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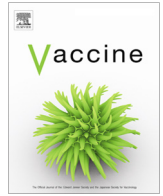
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## Short communication

## Why France is making eight new vaccines mandatory

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## ABSTRACT

France is one of the countries with the highest prevalence of vaccine hesitancy in the world. In an attempt to raise vaccination coverages, the French government made on January 1, 2018 eight more vaccines mandatory in addition to the three required until then. The process that led to this policy choice is of particular interest. We describe how vaccines became contentious in France and how French authorities came to view mandatory vaccination as the solution to the rise in vaccine hesitancy. In a bold move, French public health authorities turned to a new type of institutional device grounded in the ideal of democracy and public participation to political decision-making: “a citizen consultation”. This consultation anchored the idea that legal coercion could be the solution to France's crisis with vaccines. Time will tell whether the French extension of mandatory vaccination will reduce tensions around vaccines.

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## 1. Introduction

France is one of the countries with the highest prevalence of vaccine hesitancy in the world (40% of the French doubt the safety of vaccines, compared to 13.5% of Americans [1]). In an attempt to reach the goals set by the World Health Organization of 95% coverage for all childhood vaccines and to “restore trust”, the French government made eight more vaccines mandatory (Haemophilus influenza type B, Pertussis, Hepatitis B, Measles, Mumps, Rubella, Meningococcus C, Streptococcus pneumoniae) in addition to the three (Diphtheria Tetanus, Polio: DT-IPV) currently required. With this bill voted on the October 27, 2017 which took effect on January 1, 2018, France has joined other countries and U.S. states in a renewed use of legal mandates to raise immunization rates. The process that led to this policy choice is of particular interest to anyone interested in political decision-making or public health. In a bold move, French public health authorities turned to a new type of institutional device grounded in the ideal of democracy and public participation to political decision-making: “a citizen consultation”.

## 2. How vaccines became controversial in France

In France, the vaccination policy is designed by the Ministry for health after consultation of experts from the High Council for

Public Health (Haut Conseil de la Santé Publique). The Ministry publishes a “vaccination calendar” and doctors (mainly general practitioners and pediatricians) are in charge of administering both mandatory and recommended vaccines. In the past ten years, attitudes towards vaccination have become a subject of increasing concern for public health authorities. After two decades without vaccines hitting the news, a first vaccine scare appeared at the end of the 1990s when members of the public and nurses raised concerns over an alleged link between hepatitis B vaccination and Multiple Sclerosis. These accusations were later debunked [2]. Vaccination rates against this disease quickly plummeted and the campaign was interrupted in 1998 after only four years. However, by 2004 the alleged risks of this vaccine had ceased to make the news and immunization rates have risen since, partly due to the inclusion of the hepatitis B strain in the multivalent childhood vaccine DT-IPV and in other vaccines. The real turning point was the failure of the 2009 pandemic flu vaccination campaign. The French government aimed at vaccinating 70% of the general population and planned to spend around a billion euros in its fight against this flu. Heated debates arose in the media over a variety of aspects of this policy, including its cost and the safety of the vaccine, even before vaccination started. In the end, only around 8% of the French got vaccinated [3] and it was publicly labeled a “fiasco”. Since 2009, vaccine-related controversies have multiplied in France. Opponents of the use of aluminum-based adjuvants have gained considerable traction and media exposure since 2010. Since 2011, the vaccine against human papillomaviruses also faces

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regular public criticism by patients for its alleged long-term side-effects and by medical professionals who doubt the cost-effectiveness of this campaign. The aggravation of vaccine shortages since 2014, especially for monovalent vaccines and for the trivalent DT-IPV vaccine, has also fueled much frustration among parents looking for a la carte vaccination

Unsurprisingly, these public debates were accompanied by a growing concern in the public health sphere over lowering vaccination coverages and the possible emergence of new epidemics. These concerns were fueled by several studies highlighting the unsatisfactory level of some vaccination coverages and the wide diffusion of vaccine hesitancy. Vaccine hesitancy refers to attitudes towards vaccines that occupy an intermediate position along a continuum ranging from anti-vaccine to pro-vaccine attitudes [4]. HPV vaccination coverage has fallen from 28% of girls aged 11–14 in 2010 to 17% in 2014 [5] and seasonal flu vaccination has also decreased during this period (from 60% of at-risk groups such as people over 65, diabetics, pregnant women and health professionals in 2009 to 47% in 2017). Vaccination coverage against Measles Mumps and Rubella, while stable, is still under the threshold for herd immunity with only 74.5% of children aged 2 having taken the booster shots in 2013 and so are vaccination coverages against *Pertussis* (70% of 15 year-olds), Hepatitis B (43% of 15 year olds but 81.5% of 2 year olds) and Meningococcus (64% of 2 year-olds). Several studies also showed that France was among the countries where doubts over the efficacy and safety of some vaccines were the most pervasive [1,6].

For a long time, the main response by public health experts consisted in information campaigns and public declarations on the importance of vaccination and on the deleterious influence of anti-vaccine movements. But in August 2015, only weeks after having stated that “vaccination is not up for debate”, then Minister for Health Marisol Touraine made what appeared to be a complete U-turn and announced that a citizens’ consultation would be organized in order to find a way to restore trust in vaccines.

### 3. Participatory politics to solve France’s crisis with vaccines ? France’s citizen consultation on vaccination

After the hepatitis B vaccine scare, the second half of the 2000s was a period of intense reflection on ways to improve France’s vaccination policies [7]. But the idea that citizen participation and public debate should be a crucial part of the decision-making process only emerged after the traumatic experience of the 2009 pandemic flu vaccination campaign. One of the parliamentary enquiries set up to identify what went wrong and improve governmental preparedness to pandemic crises endorsed the idea that a lack of openness to public debate and public opinion was part of the issue with this campaign. Following this, it came to the conclusion that a “public debate” on vaccination in pandemic situations and a “General Assembly” on vaccination should be organized [8]. This suggestion that the institutional tools of participatory politics were part of the solution was to be very influential in public health circles. In the following years, several prominent institutions and expert circles were put in charge of finding a solution to French vaccine hesitancy and endorsed this recommendation [9–11]. So, when in summer 2015 then Minister for Health Marisol Touraine decided to take on the subject of vaccination after yet another case of large-scale vaccine-critical mobilization – a petition denouncing the use of aluminum as an adjuvant reached a million signatures –, a citizen concertation had already been primed as a necessary step in the policy-making process.

The chosen consultation setup was a complex one, meant to make room for the expression of the point of view of critiques of vaccines, of the public and of health professionals but also to bal-

ance them with expert knowledge on vaccines and diseases. An orientation committee was in charge of making recommendations based on (1) their own auditioning of a great variety of medical experts, members of civil society, social scientists, etc.; (2) recommendations given by two citizens’ juries randomly selected by a polling agency, one of 22 laypeople and the other of 16 health professionals, based on their own auditioning of various experts and actors in these controversies, and (3) the 10 435 comments posted on an internet platform opened from mid-September to mid-October. In its final report, released in November 2016, the orientation committee gave several recommendations for a comprehensive vaccination policy. But the main recommendation was that mandatory vaccination should be extended to all childhood vaccines until vaccination coverages were satisfactory and then be completely abrogated.

A legal development further catalyzed the policy change. In February 2017, the State Council (Conseil d’Etat), which acts as the Supreme Court for administrative justice, took on the subject of multivalent vaccines. It ruled partly in favor of parents wishing to only take the three mandatory vaccines (DT-IPV) and who could only find multi-vaccines containing other strains. It stated that parents should not be forced *de facto* to take non-mandatory vaccines. The French government therefore had to make a trivalent Difteria-Tetanus-Polio vaccine available, to abrogate these mandates or to extend mandatory vaccination to the strains included in the multivalent vaccines. A real catch 22 when considering that the vaccine manufacturer Sanofi was adamant that the trivalent vaccine they produced until 2011 generated too many side effects and that it would take years to design a new vaccine in conformity with today’s standards of quality [12–14]. This ruling meant that the status quo was not an option anymore and the extension of mandates to 8 more vaccines was presented as a priority in June 2017 [15].

The consultation was a turning point that anchored the idea that legal coercion could be the solution to France’s crisis with vaccines and that the law should extend to all childhood vaccines. This conclusion ran counter the historical trend in French public health of emphasizing individual autonomy. In the case of vaccination, this approach has been reflected in the fact that since the end of the 1960s, all new vaccines were introduced without being made mandatory, and that two older mandatory vaccination laws, pertaining to smallpox and tuberculosis, were abrogated in 1984 and 2007, respectively. Since the hepatitis B vaccine scare, an intense reflection on the ways to improve vaccination policies has occupied the French public health milieu [7]. In the debates that preceded the citizen consultation, several expert circles and institutions strongly advised putting an end to a regime where mandatory and “recommended” vaccines coexisted [7,10,11]. They argued that this distinction suggested that the latter were less important than the former. But, the abrogation of all mandates remained the point of reference in these reports, even if they warned against its risks. Only a minority of expert circles and medical associations advocated for making other vaccines mandatory and their argument was restricted to the MMR vaccine [9,16].

### 4. Conclusion

The decision to extend mandatory vaccination was applauded by most French medical associations, including the National Academy of Medicine (Académie Nationale de Médecine) and the National Academy of Pharmaceutics (Académie Nationale de Pharmacie) [17]. But others were reticent and joined several experts of vaccination behaviors in warning against the risk that this decision might polarize opinions on vaccination [18–21]. Unsurprisingly, vaccine critics denounced this decision, arguing

that the citizen consultation was a fraught process and that the recommendation of its orientation committee did not reflect the values of the public [22,23]. Time will tell whether the French extension of mandatory vaccination will reduce tensions around vaccines. It is now necessary to monitor the effects of this decision and draw lessons for the future.

### Conflict of interests

The authors declare no conflicts of interests.

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### Contributors

All authors participated in the writing of the paper. All authors have approved the final article should be true and included in the disclosure.

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