

state that even though they would usually assign great disvalue to a false-positive result, their priority on this occasion is to avoid a false-negative result (or vice versa). Moreover, patients must be properly informed about the relevant concepts. Many patients are unfamiliar with the concept of over-diagnosis and therefore may be unable to weigh the relative risk of unnecessary diagnosis and treatment against the risk of failing to discover a cancer¹⁸. Moreover, patients may not always have preferences about such outcomes. There must still be a sensible default decision threshold that can be used in cases in which patients choose to withhold their attitudes or simply have no preferences.

There is also a danger of exaggerating the precision of the probabilities. If the dataset used to train the algorithm was small or non-representative, a probability range may be a more reasonable output than a precise probability. There is also a risk that clinicians will be unwilling or unprepared to take the patient's risk-value profile into account. These recommendations would create a more complex decision task for clinicians than reliance on a pre-programmed threshold; this emphasizes the importance of training in the use of AI in clinical settings and

the co-design of diagnostic devices with physicians and patients.

These challenges notwithstanding, tailoring decision thresholds to the patient through the use of information about the patient's values and attitude about risk is vastly preferable to leaving them to be fixed by the software developer in a one-size-fits-all manner.

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The French health pass holds lessons for mandatory COVID-19 vaccination

The passe sanitaire increased levels of vaccination, but to a lower extent among the most vulnerable, and did not reduce vaccine hesitancy itself, showing the importance of outreach to underserved communities and the potential limits of mandatory vaccination policies.

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Public authorities in many countries are considering mandating vaccination against COVID-19 for the whole eligible population¹. Most countries are confronted with the difficulties of reaching the vaccination rates obtained for diseases such as measles, which are often above 95%. During the summer of 2021, French authorities implemented a health pass, or passe sanitaire, requiring everyone aged 12 and older to present proof of vaccination or a negative test for SARS-CoV-2 to access a wide array

of public spaces, including bars, libraries and hospitals. The introduction of the passe sanitaire markedly increased the number of people vaccinated against COVID-19. But, as of November 2021, coverage is plateauing at around 90% of the eligible population and a debate has arisen on whether the next step should be mandating this vaccination².

There are lessons to be learnt from the French experience with the health pass that contribute to the current debate on mandatory COVID-19 vaccination.

Barriers to vaccination

In France, vaccination coverage against COVID-19 rose steadily during the first half of 2021 until it reached a first plateau in mid-June, with around 60% of the adult population having had at least one dose³. After having vaccinated the most willing, public authorities were confronted with three classic barriers to vaccination³ (Table 1). The first was doubts regarding the safety of vaccines against COVID-19^{4,5}. The proportion of the population who intended to receive the

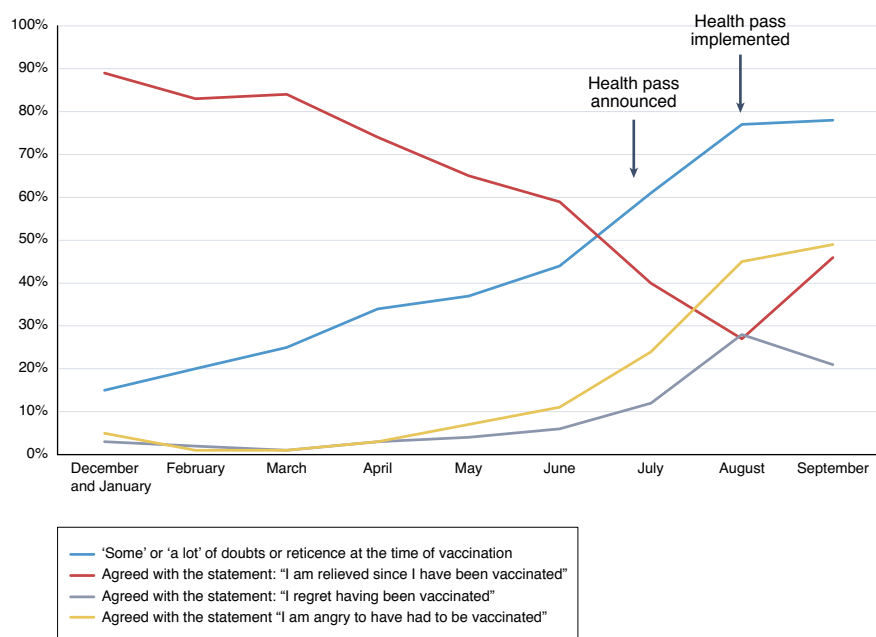


Fig. 1 | Doubts about vaccination among the vaccinated. French adults' experience of COVID-19 vaccination, depending on the month in which they received their first dose. The health pass was announced on 12 July 2021 and implemented on 9 August. $n = 1,619$ respondents who had at least one dose of the COVID-19 vaccine out of a representative sample of 2,015 people aged >18 years; data collection: 22 September 2021 to 1 October 2021.

vaccine had improved since December 2020, when 55% of the French adult population was unwilling to get the vaccine. Nevertheless, around one-quarter of the population was still unwilling in June 2021^{6,7}.

The second barrier to vaccination was complacency, as many people did not perceive COVID-19 to be a serious threat to their personal health⁶. The third barrier was that even though COVID-19 vaccines in France are free of charge, reaching those with less access to the healthcare system remained a problem. The main pathway to vaccination against COVID-19 was to book appointments via an online website, which therefore relied on the person's capacity to navigate the health system. Without a strong investment in local outreach operations, access for marginalized groups, including isolated older people, was limited. By mid-June 2021, only 70% of people aged 80 years or more had been fully vaccinated².

Increased uptake

The health pass was announced on 12 July 2021 and implemented on 9 August, as a response to the Delta variant. To enter several public places, including restaurants, people aged 12 and over would have to present proof of full vaccination or a negative COVID-19 test performed in the

previous 72 h; vaccination was also made mandatory for healthcare workers. After this announcement, the share of the eligible population vaccinated with two doses increased from 49% on 12 July to 89% by mid-December 2021. An announcement that the health pass would require a booster dose by mid-January was also followed by a wave of appointment bookings.

Any vaccination policy that relies on constraints risks stoking anti-vaccine sentiments and vaccine hesitancy^{8,9}. The health pass elicited strong criticism from opposition parties, as well as protests across France in early August attended by up to 240,000 people¹⁰. Attendance at protests against the health pass has waned markedly, but the protests were still supported by around 30% of the population as of September 2021^{7,11}.

Despite protests and opposition, public attitudes toward COVID-19 vaccination do not seem to have deteriorated. Intentions to vaccinate in mainland France continued to rise between June and July 2021, and have remained relatively stable since⁷.

However, vaccination rates have plateaued just above 90% among the eligible population in mainland France and remain low in several overseas departments and regions, such as Guadeloupe, Martinique and French Guiana, where less than 40% of the population has

had at least one dose and opposition to the health pass is much stronger^{2,12}.

Vaccinating the hesitant and the marginalized

The health pass is limited in its effectiveness, as although it has been effective in getting the complacent to book their vaccination appointments, it does not address all barriers to vaccination. For many people, the health pass had little effect, because the elderly, the poorest and the most marginalized do not engage much with the activities covered by the pass, such as eating out in restaurants. For instance, as of 12 October 2021, only 86% of over-80 year olds had been fully vaccinated².

The health pass has encouraged vaccination of many who were hesitant or reluctant, but it has not reduced hesitancy itself. A survey from September 2021 found that 42% of vaccinated people were still reluctant or had doubts about the vaccine at the time of their first dose⁷. More importantly, the share of vaccinated people with doubts about the vaccine increased from 44% to 61% after the health pass was implemented (Fig. 1).

France remains a very vaccine-hesitant country, and this hesitancy does not seem to have decreased much as a result of either the COVID-19 health pass or mandatory infant vaccines, which were extended in 2017. One of the rationales for extending mandatory infant vaccination was that such a strong gesture would signal to the public the complete faith of authorities in these vaccines¹³. Although this policy did not elicit a public backlash, trust in vaccines does not seem to have significantly improved and France is still a very vaccine-hesitant country, as demonstrated in earlier stages of the pandemic^{4,5,14}.

There is little to suggest that the health pass has convinced many skeptics about the benefits of this vaccination¹⁵ and there remains a small but considerable proportion (around 5–10% of the population) who have decided not to take the vaccine for COVID-19⁷. Vaccinating people who are hesitant or reluctant has potentially negative consequences, which can reinforce mistrust of institutions and of the healthcare system^{3,8,16}.

A feeling of coercion while being vaccinated can cause a nocebo effect, in which negative outcomes occur because of a belief that the vaccine will harm them. The nocebo effect might explain why, in our survey, the share of vaccinated people who said they suffered side effects from the vaccine increased from 34% among those who had their first dose in June to 57% of those who had their first dose in August, after the health pass was implemented.

Table 1 | Effects of the health pass in France on three dimensions of vaccine hesitancy

Reason for vaccine hesitancy	Effects of health pass	Limits of health pass
Complacency (low risk perceptions, vaccination not perceived as an urgent issue)	Very effective in persuading the complacent to get vaccinated as the vaccine made it very convenient to maintain their normal activities.	Limited effect on underserved people who do not use activities covered by the health pass, including older people, people on low incomes, migrants, and homeless people.
Confidence (trust in the safety and efficacy of the vaccines, in the health system and in policy-makers)	Some reluctant people agreed to be vaccinated, despite their enduring doubts and hostility. Limited effect in overseas departments and regions where distrust of the state is greater.	Many people remain unconvinced, with strong criticism from opposition parties, protests in metropolitan France, and social uprisings in several overseas departments and regions.
Convenience (availability and accessibility of the vaccines, levels of health literacy, the appeal of immunization services)	The health pass was accompanied by increased availability, including more appointments in vaccination centers.	There have been insufficient outreach efforts in underserved communities to address barriers to vaccination.

The importance of trust

In France, opposition to vaccines against COVID-19 is grounded in a distrust of the mainstream political system and the current government in particular^{7,11}. Some of the government's choices have not helped to build this trust. Trust is built by clearly explaining the uncertainties and constraints bearing on the decisions being made, so that the public can understand them, even when they change, and trust that they are based on the best available science¹⁷. Projecting certainty and control leads to avoidable changes in messages and the breaking of unnecessary promises.

For example, after the third lockdown, the French government required a negative COVID-19 test or proof of vaccination for large group activities, with a promise that the health pass would never include restaurants or cinemas¹⁸. This promise was broken just two months later. In November 2020, the President of France also promised that COVID-19 vaccination would never become mandatory¹⁹, a promise that has so far been kept, but that could damage trust if it were to be broken. Each time the government changed the rules, opposition parties seized the opportunity to score political points, leading to heated public debates. With the French presidential election in just a few months, mandatory vaccination policies could further politicize the COVID-19 vaccine. Making vaccination routine for everyone. Booster doses for COVID-19 are now being rolled out across high-income countries and may be required for years to come, especially for those most at-risk of severe disease. This

continued threat will require vaccination for COVID-19 to become routine for many.

It is often thought that mandates are effective because of the threat of sanctions, but evidence suggests that their efficacy also rests elsewhere. With vaccine mandates, the responsibility for monitoring vaccination status and reminding people of the necessity to take the vaccine lies with key people who can easily reach the public^{20,21}. For mandatory childhood vaccines, these tasks are usually performed by schools.

For mandatory vaccines for adults, there are no key people who are present in every adult's day-to-day life²². Enforcement could be done by employers, or alternatively by restaurants, bars and shops, as with the health pass. However, in France, such businesses were reluctant to enforce health norms and none of these actors are capable of reaching the people most at risk from COVID-19, including the unemployed and underserved communities.

Lessons from the COVID-19 health pass in France suggest that coercive measures such as mandatory vaccination can be effective in raising vaccination rates, but do not solve all of the issues that affect uptake. Mandatory vaccination for COVID-19 runs the risk of politicizing vaccination further and reinforcing distrust of vaccines, but national contexts will determine whether such a mandate is ethically justifiable or necessary to make COVID-19 vaccination routine. Regardless of whether vaccines are made mandatory or not, reaching high vaccine coverage requires a diversity of tools. Outreach programs and sustained efforts to motivate those who are hesitant

should be the cornerstone of any COVID-19 vaccination policy. □

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Interpretation of data for the work: J.K.W., P.P.W., F.G., A.G.B., E.B.N., J.-L.C., C.K., O.L. and P.V.

Competing interests

J.K.W. is a member of the Commission Technique des Vaccinations at the Haute Autorité de la Santé, O.L. is a member of the Comité scientifique sur les vaccins COVID-19, P.P.W. is a member of the Conseil d'Orientation de la Stratégie Vaccinale, and J.L.C. is responsible for the Drug and COVID working group of the French Pharmacological Society. The views expressed in this article are those of the authors, not these committees.