European Review for Medical and Pharmacological Sciences 2022; 26: 643-652

COVID-19 vaccine mandates: what are the current European public perspectives?

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Abstract. – The article aims to elaborate on European policy choices for the prevention of SARS-CoV-2 contagion, with a close focus on the rules and regulations enacted in Italy so far. European states have ruled out generalized vaccination mandates but have so far preferred to exert a form of "moral suasion", through the introduction of a digital certificate which can only be granted to those who are vaccinated, cured of COVID-19 or tested negative through an antigen test in the previous 48 hours. Italy has applied this tool, dubbed "Green Pass", very rigorously: many daily activities, including going to work, are only allowed for those who have the certificate. A one-year Green Pass is issued after vaccination, although data show that vaccine protection may subside gradually over about six months; the cost of the antigen tests every 48 hours is to be borne by the patient. Testing the unvaccinated is essential to contain the spread of the infection, but it would have been more logical to mandate that all the unvaccinated undergo regular testing (for example every ten days), instead of imposing a test every 48 hours only to be allowed to engage in some activities. The authors stress that in order to minimize the risk of future possible pandemics, prevention strategies are needed, and poor countries need to be enabled to vaccinate their populations in order to prevent new variants from developing. The pledges made by world leaders in that regard during the recent G20 summit must therefore be honored, for the sake of global health that never in our lifetime has been so threatened.

Key Words:

COVID-19, Vaccination mandate, Omicron variant, Digital vaccination certificate, Right to self-determination, Informed consent, European public policy.

Introduction

The COVID-19 pandemic has caused an unprecedented health emergency. Virtually all nations have outlined and implemented containment measures (social distancing, emphasizing hands hygiene and mask mandates in closed environments, and even outdoors during maximum alert) which have reduced the rate of viral spread, allowing the continuation of economic and social activities and interactions in a relatively safe fashion[1]. Contact tracing interventions have also been launched, particularly through the use of mobile phone applications capable of alerting users when they may have been in contact with someone carrying the SARS-CoV-2[2,3]. The scientific community, however, believes that in order to defeat the COVID-19 pandemic, a mass vaccination is needed to achieve herd immunity, so as to indirectly protect those left unvaccinated as well.

Thanks to the use of new technologies and multi-billion-dollar investments by governments, the scientific community and the pharmaceutical industry have developed four vaccines (or preventive therapy), two with mRNA (Comirnaty Pfizer/BioNTech and Moderna) and two using a viral vector (AstraZeneca, later renamed Vaxzevria, and Janssen by Johnson & Johnson[4]). The European Medicines Agency (EMA) explained how these vaccines could be marketed so quickly[5]. Under normal circumstances, human experimentation phases (clinical trial) are three and they occur in sequence (non-toxicity, efficacy, evaluation of the risk/benefit ratio). After passing these phases, the EMA issues the Standard Authorization, and starts Phase 4 (so-called post-marketing surveillance), which normally lasts five years. In COVID-19 vaccines, the different phases took place in parallel, at the same time rather than in sequence, as it routinely happens, with a partial overlap of said phases, called 'partial overlap': the next phase starts a short distance from the beginning of the previous one. This mismatch in the start of the experimentation phases has accelerated the times and allowed the marketing of the preparations; however, it has created public

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doubts and misgivings as to their safety, fueling controversy over the allegedly "still experimental" nature of vaccines. In reality, the procedure adopted, albeit in fast-track/partial overlap, is technically and scientifically appropriate, but the pharmacovigilance phase has not been completed for the expected duration. For this reason, the COVID-19 vaccines have obtained conditional authorization, based on provisional and continuously updated data, subject to revision according to the new evidence gradually acquired. Hence, an effort has been made to try and reconcile two opposite needs: speed and effectiveness on the one hand, safety on the other[6].

Ultimately, an ethical balance has been sought between the substantially expedited introduction of vaccines in order to save more lives, accepting the risk of side effects, and the choice to engage in longer and more rigorous experimentation to have a greater degree of certainty as to safety and efficacy. Given that no magic solution can ever exist, and in light of the economic, social and health catastrophe arising from various anti-COVID-19 measures such as prolonged lockdowns and business closures, non-permanently approved vaccines have also been used.

Striking a Balance Between Vaccination Mandates and the Right to Refuse Treatment

The issue of vaccination entails a complex issue: can the need to protect collective health constrain the individual right to freedom of choice in a most delicate and consequential setting such as health?

In Europe, the principle has been affirmed that vaccination is usually an individual choice based on personal conviction, because an individual may consider the benefits of the vaccine to be lower than the harm it can cause. In relation to the pandemic emergency from COVID-19, the European Union Resolution 2361 (2021), referencing Articles 8 and 9 of the European Convention on Human Rights (ECHR)[7], provided that Member States must ensure that citizens are informed that "the vaccination is not mandatory and that no one is under political, social or other pressure to be vaccinated if they do not wish to do so" (point 7.3.1) and "ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated" (point 3.2[8]).

According to the European Court of Human Rights, compulsory vaccination, as an involuntary health intervention, interferes with physical integrity and therefore can be construed as bearing on the right to respect for private life, pursuant to art. 8 of the ECHR. However, such interference does not involve a violation of art. 8, since it pursues a legitimate aim, provided that it is carried out "in accordance with the law". In fact, if vaccination is deemed safe and effective by the scientific community, the legislator can make it mandatory, because it protects both those who receive it and those who cannot be vaccinated for medical reasons. Still, two conditions must be met: that the compulsory treatment serves to prevent the damage that a person could cause to the rest of the population (therefore not exclusively to protect that same person from himself) and that the treatment is not dangerous for those who undergo it[9].

The World Health Organization (WHO) has also stressed that the vaccination requirement is ethically justified only if sufficient evidence can be produced with regard to its safety. If such data are missing or point to possible risks associated with vaccination greater than those that would be incurred without vaccination, the mandate cannot be ethically justified[10].

The possibility to issue a vaccination mandate has been discussed at length. Some are against such an obligation, because the vaccines have not completed testing and their administration could entail the risk of serious adverse reactions that would significantly affect the health of the vaccinated. On the contrary, there are those who believe that only a large-scale vaccination of the population[11] can guarantee the health of the citizenry and protect the elderly and those who cannot get vaccinated for medical reasons. Italian lawmakers have provided for compensation for the damage suffered by a citizen as a result of vaccination (law n. 210/1992). The COVID-19 vaccination poses a problem that did not arise in either mandatory or recommended vaccinations: in the latter, the risk incurred in the interest of the community was assessed during pharmacovigilance and deemed acceptable[12]. As for COVID-19 vaccines, the same pharmaceutical companies have officially stated that it is not possible to ascertain a medium and long-term risk profile, i.e., within 5 to 10 years, because it was not possible to fully carry out testing for genotoxicity and carcinogenicity. There is no denying that the administration of a new vaccine must be carefully linked to and supported by a rigorous safety assessment, all the more

so given the fact that the vaccine is not a drug for severely ill patients, but rather a treatment administered to healthy patients in order to prevent the risk of a disease that in most cases only entails mild symptoms[13]. The vaccine's objective is twofold: to protect public health, preventing the immunized person from infecting non-immunized people, and to permanently immunize those who have been vaccinated, thus protecting them from complications[14]. Nonetheless, the currently available COVID-19 vaccines cannot guarantee that such objectives will be achieved. Certainly, vaccine-based prophylaxis has proven considerably effective in safeguarding the life of the elderly, serious patients and pluripathological individuals with the most aggressive forms of infection, and this is certainly an important result in terms of individual and public health. However, doubts still linger as to the vaccines' effectiveness in protecting the community from the potential and persistent contagiousness, even among the vaccinated. Current vaccines are not of the "sterilizing" type, hence they do not ensure immunity from the virus. The vaccinated person can therefore contract the virus too, albeit in a less severe form, with the advantage of eliminating the need for hospitalization in most cases (with enormous benefits in terms of avoiding the saturation of public healthcare facilities[15]). Scientific studies[16-18] have shown that even fully vaccinated people can pass the virus on to others, although likely to a lower degree, whether vaccinated or not. The consequences vary significantly depending on the person's health conditions. There have been cases of vaccination-related complications, sometimes even fatal, albeit statistically not very significant. In Britain, out of 117 new deaths, 50 had been fully vaccinated, but these were people over 50 with pre-existing conditions[19,20]. In Israel, only 64% of vaccinated patients are reportedly covered[21]. The duration of vaccine-induced protection is still unknown; clinical trials aimed at establishing it are still underway. A very recent study[22] published in Lancet shows that the efficacy of the Pfizer-BioNTech vaccine against SARS-CoV-2 infections decreased within a six-month period, going from 88% recorded one month after full vaccination to 47%. Ultimately, a COVID-19 vaccine can prevent hospitals from filling up and limit severe manifestations of the disease but cannot achieve the level of immunity needed to keep SARS-CoV-2 from spreading. That is especially true with the "Delta" variant[23], and lastly, the Omicron variant, which was first isolated on 11th November 2021 and has since spread with alarming speed all over the world[24].

Only constant experimentation will determine how long the vaccine-induced protection can last and how often booster shots ought to be administered to keep that protection fully active. The most likely prospect is that multiple booster shots will be needed. In Italy after all the administration of a booster shot, a third dose, initially recommended for transplant patients and immunocompromised individuals has already been extended to all adults. The latest variant has infected roughly 25 million people as of this writing, 14th January 2022[25]. As of early January 2022, the requirement for all citizens to be fully vaccinated against SARS-CoV-2 has been set in only four countries: Indonesia, Turkmenistan, Micronesia and Tajikistan. The other countries have instead chosen a policy of "moral suasion" to encourage spontaneous vaccination. This policy is based on the so-called gentle push or behavioral nudging strategies. The concept of "nudging" refers to a set of policies that governments put in place in order to influence the behavior of individuals in a desired direction, without issuing mandates, binding rules or prohibitions. Such strategies consist of soft policies, aimed at swaying the people's decisions in the "right" direction, therefore based on persuasion. If the nudge is successful, the will of the individual and that of the state will come to coincide, and therefore the individual will freely decide exactly what the state or private organizations want him to decide[26].

COVID-19 Vaccination Certificates: a European Overview

The COVID-19 vaccination certificate refers to the EU Regulation 2021/953, of June 14, 2021, which established the Green Digital Certificate to facilitate the resumption of economic and social activities among European countries and within the Schengen area, and to stave off discriminatory practices between vaccinated and unvaccinated citizens. The regulation has also reiterated the ban on national vaccination mandates, even indirect ones. Such "health passports" are designed to document the vaccination, the recovery of a person from COVID-19 or the execution of a rapid molecular or antigen test with negative results, carried out in the previous 48 hours. As for the implementation of "moral suasion" policies, the European Union has not taken a joint decision, thus allowing each member state to

introduce its own rules. The UK has not introduced the mandatory Green Pass but uses it on a voluntary basis only for nightclubs, concerts and sports events. Despite the sharp increase in infections, the British government has not reversed its decision not to impose any restrictions, fearing economic backlash, and has further intensified vaccination efforts[27,28]. In Spain, the Green Pass is not required to engage in any kind of activity. In Belgium, mask-wearing is required in restaurants, shops and for those who work in the hospitality sector. Only for events with over 1,500 attendants, "COVID-19 safe tickets" have been introduced, which prove vaccination, recovery from infection or negative testing with molecular PCR tests. Travelers to Belgium must however present the Green Pass documenting full vaccination completed at least two weeks before, a negative test or a certificate of recovery in the last 180 days. In Denmark and Sweden, the vaccination certificate was adopted months earlier than in other states, and thanks to its success in bringing down infection rates, the governments have eliminated all restrictions, including mask mandates on public transportation. Following the appearance of the Omicron variant, both have extended the obligation of the Green Pass to travelers from Norway, Finland and Iceland. In addition, the vaccination certificate will be required to enter the bar, restaurant and nightclubs, but also to participate in large events. In Switzerland, as early as September 2021, the Green Pass for all age sixteen or older is mandatory for closed places, sports events and leisure facilities (theaters, cinemas, gambling halls), concerts and weddings outside of private premises. An employer can require workers to have a valid certificate, as part of their protection obligation. Germany, on the other hand, has enforced the "3G" rule: Geimpft, Getestet, Genesen, i.e., vaccinated, tested or cured[29]. To stay in public or private premises, it is necessary to produce valid certification documenting one of those three states. No obligation as yet exists for public transportation, trains, airplanes and workplaces. Testing, which used to be free of charge, has to be paid from 11 October 2021. Some cities such as Hamburg and several Länder have introduced the more restrictive "2G rule" in some public facilities: only the vaccinated or recovered are granted access. Faced with the rising curve of infections, the German government has adopted the 3G model, alongside that of the 2G and 2G +, where the Gs stand for vaccinated, recovered, tested negative. In fact, also depending on the decisions of the individual German Länder, in order to lawfully engage in various activities, a citizen in Germany must be either vaccinated/cured/tested (3G rule), or vaccinated/recovered (2G rule), or finally vaccinated/recovered with in addition to a recent negative test (2G + rule). In Germany, a vaccination mandate only stands for health care personnel, but the government is weighing the possibility of extending it to other population segments[30]. The Austrian government, in an effort to counter the looming fourth pandemic wave, has instituted a vaccination/recovery certificate requirement to lawfully access restaurants and large public events. A vaccination mandate for every Austrian resident over the age of 14 will be in force starting from 1st February 2022, with fines up to 3,600€ for transgressors[31].

In France, the vaccination pass is required in places and events with high turnout, such as cinemas, restaurants, large shopping centers, sports facilities, long-range public transportation. On the professional level, from 30 August 2021, the law mandates that healthcare and paramedic personnel be vaccinated, with suspension from employment for those failing to comply[32]. In Greece, the vaccination certificate has been mandatory for activities and clubs such as bars and restaurants from September 2021; testing negative is not enough. Among restaurants owners, some only admit people with vaccination certificates, while some guarantee that all their employees have been vaccinated as well. The obligation also applies to long-distance trains and theaters. In the workplace, whether public or private, those who are not vaccinated are obliged to be tested twice a week at their own expense. The actual vaccination obligation, on the other hand, has been in force since September 2021 only for nursing home personnel and health professionals. In Portugal and Ireland, the pass mandate has been issued for restaurants and catering activities[33].

In Italy, law decree n. 44/2021 has made vaccination against COVID-19 mandatory for healthcare professionals[34], professionals who carry out their activities in public and private health, social-health and social-welfare facilities, pharmacies, and private firms. Furthermore, with the enactment of law decree n. 105/2021, national lawmakers have also extended the obligation for schools and universities, airplanes, trains (only with interregional and national routes), ferries and ships (n. 111/2021) and to all workers in the private sector and all public employees, including Members of Parliament, Deputies and Senators

(Law Decree n. 127/2021), which has made Italy the only country in Europe to put in place such broad-ranging restrictions, in addition to mandating certification for numerous other activities (gyms, swimming pools, theaters, museums, cinemas, conferences, playgrounds, restaurants and indoor bars, (Law Decree 105/2021). Unvaccinated workers must undergo antigen tests every 48 hours, that is three times a week, and are required to pay for such testing themselves, albeit at a lowered price. The Italian government has excluded the antigenic (rapid) salivary swabs from the list of tests that allow the issuance of the certificate, although such tests are less invasive, cost less and are equally reliable, as certified by various studies[35,36] showing that such tests' results coincide 98% of the times with the results of nasopharyngeal swabs[37,38]. The exclusion of "light" tests appears to conflict with the aforementioned European regulation no. 953/2021, which, on the other hand, urges States to issue a certification in a "cost-effective" way.

To further incentivize vaccination, the government had set the validity of the Green Pass at nine months (art. 14 of Law Decree 65/2021)[39], then extended to one year, which is twice the length of time in which the vaccines have been proven effective. Such a decision is quite perplexing, because it appears to disregard the logical correspondence between the validity time of the Green Pass and the alleged vaccination coverage duration. Furthermore, it may spread a false sense of security in the population because, even if for many citizens the immunization ensured by the vaccine is over or is about to expire, they may no longer abide by precautionary behaviors such as mask wearing and social distancing, thus potentially contributing to rising infection rates.

Since the Omicron variant is substantially more transmissible, the Italian Parliament enacted the bill No. 139 on 7th January 2022, meant to grant the Green Pass only to those who have been vaccinated or recovered. The new certificate is now required to access public and private transport, indoors and outdoors restaurants, bars, hotels, swimming pools, skiing facilities and stadiums, and for visitation to hospitals and hospices. Such new measures were codified in a bill drafted on 29th December 2021 and are now in full force. The use of the "basic" Green Pass, obtainable through negative testing as well, is required to access personal care services such as hairdressers and beauticians, in addition to public offices, postal, banking and financial services, commercial activities, with a few exceptions meant to meet basic needs, such as grocery shopping and post offices. The validity of the Green Pass has been shoertened from nine to six months[40].

Moreover, the new decree also introduces a vaccination mandate for all residents over the age of 50, and a one-off 100-euro fine has been set for transgressors. For public and private sector workers over 50, the new version of the Green Pass will be required to gain access to workplaces from 15th February until 15th June 2022. The vaccination obligation is extended to all university staff members, now equated to school staff[41].

Vaccination as a Free Choice

In terms of vaccination, the authors believe that a strategy focused on persuasion and personal conviction is likely preferable, and more in keeping with the system of safeguards for personal freedom. The doctor is required to inform the patient in a truthful, clear and understandable way that vaccination may entail risks, however remote, because the same vaccine can produce different effects in different organisms. Patients need to be thoroughly informed as to the possible risks, side effects and adverse reactions[42,43], but also about the degree of immunity that can be obtained, the reported duration of vaccine coverage, the possibility of preventing or reducing viral transmission and the protection from possible reinfections[44]. Only absolute clarity and straightforward information can help tackle vaccination hesitancy, in the general population and among fragile segments such as pregnant women[45], (for whom the vaccine may contribute to lowering the overall risk associated with their condition[46,47]) which threatens to undermine immunization efforts currently underway.

Such information is particularly necessary in the vaccination against COVID-19, because some RNA or DNA vaccines represent a new approach in vaccination methodology. In this regard, the communication involving the AstraZeneca vaccine was particularly disturbing. With regard to this vaccine, the experts have shown discordant views, especially regarding the age for which it was recommended, first identified as over 60, then extended to all age groups[48,49]. Such uncertainty and confusion has led several European states, including Italy, to suspend the administration of said vaccine as a precaution, at least for certain age groups. After a few days the administration was resumed, but by then the population had become mistrustful and largely unwilling to accept

the AstraZeneca vaccine. Different strategies can and probably should be used to gain the citizens' trust. For example, promoting public discussion between experts and citizens can go a long way towards raising awareness among the citizenry and shed light on confusing aspects. Certainly, the choice of the highest Italian and foreign public officials to be filmed while undergoing inoculation has been helpful in terms of building trust among the citizenry[50] by demonstrating that our elected officials believe the vaccine to be safe. In Italy, the Presidency of the Council of Ministers has launched a widespread communication campaign on both traditional and social media[51] with the participation of celebrities and ordinary citizens with the aim of conveying a message of return to normality and trust in the near future, through a symbolic gesture: the "V" for vaccine and victory.

Discussion

The COVID-19 vaccination certificate has proven effective in increasing vaccination rates, but is sparking widespread protests in Europe[52,53], because it is viewed by some as a form of discrimination between those who have it, and therefore can exercise their constitutionally guaranteed freedoms, and those who do not, and have therefore such rights suspended. Such a discriminatory mechanism may not be warranted in terms of security and prevention, because all three conditions certified by the pass cannot scientifically guarantee the absence of viral infection, as the contagion can also occur in places where access is allowed only to those with certification. The COVID-19 pandemic has undoubtedly constrained citizens' freedom. However, almost two years after the SARS-CoV-2 was declared a pandemic, it would be unthinkable to deal with the pandemic by forcing citizens to possess the vaccination certificate, which is certainly not a decisive measure[54]. According to various sources[55,56], we are currently moving into an endemic scenario, likely to continue with a presumably seasonal trend and the circulation of new variants. Among the thousands of genomic variants of the virus so far identified, those of potential clinical and epidemiological significance are classified as variant under monitoring (VUM), variant of interest (VOI), variant of concern (VOC) and variant of high consequence (VOHC)[57].

No VOHC has been so far defined (i.e., one that would completely evade current vaccinations), while there are five VOCs: Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B. 1.617.2), and Omicron (B.1.1.529)[58-60]. The Delta variant is responsible for the vast majority of COVID-19 cases currently identified in Italy, Europe and the United States. In order to deal more effectively with COVID-19 and its variants, vaccines or tests are not enough, if not coupled with a solid and clearly defined prevention strategy. Firstly, it is necessary to reorganize the health system in general, and above all to strengthen territorial medicine. Secondly, it is necessary to intervene on the all-too-common phenomenon of overcrowded schools and classrooms (the so-called hen house classes), which worsen viral spread. In fact, controlled mechanical ventilation systems (VMC) are needed to prevent viral diffusion, which is easier and faster in environments without adequate ventilation. In addition, it is necessary to enhance distance learning, which must include the training of teachers, adequate equipment for teachers and students, with a close attention to students and families in fragile conditions arising from psycho-physical, economic and social factors. Finally, strategies need to be laid out for the improvement of public transportation.

Conclusions

The pandemic has been almost immediately met with several restrictions. Italy lived in near-total lockdown from the beginning of March to the end of May 2020. To buy basic necessities it was often necessary to stand in line, because the opening hours of the shops were significantly reduced. In this difficult situation, citizens exhibited considerable cohesion and a great sense of responsibility, because it was evident that the full exercise of their freedom could potentially endanger their own health and life as well as others'.

This cohesion now feels like a distant memory, as demonstrated by the aforementioned street protest marches. From the perspective of a risk-benefit analysis, in the current state of known side effects, the vaccine has certainly been beneficial and greatly valuable for our community as a whole.

Less acceptable is the policy of applying such different, uneven rules between vaccinated and unvaccinated citizens. The latter even have to pay for an (invasive) antigen test every 48 hours

to go to work, while science makes non-invasive and less expensive saliva swabs available. This rule would perhaps make sense if the vaccinated could not get sick and transmit the virus. The virus however is known to circulate even among vaccinated. It is reasonable to admit that the reduction in infections was also achieved thanks to the cautious behaviors (based on good hygiene practices, distancing, mask wearing, avoiding crowded places) also put in place by the unvaccinated, and sometimes violated by vaccinated individuals who mistakenly believe they cannot infect others.

This choice is fundamentally risky, since it has in fact exempted vaccinated people from the obligation to undergo antigen tests for one year, while it is known that its effectiveness significantly decreases after approximately six months. Policies should follow more logical and evidence-based rules. The duty of solidarity that each country has asked its citizens to fulfill, by encouraging them to get vaccinated, is ultimately insufficient.

In order to stop the infections, however, it is necessary to ensure vaccines are made accessible even for countries that do not have sufficient resources to buy the drug but can become the breeding ground of new dangerous variants. During the G20 summit, which took place in Rome on 30 and 31 October 2021, the ministers of health signed the "Pact of Rome"[61] with the aim of donating millions of doses of vaccine to these populations. It is a duty born out of solidarity, but also a universal collective interest: studies[62,63] have shown that the virus is capable of constantly changing and potentially becoming more aggressive and unpredictable over time[64].

Conflict of Interest

The Authors declare that they have no conflict of interests.

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