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ORIGINAL PAPER

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Evaluation of Work Quality Indicators in Medical Biochemical Laboratories

Aleksandra Pasic^{1,2}, Anes Joguncic³, Emina Smajic², Selvedina Duskan^{1,2}, Emir Sehercehajic², Sanela Hajro^{1,2}

¹Department of Clinical Biochemistry and Immunology, Clinical Center University of Sarajevo, Sarajevo, Bosnia and Herzegovina

²Faculty of Health Studies, University of Sarajevo, Sarajevo, Bosnia and Herzegovina

³Institute for Public Health, Sarajevo, Bosnia and Herzegovina

Corresponding author:

Aleksandra Pasic, MA, PhD student, Department of Clinical Biochemistry and Immunology, Clinical Center University of Sarajevo, Bolnicka 25, +38761210831- E-mail: pasic.sandra71@gmail.com, ORCID ID: <https://orcid.org/0000-0001-8588-8042>.

ABSTRACT

Background: A laboratory professional concerned with the quality of work in medical-biochemical laboratories ensures the accuracy and precision of laboratory analyses through the implementation of international and European guidelines for working with hazardous substances, through the availability and implementation of Standard Operating Procedures (SOPs). Laboratory hazards that affect the concentration and safety of workers arise from laboratory deficiencies such as: lack of preventive measures, knowledge and skills implemented through SOPs and good laboratory practice. Biophysical hazards in medical laboratories are manifested by needles and sharp objects, infectious materials, noise, vibration, radiation, poor air quality, temperature inversions. **Objective:** The aim of the research was to raise awareness of the quality of work in medical-biochemical laboratories in order to ensure the safety of workers. **Methods:** A cross-sectional questionnaire-based study was conducted among 100 laboratory professionals from Bosnia and Herzegovina (BiH) and Croatia. The research was conducted over a period of three months. **Results:** A higher percentage of exposure to infectious agents and needles and sharp objects was found among respondents from BiH compared to CRO ($p=0.018$ and $p=0.001$, respectively). We found that respondents employed in accredited laboratories are aware of exposure to hazards in a high percentage related to infectious agents, toxins ($p=0.0012$ and $p=0.0046$, respectively). A significant statistical difference was found between respondents with BiH and respondents with CRO in terms of knowledge of accreditation standards of medical-biochemical laboratories ($p=0.0155$).

Respondents who have standard operating procedures available are aware of the hazards of infectious agents ($p=0.0001$), toxins ($p=0.0466$), needles and sharp objects ($p=0.0052$), noise ($p=0.0030$), vibration ($p=0.0007$) and extreme temperatures ($p=0.0014$). **Conclusion:** Efficient implementation and continuous compliance with the ISO 15189: 2018 standard requires constant commitment and active participation of laboratory staff. Laboratories must have standard operating procedures in place and actively monitor their use.

Keywords: biosafety, hazards, standard operating procedures, ISO 15189.

1. BACKGROUND

The quality of work in medical-biochemical laboratories is manifested through accuracy, precision and efficiency. Laboratory professionals are under constant pressure due to the increased volume of work and time limit for completing the required analyses. Standardization, harmonization, evidence-based practice, education and training of employees within the laboratory, compliance with international regulations, documents and standards, medical biochemical laboratories lead to ISO 15189:2018 accreditation (1, 2).

A laboratory professional who deals with the quality of work in medical biochemical laboratories ensures the accuracy and precision of laboratory analyzes through the implementation of international and European guidelines for working with dangerous substances, through the availability and implementation of standard operating procedures (SOP). The development and implementation

of SOP is manifested through education, professional development and compliance with international standards. (3). Hazards in laboratories that affect the concentration and safety of employees arise as a result of laboratory deficiencies such as: lack of preventive measures, knowledge and skills, which are implemented through standard operating procedures and good laboratory practice. Biophysical hazards in medical biochemical laboratories are manifested through needles and sharp objects, infectious material, noise, vibrations, radiation, poor air quality, temperature inversions (4, 5, 6). The impact of noise leads to a decrease in the concentration of employees, a decrease in productivity, as well as an increase in laboratory errors (7). Analyzer vibrations can affect the hand-hand system and lead to various disorders of the cardiovascular, nervous or musculoskeletal system of the hands (8-10).

2. OBJECTIVE

The aim of this research is to raise awareness about the quality of work in medical biochemical laboratories in order to ensure the safety of employees. Therefore, the aim of this study is to examine indicators of the quality of work in medical biochemical laboratories, through the views of laboratory experts.

3. MATERIAL AND METHODS

A cross-sectional, qualitative and analytical study was conducted using self-administered questionnaire as a research instrument. The questionnaire contains 14 questions, of which 5 questions refer to the basic sociodemographic characteristics of the respondents (gender, age, country, level of education and the length of working path), 5 questions about the workplace and 4 questions about the conditions and quality of the workplace. The attitude about exposure is classified in relation to the subjective opinion of the respondent (no exposure, exposure). The questionnaire was distributed to respondents via e-mail.

Out of 100 subjects employed in medical laboratories, with different levels of education, participated in the research. The research was conducted over a period of three months (March-May 2022). Considering the complete epidemiological situation, we chose cross-sectional, descriptive and analytical online research and data collection. An anonymous survey was conducted using a "Google Form" and all participants gave informed consent. Participants were allowed to complete the survey at any time. This research was completely voluntary non-commercial, and it was conducted in accordance with the Declaration of Helsinki – Ethical principles for medical research involving human subjects.

The collected data were archived in Microsoft Office Excel 2016 and the statistical program IBM SPSS Statistics 25.00 was used for statistical data processing. Data analysis included descriptive statistics and testing the difference between expected and observed values in one or more categories in contingency tables using the chi-squared test. The threshold of statistical significance was set at the conventional level of $p \leq 0.05$.

4. RESULTS

Out of 100 respondents, 70 respondents were from Bosnia and Herzegovina (BiH) and 30 from the Republic of Croatia (CRO), of which 25% were male and 75% female. The average age of male respondents was 36.84 ± 3.38 years, and the woman 38.65 ± 4.61 years. In relation to the length of work experience, it was determined that 55% of BiH respondents and 62% of CRO respondents have been working for more than 10 years. It was found that 52% of respondents from BiH, as well as 38% of respondents from CRO had secondary professional education. 38% of BiH respondents and 56% of CRO respondents had a university education, ($\chi^2=0.683$; $p=0.159$).

In relation to the sector from which the respondent comes, 57 (81.4%) respondents from BiH worked in the public sector, and 13 (18.6%) in the private sector. Respondents from CRO 21 (70%) worked in the public sector, and 9 (30%) in the private sector. Considered as a total sample, respondents from the private sector were represented in a low percentage (22%), while 78% were from the public sector. We did not find a statistically significant difference in the number of respondents from the public or private sector between countries ($\chi^2=1,598,613$; $p=0.206$).

The respondents' self-assessment of exposure to hazards that affect concentration and safety within the laboratory in relation to the examined groups is shown in Table 1. A review of the results found that exposure to infectious agents and needles and sharp objects in a higher percentage among respondents from BiH compared to CRO ($p=0.018$ and $p=0.001$, respectively). Exposure to noise, vibrations, poor air quality, and extreme temperatures are higher in percentage among respondents from BiH, but without established statistical significance.

By looking at the results of the research on the accreditation of medical biochemical laboratories in relation to the examined group, as shown in Table 2, we found that 22% of respondents from BiH think that the laboratory they work in is accredited, as well as 50% of respondents from CRO. Among respondents with BiH, 72.7% did not know according to which standard the laboratories are accredited, and no respondent knew ISO 15189. Respondents from CRO were also of the opinion that they were accredited according to ISO 15189 in 33%. A significant statistical difference was found between respondents with a BiH and respondents from CRO when it comes to knowledge of the accreditation standards of medical-biochemical laboratories ($p=0.0155$).

Subjects' self-assessment of the level of exposure to hazards that affect the drop in concentration and safety of subjects within medical biochemical laboratories, as shown in Table 3. Respondents who are employed in accredited laboratories are more aware of exposure to hazards in a high percentage of infectious agents and toxins ($p=0.0012$ and $p=0.0046$, respectively). There is no statistically significant difference between the respondents between accredited and non-accredited laboratories when it comes to other hazards.

Respondents who had available standard operating procedures are more aware of infectious agents

($p=0.0001$), toxins ($p=0.0466$), needles and sharp objects ($p=0.0052$), noise ($p=0.0030$), vibrations ($p=0.0007$) and extreme temperatures ($p=0.0014$), as shown in Table 4.

5. DISCUSSION

Medical biochemical laboratories have a serious problem of staff exposure to biophysical hazards, a high risk of occupational injuries related to needles and sharp objects (12). According to results of our study, we found that respondents from Bosnia and Herzegovina have a higher percentage of exposure to infectious waste (63%), needles and sharp objects (70%), compared to respondents from the Republic of Croatia where the percentage ratio was (21%, 35%). In agreement with the respondents from BiH is the study by Patwary MA et al (11), who reported that respondents in 75% exposed to needles and sharp objects. The need for preventive programs, through education and training of laboratory professionals, was reported by Musa S et al (12). A study conducted in Nigeria found that the implementation of existing laws, constant education and strict supervision can influence a change in the consciousness of respondents (13).

The difference in the knowledge of respondents in the answers about the exact standard to which medical biochemical laboratories are accredited, we found that respondents from BiH have lower knowledge compared to respondents from CRO. We conclude that there is a lack of cooperation between national bodies and the management of BiH health institutions with the aim of increasing the knowledge of examinees through precisely defined guidelines and documents of international leaders in laboratory medicine and the preparation of laboratories for accreditation according to the medical laboratory standard ISO 15189:2018. The standard intended for medical laboratories includes the entire laboratory cycle with the aim of revealing quality indicators that affect accuracy and precision (14). In the study by Lapić I et al (15), the goal was to examine attitudes about the implementation of accreditation through surveys in three Croatian accredited medical laboratories and 70% of respondents have a positive attitude and 89% of respondents fully comply with the prescribed protocols. Competence assessment is considered useful by 41% of respondents. We conclude that the respondents from the Republic of Croatia, by entering the European Union, improved the old laboratory practice through strict legal norms.

Respondents' attitude about the level of exposure to hazards in medical biochemical laboratories in relation to accreditation and the availability of standard operating procedures, we found that respondents who are employed in accredited laboratories have a more developed awareness of hazards that affect the safety of respondents, such as infectious waste and toxins ($p=0.001$ $p=0.004$).

We conclude that the availability of standard operating procedures and their use in work affects the change in the respondents' awareness. Respondents who work in accredited laboratories and have available standard operating procedures are usually more often aware of the dangers of infectious agents and toxins ($p=0.001$).

($p=0.004$), ($p<0.01$, $p=0.046$). We found significant statistical differences through the availability and application of standard operating procedures of the respondents regarding exposure to needles and sharp objects ($p=0.005$), noise ($p=0.003$), vibrations ($p<0.001$) and extreme temperatures ($p=0.001$). The study was conducted with the aim of confirming the importance of the accreditation standard ISO 15189:2018 using documents, guidelines of international and European leaders of laboratory diagnostics through the views of the respondents. By reviewing the literature, we observed that the accreditation of medical laboratories and compliance with the correct guidelines through standard operating procedures can influence the development of the awareness of laboratory professionals about the dangers within the laboratory (16). The study of Aghaei Hashjin (17) concluded that the responsibility and contribution of the staff in the assessment of indicators quality greatly influences the success of quality assurance outcomes.

It is necessary to strengthen biosafety training programs as well as periodic assessments related to reducing the level of exposure to hazards within the laboratory (18). Swathi KS et al (19) indicated that with accreditation we increase the effect of good laboratory practice, respecting standard operating procedures. The awareness of laboratory professionals is a vital domain for achieving quality work. Through compliance with standards and documents, they lead to improvement of the quality of work (20). The self-awareness of healthcare workers and the strengthening of biosafety training, aimed at risk assessments and quality control, will affect the reduction of the level of exposure to potential hazards (21). In this way, they influence the development of awareness of personal responsibility for the level of exposure within the laboratory (22). The study by Hailu HA et al concluded that by good organization of work through the subjects' basic knowledge of accreditation, standard operating procedures, we can influence the subjects' awareness and reduce the level of exposure to dangers in laboratories (23). There is a need for accurate guidelines and biosafety documents to make targeted strategies to reduce exposure to hazards (24). Effective implementation and continued compliance with the ISO 15189:2018 standard requires the ongoing commitment and active participation of laboratory staff. Laboratories must have standard operating procedures available and actively monitor their use.

6. CONCLUSION

We conclude that Bosnia and Herzegovina is facing a period of intensive work on the harmonization of legislation and the adoption of national strategies, the implementation of which will enable the preservation of the health of employees as the greatest potential of the social community.

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