issue of balancing state power and individual autonomy which finds different answers depending on local

cultures (Colgrove and Bayer, 2005; Salmon et al., 2006). This is why different countries have different policies on this issue (Walkinshaw, 2011).

The citizen jury and the website could have given much information on when and how mandates can be acceptable in France. Unfortunately, the framing of the debate has largely overshadowed this issue. Only a small fraction of the citizen jury's statement document was dedicated to the question of coercion (2 pages out of ten) and it was far from providing a substantial material to decide on this subject. These two pages are not without interest. The jury states that it is divided on the subject and that those in favor of more mandates would like them to cover all childhood vaccines. However, the value judgments explaining these recommendations are missing from this document. Why vaccines for children and not adult? What about religious minorities such as Jehovah's witnesses? More importantly, one thing vaccination ethicists agree upon is that a mandate is all the more justifiable if the disease targeted is serious and transmissible, the precise point where the risk of the disease trumps personal autonomy being the crucial element to debate and identify (Colgrove, 2016). Each vaccine should therefore be debated at least somewhat separately to determine whether their epidemiological situation warrants coercion. This was not done by the jury who only provides comments on vaccination in general, "vaccines for minors" (without explaining why the age of the vaccinated should be of importance) and a sentence to the effect that a "pandemic or a sanitary emergency" would justify coercion. Comment on the website did not provide the orientation committee with more information. Without this issue being put forward in the guiding questions, only the people who already had an issue with this aspect of vaccination – i.e. antivaccinationists (Blume, 2006; Kata, 2010) – were likely to spontaneously mention this subject.

Of course, the orientation committee provided more grounds for their recommendation to extend mandatory vaccination to all recommended childhood vaccines and added the introduction of philosophical exemptions. But this dearth in information bore on their own recommendations and their justifications remain weak from an ethical point of view. They justify restricting mandates to childhood vaccines only by saying that it is "easily understandable and in conformity with a prevention policy against a collective risk". They also provide many different arguments in favor of vaccination for each of these childhood vaccines and turn them into arguments in favor of mandatory vaccination (Comité d'orientation de la concertation citoyenne sur la vaccination, 2016a, 2016b). But it remains very unclear in this document why other vaccines such as against HPV or the flu should not

be made mandatory. More importantly, it does not provide an answer to the most crucial question of all: when is it not justifiable to make a vaccine mandatory?

4. Conclusion

The 2016 citizen consultation on vaccination in France is a reminder of the difficulties of debating on issues for which there is a strong consensus in the public health community. By providing a platform to discuss issues pertaining to vaccine hesitancy and vaccine-related controversies it showed that the institutional tools of participatory democracy can provide a meaningful contribution to public health decision-making. But it should also be remembered as a warning that if some basic principles are not followed participatory devices cannot provide the quality of information and democratic legitimacy expected of them. In this particular case, it is arguable that by trying to obtain answers from the public on all aspects of vaccination policies and not only on mandatory vaccination, the organizers missed the opportunity to advance the reflection on one of the most crucial debates when it comes to vaccination. Beyond vaccination, public health deciders must realize that when trying to introduce more democracy in their decisions, how the inputs from the various actors involved in the debate are balanced and how the discussion is framed are always going to be the key issues.

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