Accompanied management and evaluation method of exposure risks to biological agents

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ABSTRACT: The presence of biological agents in the workplace may result in hazardous situations for workers. The present study was carried out in the microbiology laboratory of a Medical School and the methodology was based on the qualitative method presented in the Technical Note of Spanish Prevention (NTP 833) and the Accompanied Method of Biological Risk Management (MAGRB).

It was concluded that the MAGRB allows to distinguish and prioritize the risk associated to the different operations as a whole, taking into account safety conditions and practices, if evaluation parameters defined in the legislation of biological agents are met, something that the International method (NTP 833) does not allow doing so effectively. As the focus of worker protection, the MAGRB provides the necessary guidelines to trigger a prevention structure in all activities likely to be exposed to biological agents.

1 INTRODUCTION

Biological agents are living beings of microscopic dimensions, and all substances derived from them can have negative effects on the worker's health. The major difference between biological agents and other dangerous substances is their reproduction capacity, since under favorable conditions they can develop in a short amount of time (ACT, 2008). These micro-organisms can originate any type of infection, allergy or toxicity in the human body. Their presence in workplaces may result in risk situations for workers (Pinto, 2016).

The work involving exposure to biological agents can occur in a variety of situations and activities (Novás, 2008), (Perez, Mena, Watson, Prater, & McIntyre, 2015). Since microorganisms are ubiquitous in the environment, exposure to biological agents in various contexts is inevitable, implying very different risk situations and characterized in some cases by great specificity (Health, 2004) (Gershon, Pogorzelska, Qureshi, & Sherman), (Singh, 2016), (Ulutasdemir, Cirpan, Copur, & Tanir, 2015).

In Portugal the Law-Decree Nº. 84/97, 16th April, regulates the protection of workers against the risks of exposure to biological agents at work by classifying the biological agents into four groups according to the level of infectious risk: Group 1 – Low probability of causing illness, Group 2 – Can cause disease and constitute a danger, Group 3 – Can cause serious illness and constitute a serious risk, Group 4 – Cause serious illness and constitute a serious risk (Law-Decree Nº. 84/97). In the course of their duties, some workers are exposed to a number of living micro-organisms (viruses, bacteria, etc.) and to substances or structures that are originated from them. The activities with higher risk of exposure to biological agents are: work in food and agricultural production units; Activities in which there is contact with animals and products of animal origin; Work in health facilities, including isolation and autopsy units; Clinical and veterinary laboratories, collection, transport and waste disposal units, water and wastewater treatment facilities (Freitas, 2011).

The protection of workers is basically centered on the assessment of exposure risks, where the features of the involved agents in the activity are considered, the suitability of facilities, equipment and work practices (Nunes, 2010), (Romero, 2006), (Pinto, 2016).

Biological risk assessment is a challenge (Nácher, Alapont, Sales, & Ferrando, 2006), (Moore, et al., 2010) in first place regarding the diversity of agents and secondly because the limits of occupational exposure (VLE) for the great majority of these agents have not been defined. Pathogenic micro-organisms may be hazardous in extremely low concentrations (Larson & Aiello, 2006), and are invisible to the naked eye. "*It is imperative to be aware that a risk assessment of biological agents should be carried out on the basis of the uniqueness concerning each case"* (Teixeira, 2015). According to the World Health Organization (WHO) and the National Institute of Occupational Safety and Health - Spain (INSHT) the measurement of biological agents is not an essential element but rather its identification and assessment. The main reasons for non-measurement are: lack of confidence in the results, due to the great variability of professional activities; the high cost, time and money involved in the analysis, in particu-

lar the complete and accurate identification of biological agents in the work environment; the lack, to date, of a standardization regarding the exposure limit values for biological agents (OMS, 2004), (INSHT, 2014).
In Spain the Royal Decree Nº. 664/1997 regulates the protection of workers who are exposed to biological hazards in the workplace and the NTP 833 outlines the procedures for risk assessment, by defining exposure levels and preventive measures associated with potential risk levels (Trabajo, 2009). The accompanied method of biological risk management (MAGRB) intends to assess, in accordance with Portuguese legal requirements, the risks of exposure to biological agents. Biological agents are identified and classified according to Decree-Law 84/97 and the method allows determining the level of risk to which workers are exposed after defining the potential intrinsic and residual risk. The calculation of the intrinsic potential risk is based on two essential variables, the level of exposure (contact frequency, amount handled and production of bio aerosols) and the damage or effect (risk to workers, propagation in the community and existence or not of prophylaxis means) for a worker exposed to the biological agent. The residual risk that we can find in a facility is calculated from intrinsic potential risk, but it takes into account the already controlled risk through the different prevention and protection measures that exist. The value attributed to prevention and protection measures is obtained after the Organization has been audited, applying a checklist drawn up after the basis of Decree-Law 84/97, which quantifies percentile the level of compliance. In the end, the risk level allows to launch intervention priorities by establishing four levels of significant risks and one non-significant risk. These levels have been established as a progressive requirement and do not tolerate any deviation in the conformity procedures, facilities and containment from exposure to biological agents of groups 2, 3 and 4.

2 OBJECTIVES

Facing the difficulty of finding in Portugal, an evaluation method, which compared with the NTP 833 method complies legal requirements, the main goal in conducting this study on the management and evaluation of occupational risks in exposure to biological agents in the laboratory of microbiology was defined.
The following specific objectives have been defined:
1st Assess the risks with the simplified method (NTP 833);
2nd Assess risks using MAGRB;
3rd Verify that the methods used are in accordance with the legislation for biological agents;
4th Compare results of the evaluations obtained with both methods when evaluating safe and unsafe work practices that distinguishable according to the risks of exposure to biological agents.

3 METHODOLOGY

The study was carried out in a Medical School's microbiology laboratory, where the accomplishment of three tasks that involved the manipulation of biological agents and was developed were observed according to the in the following stages:
1st Stage - Laboratory and laboratory practices audit.
In order to carry out the laboratory and laboratory practices audit, a checklist was used on an excel spreadsheet, which allowed us to quantify the degree of conformity obtained.
This file makes it possible to analyze, for each of the tasks, the degree of conformity of the Group II, III and IV confinement measures, the individual protection measures used, the organization of SHW services, Safety at Work Handling, handling and disposal of hazardous wastes and fire safety in accordance with current legislation.
2nd Stage - Risk assessment according to the simplified method presented in NTP 833, which was done in a document prepared on an excel spreadsheet.
3rd Stage – Since the obtained result in the first two stages and considering the simplified method as insufficient, by only providing us with a qualitative evaluation, the MAGRB was developed. The method was based on NTP 833 and was developed through an excel document in order to identify and evaluate biological agents, addressing the case study to activities in which there is a deliberate intention to work with biological agents. Through the identification of hazards that may represent these agents and the possibility of exposure to them, it is intended to establish potential risk levels action priorities, magnitude and degree of requirement in the fulfillment of associated preventive actions.
The MAGRB presents as a differentiating parameter the calculation of the residual risk level. The residual risk is the risk that remains after the introduced mitigation by the control measures (prevention and protection) and is based on the value resulting the facility audit.
In the case study, the manipulation process started with receipt of a master sample confined to a maximum of four agents. In this sample there was a randomness of agents, i.e., which agents were present was unknown, only that these agents belonged to Group II was informed, and since they are the type of agents with which the laboratory in question works. For the study the data presented in Table 1 was collected.

Table 1. Data collection of the three tasks performed in the microbiology laboratory.

Analyzed parameter	Tasks		
	Reception of the sample	Work in safety chamber	Sample freezing
Group Agent	II	II	II
Production of bio aerosols	High but sporadic	Scarce	Scarce
Contact	15%	70%	15%

frequency	Working time	Working time	Working time
Handled Number	Average	Average	Average
Operators	1 Man 2 Women	1 Man 2 Women	1 Man 2 Women

4 RESULTS

In the first phase, the level of compliance was calculated, according to the existing conditions, value of the controlled risk (risk eliminated by the preventive measures and confinement), Table 2.

Table 2. Data collection in the three tasks performed in the microbiology laboratory.

Task	Level of compliance achieved (%)
Reception of the sample	5
Work in biological safety chamber	96
Sample freezing	82

In the sample receiving task, the audit determines the lowest compliance level (5%), in biological safety chamber was obtained the highest level (96%) and sample freezing (82%).
In the second phase, we performed the biological risk assessment using the simplified method presented by the Spanish Technical Note NTP 833.
The identified biological agents (bacteria) are all classified in risk group II. The amount handled is normal in all cases, while there are differences in contact frequency and bio aerosol production. The evaluation allowed to classify in level III of potential risk - high risk, all the agents in the three tasks, independently of the verified level of conformity, through the application of a Checklist, in the laboratory and laboratory practices.
In the third phase, applying the same data used in the simplified method, but taking into account the conformity value obtained in the audit, and with the method accompanied by biological risk management different results were obtained. The classification of the level of potential residual risk is different and presents in two tasks level IV - severe and imminent.
It was found that the simplified method NTP 833 did not identify the evaluation parameters provided for in Articles 6 and 7 of Decree-Law Nº 84/97 of April 16th presented in the Portuguese Law, such as supplementary risk for previous illness, the recommendations of the Directorate-General for Health, technical information on related diseases and awareness of the disease in a worker. On the other hand, MIAGRB has identified all the evaluation parameters provided for in that legislation.
When comparing the results of the evaluations obtained with the two methods, in addition to the presented results being more accurate with the accompanied method, this allowed us to identify some more elements, namely:
- Description of the activity;
- Identification of the most vulnerable workers and risky or forbidden activities;
- Identification and characterization of the biological agent;
- Means and ways of contamination or transmission;
- Symptoms according to the identified biological agent;
- Specific prevention measures by contaminant agent;
- General prevention measures of the biological risk factor;
- Confinement measures according to the identified risk group;
- Hygiene measures and individual protection;
- Training and promotion of workers' health;
- Applicable legislation.

5 CONCLUSIONS

It is concluded, therefore, that the process of risk assessment is a real challenge, according to Nácher, Alapont, Sales, and Ferrando (2006) and Moore, *et al.* (2010). The present methodology for assessing the risk of exposure to biological agents (MAGRB) allows a distinction and hierarchize the risk associated with the different operations under study, taking into account safety conditions and practices, complying Evaluation parameters defined in the legislation of biological agents, something that the international method (NTP 833) of INSHT does not allow to do effectively.
This evaluation method, the focus is on the protection of workers, the MAGRB after identifying and characterizing the biological agent also identifies the means and forms of contamination and transmission, symptomatology, prevention, confinement and protection measures, providing the necessary guidelines to trigger a prevention structure in all biologically risky activities.
It complies with all the evaluation parameters required by Portuguese legislation for biological agents.
It allows to differentiate the level of risk between the different groups of biological agents, and to distinguish between the same four levels' group taking into account greater or less mitigation of risk by the control measures.
It is very useful to use quantitative verification lists, which allow the residual level of risk to be calculated after the degree of conformity of the procedures, installations and level of obtained containment, as a way of proving the greater or lesser degree level of mitigation of the prevention measures, in the value of the intrinsic risk.
One of the steps to be taken into account during risk assessment is to evaluate the obtained results, for which we need to sustain it with reference limits or valuation criteria. It turns out that the assessment criteria (VLE - Limit Values of Exposure) for biological agents are not yet established by standard or legislation, in part because of the huge difficulty to obtain them against the characteristics of the biological agents. Indeed:

- They are capable of reproducing in a certain environment and under suitable conditions;
- They can acquire forms of resistance (spores) that allow them to survive in adverse environments over long periods of time;
- They show differences in the degree of virulence;
- They exhibit differences in the immune system response of affected organisms.

The MAGREB does not allow, nor is its objective to be able to answer all the questions that are raised to the technicians, namely in the scope considered in the previous point.

It does not answer yet another very important question, namely how to evaluate the cumulative effects of the presence of numerous agents in the same working environment and the reaction of the organism affected to these agents, facing the multiple attack to which the subject's immune system is subjected.

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