

*Presidenza del Consiglio dei Ministri*



**VACCINE PASSPORT, CERTIFICATE AND GREEN  
PASS, WITHIN THE COVID-19 PANDEMIC:  
BIOETHICAL ASPECTS**

**30 April 2021**

## Presentation

The Opinion analyses the bioethical issues of the 'health certification for non-medical use related to Covid-19 ('Covid-19 Pass') which includes the certificate certifying vaccination, the presence of antibodies and a negative swab test. This is a measure which aims to relax restrictions on freedom and at the same time contain the contagion in order to resume social, economic, cultural, religious and worship activities.

The Committee, acknowledging that this measure is being applied at a European and predictably national level and recognizing its importance in terms of 'risk management', introduces several bioethical reflections to outline certain critical issues and advantages.

In terms of critical issues, it highlights the non-equivalence between the three certifications in terms of protection against infection and duration of protection, as well as transmissibility. It also underlines the emerging discrimination between those who have had the opportunity to be vaccinated and those who, despite wanting to, have not been able to do so, as well as the problems relating to the cost of the serological test and swab test. The Committee draws attention to possible heterogeneity in the application of certification, the psychological risk of a false sense of security, the organizational problems and the risk that it will constitute the basis for broader measures, such as the biological passport or other forms of tracking or surveillance of the health conditions of the population.

The advantages are identifiable in a dutiful reward for those committed to responsible solidarity who have accepted vaccination and the risks and in incentivising vaccination uptake among those who are 'hesitant'. Furthermore, the certificate allows many subjects greater freedom of movement, in strict compliance with measures aimed at protecting public health.

The Committee recognizes the importance of the 'Covid-19 Pass' as a tool to mitigate discrimination in the current situation, in particular for those who have not been able to be vaccinated compared to those who have. It recommends provision of serological tests and swab tests free of charge, a full and comprehensible information campaign, which highlights the opportunities and limitations of the 'Covid-19 Pass', and a state regulation which ensures its homogeneity and coordination. In addition, the Committee points out the temporary nature of the measure and the non-acceptability of forms of permanent surveillance. The certificate must be a manageable tool, in digital and paper form, with measures which guarantee its authenticity. The instructions for use must be based on up-to-date scientific data and the protection of *privacy* ensured for particular health-related data.

The Opinion was prepared by the President Lorenzo d'Avack, by the Deputy Vice President Laura Palazzani and by Profs. Salvatore Amato, Carlo Casonato and Assuntina Morresi, with contributions by Stefano Canestrari, Cinzia Caporale, Bruno Dallapiccola, Antonio Da Re, Silvio Garattini, Luca Savarino and Grazia Zuffa.

The Opinion was voted by Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Riccardo Di Segni, Gianpaolo Donzelli, Silvio Garattini, Mariapia Garavaglia, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Tamar

Pitch, Lucio Romano, Luca Savarino, Monica Toraldo di Francia and Grazia Zuffa.

Prof. Maurizio Mori approved, adding an additional note.

Despite their not having the right to vote assent was given by: Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges; Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians; Dr. Amedeo Cesta, the delegate for the President of the National Research Council; Prof. Paola Di Giulio, the delegate for the President of the Superior Health Council. Prof. Carlo Petrini, the delegate for the President of the National Institute of Health,

Profs. Carlo Caltagirone, Bruno Dallapiccola, Massimo Sargiacomo, Lucetta Scaraffia absent at the time of voting subsequently assented.

Prof. Lorenzo d'Avack  
President of ICB

## 1. Introduction

To keep the spread of Covid-19 under control, non-pharmacological measures have been adopted, such as physical distancing, the use of masks, hand cleaning, body temperature detection. Up to now, these measures have allowed a certain possibility of movement and use of services, which varies according to local epidemiological conditions. The progress of the current vaccination campaign should significantly contribute to reducing restrictions, pending the achievement of community immunity (so-called herd immunity) or, hopefully, the way out of the pandemic emergency situation.

In the meantime, from various parts of the world, measures related to the easing of restrictions for people with a reduced potential for contagion have been proposed, or already adopted. This situation has been variously called 'passport', 'license', 'green pass', 'certificate' and is linked to fulfilment of three alternative requirements: 1) vaccination, 2) serological test certifying the presence of antibodies in a sufficient quantity to counteract the Sars-Cov-2 infection or certificate of recovery from the disease issued by the attending physician, 3) negative swab test in the hours preceding the activity (typically no later than 48 hours).

The Committee firstly notes how the use of expressions such as 'vaccine passport' and 'immunity license' in reference to Covid-19 can cause misunderstandings. The 'vaccination' and 'immunity' specifications are in fact misleading, because in this way undergoing the negative swab modality would be excluded to those who could not be vaccinated or do not have sufficient antibodies to fight the Covid-19 infection. Strictly speaking, therefore, with regard to a document of this type, it would be more appropriate to define it as "health certification for not strictly medical use related to Covid-19" hereinafter briefly 'Covid-19 Pass'): the specifications 'for other than medical use and 'related to Covid-19' have a bioethical value as they specify the application of the certificate to areas other than healthcare and the automatic non-extensibility to other and possible future uses not related to the pandemic, both critical bioethical issues.

The Committee starts from a first consideration: the three modalities contained in the 'Covid-19 Pass' are different and not equivalent in terms of protection and duration of protection against infection.

The vaccine represents, depending on the level of effectiveness of the various types of vaccine, the strongest instrument of protection of individual and collective health. The vaccine, on the other hand, does not guarantee total immunity, since the vaccinated person could still get infected, usually not seriously, and could perhaps still be a source of transmission of infection, albeit in a reduced way (there is currently no consolidated scientific evidence). There is also uncertainty about the duration of immunity and at least in part about the effectiveness of vaccines against variants that are already present or which may spread. In any case, the strong reduction in the risk of infection linked to the vaccine and the high probability that vaccinated people will not infect others requires that every effort be made to increase vaccine availability and extend its administration.

Not even the presence of antibodies, associated with a serological test that certifies the quantity of antibodies present in the blood, excludes the risk of a new infection and disease, even though it strongly reduces it. Again, there is no certainty about the duration of acquired natural immunity and the presence of sufficient antibodies over time. As for the serological test, it should also be

remembered that it expresses only a part of immunity, humoral immunity, but does not measure cellular immunity (B cells, T lymphocytes and macrophages) as well as immune memory. In fact, immunity has many components and is a very complex bodily function.

The swab test, on the other hand, only certifies the state of the absence of infection at the time the test is carried out, it does not exclude false negatives or, above all, the possibility that the person will fall ill immediately after carrying out a negative swab test. With regard to the latter, the different sensitivities of the tests currently available (e.g. rapid antigen tests and molecular tests) must also be considered, as well as the invasiveness of some of these tests, which could be problematic for children, if they have to be repeated in the short term (their having been excluded from vaccination like all minors).

The Committee acknowledges that the use of certificates is an instrument that is already being adopted in various Regions and is to be extended and spread at national and international level with the objective, both economic and social, of allowing a partial return to normality. Also relevant for the future, and having greater extension, is the European Commission's Proposal for a Regulation (17 March 2021)<sup>1</sup>, which is following its approval process and provides for the establishment of an 'EU Covid-19 Certificate' which includes the three types of aforementioned instruments in order to protect freedom of movement within the European Union, guaranteeing a common, stable and transparent system, which prevents individual States from adopting heterogeneous and variously discriminatory measures and allowing travel outside the EU.

In addition to adapting to this regulation to facilitate movement inside and outside the European Union, individual States, and therefore also our country, could adopt this same measure to ease the restrictions on the freedom of movement of individual citizens within national territory, facilitating access to places and services.

## **2. Health certificate for non-medical use related to Covid-19 or 'Covid-19 Pass': bioethical considerations.**

**2.1** The 'Covid-19 Pass' aims to find a balance between reducing the spread of infection and the disease and the partial resumption of economic, educational, recreational, cultural, religious and worship activities. The same measures, while not constituting a novelty in the context of epidemiological control and responding

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<sup>1</sup> The European Commission recently issued the *Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)* on March 17, 2021. The document (which, if approved, will become binding) consists of an exception to the freedom of movement provided for by the founding Treaties. The Commission provides for a document that will allow citizens to travel around Europe, respecting the principle of equality and non-discrimination, through the certification of being vaccinated, testing negative or being cured of Covid. The European legislator should provide for the recognition of all vaccines approved by the regulatory authorities in the EU, leaving the recognition of other vaccines to individual states (e.g. Sputnik). This proposal for a regulation also leaves to the responsibility of the Member States "flexibility" in the application with regard to not introducing restrictions on free movement or introducing additional ones. The goal is to ensure harmonization, safety, validity, reliability and interoperability at European level. The regulation must in any case protect the privacy and protection of personal data, their minimization, proportionality, limitation of access and punishment of abuse.

to the multiple interests linked to resuming normality, nevertheless raise a series of bioethical problems on different levels and lead the ICB to think in terms of risk management, more than to their elimination. The Committee intends to propose some elements of reflection, in order to ensure that the possible adoption of the 'Covid-19 Pass' responds to an overall equitable balance of interests<sup>2</sup>.

**2.2** With respect to the vaccination certificate, in the absence of a sufficient number of vaccine doses to treat the entire population, a discriminatory potential emerges linked to the inequality between those who have had the opportunity to get vaccinated and those who have not. And even if there were a sufficient quantity of vaccine doses for the entire population, the request for a vaccination certificate will have to take into account those who, even if they want to, will not be able to be vaccinated for medical reasons or because the vaccine has not yet been tested on them (for example, minors and pregnant women).

A discriminatory effect remains even *ex-post*, in the case of the 'Covid-19 Pass' which includes, in addition to the vaccine certificate, also the serological test or the certificate of recovery as well as the swab test, given the misalignment of the risk between vaccinated subjects and subjects who could not be vaccinated and for the cost and the necessary periodic repetition of the serological test and swab test. To tackle this discrimination, for example, it is possible to put forward the proposal to always make them free of charge, as well as to ensure in any case a clear institutional communication on the collective and personal risk that still persists.

Another problem related to the 'Covid-19 Pass' concerns the possibility that Regions or individual municipalities may request additional, non-coincident certificates, aggravating the discriminatory framework based on geographical origin. There could also be repercussions on a global level for middle and low-income countries, unable to carry out mass vaccination and, consequently, be irretrievably discriminated against<sup>3</sup>.

From a psychological point of view, given the impossibility of completely eliminating the risk of contagion, possessing a 'Covid-19 Pass', in whatever manner it is proposed, could generate a false sense of security, leading to behaviours which put at risk one's own health and that of those with whom one comes into contact with. This emphasises the need for correct and extensive information on the advantages of the 'Covid-19 Pass', but also on its limits, as well as *ad hoc* communication campaigns planned by experts.

Above all, there is the bioethical problem of using sensitive data, such as those relating to health, for purposes that are not strictly or not necessarily medical purposes. A vaccination certificate, for example, is a document which already exists in various forms within the National Health Service, and is primarily

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<sup>2</sup> N. KOFLER F. BAYLIS, *Ten Reasons why Immunity Passports are a Bad Idea*, "Nature", 581 (2020), pp.379-381; W. BEDINGFIELD, *Immunity Passports aren't a Good Way Out of the Coronavirus Crisis*, <https://www.wired.co.uk/article/coronavirus-immunity-passports> (April 10, 2020), Accessed 5th Jun 2020; F. BAYLIS., N. KOFLER, *COVID-19 Immunity Testing: a Passport to Inequity*, *Issues in "Science and Technology"*, April 29, 2020, "Health", 17, 31, 11 May 2020; G. PERSAD, E. J. EMANUEL, *The Ethics of COVID-19 Immunity-Based Licenses ("Immunity Passports")*, "JAMA", 2020; 323 (22): 2241-2242).

<sup>3</sup> Certificates based on serological testing can produce a "perverse incentive" to seek infection (in order to certify the presence of antibodies), especially in those who are not fully aware of the risks of infection and dangers of the disease, or those marginalized by society, A. PHELAN L., *COVID-19 Immunity Passports and Vaccination Certificates: Scientific, Equitable, and Legal Challenges*, "The Lancet", Volume 395, Issue 10237, 2020, 1595-1598.

intended for medical use. In addition to the necessary protection of data confidentiality, there are problems relating to intrusion into the private, personal sphere and the identification of limits and guarantees under which it is possible to modify the use of the certificate by extending it to non-medical areas, with the objective of exempting its holders from some restrictions currently in place to contain the infection. The use of the 'Covid-19 Pass' could also set a precedent for a future permanent use of the 'biological passport', i.e. the detection of certain health conditions to guarantee freedom of movement and access to certain places, services, activities or goods, within an "ethical healthcare", which distinguishes citizens according to the behaviours that are adopted, deemed more or less virtuous on the basis of the criteria established by the state and/or health authorities, introducing possible surreptitious forms of improper control of the population. The novelty of the 'Covid-19 Pass' is given by the new historical context. Today, to some extent, we have gone back to being nomads, thanks to continuous and increasingly widespread mobility; and freedom of movement is conditioned and subordinated to health certification, paving the way for the introduction of the "biological passport" not so much as the inevitable result of a sort of *slippery slope*, as for the imposition of the priority principle of protection from harm to preserve health.

Additional critical bioethical issues could derive from organizational and allocative problems, such as the difficulty of ensuring the availability of vaccines recognized by the EMA within the times and in the quantities necessary; another difficulty could consist in managing the huge demand for swabs which will presumably ensue, with the need to guarantee their availability throughout the country, at low cost or free of charge as well as ensuring the continuity of supply.

**2.3** In the face of these critical issues, emphasis must nevertheless be placed on the advantages of certificates related to vaccines: the mitigation of obligations making provision for carrying out certain activities and recognising a dutiful reward to those who, with personal and social responsibility and sense of solidarity, have accepted the vaccine and also the risk of possible side effects.

The certificate is a legal instrument and an incentive for vaccine acceptance, especially for some specific vaccines, even for those who are 'hesitant' about them, in order to favour an overall increase in the number of vaccinated people and accelerate the achievement of community immunity, given that duties, obligations or limitations cannot be imposed on those who are not put in a position to fulfil them (*ad impossibilia nemo tenetur*).

The 'Covid-19 Pass' allows for a homogeneous and precise system to replace self-certifications and the detection of certain symptoms that severely limit individual activities without guaranteeing transparent and coordinated measures for the safety of citizens on a social and economic level. It allows, in the exercise of entrepreneurial activities, to insert suitable measures to protect health in the workplace (in accordance with art.2087 of the civil code and art.29 bis of Legislative Decree 08/04/2020 n.94)<sup>4</sup> and, at least for some, to get rid of part of the restrictions due to the pandemic, with individual and collective benefits, also linked to a partial economic and social recovery<sup>5</sup>.

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<sup>4</sup> Art. 2087 of the civil code requires every entrepreneur to "adopt in the business of the business the measures which, according to the particular nature of the work, experience and technique, are necessary to protect the physical integrity and moral personality of the employees".

<sup>5</sup> R. C. BROWN H., D. KELLY, D. WILKINSON, J. SAVULESCU, *The Scientific and Ethical Feasibility of Immunity Passports*, "The Lancet", Infectious Diseases, Volume 21, Issue 3, 2021,

Despite its critical issues following the "less restrictive alternative", the 'Covid-19 Pass' allows many subjects greater freedom of movement and access to activities in compliance with public health rules. Of course, the advantages of the Covid-19 Pass' must be considered taking into account the exceptional nature of the pandemic situation, in the hope that once we return to normal conditions we should not have to, nor can we make recourse to instruments of this type. A sort of lesser evil argument can be made here: a possibility of free movement, albeit partial and subject to conditions, is justified compared to an absolute and indiscriminate prohibition, it being unfair not to allow a behaviour to anyone solely on the ground that it is not possible to allow it to everyone.

### 3. Recommendations

In light of the bioethical considerations summarized above, reiterating the difference between health certification for medical use and 'vaccination passport' and 'Covid-19 Pass' used for not only medical reasons and in the hypothesis of application of the 'Covid-19 Pass', the ICB recommends the following:

1. The Committee recognizes the importance and relevance of the use of the 'Covid-19 Pass' in order to allow a partial relaxation of the restrictions imposed by the pandemic.

2. However, the Committee highlights the emergence of some discrimination in the use of the 'Covid-19 Pass', particularly in this transition phase until vaccines are available for everyone. The Committee acknowledges that in order to mitigate discrimination in the current situation, the certificate of recovery, or a negative swab test, can also be taken into consideration as part of the 'Covid-19 Pass', in line with the proposals at European level. However, a discriminatory effect remains, taking into account the greater risk taken by subjects who have not been able to be vaccinated compared to those who are vaccinated.

3. To reduce the economic burden associated with carrying out (perhaps repeated) serological tests or swab tests, these measures should always be offered free of charge. It is necessary to ensure the concrete and effective availability of these tests throughout the national territory.

4. The use of the 'Covid-19 Pass' constitutes an extraordinary measure, linked exclusively and exceptionally to the gravity of the current pandemic crisis. The Committee deems it appropriate that the 'Covid-19 Pass' be introduced and regulated by a specific state law.

Any provision must, therefore, accurately indicate the scope of the activities, the performance of which will be granted to holders of the 'Covid-19 Pass', limiting them to those which present the most serious risks of infection, according to the criterion of proportionality. The 'Covid-19 Pass' must be kept in force for the time strictly necessary, in a proportionate and temporary manner, introducing the necessary guarantees to prevent abuse and it must not constitute the basis for more extensive and definitive automatic measures, such as the 'biological passport', or for other forms of tracking, profiling or surveillance. Any measure regarding the restriction and conditioning of individual freedoms based on health conditions that extends beyond the indicated term must be considered ethically and legally unacceptable.

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58-63; R. BROWN, J. SAVULESCU, B. WILLIAMS, D. WILKINSON, *How Much Certainty is Enough? Immunity Passports and COVID-19*, "Journal of Medical Ethics" blog, 2020.

5. When measures are proposed to ease restrictions related to the 'Covid-19 Pass', a widespread, complete and comprehensible information campaign should first be activated, highlighting the reasons, conditions, opportunities, purposes and limits of such documents and which makes the population aware of the characteristics of the various certificates contained in the 'Covid-19 Pass' and of the relative distinctions in terms of safety, reliability and effectiveness. Only on these terms is it possible to reduce the risk that the use of the 'Covid-19 Pass' will generate a false sense of security, leading to abandoning or relaxing non-pharmacological measures in place to fight the pandemic: physical distancing, hand washing, use of masks.

6. In order to avoid discrimination between citizens residing in different areas of the country, the adoption of the 'Covid-19 Pass' must be centralised and applied homogeneously throughout the whole national territory.

7. The 'Covid-19 Pass' must be understandable, free, easy to obtain; it must be available in both digital and printed form, to avoid the digital divide; it must contain measures that guarantee its authenticity, such as a QR code.

8. The instructions for use of the 'Covid-19 Pass' must be based on scientific data and updated regarding the course of the infection, on the variants of the virus, on the degree and duration of immunity, on the transmissibility of the infection in those who are vaccinated.

9. Given that these are particular health-related data, the 'Covid-19 Pass' and the overall management of the data need to be ensured protection of *privacy*, in compliance with all the regulations on the protection of personal data.

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### **Supplementary note from Prof. Maurizio Mori Green Pass, good but it marks an epochal turning point**

The preparation of the Opinion on the Green Pass or "health certification for non-medical use related to Covid-19" gave rise to an intense, in-depth and very respectful debate, which brought to the fore shared observations such as the clarification that the three modalities required by the Pass are different and not equivalent to each other in various respects. In general, I approve of the Green Pass, but in this note I propose certain additions which should have been given greater emphasis.

The Opinion starts from the assumption that the Green Pass proposal is in line with normal prophylaxis "not constituting a novelty in the field of epidemiological control" undertaking therefore to reflect on how to balance the advantages and risks of the possible adoption of such a certificate. It is true that, limited to certain contexts and aspects, health certification has been required for some time (e.g. against malaria for entry into some countries, or the one against measles), but the new historical context in which the Green Pass is located (the pandemic, globalization, its universality and telematic form, etc.) make it a far more significant historical novelty than it has been recognized to be.

On the one hand, the pivot for the hoped-for success of the Green Pass hinges on vaccination (the other two procedures are complementary and marginal), which is a welcome form of enhancement that goes beyond the

purposes of Hippocratic medicine. It must therefore be recognized that the implementation of the Green Pass will lead to accelerating abandonment of the traditional Hippocratic notion of health as a received natural gift, and the adhering to a new psycho-physical notion of health as a social construct, in which "damage to third parties" is determined by technical-scientific opportunities and no longer by nature.

On the other hand, the Green Pass is set as a precondition for the daily exercise of fundamental and constitutional freedoms such as that of free movement, whose limitation is justified by the principle of "not harming others", where "harm" is identified on the basis of the new notion of health. The expansive force of the principle understood in this way will lead to profound changes in the general management of health itself (public and non-public). The way of considering medical data will change, the responsibility for health (one's own and that of others), the distributive justice of medical resources and the criteria for triage (already examined in another Opinion), the possibility of having a "biological passport" etc.

The Opinion only catches sight of some of the many aspects involved, especially since the Green Pass will not remain an isolated and circumscribed fact, but will form the basis for a new way of managing health (both individual and public health). Other issues were deserving of greater in-depth analysis such as that of possible discrimination. The Opinion only considers the problems of the "discriminatory potential linked to the inequality between those who have had the opportunity to be vaccinated and those who have not" and leaves out the situation of those who do not want the vaccine for reasons of conscience: not because they are anti-vaxxers, but because they have ethical objections to the methods of manufacturing and/or testing of the vaccine itself. I am well aware that the problem of conscientious objection regarding the vaccine is huge, that it could not have been addressed in only a few lines and that perhaps it will be given special consideration. However, in the awareness that the Green Pass marks an epochal turning point for health management the problem should have been at least mentioned: indeed, dependent upon its solution is the question of how many limits and what limits to individual freedom are deemed plausible in order to protect health itself.