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COVID-19 hospital outbreaks: Protecting healthcare workers to protect frail patients. An Italian observational cohort study

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ABSTRACT

Objectives: To determine the prevalence of SARS-CoV-2 infection among exposed healthcare workers (HCWs) after preventive protocol implementation.
Methods: A total of 5750 HCWs were included in the study. Those in contact with COVID-19 patients were allocated into a high-risk or a low-risk group based on contact type (PPE- or non-PPE-protected); high-risk workers underwent nasopharyngeal swab tests, while among low-risk workers, swab tests were carried out only for symptomatic workers (active surveillance).
The prevalence was determined by real-time reverse transcriptase–polymerase chain reaction on nasopharyngeal samples.
Results: 3570 HCWs had contact with 1065 COVID-19 patients. Among them, 3494 were subjected to active surveillance (low-risk group); 2886 (82.60%) were subjected to a swab test; and 15 were positive (0.52%). Seventy-six HCWs (2.13% of exposed) were included in the high-risk group, and a swab test was mandatory for each participant. Overall, 66 (86.84% of high-risk) were negative, and 10 were positive (13.16%), resulting in a higher risk of infection than in the low-risk group [OR = 29.00; 95% CI:12.56-66.94; $p < 0.0001$].
Conclusion: To date, the SARS-CoV-2 infection prevalence is 0.70% among exposed HCWs and 0.435% among all HCWs working at the examined university hospital. The correct use of PPE and the early identification of symptomatic workers are essential factors to avoiding nosocomial clusters.

Introduction

In Italy, as of May 20, 2020, a high severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection rate among healthcare workers (HCWs) has been described; among them, 26,657 were infected, corresponding to 11.7% of all Italian cases. In this regard, almost 80% worked in the hospital setting or in an extra-hospital emergency system (Italian College of Health (Istituto Superiore di Sanità - ISS, 2020).

SARS-CoV-2 represents a major hazard for HCW safety: the biological risk is higher when medical procedures are performed on the respiratory tract, such as applying respiratory devices like oxygen cannulas or noninvasive ventilation (Ferioli et al., 2020). To prepare for a pandemic, infection prevention measures should be focused on reducing in-hospital transmission using correct personal protective equipment (PPE) (Wong et al., 2020), but their utilization needs to be appropriate to avoid waste. Moreover, no drug has shown effectiveness in preventing infection among patients and HCWs (Mehra et al., 2020).

To date, nasopharyngeal and oropharyngeal swabs, along with reverse transcriptase quantitative polymerase chain reaction (RT-qPCR) amplification, are the only useful tools to detect infections, but the correct population of HCWs to subject to screening is not

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clear, and an underestimation of SARS-CoV-2 prevalence is possible (Kluytmans-van den Bergh et al., 2020); antibody detection in serum is currently used as a complementary test in epidemiological studies but is not helpful for diagnosis (To et al., 2020). Learning from the postponed SARS-Cov-2 outbreak in South Italy and building on the experience gained in Lombardy (Fagiuoli et al., 2020), in early March, our Operative Unit of Occupational Medicine activated a preventive protection protocol to isolate infected workers early and analyzed the infection rate after a 50-day observation period at the University Hospital of Bari, which is one of the major COVID-19 hub centers in southern Italy.

The aim of this study was to determine the prevalence of SARS-CoV-2 infection among HCWs after preventive protocol implementation in order to verify if this strategy could be a valid alternative to massive RT-PCR screening.

Methods

Study design, setting, and population

A cohort study was carried out for all 5750 HCWs (doctors, nurses, social health assistants, technicians, administrative employers) of the University Hospital of Bari, southern Italy, beginning in the early phase of the pandemic and ending after 50 days. Observation started on March 11, 2020, and ended on April 29, 2020. Informed and written consent was obtained from all participants. All subjects were informed that data from the research protocol would be treated in an anonymous and collective way, with scientific methods and for scientific purposes in accordance with the principles of the Declaration of Helsinki. Ethical approval was not necessary because all medical and instrumental examinations were performed according to Italian law concerning the protection of workers exposed to occupational risks (D.Lgs. 81/2008). Our study was compliant with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Procedures and data collection

A preventive protocol was implemented, consulting the latest guidelines published by the World Health Organization (WHO) (2020b) and the Centers for Disease Control and prevention (CDC) (2020c). Current definitions of suspected, probable, and confirmed cases, as defined in the protocol by the European Centre for Disease Prevention and Control (ECDC), were adopted, and the assessment of “close contact” and “casual contact” (ECDC, 2020) was performed to identify HCWs exposed to a significant biological risk.

According to the WHO guidelines, general prevention measures were reinforced (WHO, 2002); in particular, these included *infection source control* to stop the transmission chain of pathogens in hospital settings (e.g., no handshakes, no coughs without surgical mask), *environmental controls* to prevent nosocomial infections (e.g., more than 12 *air changes per hour*, the disinfection of surfaces), and adequate utilization of personal protective equipment (PPE). In this regard, all HCWs were educated about correct donning and doffing procedures, which were carried out in an anteroom before and after making contact with suspected or confirmed cases and guided by warning signs to correctly perform the actions (CDC, 2020a; Spinazzè et al., 2020).

For each participant having contact with a confirmed COVID-19 case, occupational or environmental exposure was annotated, and careful history was performed. Considering the high costs of RT-PCR in massive long-term screening and the hurry to identify infected workers in the early stages of COVID-19, we performed a risk assessment for each worker, and correct PPE utilization was adopted as an essential factor to define high or low infection risk. Nasopharyngeal swab test in home isolation was mandatory for non-PPE guarded contacts, and the tests was performed at least 7 days after hazardous contact in order to reduce false negative results. On the other hand, “active surveillance” was assumed to be adequate for PPE-guarded contacts and included monitoring body temperature twice daily and screening everyone for evocative symptoms (anosmia, ageusia, fever, severe weakness, sore throat,

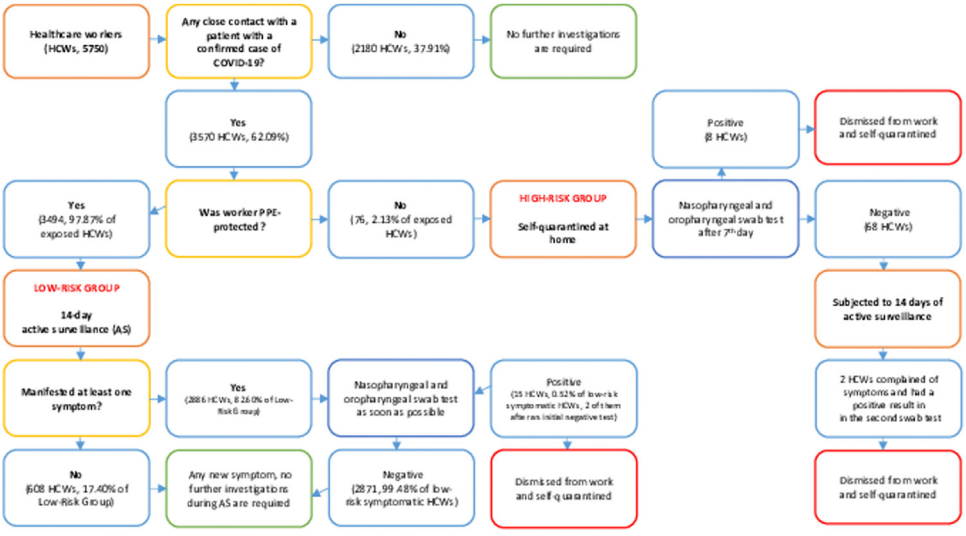

Figure 1. Preventive protocol flowchart.
The flowchart extensively describes the preventive protocol initiated in the cohort of 5750 workers. Between March 11 and April 29, 3570 HCWs (62.09% of the total) had contact with 1065 COVID-19 patients. Based on preventive officers' reports, 3494 HCWs, having PPE-protected close contacts (97.87%), were subjected to active surveillance (Low-risk Group). Among them, 2886 (82.60%) manifested at least one evocative symptom (described in Table 2) and were subjected to a swab test; 2871 (99.48% of low-risk symptomatic HCWs) were negative, and only 15 HCWs (0.53%) were positive, of whom 2 were positive after the second test. On the other hand, 76 HCWs were included in the high-risk group due to non-PPE-protected contacts, and a swab test was mandatory for each participant. Overall, 66 HCWs (86.84% of the high-risk group) were negative, and 10 were positive (13.16%), of whom 2 had a statistically higher risk of infection after the second test than the low-risk group [OR = 29.00; CI95%:12.56–66.94; $p < 0.0001$]. In yellow boxes, checkpoints are performed by prevention officers.

rhinorrhea, cough, diarrhea, dyspnea). A reporting system was activated to collect and monitor all HCW contacts with confirmed cases: in each hospital ward, a trained person in charge, dubbed a "prevention officer", verified correct PPE handling, reported contact type with COVID-19 patients to the Operative Unit of Occupational Medicine, and performed "active surveillance" for all workers in each of the wards of the medical, surgical, and administrative areas. Nasopharyngeal and oropharyngeal swabs were collected and stored in a sterile tube and analyzed in the Hospital Virology Laboratory. Diagnostic testing for SARS-CoV-2 and specimen collection were carried out following CDC guidelines (2020b). We performed RT-qPCR targeting SARS-CoV-2 RNA, following WHO recommendations (2020a): if the test was positive, the specimen received a second-level evaluation at the Italian College of Health Laboratories. Each positive worker was dismissed from work and retested until two consecutive negative results were received; the results of follow-up swab tests in positive patients were not included in the study. Data were collected using a Microsoft Excel Office 2019 (Microsoft Corporation™) form.

Statistical analysis

A simple univariate and descriptive analysis (Pearson's $\chi 2$, Goodman, and Kruskal's gamma) and the estimated asymptotic standard error (***ASE***) were carried out. Only dichotomized variables were created for risk of infection, job titles, and age classes because these showed high levels of $\chi 2$ in their univariate analysis, and odds ratios were calculated. We used Stata 12 software (Stata Corp LLC, Texas, USA). A P-value <0.05 was considered statistically significant.

Results

From March 11 to April 29, 2180 workers (37.91% of the total) reported no close contacts with patients with confirmed cases of COVID-19, and no further investigations were performed; 3570 out of 5750 HCWs (62.09%) had close contacts with patients with confirmed cases of COVID-19 based on prevention officers' reports (Figure 1).

Among these, 3494 (97.87% of exposed workers) were PPE-protected, and active surveillance was implemented (low-risk group). During observation, 608 HCWs (17.40% of HCWs belonging to the low-risk group) had no suspicious symptoms, and no further investigations were performed; however, 2886 HCWs under active surveillance (82.60% of HCWs belonging to the low-risk group) complained of at least one evocative symptom and were subjected to nasopharyngeal swab tests. In particular, 145 symptomatic workers were tested twice during the observation period due to the occurrence of new symptoms after a first negative swab, reporting a second negative result for 143 workers and a positive result for 2 workers. Overall, 2871 HCWs were negative, and 15 HCWs were positive in the low-risk group (99.48% and 0.52% of symptomatic HCWs, respectively).

On the other hand, 76 HCWs (2.13% of exposed workers) had one close contact that was not PPE-protected (high-risk group); particularly, one out of the 76 was a physician who wrongly handled her safety goggles due to eye rubbing after a COVID-19 patient examination, causing non-PPE-protected contact. Moreover, 25 out 76 were in contact with an infected colleague in a medical briefing and became symptomatic under active surveillance a few days later. Finally, 50 were cleaners who had minimal

Table 1
Number of tested, positive, and negative HCWs in the cohort study.

Hospital ward	Negative HCWs	Percentage	Positive HCWs	Percentage	Total HCWs	Percentage
Administrative workers	195	6.64%	0	0%	195	6.58%
Cardiology units	48	1.63%	0	0%	48	1.62%
Cleaners	51	1.74%	0	0%	51	1.72%
Clinical pathology units	44	1.50%	0	0%	44	1.49%
Dentistry and stomatology unit	1	0.035%	0	0%	1	0.03%
Dermatology unit	34	1.16%	0	0%	34	1.15%
Emergency rooms	110	3.75%	1	4%	111	3.75%
Endocrinology unit	26	0.89%	0	0%	26	0.88%
Forensic medicine unit	25	0.85%	0	0%	25	0.84%
Gastroenterology units	50	1.70%	0	0%	50	1.69%
General and plastic surgery units	191	6.50%	11	44%	202	6.82%
Gynecology and obstetrical unit	192	6.54%	0	0%	192	6.48%
Hematology and transfusion medicine units	56	1.91%	0	0%	56	1.89%
Hospital pharmacy	58	1.97%	0	0%	58	1.96%
Hygiene unit	1	0.035%	0	0%	1	0.03%
ICUs	497	16.92%	2	8%	499	16.85%
Infectious disease unit	99	3.37%	0	0%	99	3.34%
Internal medicine. rheumatology and oncology units	377	12.84%	0	0%	377	12.73%
Medical genetic unit	1	0.035%	0	0%	1	0.03%
Nephrology and dialysis units	105	3.58%	0	0%	105	3.55%
Neurology and stroke units	148	5.04%	1	4%	149	5.03%
Neurosurgery unit	18	0.61%	0	0%	18	0.61%
Ophthalmology unit	58	1.97%	1	4%	59	1.99%
Orthopedics and traumatology units	111	3.78%	1	4%	112	3.78%
Otolaryngology unit	1	0.035%	0	0%	1	0.03%
Pediatric units	124	4.22%	3	12%	127	4.29%
Physical and rehabilitation unit	53	1.80%	0	0%	53	1.79%
Psychiatry unit	78	2.66%	0	0%	78	2.63%
Pulmonology unit	23	0.78%	1	4%	24	0.81%
Radiology units	12	0.41%	1	4%	13	0.44%
Security guard service	48	1.63%	0	0%	48	1.62%
Thoracic surgery unit	14	0.48%	2	8%	16	0.54%
Urology units	65	2.21%	1	4%	66	2.23%
Vascular surgery unit	23	0.78%	0	0%	23	0.78%
Total	2937	100.00%	25	100.00%	2962	100.00%

PPE equipment because they were not assigned to patients' care: prevention officers used great caution for them, identifying each as a close or not-close contact. All high-risk group workers were forced to self-quarantine in home isolation and, after 7 days, underwent a nasopharyngeal swab test: 8 were immediately positive and 68 were negative, but 2 of these latter individuals included in active surveillance showed evocative symptoms and were retested, resulting in positive results. The high-risk group overall had 10 positive workers (13.16% of the total high-risk group), and the risk of infection appeared statistically higher than the prevalence found in the low-risk group [OR = 29.00; 95% CI: 12.56–66.94; $p < 0.0001$]. Overall, a very small number of subjects tested positive [n = 25 (0.88% of tested HCWs)]. The majority of positive tests were reported for females [n = 15 (61.54%)] but this result was not statistically significant. The job titles with a large number of positive tests were physicians [n = 16 (64%)], nurses [n = 6 (26.92%)], and social health assistants [n = 3 (11.54)]. Positive tests were not found among individuals with other job titles (Table 1).

The highest frequency of workers with a positive swab test was observed for the age class of 51–60 years [n = 11 (44.00%)], and the lowest frequency was observed among the workers who were more than 60 years of age [n = 2 (8.00%)]. General and plastic surgery units were first for infected workers [n = 11 (44%)], followed by pediatric [n = 3 (12%)], thoracic surgery [n = 2 (8%)], intensive care [n = 2 (8%)], emergency room [n = 1 (4%)], neurology and stroke [n = 1 (4%)], ophthalmology [n = 1 (4%)], orthopedic and traumatology [n = 1 (4%)], pulmonology [n = 1 (4%)], radiology [n = 1 (4%)], and urology [n = 1 (4%)] units (Table 1). The workers with positive tests presented eleven symptoms (fever, myalgia, asthenia, rhinorrhea, anosmia, ageusia, sore throat, dyspnea, hemoptysis, conjunctivitis, and diarrhea). The most frequent symptoms were asthenia [n = 18 (72.00%)], diarrhea [n = 15 (60.00%)], and fever [n = 13 (52.00%)] (Table 2).

The majority of the 25 positive-swab workers [n = 15 (60.00%)] were associated with a "community exposure" outside the hospital; 10 of them were related to an "in-hospital exposure" but not during working tasks [n = 10 (40.00%)].

Table 2
Results of the swab tests carried out and the frequency of symptoms in COVID-19-positive individuals among the healthcare personnel by sex.

	Male	Female
Total COVID-19 cases, n (%)	10 (40%)	15 (60%)
Age (average), years (%)	47.78 range (26–59)	47.08 range (28–62)
Physicians, n (%)	8 (80%)	8 (53, 33%)
Nurses, n (%)	2 (20%)	4 (26, 67%)
Social health assistants, n (%)	–	3 (20%)
Environmental exposures (outside the hospital), n (%)	4 (40%)	11 (73.33%)
Exposures in medical briefing (inside the hospital), n (%)	6 (60%)	3 (20.00%)
Occupational exposures due to incorrect use of personal protective equipment, n (%)	0 (0%)	1 (6.67%)
Asymptomatic, n (%)	3 (30%)	1 (6.67%)
Temperature, n (%)	7 (70%)	6 (40%)
Myalgia, n (%)	4 (40%)	8 (53.33%)
Asthenia, n (%)	7(70%)	11(73.33%)
Rhinorrhea, n (%)	4(40%)	7 (46.67%)
Anosmia, n (%)	3 (30%)	9 (60%)
Ageusia, n (%)	3 (30%)	9 (60%)
Sore throat, n (%)	4 (40%)	8 (53.33%)
Dyspnea, n (%)	3 (30%)	3 (20%)
Cough, n (%)	6 (60%)	8 (53.33%)
Conjunctivitis, n (%)	1 (10%)	5 (33.33%)
Diarrhea, n (%)	6 (60%)	9 (60%)
Headache, n (%)	1 (10%)	1 (6.67%)
Abdominal pain, n (%)	0 (0%)	1 (6.67%)

The dichotomized variables showed a highly significant risk of positive tests only for physicians [OR = 2.80 (1.26–6.22)] for job title analyses, and a statistically significant association was found only for the age group of 51–60 years [OR = 1.58 (0.72–3.46)] for age class analyses.

Discussion

To date, the SARS-CoV-2 infection rate is 0.70% among exposed HCWs and 0.435% among all HCWs at the examined university hospital in a 50-day observation period, and these data are lower than those in the most recent report (Kluytmans-van den Bergh et al., 2020). Overall, 3109 swab tests were performed on 2962 exposed HCWs during protocol implementation (Figure 2), and the ratio of positive *to* negative tests was 0.80%.

In the same period of protocol activation, overall, 1065 patients with confirmed cases of COVID-19 were admitted to the Emergency Department, and 346 were hospitalized due to their poor conditions; none of the infected HCWs needed hospital care, but all of them developed a mild viral illness. In contrast, Wang et al. (2020) found in a retrospective single-center case series that, among approximately 138 COVID-19 patients, 29% were estimated to be HCWs working in the same hospital center and were infected during shifts. After preventive protocol implementation, a small group of HCWs reported non-PPE-protected high-risk contacts with COVID-19 patients (76 workers); among these, 50 were cleaners working in a non-COVID-19-dedicated area, and for them, the Risk Assessment Document prescribed minimal PPE equipment. In this specific case, preventive officers used great caution, reporting that hazardous contact had occurred for each worker, broadly interpreting the ECDC definition of "close contact" (ECDC, 2020). However, no cleaner results were positive, likely due to no actual close contacts. The ten high-risk positive HCWs were carefully examined to understand the infection modality: one wrongly handled her PPE, while 9 were infected in a medical briefing through non-PPE-protected close contact with one infected colleague. In the aforementioned briefing, 26 people were assembled: the infector manifested evocative symptoms during active surveillance and was rapidly tested for COVID-19, with positive results. All 25 colleagues were forced to self-quarantine and were tested while in home isolation, and 9 were positive (2 after the second swab test). The hospital ward was closed for environmental sanitation. In the low-risk group, during active surveillance, 15 symptomatic HCWs were positive for SARS-CoV-2, with 2 of them being confirmed after the second swab test due to the occurrence of new symptoms; for these 15 symptomatic HCWs, environmental and non-occupational infection modalities were described due to close contacts with infected relatives (Table 2). In the latter group, the risk of infection was statistically lower than that in the high-risk group, showing that correct PPE-use avoided the spread of SARS-CoV-2 infection among HCWs despite daily close contacts of these workers with COVID-19 patients; moreover, the correct use of PPE-protected HCWs in the low-risk group from infected colleagues, similar to a kind of "PPE-guaranteed herd protection". Indeed, no occupational infection during work tasks occurred in hospital wards characterized by higher biological risk (pulmonology, internal medicine, and intensive care units) despite the remarkable number of hospitalized COVID-19 patients. Instead, occupational infection occurred through environmental spread due to incorrect hygienic practices (non-use of PPE, contact with infected kinsmen, handshakes). Curiously, 64% of infected workers were physicians and had an increased risk of infection compared to other healthcare professionals. Based on anamnesis collection, these data could reflect a low risk perception out of the hospital setting and a high frequency of wrong behavior (Figure 3).

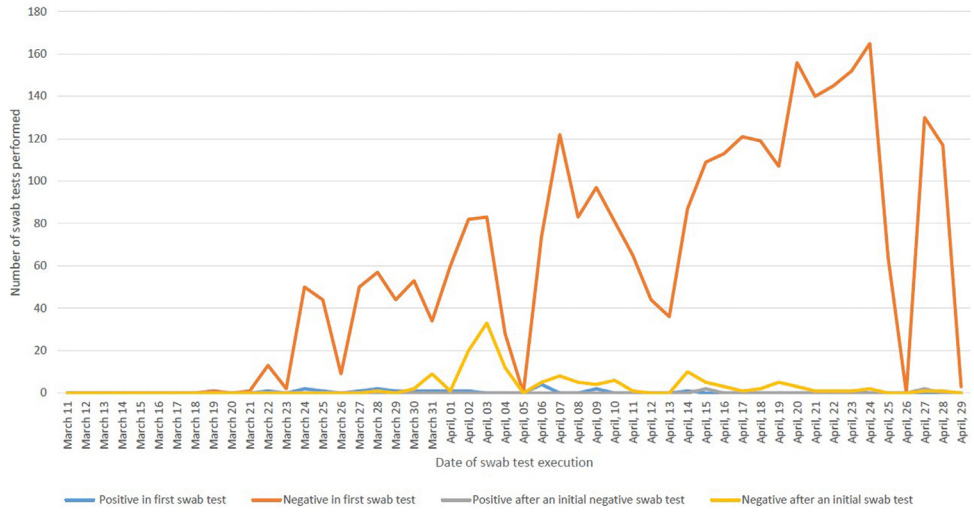

Figure 2. Nasopharyngeal and oropharyngeal swab tests.
Data from 3109 nasopharyngeal and oropharyngeal swab tests performed in the cohort of 2962 HCWs.
As shown in Figure 3, the weekly incidence of positive tests slowly decreased after protocol initiation, from 4.3% in week 2 (March 19–March 25) to 0.47% in week 7 (April 23–April 29).

However, 2854 HCWs belonging to the low-risk group complained of at least one evocative symptom, but only 0.52% of them were affected by COVID-19. Work-related stress appears to be widespread among medical practitioners and in other working settings (De Sio et al., 2020; Bulduk 2019; Eskildsen et al., 2017; Li et al., 2016) and has increased during the pandemic in COVID-19 hospitals (Blake et al., 2020); therefore, it is possible to presume that the high prevalence of symptoms could also be linked to this mental condition. Work-related stress not only affects the physician's mental and physical well-being, but also patient care quality and the overall efficiency of the healthcare system. On this basis, establishment of preventive protocols is essential to provide safe guidance for HCWs and consequently reduce their work-related stress. On the other hand, the role of some psychological approaches such as stigmatization and discrimination on the adherence to the preventive protocols should also be considered (Baldassarre et al., 2020). The fear of stigmatization and the risk of being subject to quarantine measures might delay the contact tracing, contributing to the virus spread. As for the symptoms, half of the infected HCWs complained of ageusia and anosmia as early symptoms; therefore, great attention should be given to them. On the other hand, 4 out of 25 infected workers remained asymptomatic; their isolation is crucial to avoid nosocomial clustering, particularly among hospitalized frail patients (Gandhi et al., 2020). In this regard, massive RT-PCR tests, as recommended by Fagiuoli et al. (2020), is useful for identifying infected workers. In the early stages of the disease the test could give false negative results, allowing these workers to continue working and infect other healthcare workers. We suggest that careful compliance to correct PPE utilization and biological risk stratification is more helpful to avoid nosocomial cluster, keeping high-risk workers in home isolation as soon as possible after hazardous contacts and before RT-PCR test could detect a viral genome. The very low infection rate discovered among exposed HCWs in our protocol supported this hypothesis.

Finally, 97.87% of exposed workers, corresponding to 3494 people, had PPE-protected contacts, indicating that there were enough PPE in hospital stores: hygienic measures to avoid overcrowding (e.g., reducing the number of HCWs in rooms hosting confirmed cases), PPE use for the maximum usage time, and nasopharyngeal swab execution by only one HCW per working shift are essential factors in our protocol to avoid waste.

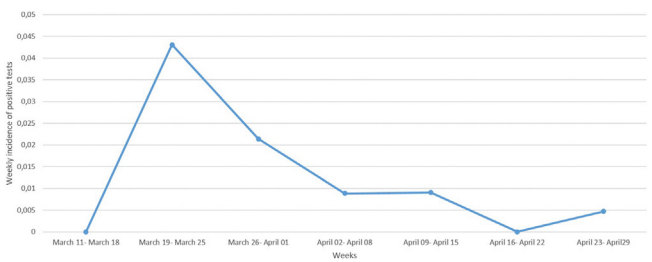

Figure 3. Incidence of positive swab tests.
Weekly incidence of positive swab tests in the worker cohort.

Limitations

This study has several limitations. First, no data about environmental contacts with COVID-19 people were available for 2180 HCWs who did not have in-hospital close contacts with COVID-19 patients; therefore, the prevalence of infection in workers due to environmental exposure is not clear in this group, and the overall prevalence could be underestimated. However, no worker in this group complained to their wards' coordinators of any evocative symptoms after the observation period, and any nosocomial cluster was declared to the Unit of Occupational Medicine in the same period. Second, low-risk asymptomatic HCWs in active surveillance were allowed to work, and nasopharyngeal swab tests were not performed in these individuals; however, the possibility of asymptomatic patients among workers is possible (Gandhi et al., 2020), and therefore the observed prevalence of infection of 0.70% in exposed HCWs could be underestimated. Third, although preventive officers were trained to recognize incorrect PPE utilization and evocative COVID-19 symptoms, overreporting or underreporting of these data could be possible (self-report bias). Overreporting of too much data would have resulted in the implementation of active surveillance and testing for SARS-CoV-2 in more individuals without infection, leading to excessive resource consumption. On the other hand, the underestimation of the aforementioned data could have led to less testing and the underestimation of the prevalence of SARS-CoV-2 infection in the overall group of HCWs. Fourth, data about the presence of antibodies in HCWs against SARS-CoV-2 were not

available; however, massive immunological screening is being carried out in the same cohort to better understand the real immunization of employees.

Conclusion

Italy has a high number of infected HCWs, with almost 80% of them working in a hospital setting. The execution of this protocol has shown good results in our hospital, recording only 25 HCWs infected by SARS-CoV-2 over 3109 swab tests, despite the high number of patients admitted to the ED and hospitalized in the period of observation. The correct use of PPE is an essential step to better assign the correct risk class to HCWs, determining whether active surveillance or home isolation is the most appropriate choice. Moreover, the careful identification of symptomatic workers is necessary to avoid missing people with mild respiratory infection and to avoid nosocomial clusters.

Conflict of interest

None.

Funding source

None declared.

Authors contribution

Luigi Vimercati, Silvio Tafuri, Loreto Gesualdo, Giovanni Migliore, and Fulvio Italo Maria Fucilli designed the work; Maria Chironna and Pasquale Stefanizzi acquired the data for the work; Luigi De Maria, Marco Quarato, Antonio Caputi, Domenica Cavone, Maria Celeste Delfino, and Stefania Sponselli analyzed the data; Luigi De Maria, Marco Quarato, and Antonio Caputi interpreted the data.

All authors participated in the drafting and revision of the work and gave the final approval of the version to be published. All authors agreed to be responsible for all aspects of the job in ensuring that issues relating to the accuracy or integrity of any part of the job were properly investigated and resolved.

Patient consent

Informed and written consent was obtained from the participants. The patients were informed that data from the research protocol would be treated in an anonymous way, with scientific methods and for scientific purposes in accordance with the principles of the Helsinki Declaration.

Ethical Approval is not necessary because all the medical and instrumental examinations were performed according to the Italian laws concerning the protection of workers exposed to occupational risks (D. Lgs. 81/2008).

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