EFFECTS OF REGULAR TESTING AS A SORT OF COVID-19 FILTER, BY IDENTIFYING, ISOLATING AND THUS FILTERING OUT CURRENTLY INFECTED PERSONS, USING ANTIGENIC TESTS AMONG HEALTHCARE WORKERS IN THREE HOSPITALS IN THE SOUTH OF ITALY

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ABSTRACT

The use of antigen tests is proposed as a substitute for the molecular test in some conditions and the Italian Regions are preparing for massive provision. This method has been introduced and tested in the local health authority ASL BT - Puglia (Italy) and then integrated with the regional health surveillance protocol for health workers thanks to the preliminary results. In the Puglia Region there has been an Integrated Health and Safety Management System SGSL (SiRGISL) since pre-COVID times, which has standardized procedures and protocols as regards to Integrated Health and Safety for the prevention of hospital worker risks.

Where the method was first tested, a screening test was introduced on 2,500 health workers operating in the three hospitals of the BT district, weekly. The nasopharyngeal swabs were carried out by the coordinators (workers safety representatives in Puglia Region SGSL), the swabs were sent to the PoCT (Point of Care Testing) analysis laboratory with immediate reading of the antigen test following by molecular test method confirmation. The study was performed in a Puglia district with high virus circulation.

About 12 thousand swabs were performed, mainly in the period, which identified 192 cases of positivity to SARS CoV2 among asymptomatic operators not detected symptomatic by the usually temperature control method at the hospital entrance.

During the third week a peak of cases (79) with a subsequent decline was revealed, otherwise the infection trend of the population district maintained a constant growth.

Early identification and removal of asymptomatic hospital workers, by means of frequent use of rapid tests, acts as a filter and reduces the chances of contagion by cutting the chains at the origin.

During a time featured by high viral circulation, the amount and the speed of the tests should be privileged over more accurate methods, difficult to manage with a very high demand.

In Puglia Region, the presence of Integrated Health and Safety Management System (SiRGISL) makes the organizational structures efficiently adaptable to the rapid change of the pandemic framework by choosing suitable technologies and methods in order to anticipate the change of the pandemic curve instead of following it.

Asymptomatic subjects detecting is a major problem in the management of epidemics even in controlled environments such as hospitals.

INTRODUCTION

According to the indications of the European Center for Disease Prevention and Control (ECDC, 2020) there are five objectives for the use of antigen tests in different phases of the pandemic: controlling transmission; monitoring the transmission rate of the SARS-CoV-2 virus and its severity; mitigating the impact of COVID-19 in health and care facilities; detecting clusters or outbreaks in specific situations; maintaining COVID-19 elimination status once it is achieved.

Recent studies¹ have highlighted the effectiveness of frequent use of antigen tests in the early stages of the disease as an effective case filter (Figure 1).

Puglia Region has dealt with the Pandemic having since December 2017 equipped itself with a regional SGSL (SiRGISL), established by a specific resolution of the Regional Council, that has already constituted



High-Frequency Testing with Low Analytic Sensitivity versus Low-Frequency Testing with High Analytic Sensitivity.

Fig. 1 - (from The New England Journal of Medicine Nov 2020)

a scientific and operational coordination for the prevention and protection service, thanks to the medical authority responsible for health surveillance and of all the professionals involved in the integrated system security.

This organizational model has allowed to face the COVID pandemic by means of a single model of regional organization of all local health authorities responding to a centrally coordinated structure.

In fact, since January 2020, the Puglia SiRGISL issued binding circulars and operational flow charts directed at the regional structures and aiming at the prevention of "SARI" in the hospital environment in a preventive perspective of the pandemic wave.

The SARS CoV2 epidemic was addressed in Puglia with a single plan of competences and responsibilities in all structures and with the immediate establishment of a single regional warehouse for PPE and all procedures.

In Puglia, a single health surveillance protocol was adopted. The protocol is periodically updated following the progress of the pandemic and the introduction of new diagnostic methods.

After the introduction of new diagnostic methods in PoCT (Point of Care antigenic tests) tested in ASL BT

(local health authority Barletta-Andria-Trani – ASL BAT) with positive results in terms of sensitivity and specificity compared to the Gold Standard - molecular tests by PCR-, the health surveillance protocol of workers in the Apulian health sector was updated by introducing the use of highly frequent antigenic tests to check homogeneous population followed by confirmation molecular tests in case of a positive antigen test and to define individual worker suitability $^{2\cdot17}$.

METHODS

In ASL BAT, in anticipation of the "second wave" starting from the last week of November 2020, the coordination of the occupational doctors and the Management of the local health authority Barletta-Andria-Trani – ASL BAT proposed the "Safe Hospital" protocol through the execution of a weekly antigen test on all hospital and 118 Service (emergency service) operators, as well as of diagnostic and treatment operating units located in Advanced Territorial Facilities (PTA) where the DVR (document for the risk assessment) showed a similar risk level as the hospital departments thus involving nearly 2500 operators.



Fig. 2 - Testing Algorithm





Tab. 2

The screening method was "AFIAS COVID-19 Ag", a fluorescence immunoassay test (FIA) for the qualitative detection of the new coronavirus (SARS-CoV-2, 2019-nCoV) in human nasopharyngeal swabs. The collection of samples was coordinated by the medical departments of the hospital (Delegate of the Employer) and the Department Coordinators (Responsible pursuant to Legislative Decree 81/08).

The samples were analyzed by the Clinical Pathology Operative Unit with contextual evaluation by means of molecular tests in case of positive antigen test according to the algorithm proposed by CDC¹¹ in figure 2.

The positive reports were sent to the occupational doctors for the appropriate obligations related to removal, fiduciary isolation and reporting of Occupational Accident.

RESULTS

From 26th October 2020 until 6th December 2020 about 12 thousand swabs were carried out. positive reports, confirmed by molecular tests, were detected

in 192 workers (104 women and 88 men).

At the same time, in the province population there were 8.050 confirmed cases with a positive ratio on the total test stably above 15% using the traditional molecular method (Graphic 1).

The peak of cases (79) in the tested working population occurred in the third week with a significant decrease of up to 2 cases during the seventh week. Whereas, the infection trend in the general population of the province under study has maintained constant growth (Graphic 2).

In only in three cases the workers reported Covid-19 related symptoms to the occupational doctor during the study period.

Thus the distribution of job titles of infected workers: nurses 97 (50,5%), doctors 38 (20%), OSS / auxiliaries 17 (9%), radiology technicians 9 (5%), laboratory technicians 5 (2.8%) Administrative 2 (1.1%), other professionals 22 (11.4%).

(1.170), other professionals 22 (11.470)

The most involved departments were: First Aid (15 cases), Diagnostics / Radiology (14 cases), Reanimation (13 cases), 118 (13 cases).





DISCUSSION

Both tests (antigenic and molecular) are able to diagnose SARSC CoV2 infection but between a less sensitive but more frequently usable method and a more sensitive but less frequently usable method it seems that, consistently with what has recently been introduced in the literature, the higher frequency made possible by PoCT methods works better as a filter in the pre-clinical phases of the disease.

The experience carried out has shown that in a context of high viral circulation such as that of the BAT province, the early removal from the workplace of positive asymptomatic subjects significantly reduced the chances of contagion by cutting the chains at the origin and caused the flattening of the infection curve among healthcare workers in contrast with the trend observed in the general population. In particular, it was possible to recognize and isolate the outbreaks that appeared early in the wards that in the second wave of the pandemic suffered greater pressure due to Covid-19 positive patients in oxygen therapy who were hospitalized for a long time and often at the same time thus generating high aerosols in the ambient air. This evidence confirms the correctness of the epidemic containment strategy based on the decision to prefer the quantity and speed of tests in high viral circulation contexts, to more accurate but difficult to manage methods in times of very high demand.

The integrated management model (OHSMS) renders the organizational structures easily adapting to the rapid change in the pandemic situation and the technologies and methods available thus anticipating the curve instead of following it. In fact, asymptomatic patients represent a certain criticality in the management of epidemics even in controlled environments such as hospitals where only temperature control does not seem sufficient.

Further studies in the field of Clinical Risk would be useful in order to highlight the reduction of COVID 19 cases among patients where a high level of screening reduces the presence of positive operators and virus circulation in workplaces that are care places.

REFERENCES

- Rethinking Covid-19 Test Sensitivity A Strategy for Containment Michael J. Mina, M.D., Ph.D., Roy Parker, Ph.D., and Daniel B. Larremore, Ph.D; The NEW ENGLAND JOURNAL of MEDICINE, 2020 Nov 26;383(22):
- Coronavirus Disease 2019–COVID-19. Kuldeep Dhama, Sharun Khan, Ruchi Tiwari, Shubhankar Sircar, Sudipta Bhat, Yashpal Singh Malik, Karam Pal Singh, Wanpen Chaicumpa, D. Katterine Bonilla-Aldana, and Alfonso J. Rodriguez-Morales. Clin Microbiol Rev. 2020 Oct; 33(4): e00028-20. Published online 2020 Jun 24. doi: 10.1128/CMR.00028-20 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7405836/ PMC Open Access Subset (accessed on 11.12.2020)
- 3. An Integrated Strategy for the Prevention of SARS-CoV-2 Infection in Healthcare Workers: A Prospective Observational Study. Anna Maria Cattelan, Lolita Sasset, Eugenia Di Meco, Silvia Cocchio, Francesco Barbaro, Silvia Cavinato, Samuele Gardin, Giovanni Carretta, Daniele Donato, Andrea Crisanti, Marco Trevenzoli, Vincenzo Baldo. Int J Environ Res Public Health. 2020 Aug 10;17(16):5785. <u>https://pubmed.ncbi.nlm.nih.gov/32785110/</u> PMCID: PMC7460144 DOI: 10.3390/ijerph17165785 Free PMC article (accessed on 11.12.2020)
- 4. COVID-19 (Corona Virus Disease) ISS SNLG https://snlg.iss.it/?p=2706 (accessed on 11.12.2020)
- ECDC. Contact tracing: public health management of persons, including healthcare workers, who have had contact with COVID-19 cases in the European Union – third update, 18 November 2020. Stockholm: ECDC; 2020 <u>https://snlg.iss.it/wp-content/</u> <u>uploads/2020/11/covid-19-contact-tracing-public-health-management-third-update.pdf</u> (accessed on 11.12.2020)

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- ECDC. Infection prevention and control and preparedness for COVID-19 in healthcare settings, 6 October 2020. ECDC: Stockholm;
 <u>https://snlg.iss.it/wp-content/uploads/2020/11/Infection-prevention-and-control-in-healthcare-settings-COVID-19_5th</u> update.pdf (accessed on 11.12.2020)
- Circolare del Ministero della salute 0035324-30/10/2020-DGPRE-DGPRE-P Test di laboratorio per SARS-CoV-2 e loro uso in sanità pubblica (nota tecnica aggiornata al 23 ottobre 2020).
- Emerging diagnostic tools for detection of COVID-19 and perspective. Nidhi Verma, Dhaval Patel, and Alok Pandya. Biomed Microdevices . 2020; 22(4): 83. Published online 2020 Nov 24. doi: 10.1007/s10544-020-00534-z PMCID: PMC7683280 PMID: 3230627 <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7683280/</u> (accessed on 11.12.2020)
- COVID 19/diagnosi. Test nasofaringeo "antigenico" rapido per il controllo della epidemia: considerazioni, possibili ambiti di applicazione e proposta operativa di gestione. Associazione Italiana di Epidemiologia, pubblicato il 29.10.2020 su <u>https://www. scienzainrete.it/articolo/test-nasofaringeo-antigenico-rapido-controllo-della-epidemia-come-e-quando-utilizzarlo</u> accessed on 11.12.2020
- COVID-19 hospital outbreaks: Protecting healthcare workers to protect frail patients. An Italian observational cohort study. Luigi Vimercati, Luigi De Maria, Marco Quarato, Antonio Caputi, Pasquale Stefanizzi, Loreto Gesualdo,Giovanni Migliore, Fulvio Italo Maria Fucilli, Domenica Cavone, Maria Celeste Delfino, Stefania Sponselli, Maria Chironna, and Silvio Tafuri. Int J Infect Dis . 2021 Jan; 102: 532–537. Published online 2020 Nov 4. doi: 10.1016/j.ijid.2020.10.098 PMCID: PMC7610093 PMID: 33157297 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7610093/ (accessed on 11.12.2020)
- 11. Interim Guidance for Antigen Testing for SARS-CoV-2 | CDC updated Dec. 5 2020 <u>https://www.cdc.gov/coronavirus/2019-ncov/</u> lab/resources/antigen-tests-guidelines.html accessed on 08.12.2020
- Monitoring approaches for health-care workers during the COVID-19 pandemic. Julia A Bielicki, MD, Xavier Duval, Prof, MD, Nina Gobat, PhD, Herman Goossens, Prof, PhD,Marion Koopmans, Prof, PhD, Evelina Tacconelli, Prof, PhD, and Sylvie van der Werf, Prof, PhD. Lancet Infect Dis . 2020 Oct; 20(10): e261–e267. Published online 2020 Jul 23. doi: 10.1016/S1473-3099(20)30458-8 PMCID: PMC7377794 PMID: 32711692 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377794/ accessed on 09.12.2020
- 13. Antibodies to SARS-CoV-2 are associated with protection against Reinfection. Sheila F Lumley, Denise O'Donnell, Nicole E Stoesser, Philippa C Matthews, Alison Howarth, Stephanie B Hatch, Brian D Marsden, Stuart Cox, Tim James, Fiona Warren, Liam J Peck, Thomas G Ritter, Zoe de Toledo, Laura Warren, David Axten, Richard J Cornall, E Yvonne Jones, David I Stuart, Gavin Screaton, Daniel Ebner7, Sarah Hoosdally, Meera Chand, Derrick W Crook, Anne-Marie O'Donnell, Christopher P Conlon, Koen B Pouwels, A Sarah Walker, Tim EA Peto, Susan Hopkins, Timothy M Walker, Katie Jeffery, David W Eyre. medRxiv preprint doi: https://doi.org/10.1101/2020.11.18.20234369; version posted November 19, 2020. It is made available under a CC-BY 4.0 International license.
- 14. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Jacqueline Dinnes, Jonathan J Deeks, Ada Adriano, Sarah Berhane, Clare Davenport, Sabine Dittrich, Devy Emperador, Yemisi Takwoingi, Jane Cunningham, Sophie Beese, Janine Dretzke, Lavinia Ferrante di Ruffano, Isobel M Harris, Malcolm J Price, Sian Taylor-Phillips, Lotty Hooft, Mariska Mg Leeflang, René Spijker, Ann Van den Bruel, Cochrane COVID-19 Diagnostic Test Accuracy Group. Cochrane Database Syst Rev 2020 Aug 26;8:CD013705. doi: 10.1002/14651858.CD013705. <u>https://pubmed.ncbi.nlm.nih.gov/32845525/</u> accessed on 11.12.2020
- 15. Testing for SARS-CoV-2 Infection Last Updated: November 3, 2020 <u>https://www.covid19treatmentguidelines.nih.gov/overview/</u> sars-cov-2-testing/ accessed on 11.12.2020
- 16. The experience of the health care workers of a severely hit SARS-CoV-2 referral Hospital in Italy: incidence, clinical course and modifiable risk factors for COVID-19 infection Marta Colaneri, Viola Novelli, Sara Cutti, Alba Muzzi, Guido Resani, Maria Cristina Monti, Claudia Rona, Anna Maria Grugnetti, Marco Rettani, Francesca Rovida, Valentina Zuccaro, Antonio Triarico, andCarlo Marena. J Public Health (Oxf) . 2020 Nov 3 : fdaa195. Published online 2020 Nov 3. doi: 10.1093/pubmed/fdaa195 PMCID: PMC7665642 PMID: 33140084 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7665642/ Accessed on 09.12.2020
- Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: Interim guidance © World Health Organization 2020. Some rights reserved. Work is available under the CC BY-NC-SA 3.0 IGO licence. WHO reference number: WHO/2019-nCoV/Antigen_Detection/2020.1