



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



The Italian policy of mandating SARS-CoV-2 vaccination for healthcare workers: Analysis of the policy processes and preliminary outcomes

Costanza Vicentini^{a,*}, Giacomo Garzaro^a, Alessandro Roberto Cornio^a, Davide Bosio^a, Enrico Bergamaschi^a, Giovanna Pacchiana Parravicini^b, Carla Maria Zotti^a

^a Department of Public Health and Paediatrics, University of Turin, Via Santena 5 bis, Turin 10126, Italy

^b Department of Law, University of Turin, Lungo Dora Siena 100/A, Turin 10154, Italy

ARTICLE INFO

Keywords:

Healthcare workers
SARS-CoV-2
COVID-19
Italy
Mandatory vaccinations
Vaccine hesitancy

ABSTRACT

Background: Italy experienced the first outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Europe, and was among the most hardly hit European countries. Growing evidence suggests healthcare workers (HCWs) are at increased risk of SARS-CoV-2 infection. Infection in HCWs can lead to cross-transmission and increase community transmission. Italy was the first country in Europe to introduce mandatory vaccinations against SARS-CoV-2 for HCWs, on April 1, 2021.

Aim: To describe the policy processes and preliminary results of the introduction of compulsory vaccination against SARS-CoV-2 for HCWs in Italy.

Results and conclusion: In Italy, the adoption of the policy was possible in the context of the public health and economic crisis resulting from the pandemic, with support from the scientific community and among favorable political conditions. Preliminary data suggest the policy has so far had a positive impact on increasing vaccine uptake and lowering infection rates among HCWs. Hopefully, the lack of serious vaccine-related adverse events and the growing evidence on vaccine effectiveness will progressively strengthen vaccine confidence among HCWs. In the context of a global pandemic, the Italian experience could provide insight for policymakers in other countries considering similar policies. Further, the ethical, legal, and policy challenges raised by the current public health emergency could be used to inform future pandemic preparedness plans.

1. Purpose of the policy

The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has spread rapidly and extensively, causing more than 200 million cumulative cases and over 4 million deaths worldwide. Italy experienced the first outbreak in Europe, and was among the most hardly hit European countries. As of October 2021, more than 4 million cumulative cases and over 130,000 deaths related to COVID-19 have been identified in Italy, the second highest death toll in Europe [1].

The most severely affected regions in the country remain those in which the earliest outbreaks occurred, mainly in Northern Italy [2]. Healthcare-associated transmission may have initially played an important role in contributing to the community spread in Northern Italy, consistent with reports from China and the UK [3–6]. SARS-CoV-2 spread quickly among healthcare workers (HCWs), with HCWs accounting for 12% of national cases by June 2020 [7]. A study conducted

in several hospitals in the UK and in Modena, in Northern Italy, found 12.5% of COVID-19 infections in patients admitted up to April 28, 2020, were hospital-acquired [8]. Growing international evidence supports the potential role of HCWs as superspreaders and of healthcare institutions as infection nodes, where cascades of superspreading events can occur [4,9,10]. This phenomenon might have been particularly salient in the early stages of the pandemic, as mitigation measures had not yet been fully established and infection control efforts were hindered by shortages in personal protective equipment [7,11].

Several reports have found HCWs are at increased risk of SARS-CoV-2 infection [3,11,12], which has important implications, first of all concerning HCWs' own safety. A review of studies of nosocomial SARS-CoV-2 infection published up to March 2020 found the majority of healthcare-associated infections (HAIs) occurred in medical staff, with the highest proportion among nurses [12]. In their systematic review, Gómez-Ochoa et al. observed a pooled prevalence of severe COVID-19 of 5% among HCWs, with a 0.5% case fatality rate (CFR) [11]. This

* Corresponding author.

E-mail address: costanza.vicentini@unito.it (C. Vicentini).

<https://doi.org/10.1016/j.healthpol.2022.11.006>

Received 27 October 2021; Received in revised form 11 October 2022; Accepted 16 November 2022

Available online 18 November 2022

0168-8510/© 2022 Elsevier B.V. All rights reserved.

estimate is lower than that of the general population [2], although demographic and clinical characteristics of HCWs must be taken into account: according to data from the Italian National Institute of Health, the CFR reached 10.2% in HCWs aged 70–79 years [13]. Second, as discussed previously, infection in HCWs can lead to cross-transmission and increase community transmission. Third, staff shortages due to HCWs on sick leave place a further strain on health-care systems, at a time of high demand [2].

Several safe and highly effective vaccines against SARS-CoV-2 were developed and made available in record time [14]. Italy was the first country in Europe to introduce mandatory vaccinations against SARS-CoV-2 for HCWs, through an emergency decree approved on April 1, 2021. Compared to prior Italian legislation, the strategy is novel in two aspects: first, in the mandatory nature of the policy, and second, in its objective, which is preserving public health. Before the introduction of this policy, specific protective measures were recommended for HCWs, based on individual workplace health and safety and occupational health assessments, including a series of vaccinations, with the objective of safeguarding the safety of both HCWs and patients [15].

Making vaccinations for HCWs mandatory has proven to be effective in achieving high uptake rates in the case of the influenza vaccine [16], although it is considered the most intrusive form of vaccine policy [17]. The issue of mandating vaccinations is complex and has important ethical, legal and practical ramifications. This paper aims to address some of these elements, and to describe the policy processes and preliminary results of the introduction of compulsory vaccination against SARS-CoV-2 for HCWs in Italy. This strategy was also adopted by other European countries such as France, Greece and Austria in the following months, as well as the USA, whereas in England vaccination was due to become mandatory for all HCWs from April 2022, although the implementation of the policy has been paused and subject to a Parliamentary consultation [18]. In the context of a global pandemic, the Italian experience could provide insight for policymakers in other countries.

2. Legal framework and legislative process

The Italian Constitution recognizes health as a fundamental right of the individual and as a collective interest that the State must safeguard. According to article 32 of the Constitution, medical interventions can be made obligatory but only under the provisions of the law, which cannot under any circumstance violate the limits imposed by respect for the human person. Article 35 of the EU Charter of Fundamental Rights refers the execution of the right of access to preventive health care and the right to benefit from medical treatment to national laws and practices.

On April 8, 2021, the European Court for Human Rights ruled in favor of mandating vaccinations for schoolchildren [19]. The Court held that any compulsory medical intervention is considered an act of interference with the right to privacy, which is protected by article 8 of the EU Charter. However, interferences are justifiable on the condition that they are in accordance with national law, pursue a legitimate aim, such as protecting public safety or the rights and freedoms of others, and are proportionate in relation to this aim. In view of this and previous rulings of the Court [20], mandating vaccinations for HCWs conforms to the principles upheld by the EU Charter, as a legitimate aim is present: growing evidence supports the effectiveness of vaccines in reducing the spread of SARS-CoV-2, thus protecting individual and collective health [14].

The Italian legislation did not contain any specific law concerning compulsory vaccinations for HCWs prior to the imposition of the SARS-CoV-2 vaccine mandate with an emergency decree, issued on April 1, 2021, and later converted into law (n. 76 of May 2021). The legislative process of the policy was subject to some controversy. Article 32 of the Italian Constitution requires mandatory medical interventions to be introduced through laws issued by the Legislative branch of Government, *i.e.* the Parliament, whereas a decree-law is an act of the Executive. Further, according to article 77 of the Constitution, the

employment of a decree-law should be reserved for extraordinary or urgent circumstances, in order to safeguard the separation of powers between the Executive and the Legislative branches of Government. However, it must be noted that the decree was successively converted into law, and therefore was subject to parliamentary scrutiny. Since the introduction of the policy, several groups of HCWs have appealed to Administrative Courts in different regions of Italy, claiming law 76/21 is unconstitutional. To date, all appeals have been denied, on the grounds that the public interest protected by law 76/21 prevails over individual freedom of choice concerning vaccinations [21].

3. Content of the policy

The main regulatory provision is the imposition of mandatory SARS-CoV-2 vaccination for HCWs and workers in healthcare-related professions, as an essential requirement for practicing these professions and for performing healthcare-related services, with validity until December 31, 2021. Law 76/21 states that HCWs can be exempted from the mandate for specific and documented medical reasons, whereas those who refuse to receive the vaccination are to be transferred to duties that do not risk transmission of SARS-CoV-2, when this is possible, or suspended without pay for the remainder of 2021.

From a practical perspective, applying the policy indirectly implies tracking the vaccination status of employees, which has some inherent data protection issues. According to the current Italian legislation (Legislative Decree, LD 81/08), occupational health professionals determine HCWs' eligibility for specific roles based on individual health assessments, with the purpose of protecting HCWs' health. The concept of fitness for work in the occupational medical field is mainly focused on protecting the health of the worker and few are the cases where the legislation has prescribed measures for the protection of third parties. Law 76/21 does not assign occupational health professionals a role in the policy implementation process, which is in line with LD 81/08, as preserving public health is not a factor that should be considered to assess the fitness for work of HCWs. It must however be noted that, according to law 76/21, receiving the SARS-CoV-2 vaccine is a prerequisite for practicing any healthcare-related profession and for performing healthcare-related services.

The main tools employed by the policy are coercion and sanctions. Although vaccine mandates have been described as “a blunt instrument to tackle a complex issue” [22], in the case of influenza vaccination for HCWs the strategy has proven more effective and less resource-intensive compared to voluntary campaigns [16]. Further, several healthcare institutions have provided counselling sessions performed by occupational health professionals to inform and attempt to persuade vaccine-hesitant HCWs, although law 76/21 does not include any provision in this regard.

The approach is not entirely new. As aforementioned, prior to the introduction of the vaccine mandate against SARS-CoV-2, HCWs in Italy were already required to be immunized against certain diseases (such as hepatitis B, influenza, measles, mumps, rubella, varicella and pertussis) to be able to work in at-risk areas [15]. However, these vaccinations are recommended rather than mandated, and in practice HCWs refusing to comply are taken off duties that could expose them to disease. More broadly, HCWs are generally expected to modify their practice in the interest of patient safety, even if this may infringe on their autonomy, for instance by respecting infection control measures and avoiding alcohol intake.

4. Political background, actors and stakeholders

The issue of mandatory vaccinations has proven to be extremely divisive and politically salient in Italy, as occurred following the introduction of the 2017 reform on compulsory childhood vaccinations. At the time, several ‘no-vax’ and ‘free vax’ demonstrations were held against the reform, and members of parliament and ministers received

threats and verbal attacks. The coalition opposed to the reform was comprised in civil society by several small associations and informal groups, organized mainly through social networks, and in parliament by the populist Five Star Movement (M5S) and the far-right party Lega Nord [23,24].

In February 2021, Mario Draghi was sworn in as Prime Minister, at the head of a unity government supported by most of the country’s main political parties. Draghi’s government replaced a previous ruling coalition lead by Giuseppe Conte and made up of the M5S and the centre-left Democratic party (PD). Conte was forced to resign after losing the support of the majority of members of Parliament. Draghi is the former head of the European Central Bank and is a widely respected figure, both nationally and internationally. At the time of his appointment, the economic recession and public health crisis due to the pandemic were important political issues, and expectations were high that Draghi would accelerate vaccination efforts [23].

In Italy, the vaccination campaign against SARS-CoV-2 began in December 2020, with HCWs included among the priority groups for vaccine allocation. Even though the regionalized organization of healthcare delivery in Italy created some political tensions, particularly in the early stages of the pandemic [25], leadership and administrative authority for the vaccine roll-out were partly centralized in response to the crisis, which included strengthening human resources, health information systems, as well as massive investments [26].

Between February and March 2021, several small outbreaks of healthcare-acquired SARS-CoV-2 infections were linked to unvaccinated HCWs. Estimates from early April 2021 suggested that up to 15% of HCWs had yet to be vaccinated, with important differences across regions [27]. These circumstances prompted governors of several regions to call for a vaccine mandate for HCWs [28].

The emergency decree concerning the compulsory vaccination of HCWs against SARS-CoV-2 was approved by the Draghi government in April 2021, on the advice of the Ministry of Health, the National Institute of Health and the Scientific Technical Committee (a task force created in February 2020 with the objective of providing guidance concerning preventive measures to combat the spread of SARS-CoV-2). As could be expected, the introduction of the mandate divided public and political opinion.

Fig. 1 summarizes the positions of actors and stakeholders, and their respective political influence. As shown in the Figure, the Ministry of Health, the Scientific Technical Committee, and the National Institute of Health were the main institutional actors in favor of the policy. The political parties most supportive of the policy were the PD and Italia Viva (center). The M5S is historically a vaccine-skeptical movement, but in this instance was divided on the issue. The position shown in the

Figure represents Giuseppe Conte, the current head of the M5S, and his supporters. Far-right parties Lega and Fratelli d’Italia were strongly against State interference with individuals’ freedom of choice concerning vaccines, but their lobbying attempts were unsuccessful. The Italian Drug Agency (AIFA), the main workers’ unions, and the union of the national Order of Physicians (FNOMCeO) were supportive towards the policy. Conversely, the most popular Nurses’ union (Nursing up) opposed mandating vaccinations [29–31].

Several demonstrations against the policy were held in Italian cities, which saw the participation of HCWs’ unions and of supporters of the anti-vaccination movement [30]. The head of Nursing up cited staffing issues that could result from suspending unvaccinated HCWs and insufficient information on vaccine safety, effectiveness and long-term adverse effects as their main reservations towards the policy [31]. This position is concerning as vaccine hesitancy among HCWs may influence patient vaccine uptake [32]. A French survey of HCWs found safety concerns intensified following the temporary ban of the AZD1222 adenovirus vaccine by the European Medicines Agency [33]. Another study conducted among HCWs in the UK also identified mistrust as an important driver of vaccine hesitancy: of vaccines (in general and of SARS-CoV-2 vaccines in particular), of healthcare systems and of scientific research [32].

Transparency and inclusiveness are considered pillars of ethical decision-making [34]. Due to the time-sensitive nature of the issue, the main stakeholders were mostly excluded from active participation in policy development and in the legislative process. However, national data on vaccine safety and efficacy and on vaccine-related adverse events have consistently been made publicly available in a transparent and timely manner [35,36]. Beyond the pandemic, building vaccine confidence in HCWs and reestablishing trust should become priorities. Improving communication strategies and tailoring them to specific HCWs’ profiles could help achieve and maintain high coverage rates [16,37].

5. Indicators and preliminary outcomes

Law 76/21 does not explicitly foresee a review mechanism, nor does it define any specific indicators for the evaluation of the implementation process or the assessment of the policy’s success. Vaccine uptake among HCWs has markedly increased since the introduction of the mandate: in August 2021, the percentage of HCWs adhering to the campaign ranged from 89% to 97.5% across Italian regions [38]. Data on the number of cases among HCWs also suggest a positive impact of the policy. As shown in Fig. 2, since the beginning of the vaccination campaign there has been a progressive decrease in the daily number of new cases among

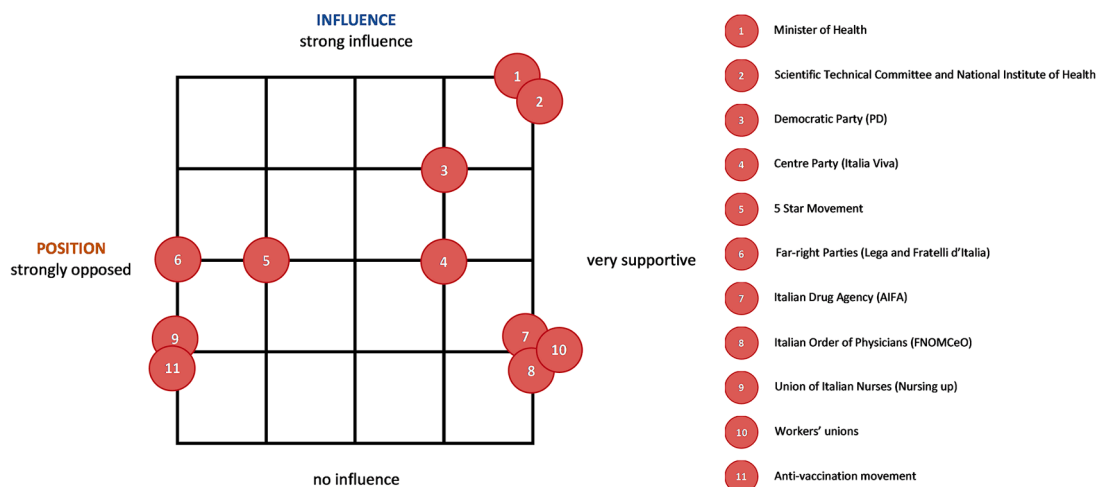


Fig. 1. Positions of actors and stakeholders towards the policy of compulsory SARS-CoV-2 vaccination for HCWs and respective political influence, Italy 2021.

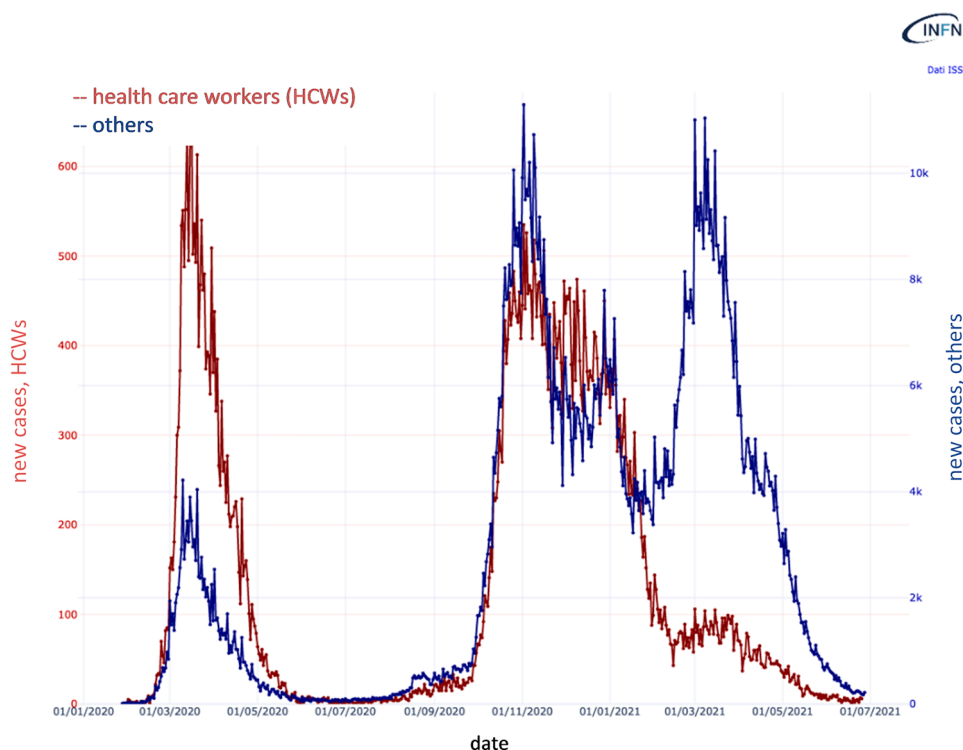


Fig. 2. Number of new cases of SARS-CoV-2 per day among healthcare workers (HCWs) and the general population in Italy, January 2020 – July 2021. Legend: Figure adapted from <https://covid19.infn.it/> (CC BY-SA 4.0).

HCWs, even though the country was experiencing its third epidemic wave. A second drop in new daily cases among HCWs was registered after the introduction of the policy, reaching a plateau below 30 new cases per day in June 2021. The proportion of cases occurring in HCWs among all national cases decreased from 10.5% at the end of April 2021 to 2.1% in September 2021 [39,40]. The general population also saw an important decrease in the number of daily new cases, from over 10,000 new cases per day at the peak of the third wave (April 2021) to fewer than 1000 new cases per day in July 2021 (Fig. 2).

However, the policy's separate impact on its main objective, safeguarding public health, is difficult to discern, as the effect of several factors including vaccine uptake in the general population, other mitigation measures and changing viral characteristics must be taken into account [40]. Further, several key elements to understand this relationship remain to be determined, such as the effectiveness of current SARS-CoV-2 vaccines in reducing transmission or the duration of the immune response elicited by vaccination, particularly in light of emerging viral strains [41].

6. Undesirable effects and potential ramifications

The implementation of the policy presented some logistic issues. Partly due to the time-limited validity of the decree, healthcare organizations opted to reorganize available staff in order to replace suspended HCWs, which could have affected healthcare delivery. However, mandating SARS-CoV-2 vaccines could have prevented staff shortages by preserving HCWs from contracting infection. In their study, Woolf *et al.* highlighted important differences in vaccine hesitancy among minority ethnic UK HCWs, with HCWs belonging to minority ethnic groups in general at significantly higher risk of being hesitant [32]. A German survey conducted among the general population found willingness to get vaccinated against SARS-CoV-2 correlated with several socio-demographic characteristics including gender, age, education and income [42]. Therefore, suspensions and sanctions could disproportionately affect certain groups of HCWs, although further study is

warranted to investigate potential discriminatory effects of law 76/21 in Italy.

Issuing a law on compulsory SARS-CoV-2 vaccines could create a precedent to mandate vaccinations against other communicable diseases for HCWs, based on the same scientific rationale. Considering previous voluntary seasonal influenza vaccination campaigns in Italy have failed to reach acceptable coverage levels among HCWs, [43] mandating vaccinations against influenza as well as SARS-CoV-2 could further increase patient safety and reduce the burden on healthcare systems [16]. Several regions of Italy have already introduced compulsory influenza vaccinations for HCWs since the pandemic, [43] although no mandate has yet been issued at the national level.

7. Conclusion

In Italy, the adoption of the emergency decree mandating SARS-CoV-2 vaccinations for HCWs was possible in the context of the public health and economic crisis resulting from the pandemic, with strong support from the scientific community and among favorable political conditions. Preliminary data suggest the policy has so far had a positive impact on increasing vaccine uptake and lowering infection rates among HCWs [44]. Hopefully, the lack of serious vaccine-related adverse events and the growing evidence on vaccine effectiveness will progressively strengthen vaccine confidence among HCWs [45].

HCWs have a professional duty to provide care and to safeguard patient safety. Therefore, HCWs should abide to any necessary and reasonable precaution to minimize harm, including preventive measures for HAIs. Healthcare institutions and governments, for their part, must ensure that HCWs fulfill these obligations. As several countries are considering mandating vaccinations against SARS-CoV-2 for HCWs, Italy's experience could provide important insight. Further, the ethical, legal, and policy challenges raised by the current public health emergency could be used to inform future pandemic preparedness plans.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of Competing Interest

The Authors have no conflict to declare.

Acknowledgments

The authors gratefully acknowledge the Working Group CovidStat INFN (Istituto Nazionale di Fisica Nucleare).

References

- [1] WHO COVID-19 Dashboard. Geneva: World Health Organization; 2020. Available at, <https://covid19.who.int/> [accessed 11.10.21].
- [2] Vicentini C, Bazzolo S, Gamba D, Zotti CM. Analysis of the fatality rate in relation to testing capacity during the first 50 days of the COVID-19 epidemic in Italy. *Am J Trop Med Hyg* 2020;103(6):2382–90. <https://doi.org/10.4269/ajtmh.20-0862>. Dec.
- [3] Poletti P, Tirani M, Cereda D, Guzzetta G, Trentini F, Marziano V, Toso C, Piatti A, Piccarreta R, Melegaro A, Andreassi A, Gramegna M, Ajelli M, Merler S. Seroprevalence of and risk factors associated with SARS-CoV-2 infection in health care workers during the early COVID-19 pandemic in Italy. *JAMA Netw Open* 2021;4(7):e2115699. <https://doi.org/10.1001/jamanetworkopen.2021.15699>. Jul 1.
- [4] Beldomenico PM. Do superspreaders generate new superspreaders? A hypothesis to explain the propagation pattern of COVID-19. *Int J Infect Dis* 2020;96:461–3. <https://doi.org/10.1016/j.ijid.2020.05.025>.
- [5] Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected Pneumonia in Wuhan, China. *JAMA* 2020; 323(11):1061–9. <https://doi.org/10.1001/jama.2020.1585>. Mar 17 Erratum in: *JAMA*. 2021 Mar 16;325(11):1113.
- [6] Bhattacharya A, Collin SM, Stimson J, Thelwall S, Nsonwu O, Gerver S, Robotham J, Wilcox M, Hopkins S, Hope R. Healthcare-associated COVID-19 in England: a national data linkage study. *J Infect* 2021. <https://doi.org/10.1016/j.jinf.2021.08.039>. Aug 30:S0163-4453(21)00443-6.
- [7] Istituto Superiore di Sanità, ISS. Sorveglianza Integrata COVID-19 in Italia, Aggiornamento Nazionale 3 Giugno 2020. Rome: ISS; 2020.
- [8] Carter B, Collins JT, Barlow-Pay F, Rickard F, Bruce E, Verduri A, Quinn TJ, Mitchell E, Price A, Vilches-Moraga A, Stechman MJ, Short R, Einarsson A, Braude P, Moug S, Myint PK, Hewitt J, Pearce L, McCarthy K, Study Collaborators C. Nosocomial COVID-19 infection: examining the risk of mortality. The COPE-nosocomial study (COVID in older people). *J Hosp Infect* 2020;106(2): 376–84. <https://doi.org/10.1016/j.jhin.2020.07.013>. Oct.
- [9] Micallef S, Piscopo TV, Casha R, Borg D, Vella C, Zammit MA, Borg J, Mallia D, Farrugia J, Vella SM, Xerri T, Portelli A, Fenech M, Fsadni C, Mallia Azzopardi C. The first wave of COVID-19 in Malta; a national cross-sectional study. *PLoS One* 2020;15(10):e0239389. <https://doi.org/10.1371/journal.pone.0239389>. Oct 15 Erratum in: *PLoS One*. 2021 Aug 3;16(8):e0255881.
- [10] Adam DC, Wu P, Wong JY, Lau EHY, Tsang TK, Cauchemez S, Leung GM, Cowling BJ. Clustering and superspreading potential of SARS-CoV-2 infections in Hong Kong. *Nat Med* 2020;26(11):1714–9. <https://doi.org/10.1038/s41591-020-1092-0>. Nov.
- [11] Gómez-Ochoa SA, Franco OH, Rojas LZ, Raguindin PF, Roa-Díaz ZM, Wyssmann BM, Guevara SLR, Echeverría LE, Glisic M, Muka T. COVID-19 in health-care workers: a living systematic review and meta-analysis of prevalence, risk factors, clinical characteristics, and outcomes. *Am J Epidemiol* 2021;190(1): 161–75. <https://doi.org/10.1093/aje/kwaa191>. Jan 4 Erratum in: *Am J Epidemiol*. 2021 Jan 4;190(1):187.
- [12] Zhou Q, Gao Y, Wang X, Liu R, Du P, Wang X, Zhang X, Lu S, Wang Z, Shi Q, Li W, Ma Y, Luo X, Fukuoka T, Ahn HS, Lee MS, Liu E, Chen Y, Luo Z, Yang K. COVID-19 evidence and recommendations working group. Nosocomial infections among patients with COVID-19, SARS and MERS: a rapid review and meta-analysis. *Ann Transl Med* 2020;8(10):629. <https://doi.org/10.21037/atm-20-3324>. May.
- [13] Istituto Superiore di Sanità, ISS. Sorveglianza Integrata COVID-19 in Italia, Aggiornamento Nazionale 14 Luglio 2020. Rome: ISS; 2020.
- [14] Shapiro J, Dean N.E., Madewell Z.J., Yang Y., Halloran M.E., Longini I. Efficacy estimates for various COVID-19 vaccines : what we know from the literature and reports 2021;28:70–91.
- [15] Ministero della Salute. Piano Nazionale Prevenzione Vaccinale 2017-2019. Rome: Ministero della Salute; 2017. Available at, <https://www.salute.gov.it/portale/vaccinazioni/dettaglioContenutiVaccinazioni.jsp?lingua=italiano&id=4828&area=vaccinazioni&menu=vuoto> [accessed 11.10.21].
- [16] Schumacher S, García JS, Cornely OA, Mellinghoff SC. Increasing influenza vaccination coverage in healthcare workers: a review on campaign strategies and their effect. *Infection* 2021;49:387–99. <https://doi.org/10.1007/s15010-020-01555-9>.
- [17] Gur-Arie R, Jamrozik E, Kingori P. No job, no job? Ethical issues in mandatory COVID-19 vaccination of healthcare personnel. *BMJ Glob Health* 2021;6(2): e004877. <https://doi.org/10.1136/bmjgh-2020-004877>. Feb.
- [18] Woolf K, Gogoi M, Martin CA, Papineni P, Lagratta S, Nellums LB, McManus IC, Guyatt AL, Melbourne C, Bryant L, Gupta A, John C, Carr S, Tobin MD, Simpson S, Gregory B, Aujayeb A, Zingwe S, Reza R, Gray LJ, Khunti K, Pareek M, U.K.R. Study Collaborative Group. Healthcare workers' views on mandatory SARS-CoV-2 vaccination in the UK: a cross-sectional, mixed-methods analysis from the UK-REACH study. *EclinicalMedicine* 2022;46:101346. <https://doi.org/10.1016/j.eclinm.2022.101346>. Apr.
- [19] Vavříčka and Others v. the Czech Republic. ECHR; 2021. p. 2021. 47621/13.
- [20] Douglas T, Forsberg L, Pugh J. Compulsory medical intervention versus external constraint in pandemic control. *J Med Ethics* 2020. <https://doi.org/10.1136/medethics-2020-106435>. Aug 20.medethics-2020-106435.
- [21] Finora tutti i ricorsi degli operatori sanitari non vaccinati sono stati respinti. Il Post 2021 August 24. Available at: <https://www.ilpost.it/2021/08/24/ricorsi-vaccino-medici-respinti/> [accessed 11.10.21].
- [22] Parker M, Bedford H, Ussher M, Stead M. Should covid vaccination be mandatory for health and care staff? *BMJ* 2021;374:n1903. <https://doi.org/10.1136/bmj.n1903>. Aug 4.
- [23] Mario Draghi Sworn in As Prime Minister of Italy. *The Guardian*; 2021. September 28. Available at, <https://www.theguardian.com/world/2021/feb/13/mario-draghi-sworn-in-as-prime-minister-of-italy> [accessed 11.10.21].
- [24] Casula M, Toth F. The 2017 Italian reform on mandatory childhood vaccinations: analysis of the policy process and early implementation. *Health Policy* 2021;125 (1):7–11. <https://doi.org/10.1016/j.healthpol.2020.11.004>. Jan.
- [25] Casula M, Terlizzi A, Toth F. Regional health services and the challenge of COVID-19. *Riv Italiana di Politiche Pubbliche* 2020;3:307–36.
- [26] OECD/European Observatory on Health Systems and Policies. Italy: Country Health Profile 2021, State of Health in the EU. Brussels: OECD Publishing, Paris/European Observatory on Health Systems and Policies; 2021.
- [27] Paterlini M. Covid-19: Italy makes vaccination mandatory for healthcare workers. *BMJ* 2021;373:n905. <https://doi.org/10.1136/bmj.n905>. Apr 6.
- [28] COVID, focolaio in un ospedale del Genovese «partito dapersonale non vaccinato». Toti: «Subito un decreto sull'obbligatorietà». *Open* 2021 March 25. Available at: <http://www.open.online/2021/03/25/covid-19-ospedale-lavagna-focolaio-portato-da-personale-non-vaccinato/> [accessed 11.10.21].
- [29] Obbligo vaccinale in Italia. Chi è Pro e Chi è Contro: Le Posizioni in Campo. *Sky TG 24*; 2021. August 22. Available at, <https://tg24.sky.it/cronaca/2021/08/22/obbligo-vaccinale-pro-contro> [accessed 11.10.22].
- [30] Chi sono i no vax: dai complottisti ai medici obiettori di coscienza. *Il Sole 24 Ore* 2021 July 7. Available at: <https://www.ilssole24ore.com/art/dai-complottisti-medici-obiettori-chi-sono-no-vax-italia-AEV5DVU> [accessed 11.10.21].
- [31] Obbligo vaccinale, La Costituzione lo prevede ma l'asinità si spacca: i medici dicono sì, critici gli infermieri. *Open* 2021 July 14. Available at: <https://www.open.online/2021/07/14/covid-19-obbligo-vaccinale-medici-infermieri/> [accessed 11.10.21].
- [32] Woolf K, McManus IC, Martin CA, Nellums LB, Guyatt AL, Melbourne C, Bryant L, Gogoi M, Wobi F, Al-Oraibi A, Hassan O, Gupta A, John C, Tobin MD, Carr S, Simpson S, Gregory B, Aujayeb A, Zingwe S, Reza R, Gray LJ, Khunti K, Pareek M, UKR Study Collaborative Group. Ethnic differences in SARS-CoV-2 vaccine hesitancy in United Kingdom healthcare workers: Results from the UK-REACH prospective nationwide cohort study. *Lancet Reg Health Eur* 2021;9:100180. <https://doi.org/10.1016/j.lanepe.2021.100180>. Oct.
- [33] Janssen C, Maillard A, Bodelet C, Claudel AL, Gaillat J, Delory T. On behalf of the acv alpin study group. hesitancy towards COVID-19 vaccination among healthcare workers: a multi-centric survey in France. *Vaccines* 2021;9(6):547. <https://doi.org/10.3390/vaccines9060547> (Basel)May 22.
- [34] Lor A, Thomas JC, Barrett DH, Ortmann LW, Herrera Guibert DJ. Key ethical issues discussed at CDC-sponsored international, regional meetings to explore cultural perspectives and contexts on pandemic influenza preparedness and response. *Int J Health Policy Manag* 2016;5(11):653–62. <https://doi.org/10.15171/ijhpm.2016.55>. Nov 1.
- [35] Istituto Superiore di Sanità, ISS. Impatto della vaccinazione COVID-19 sul rischio di infezione da SARS-CoV-2 e successivo ricovero e decesso in Italia (27.12.2020 - 14.07.2021). Valutazione Combinata Dei Dati Dell'anagrafe Nazionale Vaccini e Del Sistema di Sorveglianza Integrata COVID-19. Rome: ISS; 2021.
- [36] Agenzia Italiana del Farmaco, AIFA. Rapporto sulla Sorveglianza dei vaccini COVID-19. Rome: AIFA; 2021. Available at, <https://www.aifa.gov.it/farmacovigilanza-vaccini-covid-19> [accessed 11.10.21].
- [37] Pennings S, Symons X. Persuasion, not coercion or incentivisation, is the best means of promoting COVID-19 vaccination. *J Med Ethics* 2021;47(10):709–11. <https://doi.org/10.1136/medethics-2020-107076>. Oct.
- [38] Frati P, La Russa R, Di Fazio N, Del Fante Z, Delogu G, Fineschi V. Compulsory vaccination for healthcare workers in Italy for the prevention of SARS-CoV-2 infection. *Vaccines* 2021;9(9):966. <https://doi.org/10.3390/vaccines9090966> (Basel)Aug 29.
- [39] Istituto Superiore di Sanità, ISS. Sorveglianza Integrata COVID-19 in Italia, Aggiornamento Nazionale 28 Aprile 2021. Rome: ISS; 2021.
- [40] Istituto Superiore di Sanità, ISS. Sorveglianza Integrata COVID-19 in Italia, Aggiornamento Nazionale 24 Settembre 2021. Rome: ISS; 2021.
- [41] Koch T, Mellinghoff SC, Shamsrizi P, Addo MM, Dahlke C. Correlates of vaccine-induced protection against SARS-CoV-2. *Vaccines* 2021;9(3):238. <https://doi.org/10.3390/vaccines9030238> (Basel)Mar 10.

- [42] Graeber D, Schmidt-Petri C, Schröder C. Attitudes on voluntary and mandatory vaccination against COVID-19: evidence from Germany. *PLoS One* 2021;16(5): e0248372. <https://doi.org/10.1371/journal.pone.0248372>. May 10.
- [43] Odone A, Bucci D, Croci R, Riccò M, Affanni P, Signorelli C. Vaccine hesitancy in COVID-19 times. An update from Italy before flu season starts. *Acta Biomed* 2020; 91(3):e2020031. <https://doi.org/10.23750/abm.v91i3.10549>. Sep 7.
- [44] Bianchi FP, Stefanizzi P, De Maria L, Martinelli A, Diella G, Larocca AMV, Vimercati L, Tafuri S. Vaccination offer during the occupational health surveillance program for healthcare workers and suitability to work: an Italian retrospective cohort study. *Vaccines* 2022;10(10):1633. <https://doi.org/10.3390/vaccines10101633>.
- [45] D'Errico S, Zanon M, Concato M, Peruch M, Scopetti M, Frati P, Fineschi V. "First do no harm". No-fault compensation program for COVID-19 vaccines as feasibility and wisdom of a policy instrument to mitigate vaccine hesitancy. *Vaccines* 2021;9 (10):1116. <https://doi.org/10.3390/vaccines9101116> (Basel) Sep 30.