



Exploring the effectiveness of the Digital Green Certificate Law as Public Health instrument to increase anti-COVID-19 vaccination in a sample of working-age adult population in the Palermo Metropolitan Area

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Keywords

COVID-19 vaccination • Digital Green Certificate • Green Pass Law • Mandatory vaccination

Summary

Counteracting vaccine hesitancy should be considered an absolute priority for Public Health Authorities. A correct health communication represents one of the best ways to increase adherence to vaccination among hesitant population.

In order to increase vaccination coverage rates against COVID-19, the Italian government has issued a legislative decree with a mandatory "Digital Green Certificate" (DGC) to access workplaces for some categories considered at risk.

Methods. *We conducted a cross-sectional study with the aim to highlight the factors associated with the anti-COVID-19 vaccine acceptance and to estimate the influence of the introduction by law of the Digital Green Certificate (DGC) on the adherence to the COVID-19 vaccination campaign in a sample of individual accessing one of the main vaccination centres of the metropolitan area of Palermo, Italy. An anonymous and validated questionnaire*

was self-administered through the Google Documents® platform, between October 2021 and March 2022.

Results. *Among the 467 subjects enrolled, 43.3% were influenced on their vaccination choice by the introduction of the DGC. The multivariate analysis showed that among the respondents emerged contrasting feelings with a self-reported significantly higher sense of freedom (Adj-OR = 2.45, 95%CI = 1.51-3.97, p-value: < 0.001) but a lower sense of safety (Adj-OR = 0.19, 95%CI = 0.12-0.29, p-value: < 0.001) after vaccine administration.*

Conclusions. *Our findings, in line with the available literature, suggest that the introduction of DGC has led to a significant increase in the immunization rate and, together with an appropriate communicative approach, it could represent an effective strategy to counteract vaccine hesitancy.*

Introduction

On March 11, 2020, the World Health Organization (WHO) announced that the outbreak of "COroNaVirus Disease 2019" (COVID-19), which initially started in Asia in the city of Wuhan at the end of 2019, had become a pandemic [1]. The outbreak of COVID-19 led to an unprecedented global crisis, impacting on the political agenda, the economic and healthcare systems [2].

High pressure on healthcare systems, during the first wave, required a rapid international response to slow down the transmission of contagions, as well as the death rates associated with COVID-19 [3].

Due to the lack of vaccines or specific therapies to contrast the COVID-19 spread, drastic Public Health interventions, such as lockdowns and social distancing measures, were considered worldwide as the first step to counteract the first and second waves of the pandemic [4].

On December 2020, the European Medicines Agency (EMA) approved the use of the first COVID-19 vaccine in Europe and in Italy the first dose was administered on December 27 [5]. In the following weeks and months other vaccines were approved and, progressively, vaccination was extended to healthcare professionals, elderly, subject with comorbidities, teachers, and the general population [6].

In the middle of July 2022, in Italy, 91.5% of the population over 12 years old received a full COVID-19 vaccination cycle, with 83.5% of the target population vaccinated with the third (booster) dose. Unfortunately, in Sicily the first COVID-19 vaccination cycle was administered to 83.6% of the target, with only 77.7% receiving a booster dose [7, 8].

Many countries since the start of the COVID-19 vaccination campaign had to fight against vaccine hesitancy, consisting in a refusal of vaccination despite the availability of effective vaccines [9].

Media may play a role against the fight to SARS-CoV-2 by supporting vaccination campaigns, but may become also an enemy due to the spread of fake news [10].

To counteract the spread of COVID-19 and the vaccine hesitancy, in March 2021, the European Commission proposed the introduction of a vaccination certificate, namely Digital Green Certificate" (DGC) [11].

In the same direction, on July 2021, the Italian government issued a legislative decree implementing the use of the DGC [12], which was extended to a mandatory use for both public and private workers, health care professionals and subjects with more than 60 years old, starting from October 2021 [13].

We conducted a cross-sectional study with the aim to highlight the factors associated with the anti-COVID-19 vaccine acceptance and to estimate the influence of the DGC on the adherence to the COVID-19 vaccination campaign in a sample of individual accessing one of the main vaccination centres of the Metropolitan area of Palermo, Italy.

Material and methods

Since the beginning of the COVID-19 vaccination campaign, the vaccination centre of the Palermo University Hospital has administered 80,000 doses of COVID-19 vaccines, with more than 7,000 shots dispensed to subjects with severe allergy in secure environment, while serving the Palermo metropolitan area, one of the most density populated areas of Italy with 1,214,291 inhabitants [14].

A cross-sectional study was carried out between October 2021 and March 2022. An anonymous and previously validated questionnaire was administered to subjects accessing the COVID-19 vaccination centre of the Palermo University Hospital for COVID-19 immunization.

A simple random sampling procedure was used in order to select our sample through a Microsoft Excel spreadsheet that assigned randomly a number to enrolled subjects.

Participants were initially provided with information explaining the study aims and the personal data processing, according to Italian privacy policies, and received an informed consent before answering to the questionnaire.

QUESTIONNAIRE STRUCTURE

The questionnaire consisted of an introductory part, presenting the study aims and describing the method of treatment, conservation, and protection of personal data, as well as indicating the person responsible for the data treatment. The questionnaire, self-administered through the Google Forms® platform, consisted of 8 items distributed in four main sections investigating:

- socio-demographic information, including gender, residence, age;
- knowledge, perceptions and attitudes regarding COVID-19 vaccination;
- main information sources consulted, and considered reliable, on vaccination against COVID-19 and

influence of DGC on the decision process about COVID-19 vaccination;

- access to advertisements against COVID-19 promoted by the regional health authorities;
- factors leading to the vaccination choice.

Level of freedom and post-vaccination safety were both calculated using a Likert scale, with answer values ranging from 1 (very low) to 5 (very high).

The research team validated the questionnaire through a pilot study on a sample of 30 subjects to evaluate its reproducibility and comprehensibility. To this end, the Cronbach's alpha was calculated and corresponded to 0.92 with an adequate reliability of the test.

Once the questionnaires were completed, all data were automatically recorded on an Excel file (ver. 1997-2003) protected by password and accessible by the research group only to further ensure privacy.

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Palermo Ethical Committee 1 (resolution no. 9, October 2022).

STATISTICAL ANALYSIS

Absolute and relative frequencies were calculated for the categorical (qualitative) variables.

The association between introduction of mandatory Digital Green Certificate and other qualitative variables was explored using Fisher test or Chi-square test. To guarantee a more conservative approach all the variables found to have a p-value ≤ 0.20 at the univariate analysis were included a multivariate backward stepwise logistic regression model. The crude and adjusted odds ratios (ORs and adj-ORs) with their 95% confidence intervals (CIs) were calculated. The level of significance was set at p-value < 0.05 (two tailed).

All the data were analysed using the statistical software package Stata/MP 12.1 (StataCorp LP, College Station, TX, USA).

Results

Table I summarizes the socio-demographic characteristics of the 467 respondents recruited in the survey, having an average age of 38.3 years old (SD ± 14.2), predominantly

Tab. I. Socio-demographic characteristics of the surveyed population (n = 467).

	N	%
Gender		
Male	215	46.1
Female	252	53.9
Residence		
Palermo	301	64.4
Other	166	35.6
Age distribution		
< 50 years	353	75.6
≥ 50 years	114	24.4
Age, Mean \pm SD	38.3 \pm 14.	

Tab. II. Information sources and decisive factors on vaccination against COVID-19 of the surveyed population (n = 467).

	N	%
Subjects that have seen promotional image against COVID-19		
No	95	20.4
Yes	372	79.6
Media consulted on COVID-19 vaccine		
TV	233	49.9
Journal, magazine, poster	48	10.2
Internet/web	186	39.9
Main factors associated with vaccination acceptance		
Own choice/fear of disease	341	73.0
Relatives or friends advice/ TV, internet	34	7.2
General practitioners' advice/trusted physician	92	19.8
Influence of the GP decree on vaccination acceptance		
Yes	202	43.3
No	265	56.7

female (n = 252; 53.9% of total) and resident in the Palermo city (64.4%).

In Table II are reported the results of the answers to the questions related to the main information sources consulted and considered reliable by respondents,

the factors leading to the vaccination choice against COVID-19, and the DGC influence on the decision process about COVID-19 vaccination adhesion.

Within the study sample, 372 respondents (79.6%) confirmed to have had access to advertisements against COVID-19 promoted by the regional health authorities. Media sources consulted were mainly TV (49.9%), followed by internet/web (39.9%) and journals/magazines (10.2%).

An own choice and the fear for disease were the main factors leading to vaccination acceptance (73.0%), followed by the advice from the General practitioners or a trusted physician (19.8%) and the informal advice from relatives or friends (7.2%).

Lastly, 202 (43.3%) respondents declared to be influenced by the introduction of the DGC.

Table III and IV shows the results of the univariate and multivariable analyses aiming at estimating the impact of mandatory DGC on the decision process about COVID-19 vaccination adhesion of the 467 respondents in study.

At the univariate analysis the variables associated to the DGC influence on vaccination adhesion were the male gender (OR = 1.52, 95% CIs = 1.05-2.20; p-value: <0.05), a high perception of post-vaccination safety (OR = 0.24, 95% CIs = 0.16-0.36; p-value: < 0.001) and the advice from the General Practitioner or a trusted physician (OR = 0.58, 95% CIs = 0.36-0.85; p-value: < 0.01).

The multivariable analysis highlighted a statistically significant association between the DGC influence

Tab. III. Univariate (crude OR) analysis between influence of mandatory Digital Green Certificate (DGC) on the decision process about immunization adherence anti COVID-19 with different dependent variables considered in the study (n = 467).

Influence of the DGC decree on vaccination acceptance, n (%)		
	Crude OR (95% CIs)	p-value
Gender		
Female	reference	< 0.05
Male	1.52 (1.05-2.20)	
Residence		
Palermo	ref	0.52
Cities outside Palermo	0.99 (0.67-1.45)	
Age classes		
≥ 50 years	ref	0.39
< 50 years	1.08 (0.70-1.65)	
Perception of post-vaccination freedom		
Low	ref	0.06
High	1.37 (0.92-2.04)	
Perception of post-vaccination safety		
Low	ref	< 0.001
High	0.24 (0.16-0.36)	
Main factors associated with vaccination acceptance		
Relatives or friends advice/ TV, internet	ref	< 0.01
Own choice/fear of disease	0.82 (0.63-1.15)	
General Practitioners advice/trusted physician	0.58 (0.36-0.85)	
Media consulted on the COVID-19 vaccine		
Internet	ref	0.96
TV	1.25 (0.75-2.34)	
Journal, magazine, poster	1.36 (0.82-1.93)	

Tab. IV. Multivariate (adj-OR)* analysis between influence of mandatory Digital Green Certificate (DGC) on the decision process about immunization adherence anti COVID-19 with different dependent variables considered in the study (*multivariate analysis was performed only for variables with p-value ≤ 0.20 at the univariate) (n = 467).

Influence of the GP decree on vaccination acceptance, n (%)		
	Adj-OR (95% CIs)	p-value
Gender		
<i>Female</i>	ref	
<i>Male</i>	1.31 (0.88-1.95)	0.18
Perception of post-vaccination freedom		
<i>Low</i>	ref	
<i>High</i>	2.45 (1.51-3.97)	< 0.001
Perception of post-vaccination safety		
<i>Low</i>	ref	
<i>High</i>	0.19 (0.12-0.29)	< 0.001
Main factors associated with vaccination acceptance		
<i>Relatives or friends advice/ TV, internet</i>	ref	
<i>Own choice/fear of disease</i>	0.86 (0.75-1.27)	0.13
<i>General Practitioners advice/trusted physician</i>	0.72 (0.49-1.07)	

on vaccination adhesion of respondents and their perception of a higher post-vaccination freedom (Adj-OR = 2.45, 95% CIs = 1.51-3.97; p-value: < 0.001) and of a lower post-vaccination safety (Adj-OR = 0.19, 95% CIs = 0.12-0.29, p-value: < 0.001).

Discussion

The COVID-19 vaccination campaign, started on December 2020 in the developed Countries and in Europe, was the biggest ever known universal mass campaign conducted in the history.

The scientific community and Public Health Institutions should spread the right messages and information about COVID-19 vaccination, also to tackle circulating of fake news and governments have the task of enacting decree laws useful for increasing vaccination coverage, such as laws that making vaccination 'mandatory'. [15].

Many countries have introduced some restrictions, such as lockdowns and the use of masks to reduce the surge in cases attributable to the pandemic [16].

With the arrival of vaccines, an attempt was made to reverse the trend by trying to return to normality and reducing stringent measures but in a short time the growth of the vaccinated rate stopped due to vaccine hesitancy especially in those countries where the vaccination offer was high; this leads us to speak of an 'unvaccinated pandemic' [17, 18].

The introduction of the mandatory vaccination has contributed in the countries where it has been adopted to drastically reduce hospitalizations, deaths and cases as demonstrated by some randomized and observational studies [19].

Specifically, in the present sample, was reported a prevalence of working-age adults that are mainly healthy and for which the personal protection of anti-COVID-19 vaccination it is considered less important than elderly people or people with comorbidities [18].

The Digital Green Certificate therefore, forcing workers to receive anti-COVID-19 vaccination, represented an

essential instrument of Public Health in order to ensure the health of general population and to contribute to indirect protection of fragile and elderly people [17, 20]. The need for large-scale vaccination has led to some concerns about the transparency of vaccines as well as their long-term safety; nevertheless, it would seem that the benefits of such a large vaccination campaign during this pandemic far outweigh the risks it could cause [20]. Mandatory vaccination policies are heterogeneous across countries, in all Europe.

Countries that adopt sanctions for those who have not vaccinated have lower incidence rates of vaccine-preventable diseases than countries who do not. Although financial penalties are useful for achieving high vaccination coverage, these must be accompanied by constant availability of vaccines but above all by education on the importance of prevention measures aimed at hesitant subjects. [21]

At the same time, correct health communication is increasingly becoming a fundamental tool to guide and educate citizens in taking responsible actions. The phenomenon of the dissemination of misleading news emerged in an intrusive way during this pandemic emergency, determining a pandemic of false information (Infodemic). Website and social network were one of the most important theater of spreading of fake news where everyone, with or without competence, could say his idea about pandemic, vaccines and government decision [22]. Islam MS et al. conducted a study where a team of epidemiologist, medical doctors and scientist were formed to examine a wide range of sources such as websites, Facebook and Twitter. They identified about 2311 reports related to COVID-19 infodemic from 87 countries, most of them, 2049 (89%), were classified as rumors while the rest conspiracy theories, and stigma (182 and 82, respectively) [23].

The Sicilian regional health authority has dedicated some specific efforts in the communication process during the management of the COVID-19 health emergency, implementing a promotional campaign in support of COVID 19 vaccination. Despite our study

didn't aim to assess the effectiveness of this institutional communication campaign against COVID-19, we were able to report that it reached the vast majority of the respondents to the survey. Anyway, not surprisingly, the main sources of information on COVID-19 vaccination were television and the web, suggesting the need to provide correct information through these means.

Furthermore, within the factors leading to vaccination the interviewees recruited in our cross-sectional study a predominant role was played by the fear of contracting the COVID-19 disease, overcoming the advice of medical-doctors [24, 25]. Moreover, a large part of the respondents declared that the introduction of GP influenced their adhesion to the COVID-19 vaccination campaign. Anyway, among the study sample population emerged contrasting feelings with a self-reported significantly higher sense of freedom but a lower sense of safety after vaccine administration, this could be related to fear of expected adverse events. Negative feelings about mandatory vaccinations have been already documented in healthcare workers by international literature, forced intervention and anxiety about physical injections being the main stated motivations toward this vaccination strategy when adopted to increase influenza vaccination rates [26].

There are some limitations of the present study that need to be discussed. Firstly, there can be a lack of representativeness due to the limited number of participants. However, the vaccination centre of the Palermo University Hospital represents one of the most important centres (in terms of vaccination administered) of Sicilian Region and the sample could be considered a proxy of general population of the Metropolitan area of Palermo.

Secondly, the survey was proposed to citizens voluntary accessing the vaccination centre to get vaccinated and, for this reason, it was not possible to involve in the analysis the so-called no-vax population, even if it would have been difficult to trace the reasons behind their refusal of the COVID-19 vaccine, as they are usually reluctant to provide their responses.

Conclusions

In conclusion, as compared to other strategies used in the past to implement the vaccination rate, the DGC may represent a ploy encouraging citizens to get vaccinated without imposing a direct obligation on them. Nevertheless, the introduction of DGC has led to several public debates on a potential discrimination based on the lack of privacy with regard to the individual vaccination status [27, 28]. This was the reason why, even in Italy, protests and strikes were organised against the government decision to introduce the DGC strategy [29].

However, the vaccination campaign in Italy benefited from the introduction of the mandatory DGC, which increased the COVID-19 vaccination rates, as further confirmed by our findings.

The data presented highlighted that the many hesitant respondents have been influenced by the mandatory

DGC in their choice to vaccinate against COVID-19, even if they reported to feel less confident after having the vaccine shots, therefore informative campaigns and communicative strategies should be improved to reassure vaccinated population on COVID-19 vaccines safety and effectiveness.

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Conflicts of interest

The authors declare no conflict of interest.

Authors' contributions

C.C., D.C., D.S. and D.M.: conceptualization; C.C., W.M., F.R., N.B. and M.S.: methodology; N.B., M.S., L.D., A.C.: software; M.M., G.G., C.M.M., V.R., F.T. and F.V.: validation; C.C., N.B., L.D. and A.C.: formal analysis; W.M., F.R., V.R., and F.V.: data curation; C.C., N.B., M.S., L.D. and A.C.: writing – original draft preparation; W.M., D.C., D.S., D.M., and F.V.: writing – review and editing; W.M.: visualization; F.V.: supervision; C.C.: project administration. All authors have read and agreed to the published version of the manuscript.

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