Compulsory vaccination against SARS-CoV-2 in health care professionals in Italy: Bioethical-legal issues

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Abstract
On 17 March 2022, the Italian Council of Ministers, by means of Press Release No. 67, sanctioned the extension of the vaccine obligation against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for health workers until 31 December 2022. Healthcare workers who do not demonstrate that they have adequate vaccination coverage will be suspended from work and will not be paid. Recently, the Council of Administrative Justice of Sicily has identified possible contrasts between the vaccine obligation of health professionals and numerous constitutional principles, paving the way for an interesting bioethical-legal debate on the subject. The aim of this article is to examine the possible profiles of unconstitutionality of the measure of the Italian Government and to identify medico-legal and bioethical issues potentially related to the vaccine obligation for health professionals in a context of resolution of the emergency phase related to the coronavirus disease 2019 (COVID-19) pandemic.

Keywords
Vaccination, COVID-19, health workers, bioethics, rights

Background
In Italy, compulsory vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for healthcare personnel and other professional categories (school staff, defense and security sector, and public rescue personnel) has been imposed by decree laws.1,2 On 17 March 2022, the Council of Ministers, by means of Communiqué No. 67,3 established the extension of the vaccination requirement until 31 December 2022, for healthcare workers only. In particular, for this category of workers, vaccination may be omitted only in case of “established danger to health in relation to specific documented clinical conditions”, regardless of the age of the subject.1

In case of noncompliance with the vaccination requirement, the health professional will be suspended from “services or tasks involving interpersonal contact or involving, in any other form, the risk of spreading SARS-CoV-2 infection”.1 The health profession, by its very nature, is based on direct patient care. Not undergoing vaccination is equivalent in most cases to suspension from work and remuneration. Therefore, to date, in Italy, health personnel are obliged—except under documented clinical contraindications—to undergo the vaccine against SARS-CoV-2 if they do not want to be suspended from work.

It is essential to emphasize that the vaccination requirement for healthcare professionals will persist well beyond the end of the state of emergency for the coronavirus disease 2019 (COVID-19) pandemic (31 March 2022). In Italy, the end of the state of emergency has entailed, and will entail, a progressive easing and/or elimination of many anti-COVID-19 measures. For example, as of 25 March 2022, workers over 50 years of age—including public workers—are no longer required to present health documentation of vaccination or recovery (“Super Green Pass”); however, they may enter the workplace with only a molecular or antigenic test with a negative result for SARS-CoV-2 (“Green Pass”). In addition, as of 15 June 2022, compulsory vaccination requirements for teachers, law enforcement officers, and those over 50 years old will end permanently. Moreover, the end of the state of emergency has led to a decrease in the severity of anti-COVID-19 measures, especially with regard to the use of masks and the requirement

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of vaccination certificates for access to recreational activities (bars, restaurants, gymnasiums, cinemas, and theatres).

Thus, in a scenario of progressive relaxation of anti-COVID-19 measures, motivated by the end of the emergency phase, the vaccination requirement will persist until 31 December 2022, only for health personnel.

Bioethical-legal issues of compulsory vaccination against SARS-CoV-2 for health workers

On 22 March 2022, the Council of Administrative Justice of Sicily expressed its opinion on the issue, raising questions of constitutional legitimacy relating to both compulsory vaccination for health personnel and the suspension of the exercise of the profession in case of failure to vaccinate. This regional order will oblige the Constitutional Court to rule on the constitutional legitimacy of the mandatory vaccination of health professionals.

The judges have identified in this measure a possible conflict with many constitutionally guaranteed rights (Articles 3, 4, 21, 32, 33, 34, and 97) (Table 1). First, the vaccine requirement would conflict with two fundamental principles of the Constitution: the equal social dignity of citizens—which the Italian Republic is obliged to ensure in order to promote the full development of the human person and the participation of all workers in the social, political, and economic organization of the country—and the right to work. As previously stated, only in the case of health professionals, the right to carry out their profession will be tied to the anti-SARS-CoV-2 vaccination. Unlike a Surgeon who will need, for example, proof of hepatitis vaccination, in the case of anti-SARS-CoV-2 vaccination—in our opinion—there are not the same prerequisites for mandatory vaccination. Primarily, while the hepatitis B vaccination is certainly effective in preventing infection and its consequences, the anti-SARS-CoV-2 vaccination does not prevent from contracting the virus and/or developing a transmissible infection.

This constraint (anti-SARS-CoV-2 vaccine) is confirmed by the National Board of Physicians and Surgeons, which has defined the vaccination as “an essential requirement to carry out the professional activity that must exist initially, for the purposes of registration, and must remain in time.” Therefore, in Italy, vaccination is a prerequisite for the health care professional to obtain and maintain the license to practice the profession. Moreover, the demonstration of vaccination is also required for students and trainees. Without the anti-COVID-19 vaccination, they cannot enter healthcare facilities and perform their training activities. This limitation could violate the right to study (Articles 33 and 34 of the Constitution).

In addition, the Council of Administrative Justice pointed out that the case of compulsory vaccination could violate the constitutional right to free expression of thought (Article 21 of the Constitution). The signing of informed consent in Italy is no longer a free choice but is a necessary condition to be subjected to compulsory vaccination against SARS-CoV-2. This transforms informed consent from a “free act” to a “compulsory act”. The subject, before being vaccinated, is obliged to sign an informed consent form. Normally, the signing of informed consent should, on the contrary, be a free act, regardless of the guarantee of compulsory health care. This contradiction is even more significant because, currently, it is not possible to know all the adverse effects of vaccines, especially in the long term. In the informed consent form—which the subjects are required to sign if they intend to comply with the law and, then, undergo vaccination—the paragraph devoted to the possible side effects of the vaccine reads: “It is not possible at the moment to predict damage in the long term”. Moreover, in Italy, there is no national standardized form. This system risks transforming the informed consent form into a sort of “disclaimer” with which the health system and pharmaceutical companies could be relieved and exonerated from liability related to the unpredictable outcomes of the compulsory vaccination against SARS-CoV-2.

The fact that the subject is obliged to accept the consequences of undergoing vaccination on health (scientifically not yet known) is in clear disagreement with what was stated in 1994 by the Judges of the Italian Constitutional Court. According to Judgment No. 258/1994, the vaccine requirement can be defined as constitutionally permissible only if there is “the provision that it does not adversely affect the health status of the person who is subjected to it, except for those consequences only, which, because of their temporary nature and being small, appear normal for any health intervention and, therefore, tolerable”. This assertion is not respected in the case of vaccination against SARS-CoV-2. Such a vaccine is not only associated with unpredictable long-term complications—which are not yet scientifically known—but can cause adverse effects that, even if rare, can be very serious for health.

Risk/benefit ratio for compulsory vaccination

The negative consequences of the anti-COVID-19 vaccine are not yet ascertained and assessable in terms of severity: this does not allow one to estimate, with adequate certainty, the risk/benefit ratio of the vaccination, posing the risk of compromising the right to health (Article 32 of the Constitution).

The risk/benefit ratio is potentially unbalanced also because of some critical issues related to the COVID-19 pandemic. The first issue is the absence of a certain
advantage of vaccination for collective health: as is now known, the vaccine does not prevent the subject from contracting the virus and, therefore, transmitting it to the community. On the contrary, the possibility of contagion has increased in this phase of the pandemic because primary prevention strategies (use of masks, social distancing, etc.) are gradually being relaxed and the vaccines available today are not highly effective against all new
variants of the SARS-CoV-2.13–15 Moreover, in this phase, the possibility of transmission of the virus by infected but asymptomatic or paucisymptomatic vaccinated subjects has increased. To date, therefore, the main advantage of vaccination consists in reducing the risk, for the most fragile subjects, of developing serious consequences of the SARS-CoV-2 infection. This benefit—which cannot be quantified in absolute terms, but is limited to frail or elderly subjects—should be compared with the actual and real health risk (in case of COVID-19 infection) of the individual subject who undergoes vaccination. We believe that the estimation of this risk is indispensable in order to make compulsory vaccination for health care providers constitutionally legitimate, especially in the terminal phase of the pandemic emergency. For this purpose, a national monitoring and collection system for the short- and medium-term effects of vaccines should be developed. This would make it possible, among other things, to intensify the precautionary measures to be associated with compulsory vaccination and to tailor post-administration pharmacovigilance as much as possible. Moreover, the results of an adequate national monitoring may be useful to better know the effects of this vaccination over time. In this way, the best knowledge will enable increasingly specific informed consent forms to be drawn up. In addition, in the event of an increase in the percentage of serious effects related to the vaccine, the conclusion could be reached that the vaccine obligation is no longer reasonable.

In addition, it is important to note that the extension of the vaccination requirement for healthcare workers until December 2022 also implies an obligation to undergo a fourth vaccine dose. The effects on the individual’s health of such additional administration are not yet well assessed: forcing health care workers to accept an additional risk appears unconstitutional and disproportionate to the current collective health benefits of the compulsory SARS-CoV-2 vaccination. Moreover, as it is true that healthcare workers are particularly susceptible to being infected because they are exposed to risky environments and contacts, it is also true that they present an extremely varied risk of developing a severe form of COVID-19 in relation to age and comorbidities.

Conclusions

If the objective of extending the compulsory vaccination for health workers is to protect them from serious consequences of infection—to which they are particularly exposed for work reasons—we think that this measure should be limited to health professionals who are fragile and actually at risk of developing them (because of age or specific comorbidities). Is it legitimate to continue to force health professionals—especially if they are young and free from comorbidities—to accept unpredictable consequences of vaccination in a pandemic context that is no longer an emergency and in the face of benefits to the community not having been properly assessed? Of course, in accordance with constitutional principles, health professionals who want to be vaccinated voluntarily must be able to do so.

Therefore, before evaluating the need to extend the vaccination obligation for all healthcare personnel or a specific subcategory, it is crucial to verify, even only hypothetically, that the administration of the fourth dose of the anti-SARS-CoV-2 vaccine would not be harmful to the health of the individual. Once this has been ruled out, it will be necessary to evaluate whether compulsory vaccination for all health care providers could produce a concrete and effective benefit for the community, in light of the current pandemic context. If during the acute phase of the health emergency an _a priori_ risk for the health of the individual vaccinated could be considered acceptable, in a non-emergency phase—such as the one in which we are living—it is essential to carefully weigh all the risks and benefits of compulsory vaccination for health workers and the potentially harmful effects of the inoculation of a fourth vaccine dose. This assessment is even more important—from a medico-legal point of view—in the case of young workers with a low risk of serious complications from COVID-19.

The decision to extend the vaccination requirement for health workers should be in line with constitutional principles, should be based on updated scientific and statistical-epidemiological evidence, and should be contextualized to the new nonemergency phase. Relaxing all anti-COVID-19 measures and, at the same time, prolonging the vaccination requirement for health workers is an incoherent choice and not justifiable from the point of view of public health strategies.

It is not considered permissible to fail to adequately protect the constitutional rights and health of a single category of professionals—engaged on the front lines in dealing with the COVID-19 pandemic—for the sole purpose of creating a “false sense of security” in the community, without actual, not hypothetical, public health benefits.

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