Development and Validation of the Questionnaire for the Assessment of the Occupational Exposure and Safety in Laboratories

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Abstract— An indispensable segment of work in the laboratory is occupational exposure to numerous hazards that potentially leave serious consequences for the health of employees, while having a broader impact on the community. The unavailability of official data in our area was the basis for the creation and development of the Questionnaire for the Assessment of the Occupational Exposure and Safety in Laboratories, with the ultimate goal of creating preventative and educational programs based on the results, that will help preserve the functional capacity of employees throughout their working lives. Developed instrument fully meets the psychometric characteristics and it is adequate for research in our areas.

Index Terms— attitude, biohazard, development and validation, knowledge, laboratory equipment, laboratory professionals, occupational safety and health, occupational exposure, practice, questionnaire

1 Introduction

Laboratory professionals (LP) in the health sector are exposed to a wide range of hazards in the workplace, the effect of which cannot be completely eliminated despite the accelerated automation of work processes. Depending on the type of agent, the route and length of occupational exposure, the protective measures applied, and the health status of the LP, the potential health consequences may be different. Economic losses due to absenteeism, which are related to health problems, account for 4-6% of GDP in most countries and represent a significant burden for highly developed countries as well [1].

Since the late 1980s, it has been argued that observation of occupational diseases and injuries is a key step in prevention, as it provides a basis for channeling resources to improve working conditions in specific segments [2]. World-wide authorities such as the Occupational Safety and Health Administration, the Center for Disease Control and Prevention and the World Health Organization (WHO) are continuously creating guidelines and standards for safe work in laboratories. It is recommended that they be implemented in national programs and that a proactive approach be taken to all system links for preventive action. Monitoring of laboratory-acquired infections and causes of accidental injuries is in the domain of public health institutions, and a Belgian platform is a good example of approaching the problem [3].

Rare studies have focused on the LP population, especially in developing countries [4]. The most common area of interest for researchers is exposure to biological (especially blood-transmitted pathogens) and chemical agents. According to WHO, an additional 16,000 thousand hepatitis C infections and 66,000 hepatitis B infections are developing annually among healthcare professionals [5]. Although the WHO recommended hepatitis B vaccination, states have taken a different stance on the morbidity and working status of those infected [6]. Studies have confirmed increased exposure to LP chemical agents, with particularly significant carcinogenic and potentially carcinogenic substances that have been classified differently over the past decades [7], [8], [9], [10], [11], [12]. Musculoskeletal disorders are reported in significant cases number of LP, resulting from inadequate body postures and repetitive movements [13], [14]. Research indicates that LP in developing countries lack and do not use protective equipment, which is the result of multiple factors including underdeveloped occupational awareness, lack of information and knowledge about biosecurity, inadequate monitoring of work processes [4], [15].

Based on the available literature, no research was conducted in the territory of Bosnia and Herzegovina that included assessment of occupational exposure to hazards in laboratory work, examining the knowledge, attitude and practice of employees, as well as collecting data on the vaccine and health status of LP. Recognizing the importance of the problem globally and the unavailability of data in our area, we designed and developed a questionnaire that is linguistically tailored to our speech area for research purposes, with a focus on research goals and a theoretical concept elaborated in the scientific and professional literature.

1.1 Questionnaire

Scientific research is based on various forms of measurement. A measuring instrument is a measurement procedure, technique, or procedure that measures a significant characteristic or characteristic of an entity, and may be a variable, scale, index, test, or any other measurement procedure [16]. The answers collected through the questionnaire do not have value in themselves, but are solely a way of measuring the subjective phenomenon they seek to capture [17]. Čavaljuga and the authors cite the advantage of the questionnaire as "a cost-effective way to obtain data from a potentially large number of respondents," but emphasize that it provides "limited insight into the problem due to the selection of questions that may not be appropriate for the research topic" [18]. Since a quality questionnaire is imperative for good results, it must have a clearly defined objective to provide the basis for the question-

naire to collect data on multiple variables, while meeting the basic metric characteristics [19]. The metric characteristics of a measuring instrument are called the characteristics of the instrument on the basis of which it is judged to be useful and the justification of the conclusions drawn from the results obtained from its application, with the greatest attention being paid to validity and reliability [17]. Assessing the validity of a measuring instrument assesses its focus on the target object of measurement [16]. Content, criteria and construct validity are most commonly discussed [20]. When assessing the content validity, the extent to which the relevant content of the measurement object is "covered" is determined by the instrument and is the representation of individual contents appropriate? Assessment of content validity is mainly the result of qualitative assessment and theoretical proof, because there are no statistical criteria that would express validity by some relatively objective numerical indicator. Assessment of criterion validity determines the extent to which the results obtained by the instrument are related to the results on another variable, which appears as an external criterion of validity. Construct validity refers to the correlation of results obtained by an instrument with those obtained from other instruments. Measurement of the reliability of the questionnaire is necessary in order to prove that the questionnaire used is an appropriate measuring instrument and to use it in repeated measurements to obtain the same measuring indicators. Assessing the reliability of an instrument seeks to determine the degree of internal consistency, regardless of what it actually measures [16], [20]. Different coefficients are calculated to estimate the reliability. The results achieved by respondents in measurement instruments must be compared with certain standards or benchmarks to be interpreted, and they only make sense when compared with the results of respondents in a normative or standardization sample [20]. Calibration refers to the determination of the norms of the measuring instrument (arithmetic mean and standard deviation) by which the result of the subjects is evaluated, and the procedure is referred to as the standardization of the instrument. The arithmetic mean provides coarse information about the position of the subjects in the population, and based on the standard deviation, accurate information about the position of the subjects in the population is obtained with respect to the characteristic being measured. Instruments without proper metric characteristics lead to insufficiently accurate estimates of the state of affairs, which significantly reduces their useful value [16].

2 MATERIAL AND METHODS

The Questionnaire for the assessment of the occupational exposure and safety in laboratories (Q-AOESL) has been completed in five developmental stages.

Phase I - It included a detailed analysis of the available scientific literature on the subject of research, the applicable legal norms in the territory of our country, the guidelines of the world authorities and directives of the European Union, thus supplementing the theoretical basis for defining the research objectives and variables.

Phase II - It concerned the preparation of a pool of potential items. To create the questions we were guided by the guidelines available in [18], [21]. As a basis for creating questions examining knowledge, attitude, practice, exposure assessment, and laboratory equipment, we used available standards, guidelines and guides [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32]. A total of 158 questions were created and divided into six segments: socio-demographic data (17), general questions about respondents (26), organization of work and equipment of laboratories (22), as well as three segments covering knowledge (11), attitude (30) and practice of LP (48). The Likert scale is most often used to create answers because of the impact on homogeneity, but the same was not acceptable for our research because of the set goals and the concept of the questions. Recognizing the fact that the diversity of the answers offered will reduce the value of the Cronbach alpha coefficient as the eliminator for the validation of the instrument, we created the answers to the closed questions according to the principle of the offered options, where the respondents had to choose the one closest to their opinion. A number of questions are open-ended, as they cover a very specific segment related to occupational trauma and incidental injuries during the working life.

Phase III - We forwarded the potential 158 questions (excluding the socio-demographic segment) by following the methodology to experts in the field of science and profession (10 in total) to assess their eligibility. The group of experts included five university professors from the departments of microbiology, pathology and histology with embryology, two graduate engineers in medical-laboratory diagnostics and masters in microbiology and biochemistry, two masters in sanitary engineering and one specialist in occupational medicine. For the experts, a separate table was created in which, based on the answers provided (essential; useful, but not essential; non-essential), for each question, an evaluation of the importance of including the question in the questionnaire was required and the terminology used was corrected at the same time. Based on the expert evaluation, Content Validity Ratio (CVR) was calculated using the Lawsh method and the Content Validity Index (CVI) of all segments and the complete questionnaire [33].

Since the survey covered all profiles of laboratories involved in the health system in the country, the sets of general questions and questions on the organization and equipment of the laboratories for importance assessment were also forwarded to the experts, although we did not carry out validation for them. The reason given is that the questions are extremely heterogeneous, because they cover a wide range of laboratories and profiles of LP, and provide a basis for collecting descriptive data. Also, by creating a questionnaire, we wanted to provide a basis for research of the same or similar type, and to provide researchers opportunities to use the questions, with modifications required by certain types of laboratories.

Phase IV - It covered the distribution of questionnaires (electronic and printed form) to the respondents, using a random sample method. In order to collect as objective information as possible, we emphasized that the questionnaire was completely anonymous, and when creating the web version of the questionnaire it was impossible to leave out the answer.

Phase V - The pilot survey included 112 subjects, of whom 12

who completed the printed form were excluded because of incomplete answers. The answers were then coded for statistical analysis. For the purpose of validation of the questionnaire, the Cronbach's alpha value was calculated in order to measure the internal consistency of each factor and its total value. Factor analysis was tested using the Bartlett Sphericity Test (BST) and the Kaiser-Meyer-Olkin (KMO) test was used as an indicator of sample adequacy [34]. Based on the statistical results, a final version of the questionnaire was created.

3 Results and Discussion

In accordance with the methodology, the Lawshe method was used to evaluate the validity of the questions. Based on the results of the experts, the CVR of the individual questions and the CVI for the five segments and the complete questionnaire were calculated [33]. The CVR = (No-N / 2) / (N / 2) formula was used, where No is the number of experts who assess a question as necessary and N represents the total number of experts. To choose their number, we were guided by the methodology defined in the work of Mestro et al. [34].

TABLE 1
Analysis of quality and validity of knowledge questions

Code	Question	CVR	Cronbach's alpha
K1	Highlight pictogram on ethanol packaging?	1	0,681
K2	Are work and civilian clothes allowed contact during changing before leaving work?	1	0,662
K3	Sharp objects in the laboratory are disposed of in?	1	0,652
K4	Can the use of protective gloves cause a late allergic reaction?	1	0,659
K5	What is the most common pathway for human immunodeficiency virus transmission in laboratories?	1	0,645
K6	What is the most common pathway for transmission of hepatitis B virus in laboratories?	1	0,699
K7	Mark the most common pathway for transmission of hepatitis C virus in laboratories?	1	0,662
K8	How ofter are women allowed to lift weights greater than 15 kg?	1	0,716
K9	Highlight the most common Mycobacterium tuberculosis transmission pathway in laboratories?	1	-
K10	What is the most common pathway for the transmission of bacteria from the Brucella spp. in laboratories?	1	-
K11	Exposure to high doses of xylene (> 100 ppm) can cause?	1	-
Cronbach's alpha segment knowledge after exclusion of the question (n=8)			0,692

A CVR value of 0.8 was obtained for eight questions, while for the remaining 129 it was 1, indicating the retention and exceptional validity of all questions compared to the suggested value of 0.78 [35]. The CVI value represents the mean of all CVR values of retained questions. The CVI for segments knowledge, attitude and practice were 1, 0.99, and 0.97, respectively. The CVI value of 0.97 of the complete questionnaire indicates an extremely high level of validity, thus fulfilling the recommendations of Almanasreh et al., according to which CVI is one of the key parameters in the newly emerged instruments and has special significance in the health sciences [36]. Only one expert, a specialist in occupational medicine, requested a correction of the term used in the design of the question, and the intervention referred to the name of the incoming systematic examination performed at the time of employment. Shaughnessy et al. suggest that the layout of the questions in the questionnaire is very significant and that the questions of greatest interest should be at the outset. Knowing the way of thinking of the respondents, we did not accept the guidelines because in that case they would refuse to fill in the questionnaire, considering it too demanding. Other recommendations regarding the cover letter explaining the purpose of the research and the significance of the honest answers as well as the distribution options of the combined electronic and printed version of the questionnaire were adopted [37].

In order to test the reliability of Q-AOESL for assessing the knowledge, attitudes and practices of LP, the value of Cronbach's alpha coefficient for individual segments and the complete questionnaire were determined. The Cronbach's alpha of the instrument was 0.742, which is consistent with the results of studies according to which the value 0.7 was the most commonly used in distinction [38], [39], [40].

TABLE 2
Analysis of quality and validity of attitude questions

Code	Question	CVR	Cronbach's alpha
A1	Rate your job risk?	1	0,814
A2	How satisfied are you with your job?	1	0,825
A3	How stressful do you think your workplace is?	1	0,832
A4	Do you think you know all the risks associated with your workplace?	1	0,818
A5	Do you find that compliance with procedures and use of protective equipment reduces your exposure?	0,8	0,821
A6	Rate your exposure level to formaldehyde?	1	0,816
A7	Rate your exposure level to xylene?	1	0,807
A8	Rate your exposure level to ether?	1	0,808
A9	Rate your exposure level to ethanol?	1	0,817
A10	Rate your exposure level to chlorine?	1	0,814
A11	Rate your exposure level to acetic acid?	1	0,811
A12	Rate your exposure level to fuchsin?	1	0,811
A13	Assess your level of exposure to hepatitis B virus?	1	0,810
A14	Assess your level of exposure to hepatitis C virus?	1	0,810
A15	Assess your level of exposure to human immunodeficiency virus?	1	0,813
A16	Assess your level of exposure to Mycobacterium tuberculosis?	1	0,808
A17	Assess your level of exposure to Brucella spp.?	1	0,811
A18	Rate your general exposure to infectious agents?	1	0,811
A19	Rate your general exposure to toxins?	1	0,813
A20	Rate your general exposure to needles and sharp objects?	1	0,833
A21	Rate your general exposure to non-ionizing radiation?	1	0,814
A22	Rate your general exposure to ionizing radiation?	1	0,847
A23	Rate your general noise exposure?	1	0,839
A24	Rate your general vibration exposure?	1	0,810
A25	Rate your general exposure to to poor air quality?	1	0,810
A26	Rate your general exposure to extreme temperature inversions?	1	0,842
A27	Rate your general exposure to injury hazards?	1	0,818
A28	Which segment of work do you consider to carry the most risks?	1	0,819
A29	What you consider as a main reason for not reporting occupational injuries?	1	0,819
A30	Is your concentration reduced by?	1	-
Cronbach's alpha segment attitude after excluding questions (n = 29)			0,819

For the 11 questions in the knowledge segment, the Cronbach's alpha value was 0.428 and the ANOVA of the test was $F = 151.134$ with $p < 0.001$. Analyzing the answers, it was found that questions Z9, Z10 and Z11 reduce the homogeneity and thus the reliability of the questionnaire. After exclusion, the coefficient value increased to 0.692 for the remaining eight questions. The lower Cronbach's alpha values generally indicate increased heterogeneity, with a significant impact on the number of questions and the scale used to create the answers. Arslan and Griethuijsen and associates share the view that instruments with a Cronbach's alpha value of 0.6 are acceptable for research in the wider area [39], [41]. The psychometric

Likert scale commonly used in the questionnaires for our research was not suitable because of the specificity of the questions and the determination of cut-off values that are the basis for the assessment. Barua and Jamieson point to the same [42], [43]. The above gave the authors the opportunity to further reduce the number of knowledge segment questions in order to increase the value of Cronbach's alpha, but we considered the value of the coefficient of the total instrument to be crucial. Given that the CVR value for questions Z9, Z10 and Z11 was 1, due to the importance of exposure to biological and chemical hazards, and given the epidemiological situation and the fact that Bosnia and Herzegovina is an endemic area for brucellosis, it was left as an integral segment of the questionnaire. After the post-test, recalculation of values will begin, which will be the basis for the final decision to exclude the question. Knowledge questions were also subjected to a sample adequacy analysis, which determined the degree of correlation KMO = 0.667. The obtained value indicates a medium-strong correlation [38]. Factor analysis is justified by a significance of p <0.001.

Following the answers provided for the attitude segment questions, Cronbach's alpha = 0.819 was determined with the exception of question A30, which we transferred to the general questions segment and thus retained. The obtained values of Cronbach's alpha are qualitatively described by the authors, so the coefficient of 0.819 is categorized as a reliable, strong or credible indicator [34], [38]. Kaiser-Meyer-Olkin, as an indicator of sample adequacy, has values from 0 to 1 and is a measure for quantifying inner correlation among variables. Values in the range 0.7-0.8 indicate a strong correlation. Factor analysis is considered justified if the Bartlett test is significant (p <0.05), because then there is confirmation of the existence of correlations at least among some variables [44]. The degree of correlation for the knowledge segment was KMO = 0.713, and factor analysis was justified with a probability of p <0.001. Our results are correlated with those of the Maestro et al. segment, and the degree of correlation is higher than that of the Kums et al. study [38], [45].

In the practice segment, after excluding six questions, the Cronbach's alpha value was 0.715, the KMO of 0.611, and factor analysis was justified with a probability of p <0.001. The values indicated suggested internal consistency validity and moderately strong correlation of factor analysis. By further excluding the question, there was a possibility of increasing the value of the reliability factor of the questionnaire, but we did not consider it necessary and justified. We kept the excluded questions within the general questions segment for reasons elaborated in the knowledge segment discussion. A particularly important issue for us as researchers is P46, since the development of musculoskeletal disorders is associated with repetitive movements, which are common in the target population [14]. We excluded four questions on the respondents' vaccination period from the general questions segment, contributing to the reduction of the time required to complete the questionnaire, which averaged 21 minutes.

The square of multiple correlation shows the degree of correlation of the investigated phenomena, ie it is determined how several independent variables affect one dependent variable.

TABLE 3
Analysis of quality and validity of practice questions

The sign of the correlation coefficient (+ or -) indicates the direction of connection [46]. In our study, a correlation was

Code	Question	CVR	Cronbad alpha
P1	Do you work overtime due to increased workload?	1	0,719
P2	Do you have additional engagement in a lab after office hours?	0,8	0,715
P3	Do you use the same protective equipment for all procedures?	0,8	0,710
P4	Do you sometimes consciously make mistakes in procedures that may have a negative effect on your health but not the end result of the analysis?	1	0,724
P5	Are standard operating procedures (SOPs) available in your laboratory?	1	0,709
P6	If you are not sure of the correctness of procedures related to specific procedures, how do you solve the problem?	1	0,717
P7	Do you use formaldehyde / formalin in your laboratory?	1	0,720
P8	Do you use ether in your laboratory?	1	0,716
P9	Do you use ethanol in your laboratory?	1	0,719
P10	Do you use acetic acid in your laboratory?	1	0,718
P11	Do you use fuchsine in your laboratory?	1	0,715
P12	Do you read the manufacturer's labels on the packaging before you start?	1	0,714
P13	During laboratory procedures, I treat fuchsin and use protective equipment as if it were a substance that is?	1	0,696
P14	During lab procedures formaldehyde / formalin I treat and use protective equipment as if it were a substance that is?	1	0,694
P15	During laboratory procedures, I treat cyanide and use protective equipment as if it were a substance that is?	1	0,694
P16	During laboratory procedures, I treat methanol and use protective equipment as if it were a substance that is?	1	0,693
P17	During laboratory procedures, I treat human blood (sample and substrate supplement) and use protective equipment as if it were a substance that is?	1	0,697
P18	During laboratory procedures, I treat blood smears or tissue sections (fixed by heat or chemicals) and use protective equipment as if it were a substance that?	0,8	0,690
P19	During laboratory procedures, I treat urine sample and use protective equipment as if it were a substance?	0,8	0,706
P20	During laboratory procedures, I treat cell culture and use protective equipment as if it were a substance that is?	1	0,688
P21	Indicate how often during work activities the body is held in a bent position with> 15° slope?	1	0,717
P22	Indicate how often during work you are working in a chest-height position?	1	0,709
P23	Mark how often you squat or kneel while working?	1	0,688
P24	Indicate how often you work more than two hours on your computer during the workday?	1	0,718
P25	Indicate how often you sit for more than two hours during the working day?	1	0,708
P26	Indicate how often you stand for more than two hours during the working day?	1	0,799
P27	Indicate how often during work activities you lift loads weighing more than 15 kg?	1	0,742
P28	Do you wash your hands after removing the protective gloves?	1	0,745
P29	Do you disinfect protective gloves before disposal?	1	0,708
P30	Do you dispose of protective gloves in municipal waste?	1	0,715
P31	Do you dispose protective gloves in safety bags / containers?	1	0,717
P32	Do you use the same gloves in the following?	1	0,710
P33	Do you use your phone / cell phone with protective gloves?	1	0,747
P34	Do you open the drawers or doors with protective gloves?	1	0,725
P35	Do you touch the municipal waste bin with protective gloves?	1	0,715
P36	Do you use a rest room with safety gloves?	1	0,713
P37	Do you wear cosmetics with protective gloves? (eg lip balm)	1	0,714
P38	When using "pooled serums" do you use?	1	0,715
P39	Do you disinfect work surfaces before and after work?	1	0,722
P40	When working with patients with suspected respiratory illnesses, which mask do you use? (eg seasonal flu)	0,8	0,720
P41	Do you have a part-time job?	1	0,708
P42	Do you change your coat when leaving the lab to go the rest room?	1	0,709
P43	Are standard operating procedures (SOPs) applied in your laboratory?	1	-
P44	Do you use xylene in your laboratory?	1	-
P45	Do you use chlorine in your laboratory?	1	-
P46	Indicate how often you do repetitive joint movements during work activities?	1	-
P47	Do you use a pencil with protective gloves?	1	-
P48	Do you handle papers with protective gloves?	1	-
	Cronbach's alpha segment practice after exclusion of the question (n=42)		0,715

found between most questions, and their heterogeneity indicates that there are more answering trends. Six attitude and practice questions reported a negative sign, while the maximum positive correlation was 0.980. The positive values obtained indicated a weak, moderate or strong correlation in different segments.

Based on the results of the pilot study, we can confirm that we share the view with Shaughnessy et al. that "although it is not a high-tech product used in modern-day research, it is a powerful scientific instrument for measuring different variables" [37]. Overall, it was found the validity of the questionnaire in the practice, knowledge and attitude test with a Cronbach's alpha value of 0.742, and the number of questions that met the validation is 78. All questionnaire segments contain 151 questions and provide a basis for collecting a broad database. Cronbach's alpha segments knowledge, attitude and practice were 0.692, 0.819 and 0.715 in retrospect, which is above the values most commonly used in studies [39], [40], [41]. The ANOVA test found a significance level of $p < 0.001$, suggesting that the questionnaire could be used to test the attitude, knowledge and practice of LP. A CV value of 0.97 indicates a very high validity of the questions based on expert judgment and indirectly on the importance of conducting studies of this type. Based on the experience gained, we can recommend to all researchers that they face the challenge of creating and developing questionnaires for their areas of interest, given that they are best acquainted with the cultural values and terminology of the target population.

4 Conclusion

For the purpose of the research being conducted for the first time in the territory of Bosnia and Herzegovina, a questionnaire tailored to the population of laboratory professionals was created. The Questionnaire for the assessment of the occupational exposure and safety in laboratories (Q-AOESL) methodologically met the defined psychometric criteria for testing reliability and validity, and is an appropriate instrument for conducting future scientific studies. The results of the research provide the basis for the creation of preventive and educational programs, as well as amendments to the legal norms that define this area. Since colleagues from the region (Serbia, Macedonia and Croatia) participated in the pilot survey for validation purposes, the instrument is applicable in these areas as well, since the existence of a language barrier has not been established.

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