Volume 114 2/2023

Rivista fondata nel 1901 da Luigi Devoto Issn 0025 - 7818

La Medicina del Lavoro

Organo della Società Italiana di Medicina del Lavoro

Work, Environment & Health

Official Journal of the Italian Society of Occupational Medicine

www.lamedicinadellavoro.it

Poste Italiane s.p.a. - Sped. in A. P. - D.L. 353/2003 (conv. in L. 27/02/2004 n. 46) art. 1, comma 1, DCB Parma - Finito di stampare nel mese di Aprile 2023

Mattioli 1885

Volume 114

Issn 0025-7818

Rivista fondata nel 1901 da Luigi Devoto

elssn 2532-1080

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Tel. 02/50320125 - Fax 02/50320103
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Publisher
Mattioli 1885 srl - Casa Editrice
Strada di Lodesana 649/sx, Loc. Vaio - 43036 Fidenza (PR)
Tel. 0524/530383 - Fax 0524/82537
e-mail: edit@mattioli1885.com
www.mattioli1885.com

Pubblicazione bimestrale - Direttore Responsabile: Antonio Mutti
Autorizzazione del Presidente del Tribunale di Milano 10/5/1948 Reg. al N. 47

La Medicina del Lavoro è indicizzata da / La Medicina del Lavoro is indexed in:
PubMed/Medline; Embase/Excerpta Medica; Abstracts on Hygiene; Industrial Hygiene Digest; Securité et Santé au Travail Bit-CIS; Sociedad Iberoamericana de Informaciòn Cientifica (SIIC); Science Citation Index Expanded (SciSearch®); Journal Citation Report/Science Edition; ISI Web of Science; Scopus (Elsevier); Bibliovigilance

La Medicina del Lavoro

Editorial

Med Lav 2023; 114 (2): e2023014
DOI: 10.23749/mdl.v114i2.14451

Hey James, Write an Editorial for "*La Medicina del Lavoro*"

Last year, *Nature* reported that some scientists were already using chatbots as research assistants – to help organize their thinking, generate feedback on their work, assist with writing code and summarize research literature [1]. A chatbot named James authored several paragraphs of this editorial using Artificial Intelligence (AI) and a Large Language Model or Logic Learning Machine (LLM). We checked for possible plagiarism, obtaining the following assessment: "It looks 100% original. We found no matching text in our databases or on the internet".

As technology and industry advance, we cannot ignore their ongoing impact on workers' health and safety. It is, therefore, crucial to have a platform that addresses the complexity of work-related illnesses and injuries. "*La Medicina del Lavoro*" provides just that. The journal, established in 1909[1], has been instrumental in disseminating research, editorial reviews, and news of new technologies and laws that have improved the quality of health services for over a century. Today, its contributions are equally essential in promoting wellness and reducing workplace hazards. The range of topics covered by the journal is broad and includes occupational ergonomics, environmental health, occupational toxicology, and psychological health at work, to name a few. These topics demonstrate the scope of concern for occupational health matters.

Many work-related illnesses and injuries are complex, requiring a multi-disciplinary approach. Work settings have specific factors affecting workers' health; thus, evaluation and intervention should be tailored to the workplace. The journal encourages cross-disciplinary collaboration, which facilitates sharing of knowledge and expertise from various fields, such as occupational medicine and toxicology, epidemiology, and microbiology. As the official journal of the Italian Society of Occupational Health, it is committed to ensuring research integrity and the standards of leading publications providing valuable insights into the crucial intersection of work, environment, and health. It covers everything from occupational health to environmental sustainability, highlighting the importance of addressing these issues in the workplace.

Addressed topics include environmental sustainability, occupational hazards, and workplace safety. These articles emphasize the importance of a holistic approach to workplace health and safety, which involves addressing physical and psychological factors.

As employers strive to create healthier and safer work environments, it is crucial to consider the interplay between work, environment, and health. By adopting evidence-based policies that prioritize employee well-being, reduce occupational hazards, and promote environmental sustainability, workplaces can create a more productive, healthy, and resilient workforce. The journal also keeps up with changes in the field, such as the effects of COVID-19 on the workforce, the issue of remote work, and the implications of new technologies, such as artificial intelligence and robotics, on occupational health. Such new frontiers will certainly impact occupational health and safety. The journal remains relevant to the present and undaunted by future challenges.

Using artificial intelligence (AI) in occupational health and safety (OHS) can have numerous benefits. For example, AI can help identify and mitigate potential workplace hazards with machine learning algorithms and predictive analytics, which can analyze data from various sources such as sensors, employee feed-

1. The current title, "*La Medicina del Lavoro*," was adopted in 1925 to coincide with the discipline's official denomination for courses, congresses, and teaching licenses. Despite a new name – the first issue of "*Il Lavoro*" had been published in 1901 – it was labeled as volume 16 to express its continuity with "*Il Lavoro*" (WW1 and other reasons account for eight volumes and hence years missing in the collection). Therefore, James extrapolated the journal's foundation's date to 1909, considering that in 2023 we are publishing volume 114.

back, and other sources. This can help OHS managers to make informed decisions about workplace safety measures, equipment maintenance, and protective equipment to reduce the risks of accidents and injuries. AI can also help identify patterns, predict potential hazards, and provide real-time insights into workplace safety for immediate attention. This can help companies to minimize the likelihood of accidents or near-misses and improve the overall safety culture of the workplace.

But is there a dark side? Could something go wrong? Can LLM allow deeper insight or even discovery? While these tools may enhance efficiency and reduce errors, they may pose potential hazards to authors [3]. A primary hazard is the lack of human input and decision-making. AI-based systems may be unable to understand nuances and context within scientific writing or make incorrect decisions, leading to errors or misleading information.

This, in turn, could decrease the quality of scientific papers and may affect their credibility and impact. While these systems may seem innovative and efficient, they also have the potential to exacerbate errors and bias while stifling creativity in the scientific community. Moreover, relying on AI deprives authors of opportunities to learn and grow from their mistakes. When authors do not receive feedback from a human editor, they lose the chance to understand their errors fully and may not learn how to avoid them in future work.

Scientific research is advancing at an unprecedented pace, and as a result, the volume of academic literature is expanding exponentially. This growth in academic articles creates difficulty for academic editors to keep up with it. AI- and LLM-based editorial assistants promise to streamline the scientific publishing process. However, this innovation implies hazards that also editors need to consider. One of the potential hazards of AI-based editorial assistants is their ability to perpetuate bias. AI-based assistants are trained using existing data and pre-existing patterns, which can be biased. As a result, they might perpetuate the same bias during the submission and review process, leading to a biased review of the manuscript.

AI-based editorial assistants have incredible potential to transform scientific publishing. Still, the editorial process requires stringent checks and balances to ensure the quality of the published work. Misconduct must be ruled out in scientific papers, which are potentially affected by: (i) Plagiarism (presenting someone else's work or ideas as one's own): proper citation and attribution are crucial in scientific writing; (ii) Fabrication or falsification (manipulating or selectively presenting data to fit one's hypothesis or to achieve desired results); (iii) Misleading or inaccurate claims (researchers' personal beliefs and interests might impede an objective and balanced viewpoint in conclusions which should be both accurate and supported by evidence).

In addition to misconduct sanctioned by deontological rules, two ethical issues must be considered: (ii) Duplicate or redundant publication (it is unethical to publish the same work in multiple publications without proper disclosure or permission); (ii) Informed consent (studies involving human subjects require properly informed consent), safeguarding patients' privacy and autonomy.

Misconduct in scientific writing could have serious consequences, such as loss of reputation, loss of funding and employment, and in some cases, legal action. Thus, researchers must abide by ethical standards and principles in scientific writing, ensuring the integrity and credibility of scientific research.

Although OpenAI has tried to put guard rails on what the chatbot will do, users are already finding ways around them. Some preprints and published articles have credited ChatGPT with formal authorship [4-5]. Such a rapidly evolving situation led Nature to establish two rules which also our journal will follow: (i) No AI-based tool will be accepted as a credited author on a research paper because any attribution of authorship carries with it accountability for the work, and AI tools cannot take such responsibility; (ii) Researchers using AI-based tools should document this use in the methods or acknowledgments sections. For papers not including these sections, the introduction or another section can be used to document the use of AI, as I did in the first paragraph of this editorial. Can we detect text written using LLM? Perhaps, a cumbersome and time-consuming analysis could distinguish some peculiar characteristics of LLM, but ultimately, we expect transparency, integrity, and truth from our authors. This is, after all, the foundation that science relies on to advance [2].

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Antonio Mutti

La Medicina del Lavoro

Reviews, Commentaries, Perspectives

Med lav 2023; 114 (2): e2023013
DOI: 10.23749/mdl.v114i2.14362

Psychosocial Risks in the Changing World of Work: Moving from the Risk Assessment Culture to the Management of Opportunities

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Keywords: Psychosocial Impacts; Risk Management; Hybrid Work; Violence and Harassment at Work; Action Plan

Summary

Increased attention to psychosocial risks and their potential impacts on workers' mental and physical health has flourished due to the changes taking place in the world of work. The changes in the world of work and the recent worldwide events have exacerbated the existing psychosocial risks and brought out new psychosocial risks to be considered for protecting workers' health. This favors the opening up of national and international debate on prioritizing psychosocial risks at work at the policies, strategies, and actions level. This contribution highlights the critical issues to be addressed, the needs to be covered, and the opportunities for better and more effective OSH protection in the workplace. Starting from a definition of psychosocial risks and their potential impacts, we offer an overview of the most recent developments in policies and strategies and the contribution of research in this field over time. A critical reflection on emerging topics, main needs, and challenges for organizations and stakeholders is offered. This time of change poses great concerns but also offers a great opportunity of moving from a culture of assessment to a culture of psychosocial risk management for improving workers' well-being, productivity, and health, where the risk assessment is an important step but not a point of arrival.

1. Introduction

In recent years, the world of work has seen several changes and events that are modifying the workforce, the environments, the work equipment, and the way the work is designed and organized, with important impacts on workers' health and well-being [1, 2, 3]. Over the last ten years, the management of psychosocial risks in the workplace has been one of the main concerns in terms of occupational safety and health (OSH) both in Europe and in Italy [4, 5], even now representing a growing challenge for organizations due to the rapid changes in the work conditions. The growing digitization, the opening to collaborative robotics, the gig economy, the new flexible forms of work, and the differences – and the inequalities as well – in the workforce have exacerbated the existing psychosocial risks on one side and brought out new psychosocial risks to be considered and included for protecting workers' health [6]. Furthermore, global events such as the COVID-19 emergency, the war in Europe, and climate change

Received 27.02.2023 – Accepted 01.03.2023
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have increased potential psychological impacts due to job instability, the economic crisis, the fear for one's safety, and the adoption of new behaviors and habits, with consequent effects also at work. Indeed, in recent years there has been a progressive deterioration of mental health in Europe, which requires companies to take further actions to support and manage workers' health [7].

Considering the ongoing changes, the European Commission's Strategic Framework on Health and Safety at Work 2021-2027 called for cooperation between member states and social partners to anticipate emerging risks related to the changes in the world of work, recognizing psychosocial risks among the main priorities [8, 9, 10]. Moreover, the recent calls of European social partners for a stronger legislative framework on psychosocial risks in the workplace must be considered, too [11]. This European perspective requires a new view, moving from risk assessment to risk management. In this context, Occupational Medicine plays a central role at the national level in developing guidelines, approaches, and models in this area, contributing to create an integrated and participatory approach to managing emerging psychosocial risks.

Starting from a clear definition of psychosocial risks, their potential impacts, and their mutual relationships, this contribution aims to offer an overview of the most recent developments in policies and strategies to discuss the ongoing changes and highlight the critical issues to be addressed, the needs to be covered and the opportunities to be taken for a better and more effective OSH protection in the workplace.

2. Psychosocial Risks: Definitions and Potential Impacts

Psychosocial factors at work are defined as aspects of job design, work organization, and management (e.g., decision-making autonomy, workload, working hours, role clarity) as well as the related social context (e.g., social support from supervisors, relationships at work, support from colleagues) and the work environment (e.g., loud noise work environments, poor lighting) which can have an impact on the psychophysical health of workers [12]. How these factors are managed can have positive outcomes (job satisfaction, work involvement, productivity) and negative impacts (stress, illness, sick leave, etc.). The second case is the psychosocial hazards at work, as the potentially harmful aspects for workers' health and the organization as a whole [13]. Psychosocial risks have received great national and international attention over time due to their link with work-related stress. The impact of the psychosocial environment on workers' health occurs through the stress experience [13], this condition is relevant for the person when it is intense and prolonged over time, and it involves the depletion or overcoming of the personal resources helpful in coping.

Other aspects such as violence and harassment at work, burnout, technostress, and in turn, impacts on mental and physical health, such as depression, musculoskeletal disorders, anxiety, as well as behavioral outcomes (such as absenteeism, presenteeism, and injuries) can occur since they are a consequence of inadequate management of psychosocial and organizational risks, and they can also have a mutual negative influence in the workplaces. Some examples of this reciprocal relationship in the workplace are as follows. High-level stress workplaces impact the workers' psychological processes and conditions, such as burnout, a chronic stress syndrome that affects both the psychophysical and behavioral aspects [14-15]. The pandemic has also highlighted the increase of other psychological impacts for the workers, including a compulsion to work excessively – workaholism – [16], compassion fatigue [17], and bore out [18], which are manifested through exhaustion such as burnout and have effects on physical and psychological health, and workers' attitudes and behaviors as well. Having workers with symptoms of exhaustion within a group can lead to further deterioration of the working context, increasing the risk of stress as well, which can favor, in turn, the emergence of behavioral phenomena, such as episodes of violence at work, harassment, and mobbing in the workplace. However, these phenomena have a role of reciprocal influence since they are included among the potential causes of stress at work as indicators of conflicts and relational concerns to be managed at an organizational level, whether between colleagues or external customers.

Recently, technostress and its impact on workers' mental health have been gaining increasing priority [19]. Among others, the growing development of Information and Communication Technology has led to the introduction of new business models and increased hybrid work, such as smart working, teleworking, and platform work and the pandemic emergency has further accelerated this.

Technostress is a form of stress caused by the pervasive and dysfunctional use of technologies, which is connected to the carrying out of activities that strongly depends on the use of technology – both temporally and functionally – and this may have significant impacts both on the individual's social life and on his psychophysical well-being [19, 20]. When the technostress is due to the pervasive and dysfunctional use of technologies at work, it is part of the work-related stress, and it must be addressed, including those aspects of the work organization and management connected to the use of technologies [21]. Smart working during the COVID-19 emergency may represent a lesson learned in this sense. Although it has made it possible to keep working by highlighting the great potential of digitalization, it has also put into light the potential negative impacts of a lack of effective work organization and management in the use of remote work, including social isolation, the demand for constant availability, the work-personal interference, the worsening of informal communication [7, 22].

All the aspects mentioned above have a showed reciprocal link and a common denominator that are all the aspects of job design and work organization and management which can constitute their determinants, but also a potential solution through effective management aimed to protect workers' health and to increase job satisfaction and organizational well-being.

3. Current International and National Policies and Strategies

The progress in policies and strategies on psychosocial risks reached international and national levels, thus boosting the development of models, approaches, and practical tools for managing psychosocial risks in organizations, proving to be one of the main drivers for managing psychosocial risks [23]. For example, in Italy, the Legislative Decree 81/08 and s.m.i. raised the assessment and management of psychosocial risks in two ways: (i) the implementation of the definition of health by the World Health Organization, as "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"; (ii) the inclusion of the obligation for the employer to assess all the risks for OSH, including those connected to work-related stress by following the content of the 2004 European Framework Agreement on work-related stress (art 28).

According to the Agreement, the risk assessment focuses on those aspects of job design, work organization, and management – along with some potential objective signals of the presence of stress at work – that are linked to the content and the context of the work, namely the psychosocial risks at work. Later on, in November 2010, as required by the Decree mentioned above, the Permanent Consultative Commission for OSH published some methodological indications which currently constitute the requirements to be met for managing the risks associated with work-related stress at the national level. Such indications represent the minimal requirements, as confirmed by the Consultative Commission after the ruling n. 5/2012 by the National Psychologists Council that specified the employer may go beyond the methodological path legitimately to carry out further in-depth investigations, notwithstanding the prompt identification of the corrective measures to the risks that emerged by the preliminary assessment. Then, in the Legislative Decree 19/2014, based on the Directive 2010/32/EU that implemented the Framework Agreement between HOSPEEM and EPSU on the prevention of sharps or needlestick injuries in the hospital and health sector, the term "psychosocial and organizational risks" was explicitly reported in an OSH legislation for the first time.

At the national level, the role of research allowed organizations to offer a valid and effective answer to the legal requirements. In 2011, INAIL published a methodological proposal to assess and manage the risk associated with work-related stress and a specific web helpful platform for systematically collecting data from organizations' assessments over

time [24, 25, 26]. The INAIL's methodology offered the organizations a method based on scientific evidence and a participatory approach, including validated tools and risk cut-off based on the national workforce. This method may be integrated with managing all other OSH risks in the organizations. Between 2014 and 2016, national monitoring of the implementation of the legal requirements was carried out through a project financed by the National Centre for Disease Prevention and Control (CCM) of the Ministry of Health [27]. Findings highlighted that over 80% of the organizations included in the national sample on the national complied with the legal obligation, carrying out the WRS risk assessment and that most of these used the INAIL's methodology.

Nevertheless, it is worth noting that not all the activated assessment processes have applied the whole INAIL method actually – that includes moving to an in-depth assessment beyond the minimum legal requirements – neither have included the implementation of corrective and improving measures or the evaluation of such measures in terms of reducing WRS [28, 29]. Currently, over 10,600 organizations are using INAIL's methodology through the web platform, well-distributed throughout the country and productive sectors. The uploaded checklists are 12,393, and the filled-in questionnaires are 121,378. The data collected over time and the research experiences at a national level allowed both the updating of the methodology and the related tools with a new 2017 edition [25] and to anticipate and investigate emerging risks to provide tools for contextualized specific risks, as in the recent tools for the healthcare sector [26]. Currently, INAIL research focuses on emerging risks connected to the changes in the world of work to provide scientifically based solutions and proper tools for managing OSH risks for contributing to the ongoing debate on the future of work. Recent international and national policies, strategies, and actions further call for integrating psychosocial risks into the organization's overall management of OSH risks. A good example came from the ISO4500 "Occupational health and safety management – Psychological health and safety at work – Guidelines for managing psychosocial risks", which represents a valuable guide for managing psychosocial risks and promoting occupational well-being within an OSH management system based on ISO 45001. This standard includes psychosocial risks within a systemic approach, which poses a human-centered approach to be included within an overall and integrated system for managing the OSH risks. Then, some emerging psychosocial risks are assuming relevance in consideration of the last year's changes in the world of work, as also recalled by the recent consensus document of the national inter associative board on prevention (CIIP). Among these, we highlight the need to investigate the aspects connected to the use of smart working and other forms of flexible work, but also to include the contrast to violence and harassment at work of different nature – including cyberbullying – as also recalled by the European Parliament resolution of 5 July 2022 on mental health in the digital world of work.

It should be noted that violence and harassment at work are aspects already considered in the assessment and management of the risks associated with the WRS, which now require broader conceptualization and management – particularly in those contexts more at risk, such as the healthcare sector – due to the emergence and increase of the phenomenon, which is essential also in consideration of the law 15 January 2021 n. 4 that have ratified the International Labour Organization 2019 Convention n. 190 concerning the elimination of violence and harassment in the world of work.

4. Towards The Risk Management Approach

Changes taking place in the world of work have led to increased attention on psychosocial risks and their potential impacts on the workers' mental and physical health of workers, favoring the opening up of a national and international debate on the aspects to be integrated and included at the level of policies, strategies, and actions. The national debate is going towards the inclusion of the term psychosocial risks in OSH prevention and protection, and this gives a more explicit focus to the organizational and social aspects that can cause the experience of stress and other potential psychological, social, and behavioral impacts that can affect workers' health

and organizational well-being. Nevertheless, this does not mean work-related stress is outdated or incomplete. However, the attention is moving towards managing its potential sources – including all the potential impacts on the psychological, social, and behavioral aspects – and the reciprocal path among psychosocial aspects and other OSH issues such as musculoskeletal diseases.

Considering the ongoing changes and the effects of the pandemic, it is essential to also focus on the emerging and specific psychosocial risks of some contexts and types of work, particularly at risk (e.g., job insecurity, isolation, violence and harassment at work, technostrain). These must be included in the mapping of OSH risks, and some preventive actions should be identified strategically to prevent their impacts. The role of research is essential to provide evidence, solutions, and integrative tools for increasing support to organizations in the risk assessment phase. Multidisciplinary approaches are crucial to integrate competencies from occupational medicine, occupational psychology, and ergonomics, as well as the competencies of the OSH professionals in the organization. This would allow us to anticipate emerging psychosocial risks – as required by the European Commission – and identify more fitting prevention and management actions.

Nevertheless, the main risk to be avoided is reducing all to the introduction of new assessment measures and tools – even if these are fundamental and must be verified in terms of validity and reliability – but this is the time to seize the opportunity to include these risks within an integrated OSH management system. The integration requires a systemic approach to risk management – as shown by the recent ISO 45003 standard – including tools and measures within clear and consolidated methodological approaches. A recent example of this integration can be found in the recent integration of the INAIL methodology for the healthcare sector [26, 30]. This experience is currently under replication for other emerging risks due to digitalization and new ways of working, including smart working.

The most important challenge now is moving from a culture of assessment to a culture of psychosocial risk management as an opportunity to improve organizations in terms of workers' well-being, productivity, and health – where the assessment is an important step but not a point of arrival. The management of psychosocial risks in the workplace requires a methodological process that starts from the identification of the potential hazards associated with the work activity and the work context and leads to an assessment of their potential for damage and the relative risk, with the aim of identifying the most effective management and prevention actions to be implemented. Moving from the assessment to managing psychosocial risks in the workplace is not easy for organizations. In complying with the legal obligation, there is frequently the risk of coming to a halt after the assessment without activating a real process of change within the organizations that would involve all the organizational actors in the management and organization of work with a multidisciplinary and participatory approach. As a result, we often find never implemented action plans or less effective interventions without any effect on reducing the risk. Secondary prevention is often preferred by organizations that reinforce workers with soft skills through training without addressing potential stress sources. Evidence and experiences have demonstrated that the effectiveness of this type of organizational intervention depends on the ability to include some key methodological aspects in the process, such as: (i) the clear identification of potentially affected groups of workers, (ii) the use of participatory approaches that actively involve workers, using clear communication, (iii) the involvement of the management – including line managers – in the implementation of the most appropriate and effective actions to prevent or contain the impacts, (iv) the inclusion of the needed competences and raising the level of awareness [28, 30, 31, 32].

Moving toward effective management should also be encouraged, considering the positive circle of psychosocial risk management. Few studies have focused on the positive role of good psychosocial risk management linked to increased work engagement [33], job satisfaction, and well-being [33]. As shown above, the legislation has proven to be a strong driver for assessing risks associated with work-related stress in the past. In this time of change, we hope that the renewed attention on the aspects of job design, work organization, and

management could lead to an increase in the commitment at the national level to supporting organizations in moving towards the implementation of prevention and management actions to protect workers' health and well-being through the psychosocial risks management.

Declaration of Interest: The Authors declare no conflict of interest.

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La Medicina del Lavoro

Reviews, commentaries, perspectives

Med. Lav. 2023; 114 (2): e2023018
DOI: 10.23749/mdl.v114i2.14247

Assuming the Challenge of Developing Research Projects in Occupational Health Nursing

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Keywords: Occupational health; Occupational health nursing; Occupational health services; Research; Professional competence

Summary

In today's society of uncertainty, we are witnessing a transformation of the economic, social, demographic, digital, ecological, and employment model, which faces unforeseen challenges. These challenges require reflecting beyond their consequences, and new workplace risks call for a debate on solutions beyond traditional ones. In the specific context of companies, the main functions of occupational health nursing are to prevent, promote, protect, and restore workers' health. The integration of research into nursing practice entails the better implementation of scientific advances. Although in the real world of professional nursing practice, there is a discrepancy between the knowledge obtained through research and clinical practice, practicing based on care plans, solid practice guidelines, and scientific evidence is a maxim.

Research is a necessary, unavoidable and inherent condition for occupational health nursing. In this way, the ability to study this area of nursing knowledge in depth, to design research initiatives in the area of their competences and to have the possibility of implementing the results obtained, allows the consolidation of the preventive culture in companies. Consequently, the practice of research guarantees the updating of professional knowledge, promotes a balanced evaluation of praxis and establishes instruments of communication between related parties. It also invites self-critical reflection prior to decision-making and quantifies the cost-effectiveness of nursing practice. Furthermore, it provokes the formulation of new questions and generates both scientific evidence and added value in the discipline. These aspects translate into an improvement in the efficiency and effectiveness of the care provided in companies and greater safety in nursing interventions [1]. All of these realities strengthen the professional role of the speciality and aim to incorporate the value of research in the daily practice of the profession [2].

The cross-cutting nature of research equally affects the different levels of the company regardless of sector, activity, size, or type of risks. To a greater or lesser extent, the development of this aspect and the implementation of the findings have implications throughout the worker's professional life. In this context, the main functions of occupational health nursing are to prevent, promote, protect, and restore the health of the working population in its field of action [3]. In the scientific evolution adapted to the demands and needs related to health in organizations, nursing research is defined as a scientific process that validates and improves existing knowledge

Received 13.02.2023 - Accepted 21.03.2023
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and generates new knowledge that directly and indirectly influences its practice [4]. In recent years, various entities related to this discipline include research competence as an asset, among them: the Federation of Occupational Health Nurses within the European Union (FOHNEU) [5], the American Association of Occupational Health Nurses (AAOHN) [6, 7], the Canadian Nurses Association (CNA) [8], and the Association of Occupational Health Nurse Practitioners (AOHNP) [9]. It has also been included by the Scientific Committee on Occupational Health Nursing (SCOHN) [10, 11], the World Health Organization Regional Office for Europe [12], the Occupational Health Nursing Research Center [13], and the Faculty of Occupational Health Nursing (FOHN) [14]. In addition to their research capacity, these institutions have incorporated the following areas of action: preventive, care, teaching, management, legal, and expert.

At the same time, various international professional forums encourage this research facet. The Global Commission on the Future of Work advocates establishing lines of research to evaluate people-centered economic, social, and labor programs [15]. The National Institute of Occupational Safety and Health (NIOSH) presents a scientific agenda to stimulate innovative research and define best practices in the workplace [16]. In its Working for Health Action Plan 2022-2030, the World Health Organization (WHO) calls for the allocation of nursing resources to research proposals to be designed [17] and to study the influence of climate change on workers' health [18]. The International Labour Organization (ILO) is furthering the comparative analysis of national strategies on new work scenarios in the face of the transformation of the world of work [19]. In turn, the European Union strategic framework on health and safety at work 2021-2027 takes up the challenge of addressing musculoskeletal disorders, respiratory diseases, mental health, cancer, harassment, gender bias, and the care sector, among others, by stepping up research [20]. The Global strategic directions for nursing 2021-2025 and The National Academies of Sciences propose increasing training to develop nursing research projects that respond to the needs and demands of workers [21, 22]. Among these proposals, the International Council of Nurses (ICN) stresses evaluating the work environment, injuries, or illnesses derived from nursing work in different countries [23]. Finally, the American Nurses Association (ANA) enterprise 2023-2025 strategic plan includes research innovation projects demonstrating nursing care's transformative impact [24].

The current transformation of the economic, social, and labor model, together with the digitalization and relocation of work, is known as Industry 4.0. In this new uncertain reality, emerging risks are emerging where their prevention poses multiple challenges and allows research to be carried out using different approaches that are not mutually exclusive. Although the task is extensive, occupational health does not have an academic and research tradition compared to other areas of health. There are differences in background, current status, usefulness, application, activity evolution, systematic assessment of its validity, and the generation of relevant scientific evidence [25, 26]. Situations that further reinforce the benefits of the combination of research and professional practice constitute the basis for safe, quality, and cost-effective care for workers. This approach is underpinned by ethical and professional responsibility and is based on scientific evidence [27]. However, in the fact of accepting and incorporating an innovation, some factors limit the transfer of knowledge to practice: the profile of the professional, the culture of the organization, the knowledge of the innovation, the channels of communication, self-improvement that conditions integration into praxis [28] and even environmental factors [29].

In the professional nursing reality, there is a discrepancy between the knowledge obtained from theoretical research and actual clinical practice [30], an aspect that coexists with a solid relationship between scientific production and the quality of care provided [31]. Based on this premise, the following factors determine the development of the research profile in occupational health nursing: lack of time during the working day, inadequate training in research methodology, professional isolation [32], care pressure, and the scant research tradition [33]. In addition, the lack of knowledge in the practice of critical reading, not having enough time to read

scientific literature, barriers related to the profile of the company, and the limited capacity to implement the results [34], are issues that are a constant in both national and international studies [28], are also pointed out. Finally, it is also necessary to highlight the resistance to change [2], the limited support of managers and colleagues, the lack of social recognition, the lack of systematic reviews with a nursing perspective, and the absence of stable lines of research and nursing leaders in this field [35]. Issues that would promote a critical spirit, professional autonomy, control in decision-making, and the projection of an image as a profession, as well as increasing the body of nursing knowledge.

Research in occupational risk prevention analyses the possible relationships between exposure to risks and damage to health. Among other things, it aims to detect the damage caused by accidents, incidents, occupational diseases, or non-traumatic pathologies caused or aggravated by work and identify groups with specific intervention needs [36]. From this premise and in a post-COVID-19 context, the FOHNEU has identified the following priority lines of research related to occupational nursing: workers' access to the supply of nursing services, the impact of the pandemic on the role of the specialty and autonomy in the development of their professional competences. It also points out the approach to persistent COVID-19 in organizations, mental health problems related to the pandemic, and the interaction with the different members of the occupational risk prevention service [37]. In parallel, the impact of the pandemic on social inequalities and the identification of occupations with higher risks and which working conditions favor these situations are of interest [38]. These proposals are in addition to other lines of interest such as teleworking, digitalization, the new demographic reality, work intensification, cancer, incorporation after a prolonged absence, social determinants, and the effects of climate change or persistent COVID-19. Nevertheless, the ANA challenges nurses to lead holistically and cross-sectorally in workplace wellness programs [24].

Research ultimately aims to improve people's quality of life. In the various roles of the occupational nurse, whether as a researcher, consumer of scientific literature, or transmitter of this knowledge through various media, we must be aware of the benefits of its application both among workers and in the development of the discipline. A critical spirit with a humanistic basis, scientific motivation from a holistic perspective, and research curiosity are more than necessary.

Declaration of Interest: The author declares no conflict of interest.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023017
DOI: 10.23749/mdl.v114i2.14417

Health Promotion Interventions in Occupational Settings: Fact-Finding Survey among Italian Occupational Physicians

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Keywords: Health Promotion; Occupational Well-being; Total Worker Health; Occupational Medicine; Occupational Physician; Workplace Preventive Figures; Healthy Lifestyles; Sustainable Workplaces; Education; Participation

Abstract

Background: *Occupational Physicians (OPs) are essential for health promotion (HP) at the workplace, although their HP knowledge and perception are still under-searched.* **Methods:** *Between September and December 2022, the Italian Society of Occupational Medicine (SIML) – HP working group performed a cross-sectional survey on SIML-OPs aimed to address their approach, experience, strategies, and needs concerning HP plans.* **Results:** *A total of 336 OPs completed the questionnaire. Regarding HP's OP perception, this was reported as a social investment (34.45%) and shared responsibility for all the company's preventive figures (30.18%). Over half of the enrolled OPs declared to have been involved as HP plans' organizers (57.30%) or collaborators (54.80%) in the previous 5 years. The greatest percentage of organizers were in the younger age groups (40-59 years; 50%). Additionally, following a more limited number of companies, prevalently of medium-high dimensions, and more than 500 workers were positively associated with greater OP participation in HP initiatives. Promoting healthy lifestyles was the main target of the HP plans (88.64%). Interdisciplinary collaboration, OP training on HP procedures and information on the targeted population have been reported as effective issues to support an active engagement of OPs in HP.* **Conclusions:** *A general interest of the Italian OPs with respect to HP was demonstrated, however, information on the potential benefits of HP in workplace aligned with OP perceptions and needs seem necessary to successfully implement HP interventions.*

1. Introduction

In 1946, health was defined by the World Health Organization (WHO) as "A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [1]. Forty years later, in 1986, the WHO Ottawa Charter for Health Promotion reported that "To reach a state

Received 08.03.2023 – Accepted 17.03.2023

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of complete physical, mental and social well-being, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment" [2]. In this view, each individual should be able to fulfill his/her aspirations and needs in every field of life, including home, community, and workplaces.

In this perspective, it seems evident how workplace safety and health efforts should be focused not only on the prevention and protection from occupational risks, but also to promote the physical and mental health as well as the well-being of the workforce through a holistic "Total Worker Health® (TWH)" approach, as firstly proposed by the US National Institute for Occupational Safety and Health in 2011 [3]. This includes policies, programs, and practices that foster safer and healthier workplaces by addressing work organization, employment and supervisory practices, and workplace culture taking also into account the possible synergy between occupational risks, environment, lifestyles and personal conditions [4].

Thus, the TWH approach inevitably includes workplace health promotion (WHP) strategies to advance workers' well-being. In Italy, the first WHP model was conceived and applied in the Lombardia Region in 2013 and reached around 600 participating companies throughout the Region in 2020 [5]. It was based on the WHO model and aimed to adopt organizational changes in workplaces to make them favorable environments for the conscious adoption and diffusion of healthy lifestyles, contributing to the prevention of chronic diseases.

More recently, the Italian Ministry of Health included the TWH approach in one of the intervention lines of the National Prevention Plan (NPP) for the years 2020-2025: "Activation of technical tables for the strengthening of the overall health of the worker according to the Total Worker Health approach" [6]. In agreement with the TWH principles, the NPP pointed out that to achieve health-friendly workplaces, the involvement of all the preventive figures engaged in occupational health is necessary [7].

From this perspective, it emerges the crucial role of occupational physicians (OPs), in the design, implementation, and monitoring of TWH and HP interventions. This has also been underlined by article 25 of the Italian Legislative Decree 81/2008, which stated the role of the OP in collaborating to the implementation and valorization of voluntary programs of HP, according to the principles of social responsibility [8]. OP expertise in understanding possible health implications of exposure to occupational risks and the strong relationship with workers, supporting the deep knowledge about their health conditions, make the OP a key figure in implementing the health and well-being of the workforce in individual companies [7]. However, although recognized as an integral part of HP policies and programs in the workplace, the OPs' knowledge and perceptions regarding HP seem still an under-searched topic. Therefore, the present study aimed to address issues related to the approach, experience, strategies, and needs of OPs with respect to HP plans. This may be helpful to extrapolate insights that may assist OPs to more effectively generate interest and action to integrate occupational preventive and protective actions with improving employee health outcomes. This may strongly support workplaces to become safe, healthy, and sustainable with overall benefits for workers, employers, and the community.

This report summarizes the survey's main results, whereas additional details are provided in the Italian version of the report, which can be accessed as supplementary material including more numerous and detailed tables.

2. Methods

2.1. The Investigated Population and Data Collection

A cross-sectional HP survey was conducted between September and December 2022. Italian OPs attending the 84° National Congress of the Italian Society of Occupational Medicine (SIML), held in Genova, Liguria Region, from the 28th to the 30th of September 2022, were asked to participate in the survey completing the specifically targeted questionnaire. Additionally, OPs listed in the database of the SIML were also contacted by email and asked to respond to the same questionnaire via a Google form. In any case, voluntary and anonymous participation was assured by all the members of the SIML Working Group promoting the research program. Only those OPs actively

involved in occupational health activities in private or public enterprises, as stated by article 25 of the Italian Legislative Decree 81/2008 [8], were included in the study. No other exclusion criteria relative to socio-demographic and occupational features were applied.

2.2. Health Promotion Questionnaire

An exploratory questionnaire was developed by the Members of the SIML HP Working Group to collect information concerning the Italian OPs knowledge on HP and initiatives implemented to support the health and well-being of the workforce in different settings. It consisted in 28 items divided into multiple choices and open questions, that required at least 15 minutes to be completed. The questionnaire included a first section focused on the OP socio-demographic data, i.e., age, and regions of work, and the type of activity performed. This was aimed to explore the OP private or public operating sector, as well as the number and features of the enterprises in which they worked (i.e., economic sector, number of workers employed, occupational risks experienced). The HP knowledge was explored through questions concerning the experience that the individual OP had on the HP plans in companies, with respect also to the National and Regional initiatives, the role that these programs should have with respect to the occupational health and safety system, and the relevance of the employers as well as additional healthcare professionals and preventive figures in organizing and implementing such programs. The final section of the questionnaire was dedicated to investigating the engagement of the OPs in HP plans and their characteristics in terms of intervention targets, length of the programs, effectiveness, collaboration with other professionals involved in the health and safety at work, as well as formative needs for a more widespread development/implementation of the HP plans.

2.3. Statistical Analyses

Data are presented as frequency (percentages). The chi-square test for parametric distributions or Fisher's test for non-parametric distributions, as appropriate, were used to test for the difference among the specified groups in the questionnaire's responses. All analyses were performed using the statistical software R, version 4.0.3.

3. Results

3.1. Investigated Population

A total of 380 participants were enrolled; 164 OPs were enrolled during the national congress days, while the other 216 participated in the online survey. This seems a consistent sample with respect to the total number of SIML members (1900) and the number of members who declared to be directly employed as company OPs. The general characteristics of the investigated population are summarized in Table 1.

Males represented most of the sample (65%), and 64% of the participants had more than 50 years, with a different distribution of male and female subjects according to the diverse age groups (shown in supplementary material, p=<0.001): greater percentages of female OPs were ≤ 49 years (52%), while most of the male participants were in the ≥ 60 age group (53%). Of 380 respondents, 336 (88.4%) declared direct engagement in companies as OPs and completed the questionnaire.

Table 1. Sociodemographic characteristics of the population (N=380).

Study population	N	%
Gender		
Female	247	65.0
Male	133	35.0
Age		
< 30 years	10	2.6
30-39 years	65	17.1
40-49 years	62	16.3
50-59 years	87	22.9
>= 60 years	156	41.1
Area of Residence		
Northern Italy	191	50.5
Central Italy	108	28.6
Southern Italy	79	20.9

This number represents more than a half (57%) of the SIML OPs, and 7% of the Italian OPs (4652) who transmitted to the competent local services in 2022, the aggregated health and risk data of the workers subjected to health surveillance according to the article 40 of the Legislative Decree 81/2008, Annex 3B. Gender differences have been determined concerning the professional activity performed (p=0.006). A greater portion of female professionals (18%) declared to have not been directly engaged in companies as OP than the male ones (8.1%). About half were from Northern Italy, about 30% from Central Italy, and the remaining 20% from Southern Italy. Regions of residence included Lombardia (14.8%), Toscana (11.1%), Piemonte (10.3%), Lazio (9.3%), Campania, and Emilia Romagna (both 7.4%).

Table 2. Professional activity features of the investigated population.

Professional activity characteristics	N	%
Year of Profession's Beginning		
< 1996	106	34.0
1996-2005	104	33.3
2006-2015	53	17.0
> 2015	49	15.7
Area of Professional Activity		
Northern Italy	244	53.9
Central Italy	111	24.5
Southern Italy	98	21.6
Type of Professional Activity		
Freelance	224	66.9
Employee	56	16.7
Employee/consultant of a public facility affiliated with the employer	94	28.1
Employee/consultant of a private facility affiliated with the employer	41	12.2
Enterprises where OPs Perform Their Activity		
< 10 enterprises	145	43.7
10- 25 enterprises	53	16.0
26- 50 enterprises	43	13.0
>50 enterprises	91	27.3
Employees in Enterprises Where OPs a capo Perform Their Activity		
< 10 employees	44	13.2
11- 49 employees	107	32.0
50- 249 employees	63	18.9
>249 employees	120	35.9
Workers per OP		
< 50 workers	12	3.6
51- 100 workers	13	3.9
101- 500 workers	53	16.1
501- 1000 workers	62	18.8
1001- 1500 workers	30	9.1
>1500 workers	160	48.5
Economic Sector		
Agriculture, forestry and fishing	82	6.0
Mining from quarries and mines	20	1.5
Manufacturing activities	199	14.5
Supply of electricity, gas, steam	35	2.6
Water supply, sewerage networks, waste management	129	9.4
Construction	111	8.1
Wholesale and retail trade. car/ motorcycle repair	48	3.5
Transportation and storage	93	6.8
Accommodation and catering service activities	117	8.5
Information and communication services	41	3.0
Financial and insurance activities	40	2.9
Real estate activities	7	0.5
Professional, scientific and technical activities	38	2.8
Rental, travel agencies, business support services	10	0.7
Public administration and defense; compulsory social insurance	78	5.8
Instruction	75	5.5
Health and social assistance	152	11.1
Artistic, sports, entertainment activities	16	6.0
Other service activities	82	6.0

OP, occupational physician.

3.2. Professional Activity Characteristics

Professional features of the investigated population are reported in Table 2. Most participants (2/3) started their OP profession before 2005, while smaller portions started in the 2006-2015 period and after 2015. Freelancers characterized the majority of the enrolled population (66.87%). In line with the residence data, about half of OPs performed their professional activity in Northern Italy. Concerning the number of the followed companies, more than 40% performed their professional activity in less than 10 enterprises. More limited percentages were engaged with a greater number of companies.

As many as 27.4% were involved in more than 50 enterprises, respectively. A significant different gender related distribution (p=0.003) was determined with respect to the number of companies where the OP attended his/her professional activity (Table S2). A greater percentage of female OPs were engaged with less than 10 enterprises (57%) compared to the male ones (37%). Conversely, a lower percentage of females (6.5%) were employed in 26-50 enterprises compared to males (16%). In general, the companies where OPs worked were small (32.0% with 11-49 employees) or big ones (35.9% with > 249 employees).

More than half of the recruited OPs followed > 1000 workers. The most represented sectors were manufacturing activities, health, social work, water supply, sewerage, waste management, accommodation, food service activities, and the construction sector. Occupational risk factors were primarily the use of video display terminals, the manual handling of loads, biomechanical overload of upper extremities, chemical risk factors, and night shift work.

3.3. Health Promotion Approach

Occupational physicians were firstly asked about their opinion on the role of HP plans in occupational settings (Table 3).

They indicated that HP programs represent a social investment (34.5%), and a shared responsibility with all the figures involved in companies' preventive actions (30.2%). More limited percentages of

Table 3. Perception of HP among the investigated OP population.

HP perception	N	%
Definition best describing the aims of occupational HP programs?		
A moral duty towards workers	41	12.5
A shared responsibility with the prevention figures	99	30.2
An added value	63	19.2
A social investment	113	34.5
A regulatory obligation	12	3.7
Which of the following HP programs do you know?		
Total Worker Health (NIOSH - Centers for Disease Control and Prevention)	133	40.2
Healthy Workplaces (World Health Organization)	118	35.7
National Prevention Plan	185	55.9
Regional Prevention Plans	160	48.3
Other	10	3.0
None of the previous programs	54	16.3
Have you been involved in any of the HP interventions listed above?		
Yes	111	33.4
No	221	66.6

Table 3 (*Continued*)

HP perception	N	%
Degree of agreement with the following statements concerning HP:		
1. The enactment of Legislative D 81/08 increased occupational HP programs		
Do not agree at all	25	7.5
Disagree	89	26.6
Quiet agree	163	48.7
Very much agree	39	11.6
Totally agree	19	5.7
2. Occupational HP should be included in protocols aimed to protect workers' health		
Do not agree at all	2	0.6
Disagree	8	2.4
Quiet agree	66	19.6
Very much agree	138	41.1
Totally agree	122	36.1
3. Occupational HP programs should involve General Practitioners & other specialists		
Do not agree at all	3	0,9
Disagree	7	2,1
Quiet agree	92	27,4
Very much agree	136	41,0
Totally agree	98	29,2
Employers' interest in implementing HP programs is:		
Insufficient	27	8.1
Poor	113	33.7
Sufficient	108	32.2
Good	76	22.7
High	11	3.3

HP, health promotion.

the respondents declared HP was an added value for occupational health (19.2%), a moral duty towards the workforce (12.5%), or a regulatory obligation (3.7%). Concerning the OP knowledge regarding international, national or regional Italian initiatives on HP, about half of respondents declared to know the NPP of the Ministry of Health 2020-2025 (55.9%) and the Regional Prevention Plans 2020-2025 (48.3%). The TWH® proposed by the NIOSH and the Healthy Workplaces promoted by the WHO were known by the 40.2% and 35.7% of the OPs. However, only 33.4% had been involved in one of these interventions, without significant gender or age-based differences.

The Italian Legislative Decree n. 81, in 2008, among the OP mandatory duties (article 25), stated that the "OP collaborates in the implementation and valorization of voluntary programs of HP, according to the principles of social responsibility" [8]. In this perspective, the questionnaire included an item relative to the participants' agreement concerning a possible increase of HP programs following the issuance of the Decree mentioned above. A quiet agreement was expressed by 48.7% of the respondents about the effectiveness of such legislative intervention in increasing HP initiatives at the workplace, without gender-related differences, the number of workers employed in the enterprises where the OPs performed

their professional activity (≤ 49 vs. > 49 employees), the number of followed workers (≤ 500 vs. > 500 workers) or concerning be or not to be involved in organizing or collaborating to HP programs. Only 7.5% did not agree at all with this statement.

Additionally, almost all participants agreed on the fact that occupational HP programs should be intended as an integral part of the preventive and protective system aimed to ensure the psycho-physical health and safety of workers. There were no differences between males and females or depending on the number of workers employed in the enterprises where the OPs performed their professional activity, the total number of followed workers and the involvement as organizers or collaborators of HP initiatives. These plans should be supported by other healthcare professionals, such as general practitioners and specialists in other disciplines, as strongly agreed by 40% of the total respondents, without significant differences related to gender, the size of the companies, the number of followed workers or the direct engagement in HP plans as organizers or collaborators. OPs were asked about the interest expressed by employers, which was reported as insufficient by 41.8% of respondents, while most of the group (58.2%) considered it sufficient up to high. A different distribution was determined in such response between male and female professionals, as more female OPs (41%) reported a sufficient employers' interest compared to the 28% of the male subjects. Moreover, also a different distribution in the responses was determined for being or not being involved as organizers of HP plans ($p< 0.001$). Among OPs directly engaged in organizing HP initiatives, the percentage of those reporting at least a sufficient interest in employers was greater than those not involved in such activity (64.2% vs. 50.7%, respectively). No significant differences were reported for being involved in HP collaborations, the size of the enterprises, and the number of followed workers.

3.4. Participation in Health Promotion Plans

As regards the involvement of the OPs in HP programs at the workplace during the previous 5 years, 57.3% and 54.8% declared to have been involved as organizers or collaborators, respectively (Table 4).

A significantly different age-related distribution could be demonstrated in this item. The greatest percentages of OPs involved as organizers in such initiatives, in fact, were in the 40-49 (21%) and 50-59 (29%) aged groups, compared to those of a comparable age that did not organize HP strategies, 13% and 20%, respectively. Such differences failed to emerge when HP collaborative efforts were explored. Gender related discrepancies in organizing or collaborating to HP strategies were not demonstrated. When the organization of the HP plans was analyzed according to the characteristics of the OP activity, i.e., the number and size of companies in which they performed their activity, and the number of supervised workers, significantly different distributions of respondents could be determined. A greater proportion of professionals engaged in less than 25 companies, with medium-high dimensions (>49 workers) and following more than 500 workers was engaged in HP organization. Comparable results were obtained with respect to the collaboration in HP plans, with significant results obtained for OPs engaged in larger enterprises and with a greater number of followed workers.

In general, the organization of HP plans was supported by the employers (62.0%), the preventive and protective service of the company (60.5%), the human resource staff (45.1%), the workers' representative for safety (43.2%), the workers themselves (34.2%), as well as by the operators of the prevention departments of the local health authorities (20.7%). No significant differences in this regard emerged with respect to have been organizing or collaborating in HP plans, as well as with respect to the size of the companies where the OP activity was performed or the number of followed workers.

As declared by most of the participants (88.6%), the areas of intervention were oriented towards the promotion of healthy lifestyles, such as good nutrition, avoidance of voluptuary habits, physical activity promotion and sleep hygiene. Lower percentages of OPs were engaged in programs aimed to promote the workers' psychological well-being (37.1%), a comfortable working environment (24.2%), as well as a better home-work relationship (11.7%). The

Table 4. OP participation in HP plans.

Participation in HP plans	N	%
In the last 5 years, did you organize HP interventions?		
Yes	192	57.3
No	143	42.7
In the last 5 years, did you collaborate in HP interventions?		
Yes	183	54.8
No	151	45.2
What areas of intervention are your HP programs focused on?		
Promotion of "healthy" lifestyles (nutrition, voluptuary habits, physical activity, sleep hygiene)	234	54.8
Promotion of workers' psychological well-being	98	23.0
Promotion of a comfortable working environment	64	15.0
Promotion of a better home-work relationship	31	7.2
How long did the HP interventions last?		
A day or less	64	24.0
Some days	65	24.3
A few months	65	24.3
A few years, then interrupted	12	4.5
A few years and still ongoing	61	22.9
How do you evaluate the workers' participation?		
Insufficient	6	2.2
Poor	40	14.7
Sufficient	102	37.4
Good	105	38.4
High	20	7.3
How do you evaluate the HP interventions' effectiveness?		
Not effective at all	..	..
Not very effective	46	17.3
Quiet effective	174	65.5
Very effective	39	14.6
Completely effective	7	2.6
Have effectiveness indicators been adopted?		
Yes	180	66.7
No	48	17.8
I don't know	42	15.5
A prominent role in HP interventions was played by:		
Employer	165	23.3
Personnel/Human Resources Manager	120	17.0
Prevention and Protection Service	161	22.8
Workers' Safety Representative	115	16.3
Workers	91	12.8
Operators of the Department of Prevention	55	7.8

Table 4 (*Continued*)

Participation in HP plans	N	%
To implement occupational HP interventions, you suggest:		
Collaboration between different disciplines of the healthcare sector	222	72.1*
Information on the population to be targeted by the intervention	133	43.2*
Training of OPs on HP procedures	195	63.3*
Adequate funding	160	52.0*
Contractual provision of an economic recognition of the OP	104	33.8*
More time available	122	39.6*
Evaluation of the quality of HP programs	123	39.9*
Evaluation of the effectiveness of HP programs	174	56.5*

**Multiple choices account for the sum of percentages exceeding 100; HP, health promotion; OP, occupational physician.*

length of the HP interventions was of one day or less up to few days in 48.3% of cases and of some months in 24.3%. The programs that had a length of some years, were still ongoing at the time of the survey or were interrupted in the 22.9% and 4.5% of cases, respectively. In most cases (75.8%), OPs reported a sufficient or good voluntary participation of the workforce, without gender related differences, which was described as insufficient only by a limited percentage (2.2%) of the participants. When OPs were asked to indicate the percentage of the workforce that participated in such HP plans, 54.3% of them declared that more than a half of the company employees chase to take part into such interventions. As concerns the effectiveness of such initiatives, these were reported as quiet, very or completely effective in the 65.4%, 14.7% and 2.6% of the responses, respectively. A more limited percentage of responses described these interventions as not very effective (17.3%). Efficacy indicators were adopted in 66.7% of cases.

Another key issue explored by the questionnaire regarded the OPs perceived needs concerning the aspects that may be useful to implement the application of HP strategies in occupational settings. Among those, the collaboration between different healthcare disciplines was the most frequently reported (72.1%), followed by the specific training of OPs on HP procedures (63.3%) and the adoption of suitable methods of evaluation of the effectiveness of HP programs (56.5%). Additionally, adequate funding (52.0%), and appropriate information on the target population (43.2%), as well as a suitable quality assessment of the programs (39.9%) have been also indicated as useful means to promote their wider application. From the perspective of the OP involved in such initiatives, to have more time available (39.6%) and a contractual provision for a financial recognition of the HP required efforts (33.8%) could also represent a possible incentive to disseminate HP interventions.

4. Discussion

A healthy, safe, and productive working life is the essence of a modern and sustainable workplace [9]. In this view, key elements are improving the working environment and adopting different workplace HP initiatives to ensure the employees' well-being. The WHO prioritizes the workplace for promoting health and well-being [10]. Workplaces appear ideal for this purpose [11], providing access to a sizable segment of the adult population who spend many waking hours at work. In the United States, the Total Worker Health® program of the NIOSH sought to improve the workforce's well-being by protecting their safety and enhancing their health, motivation, and productivity. Although, in this scenario, "occupational health and safety," codified in regulations, encompasses efforts that prevent injury or illness due to workplace-specific risk factors by conducting safety training, environmental modification, and the provision of and use of collective and personal protective equipment, "health and wellbeing in the workplace" can be viewed as a broad concept comprised of personal satisfaction, work-life satisfaction, and general health [12, 13].

Many stakeholders can share an interest in HP in occupational settings ranging from employers and employees, OPs, various government departments, trade unions, universities, and organizations with a health-promoting focus. However, although essential in HP, the position and needs of OPs have still not been fully explored. In this perspective, the present study represents the first attempt to investigate the perceptions of a representative sample of Italian OPs concerning HP. Notably, while the retrieved findings are most applicable to the Italian-specific context, they may also have relevance for international settings, given the general applicability of the HP and the growing trend towards implementing health and wellbeing programs in the workplace.

In general, one-third of our investigated OP population intended HP as a social investment in workplaces, in line with the idea of the workplace as an optimal setting to support the promotion of the health of a large proportion of the working population and with the reported effectiveness of such initiatives at the community level [14, 15]. HP plans have been demonstrated effective in preventing and controlling chronic diseases, reducing the exit from the workforce and health care costs while increasing workplace productivity and promoting active aging of the employees [16]. Almost all the OPs agreed that HP programs should be considered an integral part of the workplace health and safety preventive and protective systems. In this view, a third of the respondents saw HP as a shared responsibility of all the preventive figures in the workplace. In some cases, the employers' interest was reported as insufficient, which may be because while the employer's responsibility regarding occupational health and safety is of evident importance and often legislated, the HP lines are somewhat blurred and discretionary about activities covered under the broader topic of health and wellbeing [12]. However, it seems important to note that OPs reporting at least a sufficient interest of the employers towards HP plans were also those most frequently engaged in organizing such initiatives, supporting the key role of all the workplace preventive figures' collaboration in successful HP strategies. In this view, it cannot be excluded that the OPs reporting an insufficient interest from the employers could be those who performed their activities in micro-small companies, where it was more challenging to carry out the HP plan because of limited resources, higher numbers of casual/part-time workers, and small numbers of permanent employees [11, 17]. In this setting, the contributing role of social parties and trade unions would be desirable to overcome such difficulties and favor a wide diffusion of HP policies and programs. Establishing collaborations with neighboring businesses and developing HP plans with local health authorities' support may be effective measures to create or implement joint HP programs, particularly in small and medium enterprises. Additionally, applying for grants or funding opportunities sponsored by charities or governmental organizations may help small companies implement HP initiatives.

The respondents strongly agreed upon an interdisciplinary approach to HP because this may help achieve a comprehensive approach to the initiatives' other health and wellbeing targets. These focused on healthy lifestyles and risk factors requiring expertise in different medical disciplines. Concerted action between different types of healthcare professionals, general practitioners, and hospital services is important to achieve effective HP interventions relying on existing resources, such as local health clinics, to provide health education and screenings that may positively impact the occupational and general health of the workforce.

Concerning the practical engagement in organizing or collaborating with HP plans, about half of our sample reported to have been directly involved, although a greater proportion of OPs in the 40-59 years of age declared to contribute to the organization of such programs. Interestingly, following a more limited number of companies, prevalently of medium-high dimensions and more than 500 workers were positively associated with a greater percentage of OPs participating in HP plans, owing to the cultural and economic difficulties encountered by the micro and small enterprises to implement such types of activities as detailed above. This further underlines the relevance of the contribution of all the preventive actors in the workplace, even if small, in creating suitable settings for HP, as also suggested by the figures indicated as supporters of HP plans by the interviewed OPs.

Generally, the promotion of healthy lifestyles was the target of HP interventions. Evidence exists that health risk behaviors, including smoking and alcohol use, have been reduced through HP activities at work [18-20] while physical activity and healthy eating have improved [18, 21-23]. In addition, HP positively influenced business outcomes, including reduced staff turnover and absenteeism [24]. Other potential intervention targets, such as the psychological well-being of the workforce, a comfortable occupational environment, and a better home-work interface, were less frequently addressed. These issues should be the focus of future research aimed at collecting a series of multi-targeted activities that may be specifically adapted to different occupational realities according to the peculiar conditions of work, occupational risk factors experienced, and features of the employees. Different workplace circumstances must be given consideration when designing initiatives and interventions.

In this perspective, although our OP sample reported generally good participation of workers in HP plans, such enlarged proposals might offer HP interventions to the overall company workforce, thus assuring social inclusion and equal access to the decision to participate in such activities. In order to further enlarge employees' HP participation, it could be helpful to utilize social media and other intelligent communication strategies to promote healthy behaviors and offer incentives for workers who attend health education events or engage in healthy behaviors. Workplaces could host health fairs or other community events promoting healthy behaviors and lifestyles to reach the community and the workforce.

Several factors influencing the implementation of HP programs have been identified. First, multiple contextual levels can determine OP participation in HP plans, from political to intra-personal, via inter-personal, institutional, and community/social factors. In exploring these levels, our survey pointed out that interdisciplinary collaboration, adequate training on HP procedures, and appropriate information on the targeted population is essential for OPs to engage in HP effectively. In this view, it might be essential to consider the inclusion of information and training on HP early in the productive career of the OPs to adequately develop an HP culture that they will be able to spread/share in the occupational settings where they will operate, training existing occupational medicine staff to become health ambassadors who can provide basic health information to their peers.

A suitable assessment of the quality and effectiveness of HP programs may provide incentives to implement such strategies further. A strategic HP initiative should be intended as a systematic process of needs analysis, priority setting, planning, implementation, and evaluation [25]. To this latter aim, it appears necessary to define health, psychological, social, administrative, and economic indicators of the effectiveness of the HP activities that may allow pointing out possible critical aspects and follow up obtained benefits. Additionally, funding sources can support the implementation of HP, but the OP perspective for gainful employment should also be considered for HP motivation. Moreover, while financial resources are often considered in HP program design and implementation, the OP time resource implications of scoping, planning, implementing, and participating are frequently ignored. They should be considered more explicitly and thoughtfully in the OP engagement in such strategies. Future research could be directed toward testing and quantifying these themes to advance understanding of the pathway to successful workplace health and wellbeing initiatives, programs, and policies. This would help improve the capacity of workplaces wanting to effectively implement healthy changes and generate information that more clearly explicates the drivers of this type of change. Overall, this seems in line with the strategic role of the OPs as recipients of the TWH approach and key figures in HP, as pointed out by the NPP 2020-2025. In this regard, formative initiatives should be specifically targeted to the OPs, as is in the purpose of the SIML, which is to organize a special session on HP for the next 85° National Congress. This may be helpful to inform OPs better, providing them with updated knowledge to become more confident on HP procedures and models to be applied in different occupational settings.

Even if preliminary, the obtained results sound relevant as they regard a significant portion of the

Italian OPs. Although the participants were enrolled among the members of a scientific society, and this may introduce a bias in the sample recruitment, the large number of respondents among those SIML members engaged in OP activities allowed us to point out some issues that may be considered representative of the global scenario of the Italian OPs. Moreover, the findings provide an initial figure of the approach, opinions, and needs of OPs concerning HP in the workplace. It may be interesting to implement such an initial cross-sectional analysis with future follow-up investigations to assess the influence of possible formative interventions, governmental proposals for HP, and longer occupational medicine experience on HP on the OP feedback.

5. Conclusions

The results of this study support the general interest of the Italian OPs for HP in workplaces. However, several issues still need to be addressed to assess the appropriateness of ongoing health and wellbeing initiatives and understand how to encourage the OP successful participation best. In this view, a multifaceted approach involving education about what workplace health and wellbeing encapsulates is warranted. Further, information on the potential benefits of promoting workplace health and well-being aligned with OP perceptions and needs seems necessary to successfully implement HP interventions.

Supplementary Materials: The following are available in the online version: Table S1: Age-related differences in questionnaire responses; Table S2: Gender related differences in questionnaire responses; Table S3: Differences in HP perception according to the number of the workers employed in the enterprises where the OPs performed their professional activity; Table S4: Differences in HP perception according to the number of workers followed by OPs; Table S5. Analyses of the differences with respect to have been organizing HP interventions; Table S6: Analyses of the differences with respect to have been collaborating in HP interventions.

Funding: This research received no external funding.

Acknowledgments: The Authors greatly thank dr. Daniela Pacella, dr. Dante Luigi Cioffi, dr. Maddalena Annarumma, and the Meneghini & Associati S.r.L. for their support in data collection, data management and analysis.

Declaration of Interest: The authors declare no conflict of interest.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023017
DOI: 10.23749/mdl.v114i2.14417

Health Promotion Interventions in Occupational Settings: Fact-Finding Survey Among Italian Occupational Physicians

Supplementary Materials

Table S1. Age related differences in questionnaire responses.

Age related differences	Number of responses	< 39 years, N = 75	40-49 years, N = 62	50-59 years, N = 87	=> 60 years, N = 156	p-value
Gender	380					**<0.001**
Female		43 (57%)	27 (44%)	38 (44%)	25 (16%)	
Male		32 (43%)	35 (56%)	49 (56%)	131 (84%)	
OP activity	380					**<0.001**
No		34 (45%)	3 (4.8%)	3 (3.4%)	4 (2.6%)	
Yes		41 (55%)	59 (95%)	84 (97%)	152 (97%)	
Following the enactment of Legislative Decree 81/2008 and subsequent amendments, occupational HP programs have increased	335					N.C.
Do not agree at all		3 (7.3%)	6 (10%)	6 (7.1%)	10 (6.6%)	
Disagree		6 (15%)	12 (20%)	23 (27%)	48 (32%)	
Quite agree		25 (61%)	31 (53%)	38 (45%)	69 (46%)	
Very much agree		4 (9.8%)	8 (14%)	13 (15%)	14 (9.3%)	
Totally agree		3 (7.3%)	2 (3.4%)	4 (4.8%)	10 (6.6%)	
Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	336					N.C.
Do not agree at all		0 (0%)	0 (0%)	2 (2.4%)	0 (0%)	
Disagree		1 (2.4%)	2 (3.4%)	2 (2.4%)	3 (2.0%)	
Quite agree		4 (9.8%)	9 (15%)	12 (14%)	41 (27%)	
Very much agree		16 (39%)	27 (46%)	36 (43%)	58 (38%)	
Totally agree		20 (49%)	21 (36%)	32 (38%)	50 (33%)	
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners, specialists in other disciplines)	336					N.C.
Do not agree at all		0 (0%)	1 (1.7%)	1 (1.2%)	1 (0.7%)	
Disagree		0 (0%)	3 (5.1%)	2 (2.4%)	2 (1.3%)	
Quite agree		11 (27%)	8 (14%)	20 (24%)	53 (35%)	
Very much agree		14 (34%)	25 (42%)	38 (45%)	59 (39%)	
Totally agree		16 (39%)	22 (37%)	23 (27%)	37 (24%)	

Based on your work experience, generally, the interest of employers in implementing health promotion programs is:	335					N.C.
Insufficient		2 (4.9%)	2 (3.4%)	10 (12%)	13 (8.6%)	
Poor		12 (29%)	18 (31%)	25 (30%)	58 (38%)	
Sufficient		17 (41%)	19 (32%)	26 (31%)	46 (30%)	
Good		9 (22%)	16 (27%)	19 (23%)	32 (21%)	
High		1 (2.4%)	4 (6.8%)	4 (4.8%)	2 (1.3%)	
In the last 5 years, during your work as OP, have you had the opportunity to organize health promotion interventions?	335					**0.020**
No		20 (49%)	19 (32%)	28 (33%)	76 (50%)	
Yes		21 (51%)	40 (68%)	56 (67%)	75 (50%)	
In the last 5 years, while carrying out the activity of OP, have you had the opportunity to collaborate in health promotion interventions?	334					0.562
No		17 (41%)	26 (44%)	34 (40%)	74 (49%)	
Yes		24 (59%)	33 (56%)	50 (60%)	76 (51%)	
How do you evaluate the workers' participation in such voluntary interventions?	274					N.C.
Insufficient		0 (0%)	1 (2.0%)	2 (2.6%)	3 (2.6%)	
Poor		1 (3.1%)	6 (12%)	16 (21%)	17 (15%)	
Sufficient		14 (44%)	15 (30%)	23 (30%)	50 (43%)	
Good		13 (41%)	22 (44%)	28 (37%)	42 (36%)	
High		4 (12%)	6 (12%)	7 (9.2%)	4 (3.4%)	
How do you evaluate the effectiveness of the HP interventions adopted?	267					N.C.
Not very effective		4 (12%)	3 (6.2%)	16 (22%)	23 (20%)	
Quite effective		20 (62%)	35 (73%)	40 (56%)	80 (70%)	
Very effective		7 (22%)	9 (19%)	12 (17%)	11 (9.6%)	
Completely effective		1 (3.1%)	1 (2.1%)	4 (5.6%)	1 (0.9%)	
Have effectiveness indicators been adopted (e.g. Key Performance Indicators – KPI)?	271					**0.025**
No		19 (59%)	29 (59%)	52 (71%)	81 (69%)	
I don't know		9 (28%)	4 (8.2%)	9 (12%)	20 (17%)	
Yes		4 (12%)	16 (33%)	12 (16%)	16 (14%)	

HP, health promotion; N.C, not calculable; OP, occupational physician.

Table S2. Gender related differences in in questionnaire responses.

Gender related differences	N	Female, N = 133	Male, N = 247	p-value
Age	380			**<0.001**
< 39 years		43 (32%)	32 (13%)	
40-49 years		27 (20%)	35 (14%)	
50-59 years		38 (29%)	49 (20%)	
=> 60 years		25 (19%)	131 (53%)	
OP activity	380			**0.006**
No		24 (18%)	20 (8.1%)	
Yes		109 (82%)	227 (92%)	
In how many companies are you currently appointed as OP?	332			**0.003**
< 10 enterprises		62 (57%)	83 (37%)	
10-25 enterprises		14 (13%)	39 (17%)	
26-50 enterprises		7 (6.5%)	36 (16%)	
> 50 enterprises		25 (23%)	66 (29%)	
Following the enactment of Legislative Decree 81/2008 and subsequent amendments, occupational HP programs have increased	335			0.218
Do not agree at all		7 (6.4%)	18 (8.0%)	
Disagree		21 (19%)	68 (30%)	
Quite agree		59 (54%)	104 (46%)	
Very much agree		16 (15%)	23 (10%)	
Totally agree		6 (5.5%)	13 (5.8%)	
Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	336			0.887
Do not agree at all		0 (0%)	2 (0.9%)	
Disagree		2 (1.8%)	6 (2.6%)	
Quite agree		19 (17%)	47 (21%)	
Very much agree		46 (42%)	91 (40%)	
Totally agree		42 (39%)	81 (36%)	
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners, specialists in other disciplines)	336			0.200
Do not agree at all		0 (0%)	3 (1.3%)	
Disagree		1 (0.9%)	6 (2.6%)	
Quite agree		23 (21%)	69 (30%)	

Very much agree		50 (46%)	86 (38%)	
Totally agree		35 (32%)	63 (28%)	
Based on your work experience, generally, the interest of employers in implementing health promotion programs is:	335			**0.026**
Insufficient		6 (5.6%)	21 (9.3%)	
Poor		27 (25%)	86 (38%)	
Sufficient		44 (41%)	64 (28%)	
Good		25 (23%)	51 (22%)	
High		6 (5.6%)	5 (2.2%)	
In the last 5 years, during your work as OP, have you had the opportunity to organize health promotion interventions?	335			0.159
No		53 (49%)	90 (40%)	
Yes		56 (51%)	136 (60%)	
In the last 5 years, while carrying out the activity of OP, have you had the opportunity to collaborate in health promotion interventions?	334			0.054
No		58 (53%)	93 (41%)	
Yes		51 (47%)	132 (59%)	
How do you evaluate the workers' participation in such voluntary interventions?	274			0.671
Insufficient		3 (3.5%)	3 (1.6%)	
Poor		10 (12%)	30 (16%)	
Sufficient		31 (36%)	71 (38%)	
Good		33 (39%)	72 (38%)	
High		8 (9.4%)	13 (6.9%)	
How do you evaluate the effectiveness of the HP interventions adopted?	267			0.634
Not very effective		12 (15%)	34 (18%)	
Quite effective		57 (71%)	118 (63%)	
Very effective		9 (11%)	30 (16%)	
Completely effective		2 (2.5%)	5 (2.7%)	
Have effectiveness indicators been adopted (e.g. Key Performance Indicators – KPI)?	271			0.439
No		52 (64%)	129 (68%)	
I don't know		16 (20%)	26 (14%)	
Yes		13 (16%)	35 (18%)	

HP, health promotion; OP, occupational physician.

Table S3. Differences in HP perception according to the number of the workers employed in the enterprises where the OPs performed their professional activity.

Degree of agreement with the following statements concerning HP:	N	Enterprises with >49 employees, N = 183	Enterprises with ≤ 49 employees , N = 146	p-value
Following the enactment of Legislative Decree 81/2008 and subsequent amendments. occupational HP programs have increased	328			0.087
Do not agree at all		13 (7.1%)	12 (8.2%)	
Disagree		38 (21%)	50 (34%)	
Quite agree		97 (53%)	63 (43%)	
Very much agree		22 (12%)	14 (9.6%)	
Totally agree		12 (6.6%)	7 (4.8%)	
Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	329			0.731
Do not agree at all		1 (0.5%)	1 (0.7%)	
Disagree		4 (2.2%)	4 (2.7%)	
Quite agree		33 (18%)	32 (22%)	
Very much agree		72 (39%)	61 (42%)	
Totally agree		73 (40%)	48 (33%)	
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners. specialists in other disciplines)	329			0.436
Do not agree at all		2 (1.1%)	1 (0.7%)	
Disagree		3 (1.6%)	4 (2.7%)	
Quite agree		43 (23%)	46 (32%)	
Very much agree		80 (44%)	53 (36%)	
Totally agree		55 (30%)	42 (29%)	
Based on your work experience, generally, the interest of employers in implementing HP programs is:	328			0.090
Insufficient		11 (6.0%)	15 (10%)	
Poor		56 (31%)	56 (39%)	
Sufficient		61 (33%)	47 (32%)	
Good		49 (27%)	23 (16%)	
High		6 (3.3%)	4 (2.8%)	

HP, health promotion.

Table S4. Differences in HP perception according to the number of workers followed by OPs.

Degree of agreement with the following statements concerning HP:	N	≤ 500 workers, N = 78	> 500 workers, N = 249	p-value
Following the enactment of Legislative Decree 81/2008 and subsequent amendments. occupational HP programs have increased	326			0.609
Do not agree at all		3 (3.8%)	22 (8.9%)	
Disagree		21 (27%)	65 (26%)	
Quite agree		39 (50%)	120 (48%)	
Very much agree		11 (14%)	26 (10%)	
Totally agree		4 (5.1%)	15 (6.0%)	
Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	327			0.740
Do not agree at all		0 (0%)	2 (0.8%)	
Disagree		2 (2.6%)	6 (2.4%)	
Quite agree		19 (24%)	45 (18%)	
Very much agree		31 (40%)	102 (41%)	
Totally agree		26 (33%)	94 (38%)	
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners. specialists in other disciplines)	327			0.155
Do not agree at all		0 (0%)	3 (1.2%)	
Disagree		0 (0%)	7 (2.8%)	
Quite agree		28 (36%)	61 (24%)	
Very much agree		26 (33%)	105 (42%)	
Totally agree		24 (31%)	73 (29%)	
Based on your work experience, generally, the interest of employers in implementing health promotion programs is:	326			0.252
Insufficient		4 (5.2%)	23 (9.2%)	
Poor		21 (27%)	87 (35%)	
Sufficient		28 (36%)	78 (31%)	
Good		23 (30%)	52 (21%)	
High		1 (1.3%)	9 (3.6%)	

HP, health promotion.

Table S5. Analyses of the differences with respect to have been organizing HP interventions.

	Number of responses	No, N = 143	Yes, N = 192	p-value
Gender	335			0.127
Female		53 (37%)	56 (29%)	
Male		90 (63%)	136 (71%)	
Age	335			**0.020**
< 39 years		20 (14%)	21 (11%)	
40-49 years		19 (13%)	40 (21%)	
50-59 years		28 (20%)	56 (29%)	
=> 60 years		76 (53%)	75 (39%)	
OP activity	335			
Yes		143 (100%)	192 (100%)	
In how many companies are you currently appointed as OP?	331			**0.043**
≤ 25 enterprises		75 (53%)	122 (64%)	
>25 enterprises		66 (47%)	68 (36%)	
Number of employees in the enterprises where the OPs performed their professional activity	328			**<0.001**
≤ 49 employees		57 (40%)	125 (67%)	
>49 employees		84 (60%)	62 (33%)	
Number of followed workers per OP	327			**<0.001**
≤500		47 (33%)	31 (17%)	
> 500		94 (67%)	155 (83%)	
Following the enactment of Legislative Decree 81/2008 and subsequent amendments, occupational HP programs have increased	334			0.164
Do not agree at all		14 (9.8%)	11 (5.8%)	
Disagree		45 (31%)	43 (23%)	
Quite agree		61 (43%)	102 (53%)	
Very much agree		15 (10%)	24 (13%)	
Totally agree		8 (5.6%)	11 (5.8%)	

Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	335			0.052
Do not agree at all		0 (0%)	2 (1.0%)	
Disagree		4 (2.8%)	4 (2.1%)	
Quite agree		38 (27%)	28 (15%)	
Very much agree		53 (37%)	84 (44%)	
Totally agree		48 (34%)	74 (39%)	
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners, specialists in other disciplines)	335			0.054
Do not agree at all		0 (0%)	3 (1.6%)	
Disagree		3 (2.1%)	4 (2.1%)	
Quite agree		47 (33%)	45 (23%)	
Very much agree		47 (33%)	88 (46%)	
Totally agree		46 (32%)	52 (27%)	
Based on your work experience, generally, the interest of employers in implementing HP programs is:	334			**<0.001**
Insufficient		17 (12%)	10 (5.2%)	
Poor		53 (37%)	59 (31%)	
Sufficient		51 (36%)	57 (30%)	
Good		20 (14%)	56 (29%)	
High		1 (0.7%)	10 (5.2%)	
In the last 5 years, during your work as OP, have you had the opportunity to collaborate to HP interventions?	333			**<0.001**
No		114 (80%)	37 (19%)	
Yes		28 (20%)	154 (81%)	
How do you evaluate the workers'participation in such voluntary interventions?	273			**<0.001**
Insufficient		6 (7.4%)	0 (0%)	
Poor		19 (23%)	21 (11%)	
Sufficient		35 (43%)	66 (34%)	
Good		19 (23%)	86 (45%)	
High		2 (2.5%)	19 (9.9%)	

Table S5 (*Continued*)

	Number of responses	No, N = 143	Yes, N = 192	p-value
How do you evaluate the effectiveness of the HP interventions adopted?	266			**<0.001**
Not effective at all		23 (30%)	23 (12%)	
Not very effective		51 (66%)	123 (65%)	
Quite effective		3 (3.9%)	36 (19%)	
Very effective		0 (0%)	7 (3.7%)	
Have effectiveness indicators been adopted (e.g. Key Performance Indicators – KPI)?	270			**0.001**
No		53 (67%)	127 (66%)	
I don't know		20 (25%)	22 (12%)	
Yes		6 (7.6%)	42 (22%)	

HP, health promotion; OP, occupational physician.

Table S6. Analyses of the differences with respect to have been collaborating in HP interventions.

	N	No, N = 143	Sì, N = 192	p-value
Gender	334			0.041
Female		58 (38%)	51 (28%)	
Male		93 (62%)	132 (72%)	
Age	334			0.562
< 39 years		17 (11%)	24 (13%)	
40-49 years		26 (17%)	33 (18%)	
50-59 years		34 (23%)	50 (27%)	
=> 60 years		74 (49%)	76 (42%)	
OP activity	334			
Yes		151 (100%)	183 (100%)	
In how many companies are you currently appointed as OP?	330			0.078
≤ 25 enterprises		81 (55%)	117 (64%)	
>25 enterprises		67 (45%)	65 (36%)	
Number of employees in the enterprises where the OPs performed their professional activity	327			**<0.001**
≤ 49 employees		65 (44%)	118 (66%)	
>49 employees		83 (56%)	61 (34%)	
Number of followed workers per OP	326			**<0.001**
≤500		53 (36%)	25 (14%)	
> 500		94 (64%)	154 (86%)	
Following the enactment of Legislative Decree 81/2008 and subsequent amendments, occupational HP programs have increased	333			0.453
Do not agree at all		13 (8.6%)	12 (6.6%)	
Disagree		42 (28%)	46 (25%)	
Quite agree		76 (50%)	86 (47%)	
Very much agree		14 (9.3%)	25 (14%)	
Totally agree		6 (4.0%)	13 (7.1%)	
Occupational HP programs should be understood as an integral part of a system for protecting workers' health and psycho-physical integrity	334			0.114
Do not agree at all		1 (0.7%)	1 (0.5%)	
Disagree		4 (2.6%)	4 (2.2%)	
Quite agree		38 (25%)	27 (15%)	
Very much agree		60 (40%)	76 (42%)	
Totally agree		48 (32%)	75 (41%)	

Table S6 (*Continued*)

	N	No, N = 143	Sì, N = 192	p-value
Occupational HP programs should be supported by collaboration with other health professionals (general practitioners, specialists in other disciplines)	334			0.190
Do not agree at all		0 (0%)	3 (1.6%)	
Disagree		3 (2.0%)	4 (2.2%)	
Quite agree		47 (31%)	43 (23%)	
Very much agree		54 (36%)	82 (45%)	
Totally agree		47 (31%)	51 (28%)	
Based on your work experience, generally, the interest of employers in implementing HP programs is:	333			0.058
Insufficient		18 (12%)	9 (4.9%)	
Poor		49 (33%)	63 (34%)	
Sufficient		52 (35%)	55 (30%)	
Good		28 (19%)	48 (26%)	
High		3 (2.0%)	8 (4.4%)	
In the last 5 years, during your work as OP, have you had the opportunity to organize HP interventions?	333			**<0.001**
No		114 (75%)	28 (15%)	
Yes		37 (25%)	154 (85%)	
How do you evaluate the workers' participation in such voluntary interventions?	273			**<0.001**
Insufficient		5 (5.6%)	1 (0.5%)	
Poor		21 (23%)	19 (10%)	
Sufficient		36 (40%)	65 (36%)	
Good		24 (27%)	81 (44%)	
High		4 (4.4%)	17 (9.3%)	
How do you evaluate the effectiveness of the HP interventions adopted?	266			**0.002**
Not very effective		25 (28%)	21 (12%)	
Quite effective		55 (62%)	119 (67%)	
Very effective		7 (8.0%)	32 (18%)	
Completely effective		1 (1.1%)	6 (3.4%)	
Have effectiveness indicators been adopted (e.g. Key Performance Indicators – KPI)?	270			**0.011**
No		67 (75%)	113 (62%)	
I don't know		15 (17%)	27 (15%)	
Yes		7 (7.9%)	41 (23%)	

HP, health promotion; OP, occupational physician.

La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023012
DOI: 10.23749/mdl.v114i2.13829

Differences in the Long-term Impact of the COVID-19 Pandemic on Mental Health and Professional Quality of Life of Resident and Specialist Physicians

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Keywords: COVID-19, Healthcare Workers; Mental Health; Professional Quality of Life; Burnout

Abstract

Background: *The COVID-19 pandemic created a challenging situation for healthcare workers (HCWs) worldwide. We aimed to compare the mental health and professional quality of life of residents and specialist physicians in a cohort of Italian HCWs caring for patients with COVID-19 about two years after the start of the COVID-19 pandemic.* **Methods:** *Between November 2021 and November 2022, an online survey investigating the emotional states of depression, anxiety, stress, compassion satisfaction, and compassion fatigue was administered to HCWs (N=78) at the Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome.* **Results:** *Our findings suggest that from 5 to 20% of our HCWs still showed the effects of the adverse psychological impact of the pandemic, and more than half experienced medium levels of compassion fatigue and a medium level of compassion satisfaction. Our results also show that those with fewer years of clinical practice might be at greater risk of burnout (p=0.021), anxiety, and stress symptoms (both p=0.027). In addition, they might develop a lower level of compassion satisfaction (p=0.018). Moreover, the factors that potentially contribute to poor mental health, compassion fatigue, and compassion satisfaction differ between residents and specialist physicians.* **Conclusions:** *This overview presents one of the first pictures of the long-term effects of the pandemic on the mental health and professional quality of life of an Italian sample of HCWs. Moreover, it also helps identify professionals who most need support and emphasizes the importance of improving these individuals' psychological and professional well-being, especially during a pandemic-like crisis with long-lasting effects.*

1. Introduction

From the beginning, the Coronavirus Disease (COVID-19) pandemic created a challenging situation for healthcare workers worldwide (HCWs) [1]. They had to face unpredicted changes in their work, such as lack of proper guidelines, more significant workload, physical tension, solitude and lack of social support, inadequate personal protective equipment (PPE), ethical concerns about the rationing

Received 18.10.2022 - Accepted 22.02.2023
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of treatments, and high-risk of infection [2-5]. This emergency also affected their physical and mental well-being [4-6]. On March 18, 2020, the WHO reported the psychosocial effects of the pandemic on the general population and in HCWs [1, 7]. Several studies also indicated that HCWs are particularly vulnerable to mental health issues resulting from the COVID-19 outbreak [8, 9]. For example, on May 14, 2020, a British Medical Association [10] survey showed that 45% of British UK doctors suffered from mental health problems related to or accentuated by the COVID-19 crisis.

Moreover, HCWs who were involved in handling the pandemic showed symptoms of stress and burnout [11]. Indeed, prolonged stress is a risk factor for developing burnout due to difficult working conditions and the personal characteristics of professionals [12]. In particular, stress related to the work context has been called compassion fatigue (CF) [4, 6]. CF has been described as physical and mental distress associated with the burden of helping [13]. It can lead to medical errors, deterioration of relationships with co-workers and patients, and low work satisfaction and quality of care [14, 15]. Recent studies have reported that HCWs responsible for patients whose outcome is potentially critical, such as those with COVID-19, seem at high risk of developing CF [16]. However, this issue received little attention during the pandemic. A few studies report medium CF levels during the first phase of the pandemic [4, 17].

However, COVID-19 also resulted in positive elements for HCWs (not just the burden of psychosocial issues), which need to be analyzed [4]. Indeed, during the pandemic, the public response toward HCWs was hot and seemed to be a critical positive reinforcement for them and led to a profound sense of self-efficacy [18, 19]. This positive side is called compassion satisfaction (CS), i.e., the gratification experienced by HCWs when performing their work accurately, in their relationships with colleagues, and when they perceive that their work has social worth [4]. During the COVID-19 pandemic, CS became a protective factor against developing CF [4]. Dosil et al. [17] reported that during the first phase of the pandemic, 90.6% of HCWs in Spain showed a high level of CS.

The equilibrium between CS and CF represents the level of professional quality of life [20], i.e., "the quality one feels concerning their work as a helper" [17]. Right from the beginning of the COVID-19 pandemic, Italy has been one of the countries most affected. This has had an enormous impact on the workload and mental health of HCWs [1], and several studies have investigated the psychological impact of the pandemic on these professionals.

One of these studies, i.e., De Sio et al. [1], reported a high prevalence of psychological distress (89%) and poor well-being (46%) in HCWs at the peak of the pandemic in Italy. Another study, i.e., Bettinsoli et al. [21], reported that almost 33.5% of HCWs in Italy showed psychiatric morbidity. Other studies also reported that HCWs working in COVID wards showed higher psychological issues than those working in non-COVID wards [22] and that they recognized that their current psychological well-being was worse during the COVID-19 emergency than before the outbreak [21-23]. However, Buselli et al. [4] reported that HCWS showed negative and positive psychological outcomes during the Italian lockdown. Indeed, they did not show significant levels of CF, and those who worked on the front line showed higher levels of CS.

Furthermore, there are reports in the recent literature that the significant burden of the pandemic on the National Healthcare system had a particularly negative effect on HCWs at an early career stage [24-26]. In fact, during the pandemic, residents had to deal with rescheduling clinical activities; suddenly, they found themselves with a central role in the care of COVID-19 patients, which adversely affected their psychological well-being [27-29]. Some studies report that resident doctors were at increased risk of burnout before the pandemic [30, 31] and showed more significant emotional distress, sleep disorders, depression, and anxiety during the COVID-19 emergency [32-34].

The scientific community has required high-quality data regarding the psychological impact of the COVID-19 pandemic across the whole population and on exposed groups such as HCWs [35]. Therefore, it is essential to investigate these aspects to understand better how to create a healthy, safe, and supportive work environment to ensure the mental health of HCWs [36].

To date, we need to summarize the large amount of data being reported on the mental health of HCWs. Also, few studies on this topic have been conducted in the European context, especially concerning resident doctors [17]. Additional follow-up studies seem necessary to understand the effects of the pandemic over time and on HCWs with different kinds and amounts of professional experience [1].

Thus, our study aimed to compare the mental health and professional quality of life of residents and specialist physicians in a cohort of HCWs in Central Southern Italy who cared for patients with COVID-19 about two years after the start of the COVID-19 pandemic and to analyze the factors potentially contributing to poor mental health, compassion fatigue, and compassion satisfaction in each group.

2. Methods

2.1. Participants

In November 2021, we conducted a cross-sectional survey in which we consecutively enrolled HCWs who treated COVID-19 patients at the Infectious Diseases Institute, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome. All participants were volunteers; they received no financial remuneration for their participation. In addition, we enrolled doctors (both residents and specialist physicians) who were treating patients with COVID-19. The institutional ethics committee approved the study, and all participants provided written informed consent before enrollment. We contacted participants using their institutional e-mail and enrolled subjects who consented to participate by replying to the e-mail. At this point, we have acquired informed consent and sent the link to the survey to be completed. All procedures performed in this study followed the institutional and national research committee's ethical standards, the 1964 Helsinki Declaration, and its later amendments or comparable ethical standards.

2.2. Procedure

Each participant completed an anonymous 65-item online survey. We collected information on sex, age range, commitment to a stable relationship, parenting, years of medical practice, and having been infected with COVID-19 during the pandemic. In addition, we gathered the following professional information related to the previous week: weekly working hours and weekly shifts that lasted more than 8 hours. We also collected a self-report judgment about increased work intensity after the outbreak of the pandemic (choosing yes or no as possible answers), perception of support from one's team in the workplace [using a Likert scale from 1 (no support) to 10 (great support)], concern about contracting COVID-19 and infecting family members [using a Likert scale from 1 (no concern) to 10 (extremely concerned)].

2.2.1. Professional Quality of Life Measure

To analyze the professional quality of life of our cohort of HCWs, we administered Stamm's [37] "Professional Quality of Life Scale" (ProQOL-5), which is often used with HCWs who are exposed to trauma and suffering. The ProQOL-5 is a 30-item self-report scale. Respondents assess how frequently they have experienced each work situation over the last 30 days on a Likert scale ranging from 1 (never) to 5 (very often).

The ProQOL-5 assesses two main areas: Compassion Satisfaction (CS) and Compassion Fatigue (CF); the latter is comprised of two subsets of symptoms: Burnout (BO) and secondary traumatic stress (STS), which is the additive effect of interaction with individuals who are going through a challenging emotional situation [38]. Therefore, higher scores on these scales indicate higher CS and CF (including BO and STS) values. Score ranges are also available for each category (low <22; medium: 23-41; high: >41) [38].

2.2.2. Mental Health Measure

The "Depression, Anxiety and Stress Scale" (DASS-21) was applied to measure Mental Health Status [39, 40]. The DASS-21 is a collection of three self-report scales that evaluate the emotional states of depression, anxiety, and stress. The first subscale (DASS-Depression) assesses lack of self-esteem/incentives and depressed mood. The second subscale (DASS-Anxiety) assesses fear and anticipation of

adverse events. The third subscale (DASS-Stress) assesses a persistent over-arousal condition and little frustration tolerance. Respondents assessed how often they had experienced symptoms of depression, anxiety, and stress during the past seven days on a Likert scale ranging from 0 (never) to 3 (almost always), where the higher score indicates more severe emotional distress. The subscales are scored as follows: normal (0-9), mild (10-12), moderate (13-20), severe (21-27), and extremely severe (28-42) for Depression; normal (0-6), mild (7-9), moderate (10-14), severe (15-19) and extremely severe (20-42) for Anxiety; and normal (0-10), mild (11-18), moderate (19-26), severe (27-34) and extremely severe (35-42) for Stress.

2.3. Statistical Analysis

Firstly, we tested the quantitative variables for normal distribution using Shapiro-Wilk Test, and all results were non-normally distributed. Descriptive statistics were computed for quantitative variables (median, interquartile range [IQR]) and qualitative variables (percent frequencies).

We compared the working and personal characteristics variables, the self-report measures, the three ProQOL subscales, and the DASS-21 scores of residents and specialist physicians. According to the nature of each variable, the comparison was performed using the $\chi 2$ test (or Fisher exact test when appropriate) or non-parametric test (Mann–Whitney U-test and Kruskal-Wallis test) due to the non-normality of the distributions.

Furthermore, we used the non-parametric test (Mann–Whitney U-test and Kruskal-Wallis test) to compare the three ProQOL subscales and the DASS-21 scores of the working and personal characteristics variables in each group (residents and specialist doctors) separately.

A two-tailed p-value of less than 0.05 was considered statistically significant. All analyses were performed using the SPSS version 21.0 software package (SPSS Inc., Chicago, IL).

3. Results

We enrolled 78 participants out of 100 subjects invited to participate through the institutional e-mail (response rate 78%); 42 (53.8%) were specialist physicians, and 36 (46.2%) were resident physicians. Complete demographic and professional characteristics are summarized in Table 1. The subjects in the two groups (specialist vs. resident physicians) differed significantly as to the percentage of subjects aged >35 years [p>0.001, 100% (n=42/42) vs. 11.1% (n=4/36)], committed to a stable relationship [p=0.016, 71.4%, (30/42) vs. 44.4% (16/36)] and having children [p=0.001, 71.4% (30/42) vs. 33.3% (n=12/36)].

All ProQOL-5 subscales (CS, BO, STS) and DASS-21 subscales (depression, anxiety, and stress) were non-normally distributed variables (p<0.001, p=0.001, p<0.001 and p=0.028, p<0.001, p=0.007, respectively). Also, the Likert scales regarding the self-report judgment about support from one's team in the workplace, concern about contracting COVID-19, and infecting family members emerged as non-normally distributed variables (all ps <0.001).

The mean concern about getting COVID-19 and infecting other family members was higher in resident physicians than specialist physicians (p< 0.001, 49.17 vs. 31.21 and p<0.001, 53.8 vs. 27.2, respectively). The mean support they perceived from their team in the workplace was lower in resident physicians than in specialist physicians (p=0.024, 33 vs. 44).

Regarding the DASS-21 scale, 25.6% (n=20), 5.1% (n=4), and 5.1% (n=4) of overall HCWs obtained a score that suggested the presence of mild to moderate levels of depression, anxiety, and stress, respectively; no participants scored in the "severe" or "extremely severe" range.

Regarding the ProQOL-5 subscales, most HCWs reported scores that suggested a medium level of CS (74.4%, n=58), BO (94.9%, n=74), and STS (61.5%, n= 48). No participant scored in the low range for CS or in the high range for BO and STS. Complete descriptive statistics of ProQOL-5 and DASS-21 item scales are shown in Table 2.

Specialist physicians obtained significantly higher mean scores on the CS subscale than resident physicians (p=0.018, 45 vs. 33). Furthermore, resident physicians reported significantly higher mean scores on the BO subscale than specialist physicians (p=0.021, 45 vs. 34).

Table 1. Demographic and professional characteristics of resident (N=36) and specialist HCWs (N=42).

	Resident HCWs	Specialist HCWs	
Variables	**N (%) or median (IQR)**	**N (%) or median (IQR)**	***p***
Sex			0.888
Male	16 (44.4)	18 (42.9)	
Female	20 (55.6)	24 (57.1)	
Age range, y			<0.001
<35	32 (88.9)	0 (0)	
35 or >35	4 (11.1)	42 (100)	
Commitment to a stable relationship			0.016
Yes	16 (44.4)	30 (71.4)	
No	20 (55.6)	12 (28.6)	
Children			0.001
Yes	24 (66.7)	30 (71.4)	
No	12 (33.3)	12 (28.6)	
Infected with COVID-19			0.771
Yes	6 (16.7)	6 (14.3)	
No	30 (83.3)	36 (85.7)	
Weekly working hours			0.389
25-40	12 (33.3)	18 (42.9)	
>40	24 (66.7)	24 (57.1)	
Weekly shifts >8 hours			0.528
Once/ twice	18 (50)	18 (42.9)	
3 or >3	18 (50)	24 (57.1)	
Support from one's team†, 0-10 scale	7 (6-8)	8 (7-8)	0.024
Concern about contracting COVID-19, 0-10 scale	6 (5-7)	3 (2-6)	<0.001
Concern about infecting family†, 0-10 scale	8 (8-10)	6 (4-8)	<0.001

Moreover, a significantly higher percentage of subjects in the residents' group obtained a score that suggested the existence of mild to moderate levels of anxiety and stress compared to specialist physicians [both ps= 0.027, 11.1% (n=4/36) vs. 0% (n=0/42)].

Considering the group of residents, HCWs with children obtained significantly higher mean scores on the CS (p=0.032, 23.8 vs. 15.8) and DASS-21 anxiety subscales (p<0.001, 28.5 vs. 13.5) compared to those who had no children. Moreover, HCWs committed to a stable relationship showed significantly higher mean scores for depression on the DASS-21 subscale [p=0.011, 23 vs. 14.5] compared to those not in a committed relationship.

Moreover, HCWs who obtained scores that suggested a medium level of BO and a mild to moderate range of anxiety reported lower support perceived from their team (p=0.008, 16.9 vs. 31 and p=0.012, 6.5 vs. 20, respectively) compared to those with a low level of BO and average levels of anxiety. Finally, HCWs with DASS-21 scale scores that corresponded to a mild to moderate range of depression and stress showed greater concern about getting COVID-19 (p=0.005, 27.5 vs. 15.93, and p=0.017, 30 vs. 17.06, respectively) and about infecting other family members (p=0.013, 26.5 vs. 16.21 and p=0.012, 30.5 vs. 17, respectively) compared to those with average levels.

Considering the group of specialist physicians, female HCWs obtained significantly higher mean

Table 2. Levels of Compassion Fatigue (Burnout and Secondary Traumatic Stress), Compassion Satisfaction, Depression, Anxiety, Stress, and Distress in the Study Population [resident (N=36) and specialist HCWs (N=42)].

	Resident HCWs	Specialist HCWs	
Variables	**N (%) o median (IQR) †**	**N (%) o median (IQR) †**	***p***
DASS-21 Depression Subscale†	7 (4-9)	7 (4-10)	0.809
Average (0-9)	28 (77.8)	30 (71.4)	
Mild (10-12)	2 (5.6)	12 (18.4)	
Moderate (13-20)	6 (17.7)	0 (0)	
Severe (21-27)	0 (0)	0 (0)	
Extremely Severe (28-42)	0 (0)	0 (0)	
DASS-21 Anxiety Subscale†	3 (1-4)	4 (2-4)	0.027
Average (0-6)	32 (88.9)	42 (100)	
Mild (7-9)	2 (5.6)	0 (0)	
Moderate (10-14)	2 (5.6)	0 (0)	
Severe (15-19)	0 (0)	0 (0)	
Extremely Severe (20-42)	0 (0)	0 (0)	
DASS-21 Stress Subscale†	8 (6-9)	7 (5-9)	0.027
Average (0-10)	32 (88.9)	42 (100)	
Mild (11-18)	4 (11.1)	0 (0)	
Moderate (19-26)	0 (0)	0 (0)	
Severe (27-34)	0 (0)	0 (0)	
Extremely Severe (35-42)	0 (0)	0 (0)	
ProQOL-5 BO Subscale†	28.5 (26-30)	24 (23-29)	0.021
Low (<22)	4 (11.1)	0 (0)	
Medium (23-41)	32 (88.9)	42 (100)	
High (>41)	0 (0)	0 (0)	
ProQOL-5 STS Subscale†	26.5 (19-30)	25 (20-27)	0.203
Low (<22)	12 (33.3)	18 (42.9)	
Medium (23-41)	24 (66.7)	24 (57.1)	
High (>41)	0 (0)	0 (0)	
ProQOL-5 CS Subscale†	34.5 (30-38)	41 (35-42)	0.021
Low (<22)	0 (0)	0 (0)	
Medium (23-41)	28 (77.8)	30 (71.4)	
High (>41)	8 (22.2)	12 (28.6)	

Abbreviations: N, number; IQR, interquartile range; DASS-21, Depression, Anxiety and Stress Scale; ProQOL-5, Professional Quality of Life Scale, BO burnout, STS secondary traumatic stress, CS compassion satisfaction.

scores than male HCWs on the BO and STS subscales (p=0.001, 26.75 vs. 14.5 and p<0.001, 29 vs. 11.5, respectively) and on the depression, anxiety, and stress DASS-21 subscales [p<0.001, 29.7 vs. 10.5, p<0.001, 30.5 vs. 9.5, and p>0.001, 29.7 vs. 10.5, respectively]. Moreover, female HCWs obtained lower mean scores on the CS subscale than males (p<0.001, 13.25 vs. 32.5).

Finally, HCWs with scores that suggested a medium level of CS and a mild to moderate range of depression showed greater concern about getting COVID-19 ($p=0.002$, 22.7 vs 18.5 and $p=0.011$, 29 vs. 18.5, respectively) and about infecting other family members ($p<0.001$, 29 vs 18.5 and $p<0.001$, 36.5 vs 15.5, respectively) compared to those with a high level of CS and average levels of depression.

4. Discussion

After the onset of the COVID-19 pandemic, many HCWs exhibited psychological distress and poor quality of life [41]. In addition, several studies have indicated the effects of some personal and work characteristics on their mental health and professional quality of life [42, 43].

As there is a need to recap the many data on the topic and are few scientific investigations available concerning resident doctors in the European context [17], our study aimed to explore better and compare the mental health and professional quality of the life of residents and specialist physicians in an Italian cohort of HCWs who were responsible for the care of patients with COVID-19 approximately two years after the start of the pandemic.

Our findings show that during this time frame, our cohort of HCWS experienced mild to moderate levels of depression (25.6%), anxiety and stress (both 5.1%), and medium levels of both compassion fatigue (BO 94.9% and STS 61.5%) and compassion satisfaction (74.4%).

The prevalence of psychological issues that emerged from our results is lower than that found in other Italian studies [22, 23]. However, these studies were related to an earlier time frame than ours, i.e., the pandemic's peak. Moreover, our less severe psychological outcomes may reflect the possible emotional issues of the 22% of invited subjects who did not complete the survey or a social desirability bias of those who participated.

However, our results seem to align with those of some earlier Italian studies. For example, Buselli et al. [4] reported that HCWs who faced the COVID-19 emergency simultaneously experienced negative and positive psychological consequences. Magnavita et al. [44] also reported the absence of extreme levels of compassion fatigue, probably because they were balanced by compassion satisfaction in this particular pandemic situation [17].

Furthermore, in China, there were reports of anxiety and depression peaks at the start of the outbreak that reduced with time from the outbreak [45].

Our results also show that resident physicians experienced more concern about getting COVID-19 and infecting other family members and lower support from their team in the workplace than specialist physicians. We also found that specialist physicians reported higher compassion satisfaction than resident physicians, whereas resident doctors experienced higher levels of burnout, anxiety, and stress symptoms than specialist physicians.

Many studies report similar results. First, Romiti et al. [32] argued that residents might be more vulnerable to the mental effects of COVID-19 because of the sudden escalation in their clinical responsibilities. Second, Huang et al. [46] also reported that younger professionals obtained significantly higher anxiety and depression scores, and other studies found higher resilience in HCWS who had been practicing longer [3, 48]. Third, less-experienced workers might be more easily affected by unexpected situations [42]. Moreover, Bozdag et al. [48] reported that those who have completed several years of professional practice are more resilient and readier to handle difficult situations. Fourth, Cai et al. [47] also suggested that younger HCWS were more concerned about their families as they were more likely to have young children and living parents. Finally, Dosil et al. [17] indicated that older professionals showed higher levels of compassion satisfaction due to their greater job security, which allowed them to enjoy helping patients more than their younger colleagues.

Our findings also show that HCWs with children experienced higher levels of compassion satisfaction and anxiety in the group of residents. Following our results, Bozdag et al. [48] indicated that psychological resilience decreases with more children.

Furthermore, we found that residents committed to a stable relationship suffered from higher levels of depression; this finding contrasts with previous data suggesting that a stable relationship might be a protective factor for good mental health in this

population [43], which might be explained at least in part by the quality of the couple's relationship. Although this was not the subject of our investigation, there is evidence that conditions created by COVID-19, such as isolation, separation, and the coexistence forced by the lockdown, increased the risks to the couple's relationship in terms of its quality and stability [50] and might have contributed to worsening relationship conflicts [51]. Thus, this factor is worthy of further investigation.

Our results also show that HCWs in the residents' group who perceived lower support from their team suffered from higher levels of burnout and anxiety. Sun et al. [52] identified team support as a protective factor for doctors' mental health, in line with our findings.

We also found that HCWs in both groups with more concern about infecting family members suffered from higher levels of depression and stress symptoms and lower levels of compassion satisfaction. Previous studies also reported this concern as one of the main stress factors [47] and a determinant of lowered psychological resilience [48].

Furthermore, we found that female specialist doctors reported more intense symptoms of burnout, secondary traumatic stress, depression, anxiety, and stress, and lower compassion satisfaction than males. Indeed, several international studies suggest that women are at higher risk for mental health issues such as depression, anxiety, and insomnia [47] and that males show higher psychological resilience [48]. This significant difference was also confirmed during the COVID-19 pandemic [17, 53-56].

Overall, our findings suggest that in our cohort of HCWs, those with fewer years of clinical practice needed particular care. Indeed, they might have been at greater risk of burnout, anxiety, and stress symptoms and might have had a lower level of compassion satisfaction. Moreover, the factors that potentially contribute to poor mental health, compassion fatigue, and compassion satisfaction seem to differ between residents and specialist physicians. For example, in the residents' group, those who seemed more vulnerable had children, were committed to a relationship, and felt less supported by their team. Finally, the women in the group of specialist doctors seemed the most prone to poor mental health and lower professional quality of life.

We acknowledge that our study has some limitations. First, this is a cross-sectional study, and unchecked biases can emerge in clinical routine. Thus, future longitudinal studies are necessary to check the validity of our findings. Second, because of the small sample size, our results should be cautiously assessed, and future studies with more subjects are needed to confirm our results. Indeed, based on a priori power analysis conducted in G-Power (for two-sample t-test, 0.05 significance level, a power of 0.80, a medium effect size (d=0.5), and one tail), the desired sample size would be 102 (51 in each group).

Furthermore, all of the subjects in our cohort were infectious disease specialists or residents and doctors who cared for COVID-19 patients. Future studies should include a more heterogeneous sample that includes doctors with other specialties who were not in charge of COVID-19 patients to obtain more complete results. Moreover, due to the anonymous nature of the survey, it was impossible to trace the year of specialization (lasting from 4 to 6 years in Italy) where the residents were, and thus the actual time they spent on pandemic management. Overall, the "seniority" of participants could generate a disparity between the two groups and within the residents' group. It is noteworthy that even if, hypothetically, a part of residents did not face the first wave of the pandemic and all the specialists did, residents still suffer from a higher level of burnout, anxiety, and stress than specialist physicians. In addition, our survey did not explore previous experiences during the pandemic, and we cannot describe the differences between the first and subsequent phases of the pandemic. Finally, a control group without HCWs is needed to strengthen and better understand our findings.

The present survey is a single-center study, and our data represent a specific cohort of HCWs in Central Southern Italy. It is well known that in Italy, there have been regional differences in the diffusion and burden of COVID-19 cases, especially during the first phase of the outbreak. Northern Regions recorded the highest hospitalization and admission rates to intensive care units (ICU) and

higher mortality rates than Southern ones due to socioeconomic and environmental factors and the management of the containment policy [57]. This heterogeneity affected the impact of the pandemic on HCWs' well-being. Furthermore, it is reported in the literature that HCWs from northern regions of Italy suffered from a higher burden of work-related symptoms [32]. Fondazione Policlinico Universitario A. Gemelli IRCCS has been one of the main reference centers in central Southern Italy in the fight against the pandemic since the beginning. On 16 March 2020, it was inaugurated the Columbus Covid 2 Hospital with the first 21 intensive care beds and with over 4,350 COVID-19 patients treated to date. On 21 April 2020, our center also opened Italy's first Day Hospital for post-COVID-19 check-ups and followed so far over 950 patients, receiving hundreds of new requests from all over Italy.

5. Conclusions

In conclusion, this study shows that almost two years after the outbreak of the COVID-19 pandemic, from 5 to 20% of an Italian cohort of HCWs still showed mild to moderate adverse psychological symptoms, and more than half of them experienced medium levels of compassion fatigue as well as a medium level of compassion satisfaction. Our results present a picture of the long-term effects of the pandemic on the mental health and professional quality of life of an Italian sample of HCWs.

Supporting the mental health of HCWs seems to be a crucial part of the public health response to the COVID-19 pandemic [58]. Indeed, the recent recommendations to optimize the professional well-being of HCWs could be separated into four main categories: "Social/structural support," "Work environment," "Communication/Information," and "Mental health support" [59]. For example, as proposed in previous studies, it seems important to promote compassion satisfaction among these professionals by adopting strategies to adequately manage sensitivity, empathy, and compassion to offset burnout and adverse psychological effects [2, 60-62]. Furthermore, recent studies have highlighted the need to develop resilience and its related skills [63], especially for workers who have leadership roles [64]. Higher levels of a negative emotional state seem to lower the psychological resilience level [39]. In addition, Morina et al. [65] underlined the usefulness of interventions based on cognitive behavioral therapy, i.e., psychoeducation, arousal reduction techniques, managing preoccupation, problem-solving skills, behavioral activation, and enhancement of meaningful activities. Moreover, most intervention programs proposed to date include psychosocial support, team training, and peer and institutional support [58].

Finally, this overview could help identify the professionals most in need of support. In addition, it highlights the importance of tailoring specific psychological interventions and creating a safe and supportive work environment to improve these individuals' psychological and professional well-being, especially during a pandemic-like crisis with effects that could persist for a long time.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Catholic University of Sacred Heart of Rome (ID 4302, 21st September 2021).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Declaration Of Interest: Alberto Borghetti received fee for advisory board by ViiV Healthcare, personal fee by Janssen Cilag. Simona Di Giambenedetto received speakers' honoraria and support for travel to meetings from Gilead, Janssen-Cilag (JC), Merck Sharp & Dohme (MSD) and ViiV Healthcare. Arturo Ciccullo received travel grants and congress' fee from ViiV Healthcare. All other authors: none to declare.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023021
DOI: 10.23749/mdl.v114i2.13903

Combined Effects of Noise and Hand-transmitted Vibration on Workers' Muscle and Mental Fatigues in a Simulated Construction Operation

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Keywords: Hand-transmitted Vibration; Noise; Combined Effects; Construction Destruction Tools

Abstract

Background: *The frequent use of hand-held vibrating tools by construction workers exposes them to hand-transmitted vibration (HTV) and noise. This study investigated the effect of combined exposure to HTV and noise on workers' fatigues under simulated work with a typical building destruction tool.* **Methods:** *The repeated measures study was conducted on 40 construction workers exposed to HTV (5 m/s2 rms with frequencies of 31.5, 63, and 125 Hz), HTV (10 m/s2 rms- 31.5 Hz), noise (90 dBA), and concurrent exposure (noise (90 dBA) + HTV (10 m/s2 rms- 31.5 Hz)) with the typical vibrating hand-held tool for 30 minutes. Electromyography signals determined each worker's fatigue level in the Flexor digitorum superficialis (FDS) muscle in two pre- and post-exposure periods. The subjects also filled out the visual analog scale to evaluate mental fatigue severity subjectively.* **Results:** *The mean difference of muscle fatigue parameters was significant in all scenarios except for the two scenarios of alone exposure to HTV (5 m/s2 -125 Hz) and noise exposure (p-value < 0.05). The mean difference of mental fatigue in all scenarios except for the two scenarios of exposure to HTV (5 m/s2 -125 Hz) and exposure to HTV (5 m/s2 -63 Hz) was significant (p-value < 0.05). The most differences in muscle fatigue parameters (Amplitude = 8.16±5.63, Mean frequency=-4.69±3.78) and mental fatigue (4.97±2.38) were observed in the simultaneous exposure to noise and HTV.* **Conclusion:** *Noise exposure alone cannot produce remarkable effects on muscle fatigue but can aggravate the effects of vibrations as a consequence of synergistic interaction. However, the role of noise on perceived mental fatigue was more dominant than the HTV. These findings should be considered to adapt the existing exposure limits to actual work conditions.*

1. Introduction

Electric or pneumatic vibrating hand-held tools are employed in many professions, such as repair operations, industrial production, and construction. Working in such vibration conditions for a long time may increase the hand-arm vibration syndrome (HAVS) risk. The prevalence of HAVS varies in

Received 05.11.2022 - Accepted 22.02.2023
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different countries; for example, 72,000 to 140,000 workers in Canada, 20,000 workers in the Netherlands, approximately 2,5 million workers in the United States, and 110,000 workers in Hong Kong are estimated to be exposed to hand-transmitted vibration (HTV) [1-3].

The construction industry is a leading and central pillar of the economy, which is expanding rapidly in many developed countries and cities. In this context, it is necessary to use construction machinery and vibrating tools such as jackhammers, grinding stones, screwdrivers, concrete vibrators, drills, and various cutting tools for different construction activities. When working with this type of vibrating tool, different acceleration levels of mechanical vibration are produced, and in this way, construction workers are exposed to HTV. As a result, it will be crucial to investigate the effects of HTV on construction workers; it is considered a severe occupational hazard for those who work with these vibrating tools. According to the nature of their job activities, construction workers need high physical and mental capacities to perform their tasks and must have good health and workability [1, 4, 5]. Besides vibration, exposure to noise pollution is one of the most critical factors affecting construction workers' health and abilities. Vibration sometimes intensifies noise and can even be the cause or source of noise production, as many vibrating tools are noisy. Co-exposure to vibration and noise may also occur during construction operations [4, 6].

HTV is a type of local vibration that involves the upper limbs; it causes vascular, sensory-neural, and musculoskeletal disorders collectively called hand-arm vibration syndrome [3, 7]. The neuromuscular responses, manifested in fatigue and muscle tension of upper limbs, are very significant in terms of the power to do the work. Widia et al. [8], Dewangan et al. [9], and Lai et al. [1] showed that vibration is transmitted from the handles to the hands, arms, and shoulders, causing the operator's discomfort and fatigue. In addition, due to the concurrent exposure of noise and vibration when working with these vibrating tools, noise can also create muscle tension. However, the studies showed that this issue has rarely been addressed objectively, and there are limited and contradictory studies in this field [10-12].

In addition to vibration intensity, direction, exposure time, and frequency, coupling forces and hand-arm posture can be identified as essential factors affecting muscle fatigue. Some studies investigated the effects of biodynamic factors such as coupling forces and hand-arm posture on the level of vibration transmission to the hands and its consequences. These factors are identified in Annex D of ISO 5349-1. Furthermore, the frequency content of the vibration influences the health risk caused by vibration, so some hand-held vibrating tools can generate significant vibrations at low frequencies and cause them to be transmitted to different areas of the body in the upper limbs, including arms, shoulders, back, neck, and even head [13-15]. As a result, the HTV frequency and vibration intensity can affect muscle responses and mental fatigue.

Studies have recommended that these biodynamic factors be considered when assessing workers' potential risk of disorders. However, the role of noise as one of the main physical factors in creating effects caused by simultaneous exposure to vibration has still not been clarified. It is observed that noise and HTV in many jobs with vibrating hand-held tools occur simultaneously and inseparably. Therefore, the exposure risk assessment should not be considered one-dimensionally and separately. Few studies investigated the effects of concurrent exposure to noise and HTV on different aspects of fatigue. As a result, the present study investigates the effect of HTV intensity and frequency on fatigue. It also deals with the effect of concurrent exposure to noise and HTV on construction industry workers' muscle and mental fatigue.

2. Methods

2.1 Subjects

The repeated measures study was experimentally conducted on 40 volunteer construction workers who had experience working with manual vibrating demolition tools. The inclusion criteria were having at least one year of experience working with vibrating tools; having the age range of 25-35 years; not having discomfort and MSDs in the upper limbs (neck, shoulder, arm, elbow, wrist, etc.); not

suffering from cardiovascular diseases, not suffering from respiratory and neurological disorders; not suffering from immunodeficiency diseases; having good general health (investigated through the General Health Questionnaire – 28 (GHQ-28) [16, 17] with a total score of less than 23; having no noise sensitivity (checked through the Weinstein Noise Sensitivity Scale (WNSS) [18] with a score of less than 75; having no record of drug abuse, smoking, and alcohol, not drinking liquids containing caffeine on the test days; having no record of taking cardiac drugs, anti-depressants, sedatives, and muscle drugs at least in the last month; having normal hearing and vision; and having no sleep disorders. The research team examined these inclusion criteria through self-reports and standard questionnaires. An invited specialist measured the worker's hearing and vision abilities. This study protocol has been confirmed by the Ethics Committee of Hamadan University of Medical Sciences (ethics code: IR.UMSHA.REC.1400.657), and the workers who met the inclusion criteria signed informed consent before participating in the study.

2.2 Exposure Condition Simulations

All the experiments were carried out in the environmental physiology laboratory of the Occupational Health Department of Hamadan University of Medical Sciences. Illuminance measurement was done with the Hagner Digital Luxmeter, model EC1, based on measuring the work surface's general height and 6 IES patterns and showed the illumination intensity within the permissible limits of the occupational exposure standard (300 lux). In addition, the laboratory air temperature and humidity were measured on different days using Casella Microtherm Heat Stress WBGT: the dry air temperature was controlled and fixed in the range of 22.1-23°C with an average of 22.5 °C, and relative humidity in the range of 50-53.7% with an average of 51.4%.

This experimental study was conducted on construction workers who were exposed to HTV (5 m/s2 rms -125 HZ), HTV (5 m/s2 rms- 63 HZ), HTV(5 m/s2 rms -31.5 HZ), HTV(10 m/s2 rms -31.5 HZ), noise (90 dBA) and concurrent exposure [HTV(10 m/s2 rms -31.5 HZ) + noise 90 dBA] to them for 30 minutes for six sessions under simulated work with building vibrating demolition tools. It should be noted that the exposures consisted of 6 exposure periods of 5 minutes. A one-minute interval was considered between each exposure period (5 rest periods).

Based on the pre-test field measurements among real construction sites, the vibration and noise values were selected to correspond to typical electric demolition jackhammers' noise and vibration content. The field data showed that during the destruction of the building floor employing the current medium-weighted jackhammers, most workers were exposed to the vibration and noise of 10 m/s2 and 90 dBA. Therefore, three considered scenarios as HTV (10 m/s2 rms -31.5 HZ), noise (90 dBA), and concurrent exposure (HTV(10 m/s2 rms -31.5 HZ) + noise 90 dBA) were selected based on field measurements. It should be noted that the ACGIH-TLVs were also considered to design other exposure scenarios [19]. An electrodynamic shaker induced the HTV with two handles and an amplifier connected to Lab VIEW (2018) with the ability to adjust the different intensities and frequencies of the vibration in this system. The capacity of this electrodynamic shaker was 500 newtons. It could produce different vibration accelerations in the 1-500 Hz frequency range. Furthermore, it could be adjusted and rotated at different angles to simulate the real workstation accurately. This study simulated working with jackhammers to demolish the building floor as an everyday activity, and a dynamometer measured and displayed the push force with an accuracy of 0.2 kg. The amount of vibration reached by the participants' hands was measured by SVANTEK hand-arm accelerometer connected to SV 106 6-channel vibration meters according to ISO 5349 standard [20] in three x, y, and z axes. As mentioned, the participants were exposed to 31.5, 63, and 125 Hz vibrations with a weighted equivalent acceleration of 5 m/s2 rms and 31.5 Hz vibration with a weighted equivalent acceleration of 10 m/s2 rms for 30 minutes along the arms of both hands (predominantly on the z-axis). The vibration spectrums at two acceleration levels (both unweighted and weighted) according to the international standard

Table 1. The vibration spectrums at two acceleration levels for simulating the exposure scenarios.

Exposure scenario	Acceleration (m/s^2, rms)	Frequency (Hz)									
		4	8	16	31.5	63	125	250	500	1000	Total
HTV ($5\ m/s^2$ rms -125 Hz)	***ahi(Z)***	0.016	0.018	0.03	0.092	0.203	32.23	18	0.628	0.206	36.92
	ahw(Z)	0.006	0.015	0.026	0.047	0.051	4.093	1.141	0.019	0.002	4.25
	ahi(y)	0.017	0.019	0.025	0.05	0.059	13.60	4.35	0.197	0.187	14.29
	ahw(y)	0.006	0.016	0.022	0.025	0.015	1.727	0.275	0.006	0.002	1.75
	ahi(x)	0.022	0.029	0.043	0.063	0.153	15.29	5.16	0.343	0.324	16.14
	ahw(x)	0.008	0.025	0.038	0.032	0.039	1.941	0.327	0.01	0.004	1.97
HTV ($5\ m/s^2$ rms -63 Hz)	***ahi(Z)***	0.022	0.025	0.027	0.033	16.65	4.05	3.47	0.279	0.179	17.49
	ahw(Z)	0.008	0.021	0.024	0.017	4.263	0.514	0.219	0.008	0.002	4.3
	ahi(y)	0.021	0.023	0.025	0.04	7.816	2.24	1.89	0.217	0.193	8.2
	ahw(y)	0.007	0.02	0.022	0.02	2.001	0.284	0.119	0.068	0.026	1.45
	ahi(x)	0.02	0.03	0.041	0.06	8.034	3.15	2.04	0.257	0.323	8.88
	ahw(x)	0.007	0.026	0.036	0.031	2.056	0.4	0.129	0.008	0.004	2.1
HTV ($5\ m/s^2$ rms -31.5 Hz)	***ahi(Z)***	0.199	0.232	0.025	8.307	2.07	0.523	0.667	0.151	0.191	8.62
	ahw(Z)	0.074	0.202	0.022	4.311	0.529	0.066	0.042	0.004	0.002	4.35
	ahi(y)	0.014	0.017	0.022	3.7	0.589	0.107	0.131	0.161	0.19	3.76
	ahw(y)	0.005	0.014	0.019	1.92	0.15	0.013	0.008	0.005	0.002	1.44
	ahi(x)	0.021	0.032	0.042	3.866	0.399	0.221	0.187	0.233	0.323	3.92
	ahw(x)	0.007	0.027	0.037	2.006	0.102	0.028	0.011	0.007	0.004	2.01
HTV ($10m/s^2$ rms -31.5 Hz)	***ahi(Z)***	0.037	0.043	0.047	15.01	4.02	0.986	1.14	0.284	0.358	15.62
	ahw(Z)	0.013	0.037	0.042	7.79	1.029	0.125	0.072	0.008	0.004	7.86
	ahi(y)	0.026	0.034	0.038	7.07	3.02	0.421	0.516	0.299	0.353	7.73
	ahw(y)	0.009	0.029	0.034	3.671	0.773	0.053	0.032	0.009	0.004	3.76
	ahi(x)	0.041	0.049	0.078	9.408	2.3	0.43	0.366	0.454	0.629	9.74
	ahw(x)	0.015	0.034	0.062	4.883	0.593	0.054	0.023	0.014	0.008	4.92

a_{hi}: Unweighted acceleration (m/s^2, rms), a_{hw}: Frequency-weighted acceleration (m/s^2, rms).

ISO 5349 [20] used to simulate the exposure scenarios are displayed in Table 1.

For noise exposure scenario, the participants were exposed to the recorded noise of a typical electric demolition jackhammer with equivalent noise level of 90 dBA. The noise was played by an OS003-BSWA spherical speaker and a BSWA audio amplifier SWA-100 connected to a laptop and was located at a distance of one meter from the participants. Their noise exposure was monitored by SVANTEK 971 Sound Level Meter and by installing SVANTEK 104 dosimeter on the participants' collars.

2.3 Experimental Procedure

The study used a within-subjects design, where all subjects were considered as their controls. A repeated-measures design was conducted, and the participants randomly received HTV exposure, noise exposure, and concurrent exposure for 30 minutes in six days with a minimum interval of 24 hours. The participants' postures in the case of different exposure scenarios are shown in Figure 1. The device's height was adjusted according to the participants' heights using wooden and concrete cubes of a specific size. It should be noted that the subjects' natural body and

Figure 1. Experimental setup for simulating exposure to HTV and/or noise.

hand postures as the fixed main biodynamic factor corresponded to the observed real workstation during the destruction of building floors in all exposure scenarios, as shown in Figure 1.

50 N push forces are average hand forces applied in many tool operations. Therefore, the current study also controlled the push forces at 50±8 N.

The participants held the vibrating tool handle with a standard grip (20% of their maximum voluntary contraction power), similar to the recommendation of some references such as ISO 10819 [21-24]. The push forces were monitored and displayed on two virtual dial gauges on two digital monitors in front of the subject, as shown in Figure 1.

During exposure to HTV, the participants wore hearing protection devices (ear muffs). Measurement of noise by the SVANTEK 102 noise dosimeter showed that the background noise during exposure to HTV without hearing protection devices was 64 dBA and reduced up to 52 dBA using the approved ear muffs. Before starting each test, the participants rested for 15 minutes in the calm conditions of the test chamber. Generally speaking, the participants' exposure includes six 5-minute consecutive episodes with 1-minute silence (rest) periods between scenarios. Furthermore, the results can be different on different days and hours. Therefore, participants were compared and checked with their baselines.

For each scenario, electromyographic activity (EMG) of the Flexor digitorum superficialis (FDS) muscle and the perceived mental fatigues of subjects were measured in two periods, pre- and post-exposure.

2.4 Subjective Measurement of Mental and Muscle Fatigues

The visual analog scale to evaluate fatigue severity (VAS-F) [with 10 points (0=no fatigue and 10 = maximum fatigue)] was employed to measure mental fatigue subjectively. Subjects were asked to score their level of mental fatigue from 0 to 10, according to Figure 2 [25, 26].

The current study also used a body map to select muscles to check muscle fatigue. Before starting the laboratory phase of the study in the investigated work environment, 60 workers were asked, when working with manual vibrating demolition tools, which area of the upper limbs indicated in Figure 3 do they feel the most fatigue or pain.

In this way, the subjective evaluation of muscle fatigue was done, and the greatest frequency of fatigue or pain reported among these 60 workers was position number 5, with a frequency of 25 workers, which is related to forearm/elbow muscles. Besides, studies have shown that the flexor digitorum superficialis (FDS) muscle, located in the anterior part of the forearm, plays an essential role in maintaining the position of the forearm, holding and carrying objects, and gripping and bending the fingers. Therefore, the proper functioning of this muscle in working with hand tools seems necessary to do the job correctly and prevent safety-related consequences [10, 25, 26]. Hence, using the EMG method, the FDS muscle was chosen to investigate objective fatigue.

2.5 EMG Method

Electromyography (EMG) reveals the electrical potential muscle cells produce when these cells are electrically or neurally activated. In the current study, using a Nexus-4 device with a sampling rate of 2048/sec and a bandwidth of 10-500Hz, the FDS muscle signal was recorded for 2 minutes in pre-and

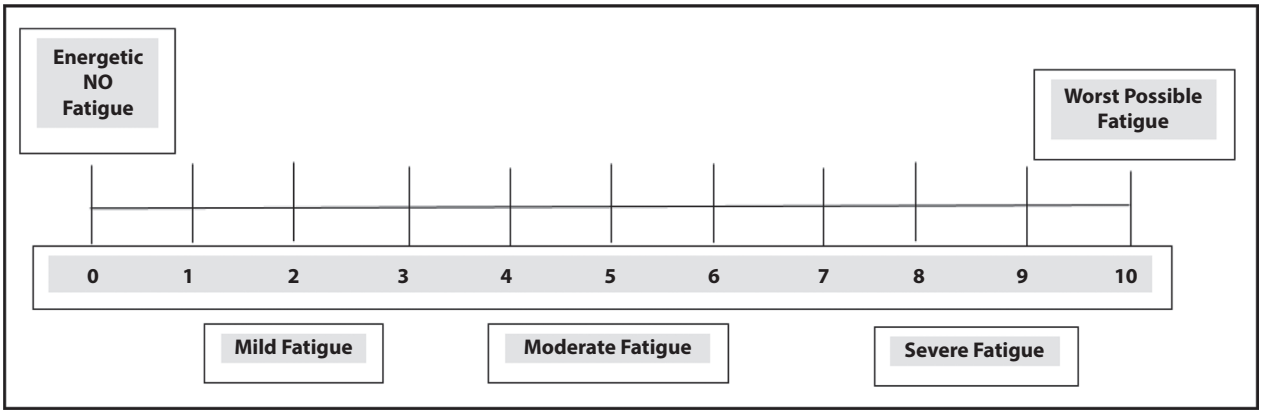

Figure 2. The visual analogue scale to evaluate fatigue severity (VAS-F).

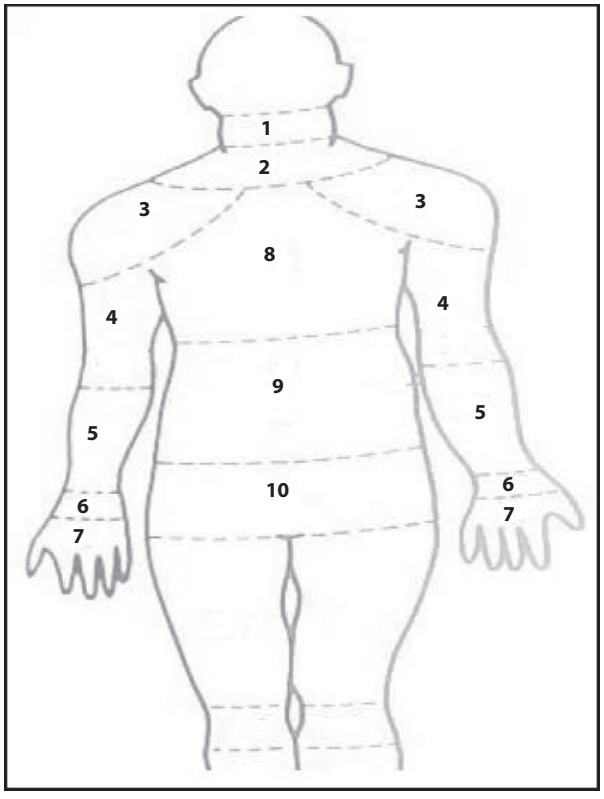

Figure 3. Body map for subjective measurement of muscle fatigue.

post-exposure periods while the subject was sitting on a chair with an average body position (straight back, the appropriate height of the chair with 90-degree knee angle and soles of feet on the floor).

Electrode placement and noise control were done based on the guidelines of the Surface EMG for Non-Invasive assessment of Muscles (SENIANM) convention. To reduce skin resistance, the sites to place the electrodes were cleaned by removing excess hair and rubbing it with alcohol. Next, the electrodes were placed parallel to the direction of the muscle fibers and at a distance of 2 cm (center to center) from each other on the protrusion of the muscle center and in the middle distance of the medial epicondyle (half the distance between the medial epicondyle of the humerus and the ulnar styloid process) [10, 27]. Figure 4 displays the sites of the electrodes on the muscle and the reference electrode. The recorded signals were checked and analyzed by BioTrace+ Software. Finally, the Joint Analysis of Spectrum and Amplitude (JASA) method was used to identify muscle fatigue. This method checks the amplitude of a signal and spectrum changes and analyzes simultaneously. In the current study, Root Mean Square (RMS) considered the amplitude modulation index and mean frequency to measure the EMG signal spectrum. Accordingly, the increase in the amplitude simultaneous to the decrease in the frequency spectrum is a sign of fatigue in the desired muscle [28].

2.6 Statistical Analysis

IBM SPSS Statistics 25 was employed for data analysis. Concerning the normal distribution of the data, the paired sample t-test was used to compare the mean scores in the pre-and post-exposure periods. Repeated-measures ANOVA was used to compare

Figure 4. Sites of electrode placement on FDS muscle and reference electrode.

the mean difference in different exposure scenarios. Pearson's correlation was used to determine the association between EMG parameters and mental fatigue. A p-value less than 0.05 was statistically established as the limit for statistical significance.

3. Results

The mean and standard deviation of age, work experience, height, and weight of the workers who participated in the current study were 30.52±3.53(year), 3.75±1.82(year), 1.77±0.06(m), 72.37±7.28(kg), respectively. In addition, the general health score and noise sensitivity score of the subjects were also 16.22±4.05 and 53.55±14.65, respectively.

The mean difference and standard deviation of EMG parameters in the pre-and post-exposure periods in all exposure scenarios are shown in Table 2. A relative increase in amplitude and a relative decrease in the frequency of the post-exposure were observed in the recorded EMG waves for all scenarios except the HTV (5 m/s2 rms -125 Hz). A comparison of the difference of means for pre- and post-exposure periods did not show a significant difference for EMG parameters in two scenarios of exposure to noise exposure scenario and HTV (5 m/s2 rms -125 Hz) scenario. However, these changes were significant in the other four scenarios (p-value < 0.05). The most changes in pre-and post-exposure periods were also observed for the concurrent exposure to HTV and noise scenario.

The changes in the mean and standard deviation of mental fatigue in the pre-and post-exposure periods in the six scenarios are shown in Table 3.

The paired t-test results showed that the mean changes for the HTV (5 m/s^2 rms -125 Hz) and (5 m/s^2 rms -63 Hz) scenarios are not significant in the before- and after-exposure periods while it is significant in the other four scenarios (p-value <0.05). The most of the mean difference was also observed in the concurrent exposure to HTV and noise scenario.

This study employed repeated measures ANOVA to investigate the mean difference between EMG parameters and mental fatigue in different exposure scenarios. The results showed that the mean difference between EMG parameters and mental fatigue in different exposure scenarios had a significant difference (p-value<0.05).

The results of the LSD follow-up test and the effect size of each exposure scenario on mental fatigue scores and EMG parameters are shown in Table 4. The results showed that concurrent exposure to HTV and noise had the most significant effect on changes in the amplitude, frequency, and mental fatigue of the studied subjects, with an effect size of 0.683, 0.612 and 0.818, respectively.

As shown in Table 4, based on the estimated effect sizes, the effect of exposure to HTV on muscle fatigue was stronger than noise. However, in combined exposure, noise has increased the dominant effect of HTV on muscle fatigue. The effect of noise on mental fatigue was greater than that of HTV. However, in combined exposure, vibration has increased the dominant effect of noise on mental fatigue. It is observed that the low-frequency HTV (5 m/s^2 rms -31.5 Hz) showed a more significant effect on muscle and mental fatigue than

Table 2. The mean difference of EMG waves amplitude and frequency in all exposure scenarios.

Exposure scenario	Variables	Mean difference ± SD	P-Value
HTV (5 m/s^2 rms -125 Hz)	Amplitude (μv rms)	0.3±2.69	0.478
	Mean frequency (Hz)	0.12±2.67	0.761
HTV (5 m/s^2 rms -63 Hz)	Amplitude (μv rms)	1.28±3.53	0.027
	Mean frequency (Hz)	-0.89±2.79	0.049
HTV (5 m/s^2 rms -31.5 Hz)	Amplitude (μv rms)	2.17±3.87	0.001
	Mean frequency (Hz)	-1.78±3.02	0.001
HTV (10 m/s^2 rms -31.5 Hz)	Amplitude (μv rms)	5.43±4.83	<0.001
	Mean frequency (Hz)	-2.62±3.56	<0.001
Noise (90dBA)	Amplitude (μv rms)	0.489±2.23	0.173
	Mean frequency (Hz)	-0.56±1.68	0.039
Noise (90dBA) + HTV (10 m/s^2 rms -31.5 Hz)	Amplitude (μv rms)	8.16±5.63	<0.001
	Mean frequency (Hz)	-4.69±3.78	<0.001

Table 3. The mean and standard deviation of mental fatigue score for pre-and post-exposure.

	Mean scores±SD			
Exposure scenarios	**Pre-exposure**	**Post-exposure**	**Mean difference ±SD**	**P-Value**
HTV (5 m/s^2 rms -125 Hz)	1.42±0.95	1.50±1.13	0.08±0.85	0.584
HTV (5 m/s^2 rms-63 Hz)	1.72±0.98	2.07±1.38	0.35±1.12	0.056
HTV (5 m/s^2 rms-31.5 Hz)	1.45±0.95	2.67±1.45	1.22±1.34	<0.001
HTV (10 m/s^2 rms-31.5 Hz)	1.25±0.83	3.27±1.35	2.02±1.44	<0.001
Noise (90dBA)	1.4±1.05	4.72±1.53	3.32±1.80	<0.001
Noise (90dBA) + HTV (10 m/s^2 rms-31.5 Hz)	1.30±1.34	6.27±1.92	4.97±2.38	<0.001

high-frequency HTV (5 m/s^2 rms -63 Hz and 125 Hz). This study also showed that for four HTV (5 m/s^2 rms -63 Hz), HTV (5 m/s^2 rms - 31.5 Hz), HTV (10 m/s^2 rms -31.5 Hz), and concurrent exposure scenarios, a significant correlation was observed between subjective and objective fatigue responses (p-value<0.05). The results of the Pearson correlation between EMG records and mental fatigue are displayed in Table 5.

4. Discussion

Given the nonlinear nature of the hand–arm vibration responses, this study is thus aimed to investigate the effects of the noise under varying levels of vibration excitation and spectrums. Based on the findings, it can be said that HTV had a more significant effect on muscle, and noise exposure increased the dominant effect of HTV on muscle fatigue. Furthermore, by comparing the effect sizes observed for the changes of amplitude and mean frequency in three scenarios with the same acceleration of 5 m/s2 rms and different frequencies of 125 Hz, 63 Hz, and 31.5 Hz, it can be said that lower HTV frequencies had a greater effect size on muscle fatigue. Moreover, increasing the acceleration of HTV with the same frequency of 31.5 Hz from 5 m/s2 rms to 10 m/s2 rms significantly increased muscle fatigue (Table 4).

The results of muscle activation level changes in the present study are consistent with Widia et al., who showed that different HTV levels ranging from 10.24 m/s2 rms to 10.69 m/s2 rms (5 minutes and 15 minutes) could increase the range of electromyographic waves recorded from muscles and reduce its power spectrum (an EMG muscle fatigue

Table 4. The pairwise comparison and the effect size of EMG data and mental fatigue in all exposure conditions.

Variables	Exposure scenario	HTV (5 m/s² rms -125 Hz)	HTV (5 m/s² rms -63 Hz)	HTV (5 m/s² rms -31.5 Hz)	HTV (10 m/s² rms -31.5 Hz)	Noise (90dBA)	Noise (90dBA) + HTV (10 m/s² rms -31.5 Hz)	Effect Size
Amplitude (μv rms)	HTV (5 m/s² rms -125 Hz)	-	0.144	0.022	<0.001	0.762	<0.001	0.013
	HTV (5 m/s² rms -63 Hz)	0.144	-	0.112	<0.001	0.229	<0.001	0.119
	HTV (5 m/s² rms -31.5 Hz)	0.022	0.112	-	<0.001	0.021	<0.001	0.244
	HTV (10 m/s² rms -31.5 Hz)	<0.001	<0.001	<0.001	-	<0.001	0.007	0.564
	Noise (90dBA)	0.762	0.229	0.021	<0.001	-	<0.001	0.047
	Noise (90dBA) + HTV (10 m/s² rms -31.5 Hz)	<0.001	<0.001	<0.001	0.007	<0.001	-	0.683
Mean frequency (Hz)	HTV (5 m/s² rms -125 Hz)	-	0.085	0.004	<0.001	0.177	<0.001	0.02
	HTV (5 m/s² rms -63 Hz)	0.085	-	0.190	0.008	0.581	<0.001	0.196
	HTV (5 m/s² rms -31.5 Hz)	0.004	0.190	-	0.091	0.024	<0.001	0.262
	HTV (10 m/s² rms -31.5 Hz)	<0.01	0.008	0.091	-	0.03	0.01	0.358
	Noise (90dBA)	0.177	0.581	0.024	0.003	-	<0.001	0.104
	Noise (90dBA) + HTV (10 m/s² rms -31.5 Hz)	<0.001	<0.001	<0.001	0.001	<0.001	-	0.612
Mental fatigue	HTV (5 m/s² rms -125 Hz)	-	0.202	<0.001	<0.001	<0.001	<0.001	0.08
	HTV (5 m/s² rms -63 Hz)	0.202	-	0.001	<0.001	<0.001	<0.001	0.091
	HTV (5 m/s² rms -31.5 Hz)	<0.001	0.01	-	<0.001	<0.001	<0.001	0.458
	HTV (10 m/s² rms -31.5 Hz)	<0.001	<0.001	<0.001	-	<0.001	<0.001	0.669
	Noise (90dBA)	<0.001	<0.001	<0.001	<0.001	-	<0.001	0.777
	Noise (90dBA) + HTV (10 m/s² rms -31.5 Hz)	<0.001	<0.001	<0.001	<0.001	<0.001	-	0.818

Table 5. Correlation between the EMG parameters and mental fatigue in different exposure scenarios.

		Amplitude (μv rms)		Mean frequency (Hz)		Mental fatigue	
Exposure scenario	**Variables**	**Correlate**	**P-Value**	**Correlate**	**P-Value**	**Correlate**	**P-Value**
HTV ($5\ m/s^2$ rms -125 Hz)	**Amplitude (μv rms)**	1	-	-0.140	0.389	0.117	0.473
	Mean frequency (Hz)	-0.14	0.389	1	-	-0.229	0.155
	Mental fatigue	0.117	0.473	-0.229	0.155	1	-
HTV ($5\ m/s^2$ rms -63 Hz)	**Amplitude (μv rms)**	1	-	-0.393	0.012	0.338	0.033
	Mean frequency (Hz)	-0.393	0.012	1	-	-0.380	0.015
	Mental fatigue	0.338	0.033	-0.380	0.015	1	-
HTV ($5\ m/s^2$ rms -31.5 Hz)	**Amplitude (μv rms)**	1	-	-0.419	0.007	0.397	0.011
	Mean frequency (Hz)	-0.419	0.007	1	-	-0.446	0.04
	Mental fatigue	0.397	0.011	-0.446	0.04	1	-
HTV ($10\ m/s^2$ rms-31.5 Hz)	**Amplitude (μv rms)**	1	-	-0.619	<0.001	0.415	0.008
	Mean frequency (Hz)	-0.619	<0.001	1	-	-0.556	<0.001
	Mental fatigue	0.415	0.008	-0.556	<0.001	1	-
Noise (90dBA)	**Amplitude (μv rms)**	1	-	-0.252	0.116	0.153	0.346
	Mean frequency (Hz)	-0.252	0.116	1	-	-0.052	0.750
	Mental fatigue	0.153	0.346	-0.052	0.750	1	-
Noise (90dBA) + HTV ($10\ m/s^2$ rms 31.5 Hz)	**Amplitude (μv rms)**	1	-	-0.684	<0.001	0.538	<0.001
	Mean frequency (Hz)	-0.684	<0.001	1	-	-0.594	<0.001
	Mental fatigue	0.538	<0.001	-0.594	<0.001	1	-

symptom) [8]. Among other studies with similar results to the present study, we can refer to Park et al. [29], and Bovenzi et al [30]. Park et al. indicated that the EMG signal output values decreased after exposure to HTV, indicating decreased muscle activation. Also, the mean frequency value change after exposure to HTV was significantly reduced. Bovenzi and colleagues showed that upper limb MSDs in HTV-exposed workers was greater than in the control group: as exposure to HTV increased, the incidence of elbow/forearm and wrist/hand skeletal disorders increased. Lu et al. (2019) depicted that the whole body's vertical vibration and the sitting position significantly affect muscle fatigue of the trunk muscles and discomfort, which is consistent with the results of the present study [31].

Kim et al. showed that noise of 90 dBA increased trunk muscle fatigue, and when playing soft music as a background, trunk muscle fatigue was the least [12]. As a result, noise affects muscle fatigue from a certain point onward, which is consistent with the results of the present study. Meanwhile, the results of the effect of noise on muscle activation have been reported differently. Bidel et al. showed that when exposed to three noise levels of 75 dBA, 85 dBA, and 95 dBA in different temperature conditions, the changes in the electrical activation of the FDS and the biceps muscle do not have a clear trend. In some scenarios, a rise in the noise level decreased muscle activation; in others, it increased the electrical activation of the muscle [10]. Kristiansen et al. indicated that noise of 65 dB for 35 minutes did not affect the level of electrical activation of the trapezius (i.e., when both the left and right muscles contract) [32]. On the other hand, Jancke et al. showed that a rise in the noise level increased the activation of facial muscles [11].

Exposure to HTV, especially at lower frequencies and greater intensities, seems to affect fatigue symptoms more than noise substantially. Therefore, it can be stated that exposure to HTV, in addition to the stress load on the hand, is also considered physical muscle activation and imposes a double load on the exposed workers. As a result, it causes more fatigue

than exposure to noise alone. Also, if the vibration acceleration is low, considering that the muscle energy metabolism is predominantly aerobic in this condition, fatigue appears later. However, in exposure to vibration with greater accelerations, the oxygen required by the muscles becomes more than the oxygen available in the blood circulation. Accordingly, the accumulation of lactic acid and more muscle effort causes fatigue in the short run [33, 34].

The present study showed that noise caused a slight increase in amplitude and a slight decrease in frequency. Also, in concurrent exposure to noise and HTV, noise could significantly increase the effect of HTV on muscle tension. It may be because exposure to noise as a stimulus can change the electrical activation of the muscle by influencing and stimulating the activation of alpha and gamma motor neurons, which are responsible for innervating the muscle fibers and stimulating the vestibular system, which leads to the creation of acoustic motor reflexes [10].

The results of the present study related to mental fatigue showed that concurrent exposure to noise and HTV (10 m/s2 rms -31.5 Hz) had the most significant effect on the subjects' mental fatigue than the independent noise exposure scenario and other scenarios with the greatest mean difference (4.97±2.38) and effect size (ES=0.818). Also, according to the observed effect size for changes in mental fatigue in three scenarios of noise exposure, HTV exposure (10 m/s2 rms -31.5 Hz), and concurrent exposure, which were 0.777, 0.669, and 0.818, respectively, it can be said that noise had a greater effect than HTV. In addition, HTV increased the effect of noise on mental fatigue.

Jahcke et al. (2011 & 2013) showed that people exposed to high noise levels reported more mental fatigue than those exposed to low noise levels [35, 36]. Another study revealed that mental fatigue increased by about 40% in the noise-exposure group compared to the control group [37].

Jiao et al. showed that exposure to body vibration affects the level of fatigue perceived by people; they stated that different vibration frequencies cause different levels of mental stress and fatigue in people [38]. Ljungberg et al. examined the subjective experience of individuals with independent and concurrent exposure to body vibration and noise, and the subjects significantly rated the concurrent exposure mode as the most annoying and difficult period [39].

This study showed that exposure to occupational noise has a stronger and more dominant role in the incidence of perceived mental fatigue than HTV. The possible reasons for these results are that noise as a stress factor leads to changes in the body of the exposed person. As a result, in response to the noise-induced stress, the impulses from the greater cortex areas are transferred to the hypothalamus through the limbic system, which releases neurotransmitters such as serotonin, norepinephrine, and acetylcholine. Also, specific cells of the hypothalamus nucleus are activated to synthesize and secrete corticotrophin-releasing factors. At the end of this process, cortisol is the primary stress hormone, produced and secreted along with catecholamines released by the sympathetic nervous system. The psychological stress caused by this inappropriate response creates an emotional overload, which also reduces the processing power of the hippocampus, and mental and perceptual activities are reduced, resulting in fatigue. It can also be stated that noise leads to changes in the limbic system, the autonomic nervous system, and the neuroendocrine system [32, 36, 40-42].

As Table 5 displays, the greatest correlation between subjective and objective fatigue responses was observed for three scenarios of HTV (5 m/s2 rms - 31.5 Hz), HTV (10 m/s2 rms -31.5 Hz), and concurrent exposure to noise and HTV (10 m/s2 rms - 31.5 Hz). The absorption of vibration energy at high frequencies was limited in the primary tissues close to the vibration source (fingers, palms, and wrists), but HTV increases with the decrease in frequency and could be distributed and absorbed in the tissues far from the upper body vibrating source (arm, neck, and head) [13, 15, 43].

There are several limitations to this empirical study. First, the participants consisted of just males, so gender was not considered as a variable in the present study. Second, this research used short-term exposures while working hours are longer in the real world. Hence, further field studies with long-term exposures are recommended to be conducted. Besides, the biodynamic response functions of muscle may vary with different exposure scenarios. Finally,

while it is challenging to consider all the possible combinations of these factors in the experiments, this study only considered some combinations of noise and vibration frequencies. It can also be due to not increasing the number of exposure scenarios and the possibility of losing participants. Moreover, the considered values are determined based on field data of jackhammer device exposure to noise and vibration.

Biodynamic factors such as body posture and coupling forces (grip and push forces) can be varied during work with vibrating hand-held tools [44, 45]. In this study, to investigate the interaction of noise and vibration simultaneously, these biodynamic factors were fixed in a recommended normal range of typical working with jackhammers. However, future studies should investigate the interaction effect of these physical variables of vibration and noise in different biodynamic conditions. The number of samples was limited to 40 participants. The cooperation of more workers to participate in the current study was impossible. They did not want to cooperate satisfactorily mainly because of interference with their working hours.

5. Conclusion

The present study produced new data on the interaction effect of noise and HTV on muscle and mental fatigue in a simulated work with building vibrating tools. This evidence can help set the dose-response threshold limit for co-exposures to physical stimuli in the workplace. The findings confirmed that concurrent exposure to HTV and noise could cause muscle fatigue, and the role of HTV in this context was stronger than that of noise. However, noise has increased the main effect of HTV on muscle fatigue. Being exposed to both HTV and noise could cause perceived mental fatigue, and the role of noise in this context was more dominant than HTV. Vibration has increased the main effect of noise on perceived mental fatigue. Vibration frequency is an effective factor in muscle and mental fatigue. By decreasing the vibration frequency with the same vibration acceleration value, the amount of muscle and mental fatigue increases. Generally, HTV is one of the most harmful factors in construction professions; concurrent with noise, it can cause muscle and mental fatigue in workplaces, endangering workers' mental and physical health. These findings can help occupational health experts adapt the existing physical agents' exposure limits to realistic conditions and update occupational health surveillance activities.

Acknowledgments: This research is extracted from a doctoral thesis project (with registration No. 140010148495) financed by the Research and Technology Deputy of Hamadan University of Medical Sciences, for which we express our deepest gratitude.

Conflict of Interest: The authors have no conflicts of interest to declare.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023020
DOI: 10.23749/mdl.v114i2.13472

Is a Dry Eye Disorder in Firefighters an Occupational Disease?

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Keywords: Dry eye disorder; Firefighters; Fire smoke; Occupational disease; Ocular surface disease index; Tear break-up time; Schirmer test

Abstract

Background: *To examine firefighters (FFs) exposed to high levels of fire smoke and, as a result, to uncover risk factors for a dry eye disorder (DED) compared to age-and gender-matched healthy individuals.* **Methods:** *In this cross-sectional study, 51 FFs from the Afyonkarahisar Municipality Fire Department were chosen randomly (Group 1). A control group (Group 2) included 51 healthy relatives of patients who had routine ocular examinations. The Ocular Surface Disease Index (OSDI) questionnaire was administered after all participants thoroughly explained the study's objectives and procedures. Then, an ocular exam was performed on-site using a portable hand biomicroscope. DED was defined as a non-anesthetic Schirmer test result of <10 mm and a tear film break-up time (TBUT) of <5 seconds.* **Results:** *Groups 1 and 2 had mean ages of 44.82±7.29 and 44.73±7.41 years, respectively (p=0.946). The median work duration in Group 1 was 14 years (min-max: 1-27 years). The TBUT test revealed a significantly increased DED prevalence in Group 1 than in Group 2 (p=0.046). Despite the non-significant difference (p=0.276), the Schirmer test revealed that Group 1 had a higher DED prevalence than Group 2. The OSDI score showed that Group 1 had more mild, moderate, and severe DED than Group 2 (p=0.359). In addition, longer work duration was associated with a higher DED prevalence (p=0.179).* **Conclusions:** *Given the high prevalence of fire smoke-induced DED in FFs, preventive measures such as regular ocular exams, recommending personal protective equipment usage, and health education programs can assist in avoiding complications and reducing the burden of ocular diseases.*

1. Introduction

Occupational hazards have been regarded as potential reasons for ocular morbidity in various professions [1]. Fire, smoke, dust, flying particles, and other factors can contribute to occupational-related ocular disorders [2]. Repeated exposure to these toxic agents predisposes the eyes to a spectrum of ocular surface pathologies, including dry eye disorder (DED) [3]. This disorder is an ocular surface inflammatory condition characterized by increased osmolarity in the tear film, resulting in discomfort, burning, and stinging [4]. DED is often caused by reduced tear production (aqueous-deficient) and increased tear film evaporation (hyper-evaporative). While aqueous-deficient DED is caused by lacrimal gland pathology, hyper-evaporative DED is caused by a decrease in the blink reflex caused by prolonged screen exposure or being in air-conditioned environments, resulting

Received 22.07.2022 - Accepted 22.02.2023
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in dry eye symptoms [5]. The prevalence of DED ranges from 3.9 to 33.7%, and advanced age and prolonged computer use have been linked to an increased DED frequency. Conditions, including prior refractive surgery, contact lens (CL) wear, diabetes, hypertension, thyroid disease, and poor sleep quality, may also aggravate DED [6]. Aside from decreased employees' work performance and productivity [7], DED has long been recognized for its effects on visual function, interference with daily activities such as computer use, reading books and newspapers [8], as well as its association with poor quality of life [9].

As far as fire is concerned, this is an essential component of our daily lives [10]. Accordingly, the possibility of fire incidents continues to be challenging, and efficient fire suppression by firefighters (FFs) is essential in reducing human and economic damage [11]. The terms "firefighting" and "firefighters (FFs)" are broad in scope, encompassing a wide range of fire scenarios such as municipal, wild-land, industrial, military, aviation, and oil wells. Generally, FFs respond to a wide range of incidents, including structure, wild-land, vehicle fires, vehicle accidents, medical emergencies, hazardous material releases, and building collapses [12]. In essence, municipal, structural firefighting is divided into two stages: (i) knockdown (when firefighters control and extinguish the fire) and (ii) overhaul (when any remaining small fires are extinguished). Almost 90% of municipal structural fires are killed or abandoned and fought from the outside in up to 10 minutes, resulting in a 10-min average duration of heavy physical activity at fires [13]. Larger fires, on the other hand, can take much longer to extinguish. Although the atmosphere during overhaul is not as hot or smoky as it is during knockdown, it still contains combustion products from small fires or smoldering material. For this reason, exposure levels can differ significantly between the two stages of firefighting [14]. Occupational exposure as an FF is complex, encompassing many hazards caused by fires and non-fire incidents. Frankly, FFs work in one of the most dangerous occupations, involving daily firefighting activities that are both physically and psychologically demanding to ensure the public's safety and well-being [15]. They are repeatedly exposed at work to a wide range of pollutants emitted during fire incidents, including particulate matter, carbon monoxide, nitrogen dioxide, volatile organic compounds such as polycyclic aromatic hydrocarbons (PAHs), polybrominated diphenyl ethers, and so on [16]. They are also exposed to temperatures ranging from 1200 °C to 1400 °C while fighting fires due to thermal sources such as smoke blankets, hot surfaces, and hot fumes. This could hurt their overall health as well as their ocular health.

Furthermore, occupational exposure as an FF has been labeled "carcinogenic to humans" due to "sufficient" evidence of humans developing cancer, such as mesothelioma and bladder cancer, among other things. According to "strong" mechanistic evidence, this exposure may also result in key carcinogen characteristics in humans, including being genotoxic, causing epigenetic changes, oxidative stress, chronic inflammation, and modulating receptor-mediated effects [12]. FFs are also almost always in perilous situations when fighting fires; thus, inadequate safety standards and personal protective equipment (PPE) may result in ocular surface pathologies, particularly DED, and, ultimately, general ill health [17].

Specifically, most studies have investigated DED prevalence concerning direct or passive cigarette smoking [18, 19]. However, there have been few studies on FFs regarding fire smoke-related ocular surface pathologies, particularly DED, which is a significant component of the global ocular health burden. Aside from developing cardiovascular [20] and mental disorders [21], as well as an increased risk of cancer development [12], FFs are at a high risk of developing ocular pathologies, whether acute or chronic, particularly DED, due to their physical and chemical environments.

Fire smoke exposure has the potential to be a debatable issue that FFs must deal with daily. Therefore, the current study intended to examine FFs who are likely to be exposed to high levels of fire smoke and, as a result, to uncover any associated risk for DED compared to age-and gender-matched healthy individuals.

2. Methods

2.1. Ethics Consideration and Study Consent

The study protocol followed the ethical principles of the Helsinki Declaration and was fully approved by the Afyonkarahisar Health Sciences University Ethics Committee with approval number 2022/316. All participants provided written informed consent before participation.

2.2. Study Design and Participant Selection

This non-interventional, cross-sectional study was conducted from June 3 to June 30, 2022. Initially, the study included all 59 FFs from the nearby Afyonkarahisar Municipality Fire Department. They had no hypertension or thyroid problems. After excluding two FFs with diabetes, two with glaucoma, one on antihistamines, one with a history of cataract surgery, one with prior refractive surgery, and one CL user (defined as wearing CLs≥1 day/week), 51 FFs (Group 1) with direct firefighting experience were eventually determined to be eligible for the study.

A control group (Group 2) included 51 age- and gender-matched healthy individuals who were relatives of patients who had routine ocular examinations at the ophthalmology clinic. These individuals had no systemic or ocular diseases, as determined by comprehensive systemic and ophthalmological exams, and they met all of the FF inclusion criteria. Given that smoking may be a predisposing factor for DED, the number of controls who smoked regularly (every day) was determined to be 27 (52.9%), the same as in FFs. In this context, regular smokers were defined as those who smoked >1 cigarette per day [22].

2.3. The Ocular Surface Disease Index

The Ocular Surface Disease Index (OSDI; Allergan, Inc, Irvine, California), a patient-reported outcome questionnaire, was created to provide a quick assessment of the range of ocular surface symptoms associated with chronic DED, their severity, and impact on the patient's functional capacity [23]. It is low-burdening to the patient, takes about 5 minutes to finish, and has been applied efficiently by physicians and researchers. This questionnaire has three sections: (i) ocular symptoms, (ii) vision-related function, and (iii) environmental triggers. Essentially, the objectives are to make ocular surface disease diagnosis faster and more reliable and to explain the discrepancy in ocular disability caused by DED. It also enables physicians to collect extensive subjective data in addition to clinical history, and it has the potential to evaluate the efficacy of a specific DED therapy [23, 24].

Initially, all participants in this study were thoroughly explained the study's objectives and procedures by a senior ophthalmologist (HHG), who was also in charge of all questionnaire procedures. Then, the Ocular OSDI questionnaire was distributed to Group 1 at the fire department and Group 2 at an ophthalmology clinic during an ophthalmological assessment. The OSDI questionnaire consists of 12 items graded on a scale of 0 to 4, with 0 indicating no time, 1 sometimes, 2 half of the time, 3 most of the time, and 4 all the time. The total OSDI score was calculated as follows: OSDI=([sum of scores for all questions answered]×25)/([total number of questions answered]). The OSDI was scored on a scale of 0-100, with higher scores indicating more severe DED. The OSDI score was grouped as per the following: normal ocular surface (0-12 points), as well as mild (13-22 points), moderate (23-32 points), and severe (≥33 points) ocular surface disease. The OSDI was scored based on the reported guidelines. This questionnaire has adequate internal consistency, test-retest reliability, validity, sensitivity, and specificity for ocular surface disease patients [24].

Aside from socio-demographic characteristics such as age and gender, questionnaire participants were also asked if they had ever had any ocular surgical procedures or smoked.

2.4. Ophthalmological Assessment

Since the FFs were on duty, they were all ophthalmologically assessed by a single experienced ophthalmologist (IEA) using a portable hand biomicroscope (Portable Slit Lamp, Reichert Inc, NY, USA) in a large fire department-designated room with standard lighting. The same ideal conditions were applied to Group 2, whose assessment was performed in the

designated space at the ophthalmology clinic. The evaluation was carried out between 13:00-15:00 to avoid the potential influence of diurnal variations in the tear film layer. First, a non-anesthetic Schirmer test was performed by placing a Schirmer strip (Biotech, Ahmedabad, India) on the outer third of the lower eyelid and waiting five minutes. A saline drop was then placed on the fluorescein strip (Biotech, Ahmedabad, India), followed by a tear film break-up time (TBUT) test using the biomicroscope's blue cobalt filter with 10 times magnification [25]. DED was defined as a non-anesthetic Schirmer test result of less <10 mm or a TBUT of <5 seconds [26].

2.5. Statistical Analysis

The PAWS Statistics 18 program was used for statistical analysis. The Kolmogorov-Smirnov test was used to assess the distribution of data. Categorical variables were presented as percentages and frequencies, normally distributed continuous variables as mean±standard deviation, and non-normally distributed continuous variables as medians and quartiles (IQR). Chi-Square and Fisher-Freeman-Halton Tests were used to compare categorical variables. Further, the Independent t-Test was used to evaluate normally distributed data, whereas the Mann Whitney U test was used to assess non-normally distributed data. A logistic regression analysis was performed between subgroup variables. The statistical significance level for two-tailed data was set at $p<0.05$.

3. Results

Groups 1 and 2 were all males, with mean ages of 44.82±7.29 and 44.73±7.41 years, respectively (p=0.946). The median work duration for Group 1 was 14 years (min-max: 1-27 years) (IQR=7.0-22.0).

3.1. The Tear Film Test Results

The TBUT test revealed a statistically significant four-fold increase in DED prevalence in Group 1 compared to Group 2 (p=0.046). Even though the difference was not statistically significant (p=0.276), the Schirmer test also revealed that Group 1 had a higher DED prevalence than Group 2. Moreover, participants with DED who had an OSDI score of >12 were twice as numerous in Group 1 as they were in Group 2 (p=0.062) (Table 1).

Given a statistically significant difference in TBUT values between Groups 1 and 2, a logistic regression analysis, including age, smoking, and other group variables, was performed based on the TBUT results. Again, no statistically significant difference was found (p=0.170).

The OSDI score was used to categorize participants as having mild, moderate, or severe DED, as represented by OSDI Groups 1, 2, and 3. Statistically, non-significant differences existed between the FFs and the healthy individuals (p=0.359) (Table 2).

Table 1. A comparative analysis of DED test results between the two study groups.

Tests	Group 1, n (%)	Group 2, n (%)	P value
Schirmer	10 (19.6)	6 (11.8)	0.276
TBUT 8	8 (15.7)	2 (3.9)	0.046
OSDI*	16 (31.4)	8 (15.7)	0.062

*DED=Dry eye disorder, Group 1=Firefighters, Group 2=Healthy individuals, TBUT=Tear break-up time, OSDI=Ocular surface disease index, n=Number of participants, %=Percentage, *Individuals with DED were compared with a score of >12 according to the OSDI score.*

Table 2. A comparative analysis of DED severity based on OSDI score between firefighters and healthy individuals.

	OSDI Score					
	0	1 (mild DED)	2 (moderate DED)	3 (severe DED)	Total	P
Group 1, n (%)	35 (68.6)	8 (15.7)	6 (11.8)	2 (3.9)	51 (100)	
Group 2, n (%)	43 (84.3)	4 (7.8)	3 (5.9)	1 (2.0)	51 (100)	
Total	78 (76.5)	12 (11.8)	9 (8.8)	3 (2.9)	102 (100)	0.359

DED=Dry eye disorder, Group 1=Firefighters, Group 2=Healthy individuals, OSDI=Ocular surface disease index, n=Number of participants, %=Percentage.

3.2. Work Duration-Based Tear-Film Intra-Group Analysis

Group 1 was further evaluated independently of Group 2 based on work duration in years. In fact, when the Kolmogorov-Smirnov test was used to assess FF work duration, it was discovered that it did not fit the normal distribution. Thus, Group 1 was divided into two sub-groups based on the median value corresponding to 14 years of work duration: ≥14 years and <14 years FFs. These sub-groups could not be divided equally because the 10 FFs with the median value had worked for 14 years. Consequently, 28 (54.9%) had served as FFs for ≥14 years, while 23 (45.1%) had served for <14 years. Schirmer test revealed DED in 8 (28.6%) and 2 (8.7%) FFs with ≥14 and <14 years of work duration, respectively (p=0.075). The TBUT test revealed DED in 6 (21.4%) and 2 (8.7%) FFs with ≥14 and <14 years of work duration, respectively (p=0.213). According to the OSDI test, DED was found in 11 (39.3%) of the FFs with ≥14 years of work duration, with 4 (14.2%) having mild DED and 7 (25.0%) having moderate and severe DED. However, among FFs with <14 years of work duration, 5 (23.8%) were found to have DED based on the OSDI test, with 4 (19.0%) having mild DED and 1 (4.8%) having moderate and severe DED. Overall, the longer the work duration, the higher the DED proportion; however, no statistically significant difference between the two sub-groups was found in intra-group comparative analysis (p=0.179).

4. Discussion

Generally, FFs operate in one of the most hazardous occupations, with higher-than-average workplace fatalities and injuries. They conduct physically demanding tasks such as firefighting, search and rescue, exterior ventilation, and overhaul on the fire ground. They are also exposed to extremely high levels of a variety of toxic and carcinogenic chemicals, which may be associated with systemic pathological conditions and ocular surface pathologies [27]. Most studies have shown that FFs are at high risk of developing occupational diseases [28, 29]. The current study examined FFs who were likely to be exposed to high levels of fire smoke to see if there was any risk of DED, providing an important overview of their ocular surface health. Extremely high temperatures and smoke containing gaseous pollutants and particulate toxins may be associated with an increased DED prevalence among FFs, as well as an increased risk of other disorders such as cardiovascular [18, 30], mental [21], and neoplasia [12].

DED is one of the most common ophthalmological health issues [31, 32], and its prevalence is increasing, resulting in a lower quality of life [32]. It is thought to affect nearly one-third of the world's population [31]. As noted previously, most studies have investigated the prevalence of DED concerning cigarette smoking, whether direct or passive [18, 19]. However, to our knowledge, this is the first study to investigate DED, whether it is an occupational disease or not, and its potential risk factors in FFs, a group of workers frequently exposed to fire smoke from various sources.

Usually, fire smoke is composed of unburned microscopic particles, gases, and water vapor. Standing near fire smoke allows tiny particles to enter the eyes unknowingly, causing ocular irritation, which is why FFs are recommended to wear PPE [33]. In addition, fire smoke particles, which are undetectable, linger in the air for a long time after the smoke has cleared [34]; thus, FFs can go about their business without being aware of the presence of the particles. Consequently, if smoke enters the eyes, the particles are likely to become trapped there as well, resulting in stinging, burning, hyperemia, excessive watering, and temporary vision changes caused by ocular rubbing-induced corneal damage in the short-term [3].

In the current study, FFs were found to be significantly associated with increased DED prevalence, four times higher than in healthy individuals, and prominent corneal staining in the TBUT test. Moreover, the Schirmer test revealed FFs to be associated with nearly twice the DED prevalence than healthy individuals, as did the OSDI questionnaire assessment, despite non-significant differences in both test results. The current study also investigated whether there was any relationship between FF work duration and DED prevalence. In this context, work duration had no significant impact on DED prevalence, as evidenced by the TBUT and

Schirmer tests and the OSDI score. Nonetheless, those who had worked for a more extended period, in this case ≥14 years, were more likely to be detected with DED. These findings clearly show that FFs may be at higher risk of developing DED when compared to healthy individuals, significantly as their work duration increases [35, 36]. In addition, longer working experience entails greater exposure to fire smoke hazards [34, 37], which can result in the development of some ocular surface pathologies like DED.

Exposure to fire smoke and gases is challenging to characterize. This is primarily due to a combination of factors, including longer work schedules throughout the year, wide variations in FFs' time spent at fires, intermittent exposures, exposure to a complex mixture of gases, vapors, and particulate matter, as well as the unrevealed effect of heat. Because of the variety of chemicals in smoke, some may produce metabolites that, alone or in combination with other substances or metabolites, may be extremely dangerous, causing DED in this context [38].

Fire smoke microscopic particles and gases are two physical phases of combustion products. Microscopic particles, however, should be viewed as a complex mixture consisting of a particle core onto which other substances, such as gases and volatile organic compounds, are adsorbed. Gaseous combustion products are primarily of acute and on-scene concern, though they may have long-term consequences. Following ocular contact, the solubility of gases in water governs almost entirely their penetration into deep ocular tissues. This can lead to acute and, in the case of long-term exposure, chronic inflammatory damage to tear production processes and the entire ocular surface [34].

The carbonaceous smoke particles produced by fire are almost entirely the result of the combustion of organic matter. Visible flame fires produce smaller particles than smoldering or charring fires without flames, owing to inefficient combustion. Particles produced by both flaming and nonflaming fires can aggregate to form larger particles over time [16, 39]. This could be related to increased ocular surface problems in FFs, particularly DED, as evidenced in the current study, where prolonged exposure to fire smoke was associated with an increased DED prevalence. It is essential to remember that fire smoke is not the same as cigarette smoke, which is far more complex and contains chemicals like nicotine that suppress acute inflammation. Fire smoke particles also differ significantly from fine particulate air pollution, primarily sulfate-derived instead of carbonaceous [39].

Fire smoke can alter the composition of tears in two ways: gases in smoke cause increased evaporation of the water component of tears, and toxins and particulates cause increased protein production. Several approaches are available to alleviate the symptoms of fire smoke-induced DED in FFs. This includes using artificial tears to reestablish the proper balance of tear components, as well as tear duct plugs inserted in the natural tear drainage openings in the eyelids to help maintain natural tears on the eyes for a longer period. Furthermore, despite the lack of clinical DED, FFs may benefit from commercially available hyaluronic acid-containing artificial tear drops as a preventative measure following a fire incident. This approach could alleviate fire smoke-induced ocular surface inflammation by facilitating ocular surface cleaning. This may be the first study in the literature to address this specific topic; therefore, additional research may be worthwhile.

Moreover, FFs must wear protective equipment such as helmets, boots, gloves, and so on, in addition to thermal protective clothing, to effectively and efficiently suppress fires [40]. These widely used devices, which are generally certified by the International Organization for Standardization (ISO), the European Committee for Standardization (EN), or the National Fire Protection Association of the United States (NFPA), reduce FF injuries and fatalities by providing adequate comfort as well as protection for various body parts, including the eyes [41]. While any level of fire smoke exposure is hazardous to anyone, it is especially dangerous to FFs with DED or ocular allergies. After all, FFs can achieve optimum ocular protection from fire smoke by wearing PPE [33]. Generally, PPE refers to the equipment worn by FFs, including eye and hearing protection, helmets, trousers, coats, boots, protective gloves and hoods, self-contained breathing

apparatus, and personal alert safety system devices. Although eye injuries are among the most common injuries sustained by FFs while fighting fires, they are not always reported because they are not always incapacitating. Unfortunately, severe eye injuries can also occur; however, they are relatively easy to avoid. Self-contained breathing apparatus face-pieces, helmet-mounted face-shields, goggles, and safety glasses are just a few examples of eye PPE. In addition, when engaging in firefighting activities that require protection from flying particles or chemical splashes, NFPA requires using goggles or other relevant primary eye protection [42].

Demographically, males consist of a more significant proportion of FFs. Most male FFs are frequently involved in mainstream firefighting, whereas female FFs are primarily engaged in administrative duties. This disparity could be explained by the fact that the FF profession is high-risk, making it more appealing to males, who are more likely to work in high-risk occupations [37,43]. In the current study, all FFs were males, preventing a comparison of DED prevalence by gender. Even so, because DED prevalence appears to be increasing in FFs compared to healthy individuals, this finding supports previous reports, even if no relevant conclusions can be drawn because the study only examined male FFs.

Fundamentally, DED is a multifactorial disorder that significantly impacts the quality of life and work productivity [44]. Not only do FFs' unhealthy culture, shift work, and irregular sleep patterns play a role in DED, but so do genetic and environmental factors, with environmental factors accounting for up to 70% of the variation in DED symptoms [45]. Several studies have linked specific ecological factors to DED, including air pollution [46], use of visual display terminals [47], low humidity, and air conditioning [48]. In line with these reports, the occupation, in this case, firefighting, could undoubtedly play a significant role in DED. Many other risk factors, such as smoking, have been shown to impact disease outcomes, including DED. With the exception of Beaumont et al. [49], almost no studies on FFs have adjusted for confounders such as smoking. The most serious source of consternation, however, maybe work duration. This is due to the fact that work duration, exposure duration, latency of a particular pathology and age are all closely related but not the same, and there is never enough evidence to separate the covariance. In epidemiologic studies of FFs, smoking is the most common potential confounding factor, as it is in many, if not the majority, of occupational and public health epidemiology studies. Even so, it may not have as strong an impact as generally believed, and it is likely to be less of a problem than in other occupations. It has never been proven that FFs smoke more than the general population. Besides, the scant historical data suggests that, at least in modern times, FFs smoked less than other occupations. Since cigarette smoke is a combustion product, it contains many of the same carcinogenic and toxic constituents as fire smoke. As a result, smoking poses a unique challenge in the study of various systemic and ocular pathologies, including DED.

Smoking is inversely related to socio-economic class and is more common in certain occupations, particularly those that are either boring, requiring stimulation as a relief from tedium, or involve social mixing, owing in part to the transactional nature of sharing smokes. Intriguingly, firefighting possesses both of these characteristics and is considered a working- class, or 'blue-collar,' occupation, implying higher cigarette smoking. This was, however, more applicable in the past than now. Modern FFs are far more knowledgeable, health- conscious, and concerned about the effects of smoke as a result of their occupation [34]. Despite this, FFs have a high rate of co-occurring mental illness and substance abuse. This is a primary challenge for FFs because substance abuse has the potential to impair cognitive and behavioral performance, posing workplace productivity issues as well as safety risks such as improper use of PPE during fire incidents. It has also been reported that 30% of FFs have alcohol problems, which is twice the rate of the general population [50]. Furthermore, the effect of shiftwork on sleep patterns and overall health in FFs has been reported to be significant. Many FFs noted sleeping problems, particularly during the day when working the night shift, while others claimed that their sleeping problems were entirely related to hypervigilance, as the readiness to respond to alarms while on duty transfers to off-duty life [27]. Therefore,

despite focusing primarily on DED prevalence among FFS in relation to fire smoke exposure in the current study, other factors could, of course, influence the rate of DED among FFs. Nonetheless, as noted earlier, no participants reported consuming alcohol or any other substance abuse, with the exception of participants in both FFs and healthy individuals who used to smoke regularly. Furthermore, in the current study, work duration had no significant effect on DED prevalence, and participants in both groups were age- and gender-matched.

There are some limitations to the current study. Because of the study's cross-sectional single-centered design, it may have been difficult to decipher relatively more clinically significant prospective findings regarding the relationship between DED and fire smoke exposure, as well as FFs' work duration. Another limitation could be the small number of study participants, as well as the fact that no FF was asked if he had recently been involved in any firefighting operations. Ocular examination immediately following firefighting may reveal an expectedly increased DED incidence due to intense smoke exposure. Nevertheless, given that FFs work 24-hour shifts, it should be noted that they may experience difficulty sleeping, which may have an impact on DED. The healthy worker effect (HWE) is one of the most pressing issues confronting occupational health researchers [27]. This phenomenon could also limit the current study in that it is a special type of selection bias, commonly seen in observational studies of occupational exposures with an incorrect choice of comparison group, usually the general population. Matter of fact, the general population is, by definition, a mixed bag of healthy and unhealthy individuals. The employed workforce is expected to have fewer sick individuals than the general population [27, 51]. Several professions, such as FFs, require strenuous physical and endurance tests prior to recruitment to assess their physical as well as ophthalmological health. Consequently, comparisons of DED prevalence between FF cohorts who are fitter and healthier and healthy relatives of patients having routine ocular examinations, in this case, may be skewed because not everyone in the latter group is at risk of being recruited, resulting in an underestimation of DED among FFs. Additionally, it is clear that FFs in the current study did not use computers regularly and were directly responsible for firefighting. However, given the prevalence of smartphone use, the fact that the FFs' time spent with their smartphones was not questioned may be viewed as another study limitation.

Despite the limitations, we believe that the current study, as the first of its kind, has yielded valuable results, particularly in relation to the global ocular health problem of DED. This may eventually raise questions about whether an occupational disease is the best definition for these frequently diverse smoke-exposed FFs.

5. Conclusions

Because of the high prevalence of DED caused by fire smoke in FFs, pragmatic measures are required. As detailed above, regular ocular exams, recommendations to wear PPE regularly, and health education programs that can improve the current situation, avoid potential complications, and reduce the burden of ophthalmological pathologies are examples of such measures. This could be especially beneficial for both occupational health and work productivity. As a result, this evidence-based association may help define fire smoke-induced occupational ocular disorder and highlight the importance of taking a thorough occupational and social history in patients with DED to better understand the symptom etiological factors. When implemented earlier and with more resources, a better understanding of occupational hazards and agreed-upon and coordinated actions among occupational physicians, primary care physicians, and specialists such as ophthalmologists will produce far more effective results. Nonetheless, further large-scale prospective research into DED prevalence among FFs and whether it is an occupational disease could yield clinically and occupationally valuable results.

Declaration of Interest: The authors declare no conflict of interest to disclose.

Institutional Review Board Statement: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards (IRB approval number: 2022/316.)

Informed Consent Statement: Informed consent was obtained from all participants.

Availability of Data And Materials: The manuscript contains all data. The datasets used and/or analyzed during the current study, however, are available upon reasonable request from the corresponding author.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023016
DOI: 10.23749/mdl.v114i2.14300

Prevalence of and Risk Factors for Hepatitis C Virus Infection in World Trade Center Responders

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Keywords: Sewage; Human Remains; Blood and Bodily Fluids; Linkage to Care; Nested Case-control Study; Occupational Exposure

Abstract

Background: *The risk of hepatitis C virus (HCV) infection among emergency responders exposed to human remains, blood/bodily fluids, and/or sewage is unknown.* **Methods:** *A cross-sectional study of 3,871 World Trade Center General Responder Cohort (WTCGRC) members followed at the Icahn School of Medicine at Mount Sinai, born from 1945-1965, and recruited from 2016-2018 were tested for HCV infection, and prevalence was compared to National Health and Nutrition Examination Survey data from 2003 to 2012. A nested case-control study compared 61 HCV antibody positive cases to 2571 controls. Multivariable logistic regression models adjusting for time of birth, traditional HCV risk factors, and type of work at the World Trade Center (WTC) site, determined if contact with human remains, blood/bodily fluids, and/or sewage at the WTC site was associated with HCV infection.* **Results:** *The age-standardized point prevalence of HCV infection among WTCGRC members was 2.98% [95% CI (2.39, 3.56)] and in the US population was 3.33% [95% CI (2.54, 4.11)] [% difference=0.35%, 95% CI (- 0.31%, 1.01%), P=0.47]. In separate multivariable models, adjusting for possible confounders, contact with human remains was not associated with HCV infection [OR=1.10, 95% CI (0.63, 1.91), P=0.74)], contact with blood and/or bodily fluids was not associated with HCV infection [OR=1.45, 95% CI (0.82, 2.56), P=0.20], and contact with sewage was associated with HCV infection [OR=1.72, 95% CI (1.00, 2.98), P=0.05].* **Conclusion:** *Contact with sewage may increase the risk of HCV infection.*

1. Introduction

Chronic hepatitis C virus (HCV) infection increases the risk of liver cirrhosis and hepatocellular carcinoma [1, 2]. While multiple risk factors for HCV infection have been recognized, at least 20% of persons with HCV infection do not have a known risk factor [3, 4] which suggests there are unrecognized risk factors. The Occupational Safety and Health Administration of the US Department Labor standards for blood-borne pathogens (29 Code of Federal Regulations 1910.1030) [5] and personal protective equipment (29 Code of Federal Regulations 1910 Subpart 1) [6] require employers to protect workers from occupational exposure to infectious agents. Thus, persons employed in

Received 18.02.2023 - Accepted 17.03.2023
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occupations with expected exposure to human remains, blood or bodily fluids, and stool with visible blood are educated about the risks of HCV from these agents, and provided with and expected to wear protective gear. During the course of an emergency response, workers and volunteers may be unexpectedly exposed to these agents. The prevalence of and risk factors for HCV infection has not been previously assessed in persons exposed to these agents during an emergency response.

The World Trade Center General Responders Cohort (WTCGRC) comprises workers and volunteers who participated in the emergency response activities at the World Trade Center (WTC) site and are followed at the Icahn School of Medicine at Mount Sinai and other medical institutions to monitor their health. At their enrollment interview, WTCGRC members were specifically asked about contact with "human remains", "blood or bodily fluids", and "sewage" during their WTC activities. This cohort offers an opportunity to study the risk of HCV infection in emergency response workers exposed to these agents.

A cross-sectional study determined the prevalence of HCV in WTC responders and compared it to the prevalence of HCV in the US population. A nested case-control study then determined if contact with human remains, blood or bodily fluids, and sewage (wastewater and excrement conveyed in sewers) during emergency response work is associated with an increased risk of HCV infection.

2. Methods

The WTCGRC has been described elsewhere [7]. The cohort consists of WTC responders who worked or volunteered in lower Manhattan, or the Staten Island landfill or barge-loading piers for 4 hours or more from September 11 to 14, 2001; 24 hours or more during September 2001; or 80 hours or more from September 2001 to December 2001. Recruitment began on July 16, 2002, and is ongoing.

Recruitment into WTCGRC was done by extensive outreach [7]. Participation is voluntary and includes a comprehensive baseline examination which includes collection of questionnaire data, a history and physical examination, and collection of bloodwork. Monitoring assessments are given every 12 to 18 months and similarly include collection of questionnaire data, a history and physical examination, and collection of bloodwork. All assessments occur at one of several World Trade Center Clinical Centers of Excellence [8]. As of March 31, 2014, 33,863 persons were eligible for inclusion in the cohort and had completed a Visit 1 [9]. WTCGRC participants may participate in health monitoring yet opt out of research. Thus, there are members of the WTCGRC who routinely attend their monitoring visits, but their data is unavailable to researchers.

According to CDC, persons born from 1945-1965 are at higher risk for HCV infection than other birth cohorts [10]. For this HCV Study, responders who presented to the Icahn School of Medicine at Mount Sinai site for a WTCGRC visit (Visit 1 or higher), and were born from 1945 through 1965, were given information about HCV infection and offered study participation that included free HCV testing.

Interested persons completed the informed consent process, signed the informed consent document, and completed the HCV Risk Factor Questionnaire (see below). Recruitment began on December 15, 2016, with materials in English. Spanish materials were available on November 3, 2017, and Polish materials were available on May 4, 2018. The last day of recruitment was July 12, 2018. Persons who declined to participate in the WTCGRC Research Study were included in this study at their discretion, and with the understanding that data beyond the HCV Risk Factor Questionnaire would not be accessed. Enrollment continued until the study sample size was reached. (Sample size is defined below.)

The HCV Risk Factor Questionnaire assessed demographic data (year of birth, country of origin, current type of medical insurance); previous testing, results, and treatment for HCV infection; and traditional risk factors for HCV infection (blood transfusion or organ transplant before July 1992, receipt of clotting factor concentrate produced before 1987, receipt of long-term hemodialysis, receipt of blood from an HCV-infected donor, birth to an HCV-infected mother, history of human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), history of injecting drug use (IDU), and needle stick, sharps, or mucosal exposure to HCV-infected blood as a health

care, emergency medical, or public safety worker) [10]. As a point of clarification, the HCV Risk Factor Questionnaire was administered on the date of HCV antibody testing and asked participants if they ever had any of the traditional risk factors for HCV infection (Supplementary Material, Table S1).

After completing the HCV Risk Factor Questionnaire, study participants completed their usual visit. In addition to blood drawn for routine testing, two 2 mL tubes of blood were drawn. Blood from the first tube was tested for HCV antibody. For those with a positive HCV antibody test, blood from the second tube was tested for HCV RNA using polymerase chain reaction (PCR). Otherwise, blood from the second tube was discarded. Persons with a positive HCV antibody test were defined as having current or prior HCV infection. Current HCV infection was defined by detectable HCV ribonucleic acid (RNA) and prior HCV infection was defined by undetectable HCV RNA. All participants were notified of their results by letter, telephone call, or email based on their preference. Persons with current HCV infection received telephone calls with offers of referral to liver specialists at either the co-located Mount Sinai Liver Medicine Practice or a federally qualified health center in their preferred location. Persons who attended at least one outpatient visit with a liver specialist were defined as being linked to care.

2.1. Statistical Analysis

2.1.1. Cross-sectional Study

For the cross-sectional study, the age-standardized prevalence of HCV infection in this study sample was determined using the US population in the 2010 census as the standard population, and was compared to the age-standardized prevalence of anti-HCV antibodies in the general US population based on National Health and Nutrition Examination Survey (NHANES) data from 2003 through 2012 using the appropriate weights [11]. The sample size was calculated to provide adequate statistical power for this analysis. With 3900 persons and an expected prevalence of HCV in the US population of 3.2%, this analysis would have 80% power to detect as statistically significant (at α=0.05) a 0.8% difference between the expected prevalence of HCV infection in the US population (3.2%) and the prevalence of HCV among members of the WTCGRC (either$\geq$4.0% or$\leq$2.4%).

2.1.2. Nested Case-control Study

2.1.2.1. Study Population

WTCGRC members who consented to research were eligible for inclusion in the nested case-control study. A case was defined as a person with current or prior HCV infection and was measured by a positive HCV antibody test. Controls were persons without HCV infection. Persons with an indeterminate HCV antibody test were removed from the analysis. (All data used in the nested case-control study and the data source are provided in Supplementary Material, Table S1.)

2.1.2.2. Three Main Exposures

Data for the three main exposures were obtained from the WTCGRC baseline questionnaire. Within the baseline questionnaire, study personnel determined if WTCGRC members had participated in WTC activities in three intervals: September through October 2001, November through December 2001, and January through June 2002. For those intervals in which the member participated, study personnel asked if they had "contact" with "human remains", "blood or bodily fluids", and/or "sewage". Participants were defined as having exposure if they reported contact during any of these three periods.

2.1.2.3. Possible Confounders

Possible confounders for this study included traditional HCV risk factors, demographic characteristics, and activities at the WTC site. Traditional HCV risk factors were obtained from the HCV Risk Factor Questionnaire. Sex, race, and ethnicity were obtained from the WTCGRC baseline questionnaire. Year of birth, country of birth, and insurance status were obtained from the Hepatitis C Risk Factor Questionnaire. While household contacts

with HCV infection [12], sexual risk behaviors [13], and level of education [14] have been identified as risk factors for HCV infection, these characteristics were not captured in our questionnaire and were therefore not included in this analysis.

Data on activities at the WTC site was obtained from the WTCGRC baseline questionnaire and included year of enrollment in the WTCGRC, type of work done as a volunteer or worker, use of gloves, use of personal protective equipment, and seeking care for injuries which pierced the skin. For type of work done as volunteer or worker, participants were handed a list of types of work organized by Department of Labor Codes and WTC Activity codes and asked "What activity code best describes what you were doing during this period?" for each of four periods (September 2001, October 2001, November to December 2001, and January to June 2002). Study personnel entered up to three activity codes for each period. A time-weighted measure of protective glove use and protective clothing use was based on participants' reported use of protective gloves and/or protective clothing (rarely/never, sometimes, most of the time, all the time) during each of each three time periods: September-October, November-December, and January-June.

WTCGRC participants reported up to four injuries or illnesses acquired during the WTC activities for which they sought medical care while working at the WTC site. Members were identified as having skin/mucous membrane injury if they indicated seeking medical care for an abrasion, amputation, blister, burn, contusion (bruise), crush, cut/puncture, eye injury, foreign body, and skin irritation/rash.

2.1.2.4. Analytic Approach

It was decided *a priori* that the final analysis would adjust for traditional HCV risk factors and birth year. Thus, the nested case-control study analyses were limited to participants who had complete exposure data for at least one of the three main exposures, complete data on the traditional HCV risk factors, and reported a year of birth.

Demographic characteristics and activities at the WTC site were evaluated in univariable analysis. Characteristics with a p-value of <.20 were further evaluated in forward, backward, and stepwise manual and machine-assisted multivariable logistic regression analysis with HCV infection as the outcome to find those characteristics independently associated with HCV infection (P ≤.05). Characteristics independently associated with HCV infection were identified as possible confounders and were adjusted for in further analyses.

The final analysis included three multivariable logistic models, one for each main exposure. These models included HCV infection as the outcome and were adjusted for age, traditional HCV risk factors, and the identified possible confounders.

This study was approved by the Icahn School of Medicine Institutional Review Board (Study 16-01343) which conforms to the ethical guidelines of the 1975 Declaration of Helsinki. All participants gave informed consent before taking part. All statistical analyses were conducted in SAS (Version 9.4). A p-value ≤ 0.05 was considered statistically significant. All study data are protected with an Assurance of Confidentiality.

3. Results

3.1. Cross-sectional Study

A total of 3,935 WTCGRC members enrolled in this current study. Of those, 64 persons were excluded (18 born outside the birth cohort, 21 missing laboratory data, 15 with "indeterminate" HCV antibody results with negative HCV RNA PCR testing, and 10 withdrawals). Of the remaining 3,871, 109 (2.8%) had HCV infection.

The prevalence of HCV infection in study participants was similar to the prevalence in the US population (Supplementary Material, Figure S1). The age-standardized point prevalence of HCV infection in the WTC Cohort was 2.98% [95% CI (2.39, 3.56)] and in the US population was 3.33% [95% CI (2.54, 4.11)] [% difference=0.35%, 95% CI (-0.31%, 1.01%), P=0.47].

Of the 109 persons with antibodies to HCV, 14 (13%) had current infection based on the presence of HCV RNA in their blood, 39 (36%) reported previous treatment for HCV infection, 39 (36%) reported no previous treatment for HCV infection, and 17 (16%) reported they did not know if they

had been treated or did not answer the question. Because HCV treatment status is unknown in these last 17 persons, the range of spontaneous clearance of HCV infection in this group is between 36% (39/109) and 51% (56/109).

Of the 14 persons diagnosed with current HCV infection, two were in care for HCV infection at the time of screening, and 12 were referred for specialized care by study personnel. Of the 12, 11 (92%) requested a referral to the Mount Sinai Liver Medicine Practice, and one requested a referral to a federally qualified health center based on insurance status. Of the 12 referred for care, 10 (83%) were linked to care (attended an in-person appointment with a liver specialist). Of the 10 linked to care, nine persons were prescribed and received anti-HCV therapy and achieved sustained virologic response.

3.2. Nested Case-control Study

Of the 3,871 participants in the cross-sectional study, 507 persons did not have available exposure data (89 did not consent to participate in the WTCGRC Research Study, eight had data that were not yet integrated into the WTCGRC Research Study database, and 410 did not have complete data on at least one of the three main exposures) leaving 3,364 persons. Of the 3,364 persons, 732 did not provide complete information on traditional HCV risk factors leaving 2,632 persons for the nested case-control study (Table 1).

Of the 2,632 persons included in the nested case-control study, 61 (2.3%) had HCV antibodies indicating prior or current HCV infection and were identified as cases.

Table 1. Participants with and without hepatitis C virus (HCV) antibodies in the nested case-controls study[a].

		HCV Antibody+	HCV Antibody-	
Characteristics		**N=61 (%)**	**N=2571 (%)**	**P-value**
Demographics				
Sex				.34[b]
	Male	54 (89)	2160 (84)	
	Female	7 (11)	411 (16)	
Time period of birth				.001[b]
	1945 - 1949	3 (5)	210 (8)	
	1950 - 1954	20 (33)	391 (15)	
	1955 - 1959	18 (30)	694 (27)	
	1960 - 1965	20 (33)	1276 (50)	
Race				.33[b]
	White	30 (49)	1433 (56)	
	Multi-Racial	14 (23)	411 (16)	
	Black	11 (18)	451 (18)	
	Asian	0	37 (1)	
	American Indian / Alaskan Native	1 (2)	7 (0.3)	
	Pacific Islander	0	1 (0.1)	
	Not answered	5 (8)	231 (9)	
Latino (N=2533)				.35[b]
	Yes	16 (28)	554 (22)	
	No	42 (72)	1921 (78)	

Table 1 (*Continued*)

Characteristics		HCV Antibody+ N=61 (%)	HCV Antibody- N=2571 (%)	P-value
Insurance status (N=2501)				.005[b]
	Medicaid	3 (5)	75 (3)	
	Medicare	17 (31)	369 (15)	
	No insurance	2 (4)	60 (2)	
	Private insurance	33 (60)	1942 (79)	
Born in the United States (N=2566)				.11[b]
	Yes	51 (86)	1950 (78)	
	No	8 (14)	557 (22)	
Main Exposures				
Contact with human remains				.95[b]
	Yes	28 (46)	1190 (46)	
	No	33 (54)	1381 (54)	
Contact with blood and/or bodily fluids				.25[b]
	Yes	22 (36)	752 (29)	
	No	39 (64)	1819 (71)	
Contact with Sewage				.02[b]
	Yes	37 (61)	1175 (46)	
	No	24 (39)	1396 (54)	
Traditional HCV risk factors				
Blood transfusion or organ transplant before July 1992		1 (2)	36 (1)	.58[c]
Receipt of clotting factor concentrate produced before 1987		0	5 (0.2)	1.00[c]
Receipt of long-term hemodialysis		1 (2)	2 (0.1)	.07[c]
Receipt of blood from an HCV-infected donor		1 (2)	8 (0.3)	.19[c]
Born to HCV-infected mother		0	12 (0.5)	1.00[c]
HIV or AIDS		1 (2)	2 (0.1)	.07[c]
History of injecting drug use		3 (5)	0	<.001[c]
Needle stick, sharps, or mucosal exposure to HCV-infected blood as a health care, emergency medical or public safety worker		1 (2)	34 (1)	.56[c]
Activities at the WTC site[d]				
Year of enrollment in the World Trade Center General Responder Cohort				.85[b]
	2002-2005	31 (51)	1219 (47)	
	2006-2009	17 (28)	764 (30)	
	2010-2013	4 (7)	241 (9)	
	2014-2018	9 (15)	347 (14)	
Type of work at WTC site (N=2611)‡				
	Laborers	3 (5)	31 (1)	.004[c]
	Perimeter Security	2 (3)	543 (20)	<.001[c]

Table 1 (*Continued*)

Characteristics		HCV Antibody+ N=61 (%)	HCV Antibody- N=2571 (%)	P-value
	Police Officer	0	344 (13)	<.001[c]
	Truck drivers	3 (5)	21 (1)	.02[c]
Time-weighted glove use (N=2562)				.02[e]
	Rarely/Never	12 (20)	741 (30)	
	Sometimes	6 (10)	442 (18)	
	Most of the time	16 (27)	505 (20)	
	Always	26 (43)	814 (33)	
Time-weighted personal protective equipment use (N=2562)				.54[e]
	Rarely/Never	43 (73)	1840 (74)	
	Sometimes	9 (15)	216 (9)	
	Most of the time	2 (3)	118 (5)	
	Always	5 (8)	304 (12)	
Received medical care for an injury which pierced the skin (N=1720)				.76[c]
	Yes	2 (5)	137 (8)	
	No	35 (95)	1546 (92)	

HCV: hepatitis C virus, WTC: World Trade Center, HIV: human immunodeficiency virus, AIDS: acquired immunodeficiency syndrome
[a] Unless otherwise noted, data is presented for all 61 cases (persons who had HCV antibodies) and 2571 controls (persons without HCV antibodies).
[b] Analyzed using Chi-square analysis.
[c] Analyzed using Fisher's Exact analysis.
[d] Data on all categories of work at the WTC site are included in Supplementary Material, Table S2.
[e] Analyzed using Chi-square test for linear trend.

Participants in the nested case-control study were 84% men, 56% white, 18% black, 16% multi-racial, 9% not-reported, 1% Asian, 0.3% American Indian and Alaskan Native, 0.04% Pacific Islander, and 23% Latino. There was a higher prevalence of black WTCGRC members in this HCV Study compared to the full WTCGRC Research Study [7]. The median age on enrollment was 58 years [interquartile range (IQR) 54, 62].

Cases and controls were of similar sex, race, ethnicity, insurance status, and USA birth but differed in time period of birth (P=.001) (Table 1). Cases and controls did not differ in their contact with human remains (P=.95) and blood and/or bodily fluid (P=.25), but did differ in their contact with sewage (P=.02).

After evaluating demographic characteristics and activities at the WTC site in univariable and multivariable analysis adjusting for time period of birth and traditional HCV risk factors, working or volunteering for perimeter security at the WTC site, and working or volunteering as a truck driver at the WTC site were both associated with HCV infection. (Characteristics of the persons working or volunteering for perimeter security and characteristics of persons working or volunteering as a truck driver at the WTC are presented in Supplementary Materials, Table S3, and Table S4, respectively.) Thus, the final models adjusted for time period of birth, traditional HCV risk factors, working or volunteering for perimeter security at the WTC site, and working or volunteering as a truck driver at the WTC site.

In multivariable logistic regression models, adjusting for possible confounders (time period of birth, traditional HCV risk factors, perimeter security work at the WTC, driving a truck during WTC), contact with human remains was not associated with HCV infection [Table 2, Model 1: OR=1.10, 95% CI (0.63, 1.91), P=0.74) and contact with blood and/or bodily fluids was not associated with HCV infection [Table 2, Model 2: OR=1.45, 95% CI (0.82, 2.56), P=0.20]. Contact with sewage was associated with HCV infection [Table 2, Model 3: OR=1.72, 95% CI (1.00, 2.98), P=0.05].

4. DISCUSSION

This study suggests the prevalence of HCV infection in WTCGRC members born from 1945 through 1965 is comparable to that of the US population, the spontaneous HCV infection clearance rate in this population is similar to the general

Table 2. Multivariable logistic regression models for risk of HCV infection (N=2632)[a].

	HCV Antibody+	HCV Antibody-	Model 1	Model 2	Model 3
Characteristics	**N=61 (%)**	**N=2571(%)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
Main exposures					
Contact with human remains					
Yes	28 (46)	1190 (46)	1.10 (0.63, 1.91)[b]		
No	33 (54)	1381 (54)	1.00		
Contact with blood and/or bodily fluids					
Yes	22 (36)	752 (29)		1.45 (0.82, 2.56)[c]	
No	39 (64)	1819 (71)		1.00	
Contact with sewage					
Yes	37 (61)	1175 (46)			1.72 (1.00, 2.98)[d]
No	24 (39)	1396 (54)			1.00
Other characteristics independently associated with HCV infection					
Perimeter security during WTC activities					
Yes	2 (3)	518 (20)	0.17 (0.04, 0.70)[e]	0.17 (0.04, 0.70)[e]	0.17 (0.04, 0.70)[e]
No	59 (97)	2032 (80)	1.00	1.00	1.00
Truck driver during WTC activities					
Yes	3 (5)	21 (1)	6.26 (1.73, 22.68)[f]	6.65 (1.86, 23.74)[g]	6.27 (1.76, 22.27)[f]
No	58 (95)	2529 (99)	1.00	1.00	1.00

HCV: hepatitis C virus, WTC: World Trade Center

[a] *All models adjusted for time period of birth (1945- 1949, 1950-1954, 1955-1959, 1960-1965) and traditional HCV risk factors (blood transfusion or organ transplant before July 1992, receipt of clotting factor concentrate produced before 1987, receipt of long-term hemodialysis, receipt of blood from HCV-infected donor, birth to HCV-infected mother, history of human immunodeficiency virus infection or acquired immunodeficiency syndrome, history of injecting drug use, and needle stick, sharps, or mucosal exposure to HCV-infected blood as a health care, emergency medical, or public safety worker).*

[b] *P = .74*

[c] *P = .20*

[d] *P = .05*

[e] *P = .01*

[f] *P = .005*

[g] *P = .004*

population, and an ongoing cohort study is an effective site for screening for HCV and linkage to care. Contact with sewage at the WTC site may be associated with an increased risk of HCV infection.

The similar prevalence of HCV infection in WTCGRC members born from 1945 through 1965 and in the general US population initially appears reassuring. However, the WTCGRC members, by definition, are persons who worked at the WTC site. Comparisons of groups of workers to the general population may suffer from the "healthy worker effect" bias. In their often-cited article, Li and Sung write, "the 'healthy worker effect' reflects that an individual must be relatively healthy to be employable in a workforce, and both morbidity and mortality rates within the workforce are usually lower than in the general population" [15]. Thus, the similar prevalence of HCV infection in WTCGRC members and the general US population may be reassuring or may reflect an increased risk of HCV infection in WTCGRC workers, which is obfuscated by the healthy worker effect. While Li and Sung would recommend comparing HCV infections among members of the WTCGRC cohort to an external work comparison group [15], such a comparison is beyond the scope of this current study.

The rate of spontaneous clearance of HCV infection in this study was between 36% and 51%, consistent with the current literature. While the oft-cited systematic review of spontaneous clearance by Micallef et al. found spontaneous clearance of HCV infection to be 26% (95% CI: 22%, 29%) [16], a more recent systemic review and meta-analysis of studies with longer follow-up done by Aisyah et al. found spontaneous clearance at 24 months to be 37.1% (95% CI: 23.7%, 52.8%) [17].

This study was effective at using an existing cohort study to screen persons for HCV infection and to link infected persons with care. Previous research has suggested that sites which both screen for HCV and provide treatment for HCV are more successful at linking HCV-infected persons to care. Galbraith et al reported 21% (21/100) of patients with HCV infection were linked to care after screening done in a hospital emergency department, a site in which screening and treatment were not co-located [18]. In contrast, Jonas et al reported 81% (214/277) linkage to care in a study of 11,200 persons born from 1945 through 1965 who were screened during routine outpatient visits at Kaiser Permanente [19], a site in which screening and treatment were co-located. In their study in which 4,514 persons were screened for HCV infection at 5 different federally qualified health centers, Coyle et al reported that the most successful linkage-to-care rate was seen at the one health center in which HCV testing, care, and treatment were provided in the same setting [67.6% (167 out of 247)] [20]. The high percentage of persons linked to care in this study is likely due to both the continuing relationship of the participants with the WTCGRC Research Study and the co-location of the Mount Sinai Liver Medicine Practice.

This is the first well-designed epidemiologic study to suggest an association between contact with sewage and HCV infection. A study in 1999 described two sewer workers with no recognized HCV risk factors and routine skin contact with sewer water, who were diagnosed with HCV infection [21]. A cross-sectional study of 19,503 persons in Brazil, ages 10 to 69, from all 26 State capitals and the Federal District, found that families without public sewage disposal had an increased risk of HCV infection [OR=2.53, 95% CI (1.38, 4.65)] after adjusting for age, IDU, use of sniffed drugs, injection with a glass syringe, and hospitalization [22]. The authors interpreted this finding as an association between HCV infection and low socioeconomic status, and did not discuss the possibility of contact with sewage as a risk factor for HCV infection.

There are few HCV seroprevalence studies among persons with occupational contact with sewage. A study of 107 sanitary workers in Pakistan, ages 20 to 48, with at least five years of exposure to opening drains, large sewage ducts, and sewage piping, found 39 (36%) had HCV antibodies [23]. This was higher than the prevalence of HCV infection in the general population of Pakistan (2.6%-5.3%). A study of 410 sanitary workers in Alexandria, Egypt, found 9.8% had HCV antibodies [24]. This was similar to the estimated prevalence of HCV infection in the region's general population. However, generalizing findings from this Egyptian study is difficult. Egypt has a history of mass spread of HCV infection during a campaign to fight schistosomiasis, which was

followed by mass treatment for infected persons and mass education campaigns to prevent further spread [25].

The association between contact with sewage and HCV infection may not be real. There are well-established risk factors for which this study was unable to adjust, including household contacts with HCV infection [12], sexual risk behaviors [13], and level of education [14], because our questionnaire did not capture this information. However, it is not clear how exposure to sewage at the WTC site would correlate with these unmeasured risk factors. Additionally, some may question the validity of an association with a P-value of 0.05 found in this analysis. However, a P-value ≤ 0.05 is the generally accepted level by which statistical significance is measured, the one used for this study design, and, therefore, the one we must follow in interpreting our results.

In this study, work as a truck driver was associated with an increased risk of HCV infection and work at perimeter security was associated with a decreased risk of HCV infection. The association between work as a truck driver and increased risk of HCV infection is consistent with previous research [26]; this consistency provides validation for this study. The decreased risk of HCV infection among persons working at perimeter security may suggest distance from the site was protective against HCV infection. This may lend further support to an increased risk of HCV infection when exposed to sewage at the site.

While the association between HCV infection and contact with sewage has not been widely reported, this association is biologically plausible. A cross-sectional study of 98 stool samples without occult blood from 98 persons with chronic HCV infection, found 68 (69%) had detectable HCV RNA [27]. Similarly, a cross-sectional study of 12 stool samples from 12 persons with chronic HCV infection, found 10 (83%) had detectable HCV RNA [28]. Ciesek et al found HCV RNA infectivity in a liquid environment lasted up to 5 months at lower temperatures (4 °C) and up to 21 days at room temperature (21 °C) [29]. Paintsil et al found that an HCV clone dried on fomite surfaces maintained its infectivity for up to 6 weeks at 4 °C and 22 °C [30]. Thus, WTCGRC members who reported sewage contact may have come into contact with infective HCV RNA and acquired HCV infection through breaks in their skin or mucous membranes.

This study did not find associations between contact with human remains and/or blood and bodily fluid, and HCV infection. The OSHA requirements for the use of protective gear when contacting these substances [5, 6] has likely increased worker awareness of their danger and may have led to self-protective behaviors, like avoidance of these substances when possible and washing hands immediately after contact.

There are several limitations to this study. Most importantly, the WTCGRC baseline questionnaire did not clearly define what constitutes "contact with sewage" allowing responders individual interpretations. However, given the lack of knowledge of most responders about their HCV status at the time they completed the baseline questionnaire, such misclassification would have been non-differential, leading to an underestimate of the association between contact with sewage and HCV infection. Because some participants enrolled in the WTCGRC Research Study many years after the WTC events, there may be misclassification of exposure due to difficulties with recall. Here to, it is likely that the misclassification would have been non-differential, leading to an underestimate of the association between contact with sewage and HCV infection. This study is unable to determine when HCV infection occurred. IDU is closely associated with HCV infection and participants may not report past IDU. However, it is unlikely that IDU use is correlated with contact with sewage at the WTC site, and, therefore, missing data on IDU is unlikely to confound the relationship between sewage and HCV infection. There are some unmeasured confounders in this study including occupation before and after WTC.

5. Conclusions

This study suggests that existing cohort studies may serve as venues for HCV screening and linkage to care. More research is needed on the relationship between contact with sewage and HCV infection. The combination of the current nested

case-control study and the cross-sectional study of HCV in Brazil [22] suggests that contact with sewage may be a risk factor for HCV in persons with occupational contact with sewage and persons with non-occupational contact with sewage. The CDC now recommends that all adults in the US, ages 18 and over, get tested for HCV at least once in their lifetime [31]. Additional research is needed to determine if the association we detected is real and whether additional HCV screening is appropriate for persons with ongoing contact with sewage.

Supplementary Materials: The following are available in the online version: Table S1: Data sources for nested case-control study, Figure S1: Prevalence of hepatitis C virus antibodies by year of birth in members of the World Trade Center General Responder Cohort and the US population, Table S2: Association between participant activity at the World Trade Center site and hepatitis C virus antibody status, Table S3. Characteristics of World Trade Center (WTC) perimeter security workers from a subset of the WTC General Responder Cohort, recruited and tested for hepatitis C virus antibodies from December 15, 2016 – July 12, 2018 (N=520), Table S4. Characteristics of World Trade Center (WTC) truck drivers from a subset of the WTC General Responder Cohort, recruited and tested for HCV from December 15, 2016 – July 12, 2018 (N=24).

Funding: This work was supported by the US Centers for Disease Control and Prevention (National Institute for Occupational Safety and Health Grant U01OH011307). The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Institutional Review Board Statement: This study was approved by the Icahn School of Medicine Institutional Review Board (Study 16-01343) that conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

Informed Consent Statement: Written informed consent was obtained from all individual participants included in the study.

Acknowledgments: We thank the staff of the World Trade Center Clinical Centers of Excellence; the labor, community, and volunteer organization stakeholders; and the World Trade Center rescue and recovery workers, who responded generously with their service to the World Trade Center attacks and to whom the World Trade Center programs are dedicated.

Declaration of Interest: Douglas T. Dieterich is a consultant and speaker for Gilead and AbbVie. The other authors declare no conflicts of interest.

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La Medicina del Lavoro

Original article

Med Lav 2023; 114 (2): e2023016
DOI:10.23749/mdl.v114i2.14300

Prevalence of and Risk Factors for Hepatitis C Virus Infection in World Trade Center Responders

Supplementary Materials

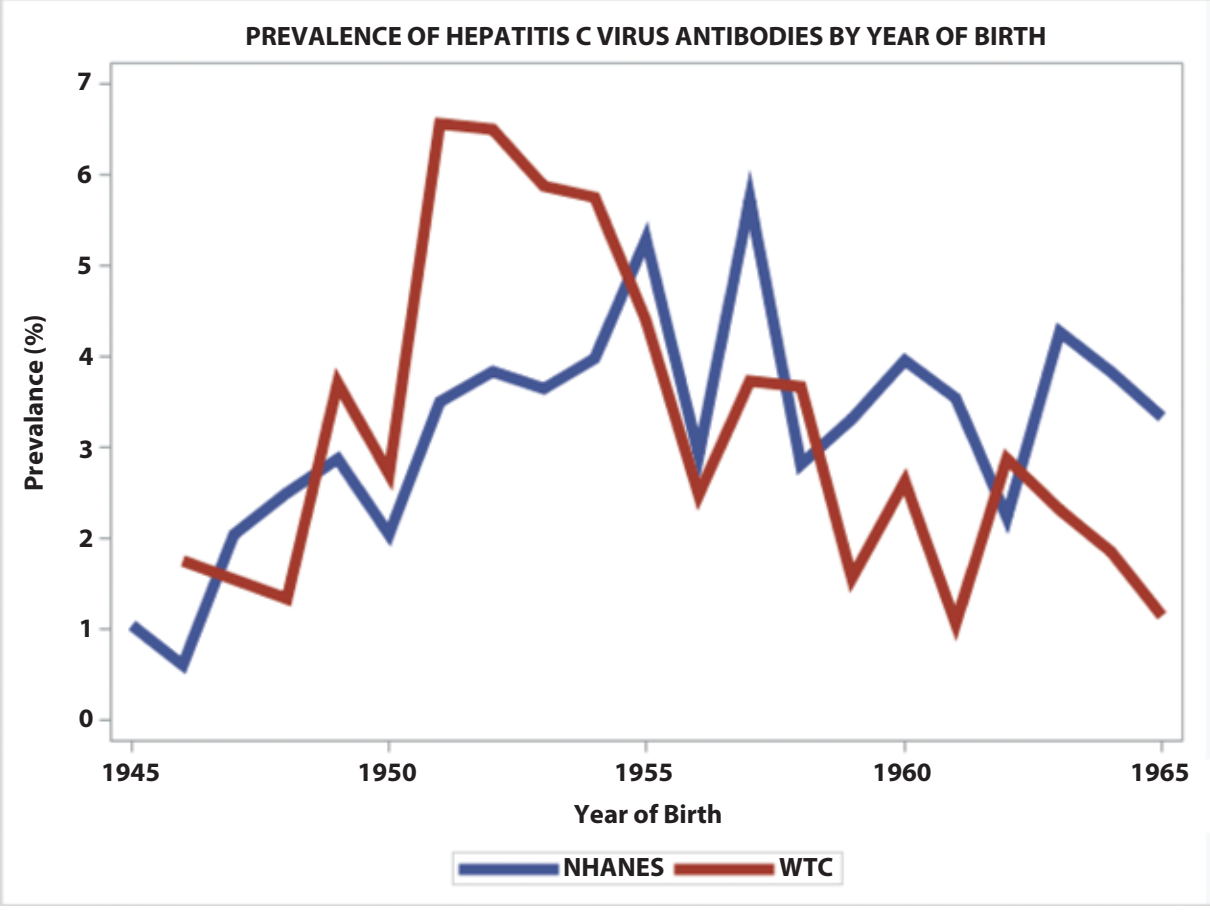

Figure S1. Prevalence of hepatitis C virus antibodies by year of birth in 3,871 members of the World Trade Center General Responder Cohort (recruited and tested from December 15, 2016 - July 12, 2018) and the US population based on National Health and Nutrition Examination Survey (NHANES) data from 2003 through 2012.

Table S1. Data sources for nested case-control study.

Data	World Trade Center General Responder Cohort (WTCGRC) Baseline Questionnaire	Hepatitis C Virus Risk Factor Questionnaire	Blood draw for hepatitis C virus antibodies
Time of data collection in relation to the World Trade Center General Responder Cohort Study	Baseline visit for WTCGRC (Visit 1)	Visit to for enrollment or monitoring WTCGRC (Visit 1 or higher)	
Date of data collection for the 2632 persons in current study	July 18, 2002 – May 8, 2018	December 15, 2016 – July 12, 2018 (The HCV Risk Factor Questionnaire and the blood draw were done on the same day)	
Study outcome – Hepatitis C Virus Antibody status			X
Main exposures			
Human remains	X		
Blood and bodily fluids	X		
Sewage	X		
A priori confounders (included in the final multivariable logistic regression models)			
Year of birth		X	
Traditional risk factors for HCV infection			
• Blood transfusion/organ transplant before July 1992		X	
• Receipt of clotting factor concentrate produced before 1987		X	
• Hemodialysis		X	
• Receipt of blood from an HCV-infected donor		X	
• Birth to an HCV-infected mother		X	
• History of HIV/AIDS		X	
• History of injecting drug use			
• Needle stick, sharps or mucosal exposure as a health care, emergency medical, or public safety worker		X	
Characteristics evaluated as possible confounders			
Demographics			
• Sex	X		
• Race	X		
• Ethnicity	X		
• Country of birth		X	
• Insurance status		X	

Table S1 (*Continued*)

Data	World Trade Center General Responder Cohort (WTCGRC) Baseline Questionnaire	Hepatitis C Virus Risk Factor Questionnaire	Blood draw for hepatitis C virus antibodies
Activities at the WTC site			
• Year of enrollment in WTCGRC	X		
• Type of work at the WTC site	X		
• Use of protective gloves	X		
• Use of protective clothing	X		
• Seeking care for injury or illness	X		

Table S2. Association between participant activity at the World Trade Center site and hepatitis C virus (HCV) antibody status among of a subset of the World Trade Center General Responder Cohort, recruited and tested for HCV from December 15, 2016 - July 12, 2018 (N=2,632).

Activity (in order of questionnaire)	Total N	HCV Antibody+ N=61 (%)	HCV Antibody- † N=2571 (%)	P-value
Department of Labor Codes				
Barge workers (53-5021.00)	3	1 (2)	2 (0.1)	0.07‡
Boiler makers (47-2011.00)	0	0	0	
Carpenters (47-2051.00)	21	1 (2)	20 (1)	0.39‡
Carpet, floor, and tile installers and finishers (47-2041.00)	0	0	0	
Construction and building inspectors (47-4011.00)	2	0	2 (0.1)	1.00‡
Construction equipment operators (47-2073.00)	2	0	2 (0.1)	1.00‡
Dock builders (47-2031.00)	3	0	3 (0.1)	1.00‡
Drywall installers, ceiling tile installers, and tapers (47-2081.00)	1	0	1 (0.04)	1.00‡
Electricians (47-2111.00)	25	1 (2)	24 (1)	0.45‡
Elevator installers and repairers (47-4021.00)	1	0	1 (0.04)	1.00‡
Engineers (structural/other, operating & (heavy) equipment operators coded together) (17-2199.00)	33	0	33 (1)	1.00‡
Equipment workers (49-2022.01)	5	0	5 (0.2)	1.00‡
Glaziers (47-2121.00)	1	0	1 (0.04)	1.00‡
Hazardous materials removal workers (47-4041.00)	6	0	6 (0.2)	1.00‡
Heating, air & refrigeration mechanics (49-9021.00)	5	1 (2)	4 (0.2)	0.11‡
Highway maintenance workers (47-4051.00)	4	1 (2)	3 (0.1)	0.09‡
Insulation workers (47-2131.00)	3	0	3 (0.1)	1.00‡
Ironworkers, structural and reinforcing iron and metal workers (47-2221.00)	77	2 (3)	75 (3)	0.70‡
Laborers (53-7062.00)	34	3 (5)	31 (1)	0.04‡
Landscapers & groundskeepers (37-3011.00)	0	0	0	
Masons: brick, block and stone (47-2021.00)	1	0	1 (0.04)	1.00‡
Masons: cement, concrete finishers, segmental pavers, and terrazzo workers (47-2031.00)	0	0	0	
Masons: plasterers and stucco (47-2161.00)	0	0	0	
Mechanics (49-3011.00)	17	0	17 (1)	1.00‡

Table S2 (*Continued*)

Activity (in order of questionnaire)	Total N	HCV Antibody+ N=61 (%)	HCV Antibody- † N=2571 (%)	P-value
Painters and paperhangers (47-2141.00)	0	0	0	
Paving, surfacing, & tamping workers (47-2071.00)	1	0	1 (0.04)	1.00‡
Pipe layers, plumbers, pipe fitters, and steam fitters (47-2151.00)	9	0	9 (0.4)	1.00‡
Roofers (47-2181.00)	0	0	0	
Sheet metal workers (47-2211.00)	5	0	5 (0.2)	1.00‡
Truck drivers (53-3032.00)	24	3 (5)	21 (1)	0.02‡
Military (55-0000)	2	0	2 (0.1)	1.00‡
World Trade Center Site Activities				
Body bag work	71	3 (5)	68 (3)	0.23‡
Bucket brigade	439	8 (13)	431 (17)	0.43§
Cable installation/repair/splicing (EXCLUDING work performed in manholes)	44	1 (2)	43 (2)	1.00‡
Cable installation/repair/splicing (INCLUDING work performed in manholes)	46	3 (5)	43 (2)	0.09‡
Canteen services	67	2 (3)	65 (3)	0.67‡
Counselor	16	0	16 (1)	1.00‡
Custodian	97	1 (2)	96 (4)	0.73‡
Dog handlers	1	0	1 (0.04)	1.00‡
Dust suppression	34	0	34 (1)	1.00‡
Emergency medical technician	16	1 (2)	15 (1)	0.32‡
Escorting	161	3 (5)	158 (6)	1.00‡
Excavation / Confined space work	38	0	38 (1)	1.00‡
Fire Fighter	20	0	20 (1)	1.00‡
Industrial Hygienist	4	0	4 (0.2)	1.00‡
Morgue work	98	1 (2)	97 (4)	0.73‡
Police Officer	344	0	344 (13)	<0.001‡
Perimeter security	520	2 (3)	518 (20)	<0.001‡
Sanitation workers	37	1 (2)	36 (1)	0.59‡
Search and rescue	423	9 (15)	414 (16)	0.86§
Sifting (EXCLUDING conveyer belt)	135	2 (3)	133 (5)	0.77‡
Sifting (INCLUDING conveyer belt)	192	2 (3)	190 (7)	0.32‡
Towing	7	0	7 (0.3)	1.00‡
Truck loading/unloading	69	2 (3)	67 (3)	0.68‡
Truck routing	16	1 (2)	15 (1)	0.32‡
Other	636	20 (33)	616 (24)	0.12§

HCV: hepatitis C virus

† Of the 2571 persons without HCV antibodies (controls), 21 (1%) did not provide any data about the type of activities they performed at the WTC site. The percentages presented here are percentages among the controls for whom there is data on activity at the WTC site.

‡Analyzed using Fishers Exact test determined the association between participation in the listed activity vs. no participation in the listed activity and HCV infection.

§Analyzed using Chi-Square Test determined the association between participation in the listed activity vs. no participation in the listed activity and HCV infection.

Table S3. Characteristics of World Trade Center (WTC) perimeter security workers from a subset of the WTC General Responder Cohort, recruited and tested for hepatitis C virus antibodies from December 15, 2016 – July 12, 2018 (N=520).

	HCV Antibody+	HCV Antibody-	
Characteristics	**N=2 (%)**	**N=518 (%)**	**P-value**
Demographics			
Sex			
Male	1 (50)	415 (80)	.36*
Female	1 (50)	103 (20)	
Time period of birth			
1945 - 1949	0	16 (3)	.57*
1950 - 1954	0	42 (8)	
1955 - 1959	1 (50)	119 (23)	
1960 - 1965	1 (50)	341 (66)	
Race			
White	0	260 (50)	.11*
Multi-Racial	1 (50)	98 (19)	
Black	0	103 (20)	
Asian	0	7 (1)	
American Indian / Alaskan Native	0	1 (0.2)	
Pacific Islander	0	0	
Not answered	1 (50)	49 (9)	
Latino			
Yes	2 (100)	144 (29)	.08*
No	0	361 (71)	
Insurance status (N=496)			
Medicaid	0	2 (0.4)	1.00*
Medicare	0	39 (8)	
No insurance	0	4 (1)	
Private insurance	1 (100)	450 (91)	
Born in the United States (N=514)			
Yes	1 (50)	432 (84)	.29*
No	1 (50)	80 (16)	
Main Exposures			
Contact with human remains			
Yes	1 (50)	255(49)	1.00*
No	1 (50)	263 (51)	
Contact with blood and/or bodily fluids			
Yes	1 (50)	158 (31)	.52*
No	1 (50)	360 (69)	

Table S3 (*Continued*)

Characteristics		HCV Antibody+ N=2 (%)	HCV Antibody- N=518 (%)	P-value
Contact with Sewage				
	Yes	1 (50)	243 (47)	1.00*
	No	1 (50)	275 (53)	
Traditional HCV risk factors				
Blood transfusion or organ transplant before July 1992		0	10 (2)	1.00*
Receipt of clotting factor concentrate produced before 1987		0	1 (0.2)	1.00*
Receipt of long-term hemodialysis		0	0	ND
Receipt of blood from an HCV-infected donor		0	3 (1)	1.00*
Born to HCV-infected mother		0	3 (1)	1.00*
HIV or AIDS		0	0	ND
History of injecting drug use		0	0	ND
Needle stick, sharps, or mucosal exposure to HCV-infected blood as a health care, emergency medical or public safety worker		1 (50)	8 (2)	.03*

ND – Not defined.
**Analyzed using Fisher's Exact test.*

Table S4. Characteristics of World Trade Center (WTC) truck drivers from a subset of the WTC General Responder Cohort, recruited and tested for HCV from December 15, 2016 – July 12, 2018 (N=24).

Characteristics		HCV Antibody+ N=3 (%)	HCV Antibody- N=21 (%)	P-value
Demographics				
Sex				
	Male	2 (67)	20 (95)	.24*
	Female	1 (33)	1 (5)	
Time period of birth				
	1945 - 1949	0	1 (5)	.41*
	1950 - 1954	1 (33)	2 (10)	
	1955 - 1959	2 (67)	8 (38)	
	1960 - 1965	0	10 (48)	
Race				
	White	0	10 (48)	.24*
	Multi-Racial	2 (67)	5 (24)	
	Black	1 (33)	6 (29)	
Latino				
	Yes	2 (67)	5 (24)	.19*
	No	1 (33)	16 (76)	

Table S4 (*Continued*)

Characteristics		HCV Antibody+ N=3 (%)	HCV Antibody- N=21 (%)	P-value
Insurance status (N=20)				
	Medicaid	0	1 (6)	.51*
	Medicare	1 (33)	2 (12)	
	Private insurance	2 (67)	14 (82)	
Born in the United States (N=23)				
	Yes	1 (50)	16 (76)	.46*
	No	1 (50)	5 (24)	
Main Exposures				
Contact with human remains				
	Yes	0	0	ND
	No	3 (100)	21 (100)	
Contact with blood and/or bodily fluids				
	Yes	1 (33)	0	.13*
	No	2 (67)	21 (100)	
Contact with Sewage				
	Yes	2 (67)	7 (33)	.53*
	No	1 (33)	14 (67)	
Traditional HCV risk factors				
Blood transfusion or organ transplant before July 1992		0	1 (5)	1.00*
Receipt of clotting factor concentrate produced before 1987		0	0	ND
Receipt of long-term hemodialysis		0	0	ND
Receipt of blood from an HCV-infected donor		0	0	ND
Born to HCV-infected mother		0	0	ND
HIV or AIDS		0	0	ND
History of injecting drug use		0	0	ND
Needle stick, sharps, or mucosal exposure to HCV-infected blood as a health care, emergency medical or public safety worker		0	0	ND

ND – Not defined.
**Analyzed using Fisher's Exact test.*

La Medicina del Lavoro

Original article

Med. Lav. 2023; 114 (2): e2023015
DOI: 10.23749/mdl.v114i2.13975

Alarm Fatigue in Nursing Students Undertaking Clinical Training in Intensive Care Units: A Multicenter Study

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Keywords: Alarm Fatigue; Nursing Students; Intensive Care Unit; Patient Safety

Abstract

Background: *The frequency of alarms from monitors and other electro-medical devices is of great utility but can increase the professional's workload and expose nurses in the intensive care unit to Alarm Fatigue. A recent study suggested that students in training can also experience the problem during their first clinical experiences in intensive care. Unfortunately, no data are available about the Italian panorama. To explore Alarm Fatigue among Bachelor of Science in Nursing students at the end of their internship experience in intensive care settings.* **Methods:** *Multicenter cross-sectional design. A convenience sample of nurses from 3 Italian university hospitals was recruited. The students completed the revised version of the "Alarm Fatigue questionnaire-ita" at the end of the clinical internship in intensive care settings.* **Results:** *130 nursing students were enrolled (response rate 59.36%). The overall level of Alarm Fatigue was Me= 24.5 IQR [17.5, 30.5]. In addition, 9.23% of the sample reported errors or near misses related to Alarm Fatigue during the internship experience. The alarm fatigue level was higher in students who committed "errors/almost errors" (p=0.038) and in "student workers" (p=0.005).* **Discussion:** *The extent of alarm fatigue experienced by nursing students requires developing a preventive strategy.*

1. Introduction

The continuous advance in medicine and technologies nowadays allows healthcare organizations to benefit from a variety of equipment and devices to support day-to-day clinical practice; this can be found in every care setting, but particularly in high-intensity clinical care settings such as intensive care, where patients are subjected to continuous monitoring, often with devices capable of alerting staff with special alarm systems [1-4]. Although a prompt response to alarms coming from monitors and other electro-medical devices is of great utility to healthcare professionals, supporting them in the rapid recognition of potentially dangerous situations, the International literature shows that the rising use of the devices themselves may represent, even paradoxically, a risk factor for patient safety: the frequency of "false alarms" is often very high and represents a danger because it can increase the professional's

Received 22.11.2022 – Accepted 15.03.2023
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workload, and above all, because it can make him progressively less sensitive and therefore responsive to all alarms [1, 4, 5].

The occurrence and progression of this status can expose any practitioner and particularly the nurses, to the risk of developing "Alarm Fatigue" (AF) [2, 4, 6, 7], which can be defined as a sensory overload capable of causing progressive desensitization to alarms due to exposure to a high number of alarms that turn out to be false or not clinically significant [8].

Higher levels of AF may be associated with the behavioral responses of nurses being inappropriate, such as setting alarms out of safe limits, turning down the volume, or even turning off the alarm signals, thus constituting a possible risk to patient safety [3, 9, 10]. Therefore, the improvement of AF management is an area of increasing interest, and in 2022, the accreditation organization for excellence Joint Commission reaffirmed it as one of the international goals for patient safety [11].

Understanding the exact character and extent of AF in nurses is just the first step in a multidimensional approach aimed at improving work processes and consequently reducing the risk for patients and increasing the safety of the healthcare facilities performed; [12] the topic is therefore increasingly being investigated worldwide [2, 13-15]. Carelli et al. (2022) [3] first documented its prevalence in the Italian healthcare scenario and showed the association between specific AF behaviour and professional errors.

A recent study [7] has also pointed out that the problem of Alarm Fatigue is not limited to professionals but can also be experienced by students in training during their first clinical experiences in intensive care. However, the lack of in-depth investigations on this subject in the Italian academic panorama suggests the need to investigate the phenomenon in nursing degree courses as well to provide health and education systems with early guidance for a better understanding and consequent proactive management of the problem.

This study aimed to explore the phenomenon of Alarm Fatigue among students of the Bachelor of Science in Nursing at the end of their internship experience in intensive care settings.

2. Methods

2.1. Design and Setting

The administration of a research questionnaire developed a cross-sectional multicenter study. Students of three Italian schools of nursing (the University of Milan, the University of Roma - La Sapienza, University of Foggia) were enrolled. In addition, all students who undertook at least one internship experience in an intensive care unit during the study period were enrolled.

Since this is the first research investigating the FA of students in the Italian context, the estimated sample size was based on the prior study by Week et al. [7], in which 89 students were enrolled. Based on their results, a minimum of 100 students was initially hypothesized.

2.2. Sample and Data Collection

For each nursing school, two research team members were identified to explain the purpose of the survey, how to fill out the instrument and to organize data collection from March 1 to July 31 2022. At the end of the presentation, the research team members sent a web link generated via an online application to the student's e-mail address of the school of nursing, which included the research instrument.

Students were invited to participate after their clinical experience in an intensive care unit. All students who undertook at least one internship experience in an intensive care unit during the study period were enrolled; those who interrupted the experience before seven days were excluded.

2.3. The Instrument

The instrument was composed of two sections: (i) socio-demographic and academic data collection form (age, gender, work commitment, if any, university, unit and length of the internship experience, direct or indirect AF-related errors/errors during the clinical experience); (ii) the modified Alarm Fatigue Questionnaire-ita survey instrument.

1. I adjust/I should adjust alarm settings based on the patient's condition
2. I turn off/I should turn off alarms at the beginning of each shift
3. In general, I hear a certain amount of noise in the ward
4. I believe that much of the noise in the ward is due to alarms from monitoring equipment
5. I pay more attention to alarms on certain shifts
6. On some shifts, the heavy workload in the department prevents me from responding quickly to alarms
7. When alarms go off repeatedly, I become indifferent to them
8. The sound of the alarm makes me nervous
9. I react differently if the alarm shows a high (high volume or red) or low priority (low volume or yellow/green)
10. When I am angry and nervous, I am more bothered by alarm sounds
11. When alarms go off repeatedly and continuously, I lose patience
12. Alarm sounds prevent me from focusing on my professional activities
13. During visiting hours, I pay less attention to equipment alarms

Torabizadeh developed the "Alarm Fatigue Questionnaire" in 2017 [15], and it was recently validated in Italian by Carelli et al. confirming its good validity and reliability properties.

It comprises 13 items; the participants are asked to quantify the frequency of any of the behaviours regarding alarm management described in each item. The total score of the tool ranges from 0 (lowest impact of fatigue) to 52 (highest impact of fatigue). In agreement with the original study, for each item, a median score ≥ 3 indicated an Alarm Fatigue behaviour.

Since the instrument was validated on a different population, it was necessary to test its properties on students as well; the scale was submitted to 4 nursing students and four tutor nurses to evaluate face and content validity. They were asked for their opinion regarding the level of understanding of the statements, the relevance of each item (on a ten-point Likert scale), and the need for changes. Based on the judgement of the evaluators involved, it proved necessary to modify two items of the scale: item 1, "I adjust alarm settings based on patient condition", was modified to "I adjust/I would adjust alarm settings based on patient condition"; item 2 "I turn off alarms at the beginning of each shift" was modified in "I turn off/I would turn off alarms at the beginning of each shift". Finally, the content validity of each statement (I-CVI) and the tool (S-CVI) were calculated.

2.4. Ethical Considerations

The directors approved the study of every center involved in the study under the Helsinki Declaration as revised in 2008. We complied with the rules of each local Ethical committee, which did not require approval for studies on this topic and this type of data at the time of data collection. Informed consent was collected for each participant prior to participating in the study. Anonymous double-blind survey administration allowed a reduction of the risk of social-desirability bias.

2.5. Statistical Analysis

Continuous variables were described as mean and standard deviation if normally distributed or with median and interquartile range otherwise. The Kolmogorov-Smirnov test assessed the normality of data distribution.

Internal consistency was assessed by measuring Cronbach's Alpha coefficient.

The significance level was set at 5% for all calculations. The analyses were conducted with SPSS 24 edition. The relation of alarm fatigue scores with different variables was assessed using the non-parametric Mann-Whitney test.

3. Results

3.1. Sample Characteristics

One hundred thirty students were enrolled (response rate 59.36%). The median age was

22 years, IQR [22, 24], between 21 and 31 years. The majority of them were female (n=94, 72.31%). 46 (35.38%) attended the course at the University of Milan, 39 (30.0%) at the University of Roma – La Sapienza, and 45 (34.62%) at the University of Foggia. One hundred eight students were not employed (83.08%), 21 had part-time jobs (16.15%), and only 1 had full-time employment (0.77%). Eight student-workers (6.15%) had jobs in an environment where alarms were regularly present.

All the students had just finished their internship experience in the intensive area; 28 (21.54%) had already had at least one other experience in the same setting during their academic career. The units where the last internship experience was carried out were mainly ICU and First Aid (Table 1). The median length of the internship was 45 days, IQR [30, 60], with no differences between settings (p=0.259).

3.2. Errors and Alarm Fatigue

28.46% of the sample (n=37) reported that errors or near misses related to Alarm Fatigue by healthcare professionals or other nursing students had occurred during the internship experience they had just completed. In addition, 9.23% (n=12) also stated that they had made or nearly made errors themselves (Table 2).

Table 1. Sample characteristics.

UNIVERSITY, n (%)	
Milan	46 (35.38)
Roma/ La Sapienza	39 (30.0)
Foggia	45 (34.62)
Prior experience in the critical area, n (%)	
None	102 (78.46)
1	22 (16.92)
2	6 (4.62)
Ward of the ongoing internship experience, n (%)	
Emergency room	41 (31.54)
Resuscitation	53 (40.77)
Cardiac Intensive Care Unit (CICU)	15 (11.54)
Neonatal Intensive Care	8 (6.15)
Covid intensive care unit	6 (4.62)
Post-operative intensive care unit	5 (3.85)
Operating room	2 (1.54)

Table 2. Direct and indirect experiences of adverse events during clinical practice and related, in students' perception, to alarm fatigue.

Alarm Fatigue accidents committed by professionals or other students, n (%)	
No	63 (48.46)
Yes	37 (28.46)
I do not know/ I do not remember	30 (23.08)
Alarm Fatigue accidents by the sample, n (%)	
No	93 (71.54)
Yes	12 (9.23)
I do not know/ I do not remember	25 (19.23)

3.3. Tool Properties

The modified version of the Alarm fatigue questionnaire-ita obtained an S-CVI of 98.5%; all items obtained an I-CVI >90.0%. The Cronbach's alpha coefficient was 0.856; removing every item yielded a minimum value of 0.828.

3.4. Alarm Fatigue in Nursing Students

The overall level of Alarm Fatigue was Me=24.5 IQR [17.5, 30.5] compared to a theoretical range of 0 to 52. Table 3 shows the number of subjects with a median score ≥ 3 for each item on the scale representing a fatigue alarm condition. Over 50% of the sample achieved median scores ≥ 3 in items 2, 5, 7, 11, and 13.

3.5. Alarm Fatigue and Socio-demographic and Academic Variables

The level of alarm fatigue increased significantly between the variables "errors/almost errors committed" and "student worker": the 12 students who reported having committed errors/almost errors during their internship experience in the critical area showed an Alarm Fatigue score of Me=29.

Table 3. Relationship between behaviours assumed and experiences of alarm fatigue incidents.

	AF Me≥ 3	No AF Me<3
	n (%)	n (%)
1. I adjust/I should adjust alarm settings based on the patient's condition	62 (47.69)	68 (52.31)
2. I turn off/I should turn off alarms at the beginning of each shift	76 (58.46)	54 (41.54)
3. In general, I hear a certain amount of noise in the ward	37 (28.46)	93 (71.54)
4. I believe that much of the noise in the ward is due to alarms from monitoring equipment	35 (26.92)	95 (73.08)
5. I pay more attention to alarms on certain shifts	68 (52.31)	62 (47.69)
6. On some shifts, the heavy workload in the department prevents me from responding quickly to alarms	31 (23.85)	99 (76.15)
7. When alarms go off repeatedly, I become indifferent to them	76 (58.46)	54 (41.54)
8. The sound of the alarm makes me nervous	33 (25.38)	97 (74.62)
9. I react differently if the alarm identifies a higher (high volume or red colour) or lower priority (low volume or yellow/green colour)	61 (46.92)	69 (53.08)
10. When I am angry and nervous, I am more bothered by alarm sounds	46 (35.38)	84 (64.62)
11. When alarms go off repeatedly and continuously, I lose patience	66 (50.77)	64 (49.23)
12. Alarm sounds prevent me from focusing on my professional activities	54 (41.54)	76 (58.46)
13. During visiting hours, I pay less attention to equipment alarms	83 (63.85)	47 (36.15)

5 IQR [23.0, 33.3], significantly higher (p=0.038) than those who had not committed any (Me=24.0 IQR [17.5, 29.4]).

Similarly, the 22 student-workers showed significantly higher levels of fatigue (Me=29.5 IQR [24.25, 33.0] vs Me=23.5 IQR [17.5, 30.0] p=0.005); furthermore, the eight students who reported working in an environment where sounds and alarms are regularly present scored even higher Me=30.5 IQR [26.0, 38.5].

No significant differences regarding gender (p=0.203), University Hospital (p=0.535), referred errors or near misses (p=0.292), and the number of clinical experiences in the critical area (p=0.301). Moreover, the overall length of the internship (p=0.083) was detected (Table 4).

4. Discussion

AF is an emerging problem in all clinical areas that make extensive use of the equipment and electromedical devices equipped with acoustic alarm systems; improving knowledge and understanding of the phenomenon and developing preventive policies can be a potential way of ensuring patient safety [16, 17].

Trainee students and nurses are highly exposed to the alarms; therefore, fatigue can be a stressful aspect of their clinical and academic experience. The overall level of fatigue in our sample obtained a median value of 24.5; it can be considered a medium if We consider a theoretical range from 0 to 52.

Since this is a student sample, i.e., people with less exposure to alarms than nurses given the limited period of training experience, the finding indicates a situation worthy of attention as the level of Alarm Fatigue achieved is only mildly lower than that found in professionals [3].

It suggests the hypothesis that the phenomenon may present itself very quickly and at a level of seriousness that is already significant in the event of the subject's exposure to alarms and that this situation may worsen further over time. In addition, the level of Alarm Fatigue experienced by the student suggests the idea that the distress also has in the reduced clinical experience and professional self-doubt of

Table 4. Relationship between Alarm Fatigue and socio-demographic and academic variables.

Variable		Alarm Fatigue Me [IQR]	p
Errors	Yes	29. 5 [23.0, 33.3]	*0.038*
	No	24.0 [17.5, 29.4].	
Referred errors	Yes	26.0 [19.0, 30.5]	0.292
	No	24.5 [17.25, 30.]	
Gender	Female	24.5 [17.5, 30.5]	0.203
	Male	24.0 [18.0, 30.0]	
Worker	Yes	29.5 [24.25, 33.0]	*0.005*
	No	23.5 [17.5, 30.0]	
University Hospital	Unimi	24.5 [18.0, 29.5]	0.535
	Uniroma	25.0 [18.25, 30.25]	
	Unifo	24.5 [17.5, 30.5]	
Clinical experience	1	24.5 [17.5, 30.0]	0.301
	2	25.5 [18.25, 32.0]	
Length	<45 days	23.5 IQR [17.0, 30.5]	0.083
	=>45 days	25.0 IQR [18.0, 30.5]	

the nursing student, who for the first time is undertaking training in a highly complex setting such as the critical care area, two significant causes for the rapid onset of Alarm Fatigue.

Following the results of Carelli et al. [3], the alarm-fatigue behaviors shown by the majority of the students were reported in items 2, 7 and 13; item 2, "I turn off alarms at the beginning of each shift", showed the adoption of a very hazardous behaviour as it has, as a logical consequence, the reduced possibility of being alerted to potentially dangerous clinical situations for patients. Instead, items 7, "When alarms go off repeatedly, I become indifferent to them", and 13, "During visiting hours, I pay less attention to equipment alarms", describe negative attitudes of students regarding the indifference generated by alarm fatigue in two different situations which could influence the clinical practice and patient safety.

About 30% of the student nurses reported indirect experience of errors potentially associated with AF during their clinical internship. This data, only seemingly low, agrees with previous work [3] and offers further evidence regarding the frequency of the phenomenon among healthcare professionals. Also of interest is the finding concerning direct errors: 9.23% of the students reported direct experience of errors; this result is only apparently of little concern, but it does frame, albeit preliminarily, how even the student is not free from committing errors due to the initial Fatigue Alarm discomfort. This result is only apparently of little concern, but it does frame, albeit preliminarily, how even the student is not free from committing errors due to the initial Fatigue Alarm discomfort; it is also necessary to underline that the data may be affected by significant under-reporting (many episodes may potentially not be reported due to shame or fear of being judged) which therefore precludes, at the current level of knowledge, a full understanding of the phenomenon. Perhaps not surprisingly, the 12 students who reported having made errors/almost errors had a significantly higher median Alarm Fatigue score than those who reported having made no errors: the relationship between these two constructs seems very reasonable and represented by a two-way direction, i.e. of mutual influence. Furthermore, the fact that higher levels of Alarm Fatigue are found among working students also demonstrates that stressors external to the student's academic pathway may further expose him to the risk of AF [16].

The relationship with the variables "gender", "operational unit" and "university" did not lead to any significant differences, confirming the findings on nursing staff [3]; the absence of differences in AF scores for the variable 'university' further supports the idea that the diffusion of the problem concerns the nursing students population as a whole, independently of the location of study, and logistic and structural characteristics that may differ in each setting. However, an in-depth study considering these variables' potential influence is desirable.

Finally, the Alarm Fatigue scores obtained by those who had already carried out at least one other clinical experience in the critical area were higher (although not reaching the threshold of statistical significance); in these subjects, the exposure to alarms was more prolonged in duration and therefore higher than in those who had carried out their experience in the critical area for the first time, it is therefore plausible that the levels of alarm fatigue are higher; in the literature, the influence of the duration of exposure on nurses offers discordant results; for example, the study by Lewandowska et al. [2] suggests that nurses with more experience in the critical care area should show more comfort in setting alarms while Carelli et al. [3] shown that longtime experience was associated with higher levels of Alarm Fatigue.

Finally, we found that the modified version of the "Alarm Fatigue Questionnaire-ita" is valid and reliable and thus able to assess the phenomenon in Italian nursing students.

We enrolled nursing students from three University hospitals in different Italian areas; however, the research was limited by a small sample size, even though it was larger than the study by Week et al. [7], which represents only a small portion of the Italian student population; in-depth studies on larger samples may also add to the generalizability to the findings and are therefore recommended. Furthermore, the absence of further investigation regarding AF into the student population, except for the study of Weeks et al. [7] carried out, however, with a different tool, does not allow for a comparison with the results obtained. It will also be interesting to study the association between alarm fatigue levels and other psychological disturbances, such as burnout and moral distress, which have already been extensively studied in nurses [18, 19].

5. Conclusions

Alarms are an unavoidable element in the intensive care unit that exposes not exclusively nurses but also students to the risk of Alarm Fatigue. The negative consequences on the individual's psychological well-being and the effects on patient safety require the introduction of alarm management strategies and support for the need for programs to address alarm fatigue in nursing students.

Therefore, nurse educators, academic education programs, and hospital risk management departments should provide evidence-based tools and strategies to increase awareness of alarm fatigue among students. Furthermore, research and daily clinical experience can support the identification of solutions and increase awareness and responsiveness among nursing students to prepare them for clinical practice better and, consequently, improve patient safety and quality of care.

Declaration of Interest: No conflict of interest has been declared by the authors.

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