sciendo

DOI: 10.2478/rjom-2021-0008

Original papers

ORCHESTRA project in Romania - a prospective occupational cohort to study the impact of COVID-19 pandemic on healthcare workers

Dana Mateș[1], Violeta Claudia Calotă[1], Cătălin Alexandru Staicu[1], Lavinia Călugărenu[1], Mădălina Ipate[1], Michaela Mărgineanu[1], Marina Ruxandra Oțelea[2], Ovidiu Persecă[1], Felicia Steliana Popescu[1], Agripina Rașcu[2,3], Silvia Teodorescu[1], Georgeta Botin[1], Angelica Voinoiu[1], Andra Neamțu[1]

[1] National Institute of Public Health, Bucharest, Romania
[2] University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania
[3] Department of Occupational Medicine, Colentina Clinical Hospital, Bucharest, Romania

Corresponding author
Violeta Claudia Calotă
violeta.calota@insp.gov.ro

Abstract

ORCHESTRA is a three-year international research project funded by the European Union's Horizon 2020 research and innovation programme, led by the University of Verona and involving 26 partners (extending to a wider network of 37 partners) from 15 countries. Romania is partner in ORCHESTRA project and is represented by The National Institute of Public Health. The challenge for the Romanian team is to enroll a prospective cohort of more than 1 000 health care workers and to follow-up, for at least 12 months, the impact of the pandemic at three main levels: mental health, long term consequences of COVID-19 and variation of the immune response in vaccinated. Secondary objectives are: the variation of risk perception during the pandemic, the preventive measures at workplace and how these evolved during the pandemic, vaccination acceptance and reasons of refusal.

This paper aims to present a brief overview of the study design in Romania and the cohort description at baseline.

Keywords: *occupational cohort, health care workers, COVID-19 pandemic*

Introduction

The COVID-19 pandemic has shown the importance of the countries working together to share experiences, data and resources. In the area of research, the ERAvsCorona Action plan1 was rapidly agreed between the European Commission and the EU Member States when the pandemic hit Europe in spring 2020. This plan has guided research and innovation actions and investments to speed up the work necessary to deal with the devastating situation the world was facing.

An important aspect for co-operation in response to the COVID-19 pandemic was the rapid set up and mobilization of pan-European clinical and population

cohorts. Connecting these cohorts ensure research are conducted in the most effective and best possible way and that the most promising or important questions or aspects can be addressed rapidly. Such networks are, and will be, at the core of the continued work to build up a better preparedness for future pandemics.

One of the first project funded by the European Union's Horizon 2020 research and innovation programme under the ERAvsCORONA Action Plan aimed at connecting European and international cohorts is ORCHESTRA (https://orchestra-cohort.eu/)

ORCHESTRA is a three-year international research project led by the University of Verona and involving 26 partners (extending to a wider network of 37 partners) from 15 countries: Argentina, Belgium, Brazil, Congo, France, Gabon, Germany, India, Italy, Luxemburg, Netherlands, Romania, Slovakia, Spain, Venezuela.

The vision of the project is to establish an international large-scale cohort for the conduct of retrospective and prospective studies in order to generate rigorous evidence to improve the prevention and treatment of COVID-19 and to be better prepared for future pandemics.

The main objectives of the project are:

• to develop evidence-based recommendations for effective prevention, protection and optimized treatment of COVID-19 patients (including long-term consequences) with a special focus on 'at risk' population, including healthcare workers and fragile individuals;

• to assess impact of environmental factors, socio-economic determinants, lifestyle and confinement measures on the spread of COVID-19;

• to provide knowledge on the efficacy of vaccines against SARS-CoV-2;

• to provide a model for responsiveness for future pandemic outbreaks.

ORCHESTRA consists of 11 work packages with different tasks. Work Packages 2 – 5 deals with four different cohorts: patients with COVID-19 and long-term sequelae; population-based cohorts; fragile population cohorts; health care workers cohorts. Work Packages 6 – 11 manage the biobanking, data management, dissemination, statistics and ethics aspects of the project.

Health care workers (HCW) are a group at high risk of infection in general [1] and specifically SARS-CoV-2 infection [2, 3]. In the last year, one large Italian multi-center study on more than 10 000 HCW revealed that the prevalence of infection varied across the participating centers, with results ranging from 3.0% to 22.0% and was strongly correlated with that of the respective geographic areas [4].

The vaccination strategy in many EU countries, prioritized the HCW as front-line workers and offered the jab early in January-February 2021. In this way, this group became particularly interesting to investigate the post-vaccination long term effects and the breakthrough infections.

Although the preventive measures (including the roll-out of vaccination) reduced the incidence of the diseases among HCW, the effect of the pandemic are still impacting their physical and mental wellbeing. Long term effects of COVID-19 among the diseased HCW (the so called long COVID) but also the psychological consequences of COVID-19 exposure in non-diseased (including the burnout and mood disturbance), are of particular concern especially after the three consecutive waves of the pandemic.

Therefore, Work Package 5 has been dedicated to this particular occupational group to investigate: the incidence of COVID-19 infection, the primary and secondary outcomes of COVID-19 occupational exposure but also the immune response after vaccination and to draw strategies for better protective measures.

Romania is partner in ORCHESTRA project and is represented by The National Institute of Public Health who is co-leading Work Package 5. The research team is multidisciplinary comprising experts from various domain: occupational health, public health, hygiene, epidemiology, biostatistics. Its goal is trying to find out what impact the past year have had on the live and work of HCW, in particular those working in primary health care, and wondering what lasting lessons can be drawn from the pandemic.

Primary care, defined by WHO as ranging from promotion and prevention to treatment, rehabilitation and palliative care, "was an essential foundation for the global response to COVID-19 with a significant role in maintaining the delivery of essential health services, identifying and triaging possible COVID-19 cases, making an early diagnosis, helping vulnerable people, reducing the demand for hospital services"[6]. Other major roles are to strengthen risk communication and community engagement, support provision of vaccination services. However, health professionals working in primary health care where somehow left behind by the researchers.

Therefore, the challenge was to enroll a prospective cohort of more than 1 000 HCW and to follow-up, for at least 12 months, the impact of the pandemic at three main levels: mental health, long term consequences of COVID-19 and variation of the immune response in

vaccinated. Secondary objectives are: the variation of risk perception during the pandemic, the preventive measures at workplace and how these evolved during the pandemic, vaccination acceptance and reasons of refusal.

This paper aims to present a brief overview of the study design in Romania and the cohort description.

Material and method

The HCW target group included all medical and non-medical support jobs, associated with the health care sector; active professionals from various occupational groups, and with different levels of expertise, working in the public and private health care domain were considered eligible. Identification of the contact data (emails) was based on publicly available information.

Given an estimated response rate of 11-13% for the online surveys, more than 9 000 eligible participants were identified in order to ensure the minimum target of respondents.

The public health authorities, the medical schools, the professional medical associations were also targeted and invited to disseminate to their members the invitation to enroll in the project, using a dedicated weblink.

The data capture tool was a questionnaire elaborated during several rounds of working groups meetings; all the relevant exposure variables in relation with the study concept, the goal and objectives where selected. In parallel, a core of common independent variables, required as minimum standard for all the new cohorts of the ORCHESTRA project, had to be implemented.

The main sections included were: demographics, occupational history, work description and workplace characteristics, including health and safety and infection control protocols, personal medical history, SARS-Cov2 infection (diagnosis, clinical course of the disease, complications and sequalae), vaccination and post vaccination serology. A special section was dedicated to occupational stressors. Burnout was evaluated using The Maslach Burnout Inventory translated in the Romanian language for research purposes, using an open source (http://researchcentral.ro/index.php?action=listateste&ID=412).

The content validity of the questionnaire was evaluated by the expert's panel. The questionnaire was translated into an electronic data capture tool, using the SurveyMonkey platform. A qualitative and quantitative pilot testing was performed and the online questionnaire was adjusted accordingly.

The study protocol was approved by the Ethic Committee of the National Institute of Public Health. The enrollment started in May 2021 and ended in June 2021.

An invitation letter explaining the study rationale, the type of information collected, the use of data and the data protection procedures was distributed to each potential participant via email. The weblink for the questionnaire was distributed also via social media platforms and professionals' networks to maximise reach and encourage participation.

We collected self-reported data on 83 independent variables. For investigating the stress determinants and psychosocial consequences of the pandemic, we assessed the latent variables using validated rating scales. For the cohort description, the data were collated using Microsoft Excel and summarized as median for non-normal data, and as proportions (percentage) for categorical data. The collected data were stored securely and processed confidentially in compliance with national data protection law and the European Union General Data Protection Regulations.

Results

A total of 9321 invitations were sent to eligible participants via email. A total of 26 professional associations, universities, medical organizations received the invitation to distribute the questionnaire to their members.

A total of 2647 participants answered to the invitation and replied to at least three questions; 1867 finalized the online questionnaire and where fully enrolled in the cohort.

The response rate calculated for the group targeted via email was 15.5%.

The majority of the participants are female (82.6%) and the mean age is 48.

The main demographic and lifestyle characteristics are described in Table 1.

The largest group of the respondents (70.7%) are medical doctors followed by registered nurses (14.4%), administrative staff (4.5%), pharmacists (4.2%) and others jobs with percentages less than 1%.

Three quarters of the participants (75.1%) are experienced workers, with duration of employment greater than 10 years.

The highest proportion of participants works in private offices of family medicine (24%), followed by those employed in central and regional public health authorities (21.3%), in hospitals (22%), in offices of various medical specialty (8.2%) and dental practices (3.7%). Less than one fifth (18.1%) reported to work in COVID-19 designated units; 21.5% reported to have been redeployed into a different role or different

Table 1. The main demographic and lifestyle characteristics

Selected characteristics of study population			
		respondents (N)	%
Gender	M	340	18.2
	F	1532	81.8
Marital status	Married (or in a relationship)	1390	74.2
	Unmarried	245	13
	Divorced	186	9.9
	Widow	51	2.7
Ethnicity	Romanian	1790	96.1
	Hungarian	41	2.2
	other (%<0.5)	32	1.7
Residence	Village / small town	242	12.9
	Medium city	332	17.8
	Big city (or its outskirts)	1292	69
	Open ground (outside the village, individual house)	6	0.3

work location during the pandemic. The largest proportion of participants (69.9%) reported to have contact with patients at workplace.

More than half (55%) of the participants work in health care settings from the public sector and the reminder (45%) in private practices.

Different clinical forms of COVID-19 were reported by 481 (25.6%) participants but only 379 (20.2%) have had confirmation with a PCR or rapid antigen test; 294 (77.5%) of those who tested positive for SARS-CoV-2 reported to have contact with patients at workplace.

Discussion

The health impact of COVID-19 on the HCW is an emerging area of study and future updates are anticipated mainly because more data will be available to allow a direct link between SARS-CoV2 infection and its medium- and long-term effects [5].

The traditional prospective cohort study design is based on direct interaction with eligible participants and collection of data via direct or phone interview. But the waves of lockdowns and re-openings at varying times in different counties, the medical staff who were either furloughed or co-opted to aid hospitals' COVID-19 treatment efforts complicated the study design approach and the research team had to switch from the classical enrollment with face-to-face interview to the remote data collection using online platforms.

In our cohort, the response rate was lower than in other COVID-19 cohort studies carried out among medical academic staff [6] and could be attributed to the favorable course of the pandemic at baseline recruitment (May-June 2021) resulting in a decreased interest of the participants. Differences in health literacy and online access are also reported to strongly skew participation, especially in regions with large differences in educational and socioeconomic levels [7].

The structure of our cohort with a large majority of medical doctors and low proportion of nurses could have been influenced by the accessibility and the ease of use of our online tool. Other factors such as low interest, lack of time or lack of confidence in understanding scientific research were reported as being barriers in the participation of nurses in medical research [8].

As with all the online research, selection bias is a possible drawback of our study [7]. However, to prevent such risk we used multiple distribution channels to reach various subgroups of the target population and we included balanced information in the introductory message to sufficiently inform potential participants and to avoid eliciting interest from a particular subgroup [9].

Although convenient for survey purposes, our remote approach could come at a cost also in terms of data quality and quantity. With an abundance of online surveys launched in association with COVID-19 pandemic, some participants may have

felt overwhelmed by the large number of questions and questionnaires, with the risk to lose their interest and abandon the survey. So, the research team had to elaborate a comprehensive questionnaire, long enough to cover all the information needed but also easily accessible, enjoyable and thought-provoking. Skip logic schemes, validation rules and automatic data filtering have been incorporated to route participants to the next question based on their previous answers.

Comparison of psychosocial impact and risk perception over time, across different settings and between subgroups, will be of special interest in the follow up of our cohort with participants exposed to rapidly changing environments because of COVID-19 or related preventive measures [10].

Now that vaccines have sent the crisis phase of the pandemic into remission, the research team will need to find out ways to retain the participants for the next rounds of follow-up. Communication and dissemination activities are foreseen in the next months via online channels but with the hope to organize more direct, in person interactions with the participants.

Keeping participants informed on the study results is another strategy to encourage adherence in the follow-up rounds [11]; we offered to all respondents the possibility to opt for a periodic report on the study results via email or via the project dedicated site.

Conclusion

Most of the studies focused on working conditions and physical and mental impact in healthcare staff during COVID-19 pandemic has targeted the frontline workers in hospitals and medical emergency services. Little is known about the medical staff working in primary care who also faced high professional, physical and mental demands during the crisis. Larger prospective cohorts, with broader representation of these occupational groups, standardized protocols to harmonize data collection and reduce reporting variability are needed.

The Romanian ORCHESTRA cohort is the first online prospective occupational health research initiative targeting the long-term impact of COVID-19 surge on the health professionals working in a broad group of primary health care settings.

The success of the ORCHESTRA project in Romania largely depends on the contribution of each participant at enrollment and during the consecutive follow-up; each individual response enhances the value of the data, and will help to produce aggregate strong results.

Acknowledgements

The ORCHESTRA project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016167.

The views expressed in this paper are the sole responsibility of the authors and the Commission is not responsible for any use that may be made of the information it contains.

References

1. M. G. Baker, T. K. Peckham, și N. S. Seixas, „Estimating the burden of United States workers exposed to infection or disease: a key factor in containing risk of COVID-19 infection", medRxiv, p. 2020.03.02.20030288, ian. 2020, doi:10.1101/2020.03.02.20030288.
2. Z. Wu și J. M. McGoogan, „Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention", JAMA, vol. 323, nr. 13, pp. 1239–1242, apr. 2020, doi: 10.1001/jama.2020.2648.
3. P. Zhou, Z. Huang, Y. Xiao, X. Huang, și X.-G. Fan, „Protecting Chinese healthcare workers while combating the 2019 novel coronavirus", Infect Control Hosp Epidemiol, vol. 41, nr. 6, pp. 745–746, iun. 2020, doi: 10.1017/ice.2020.60.
4. P. Boffetta et al., „Determinants of SARS-CoV-2 infection in Italian healthcare workers: a multicenter study", medRxiv, p. 2020.07.29.20158717, ian. 2020, doi:10.1101/2020.07.29.20158717.
5. M. Michelen et al., „Characterising long-term covid-19: a rapid living systematic review", medRxiv, p. 2020.12.08.20246025, ian. 2020, doi: 10.1101/2020.12.08.20246025.
6. World Health Organization. Regional Office for the Western Pacific, „Role of primary care in the COVID-19 response", Manila : WHO Regional Office for the Western Pacific, apr. 2020. [Online]. Disponibil la: http://iris.wpro.who.int/handle/10665.1/14510
7. K. A. S. Davis et al., „Indicators of past COVID-19 infection status: Findings from a large occupational cohort of staff and postgraduate research students from a UK university", medRxiv, p. 2020.12.07.20245183, ian. 2021, doi:10.1101/2020.12.07.20245183.
8. J. De Man, L. Campbell, H. Tabana, și E. Wouters, „The pandemic of online research in times of COVID-19", BMJ Open, vol. 11, nr. 2, p. e043866, feb. 2021, doi: 10.1136/bmjopen-2020-043866.
9. Siti Romaino Mohd Nor et al., „FACTORS INFLUENCING NURSES' PARTICIPATION IN CLINICAL RESEARCH : A CROSS-SECTIONAL SURVEY IN HOSPITAL PUTRAJAYA, MALAYSIA", The Malaysian Journal of Nursing, vol. 12, nr. 4, pp. 60–71, apr. 2021, doi: 10.31674/mjn.2021.v12i04.009.
10. G. Eysenbach și J. Wyatt, „Using the Internet for surveys and health research", J Med Internet Res, vol. 4, nr. 2, pp. E13–E13, 2002, doi: 10.2196/jmir.4.2.e13.
11. C. R. Schneider et al., „COVID-19 risk perception: a longitudinal analysis of its predictors and associations with health protective behaviours in the United Kingdom", null, vol. 24, nr. 3–4, pp. 294–313, apr. 2021, doi: 10.1080/13669877.2021.1890637.
12. J. De Man et al., „Disentangling depression in Belgian higher education students amidst the first COVID-19 lockdown (April-May 2020)", Archives of Public Health, vol. 79, nr. 1, p. 3, ian. 2021, doi: 10.1186/s13690-020-00522-y.