

# MEDICINA y SEGURIDAD *del trabajo*

## Originales

### Methodology implementation in order to evaluate the biological risks in the Centre for Research and Rehabilitation of Hereditary Ataxias of Cuba. A biosecurity surveillance method

Aplicación de la metodología para la evaluación del riesgo biológico en el Centro para la Investigación y Rehabilitación de las Ataxias Hereditarias, Cuba. Una forma de vigilancia en Bioseguridad

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Recibido: 06-06-14

Aceptado: 07-11-14

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## Abstract

**Introduction:** The Center for Research and Rehabilitation of Hereditary Ataxias faces biological risks. Nevertheless a Biosafety system was not yet implemented.

**Objective:** To apply the methodology in order to evaluate these risks

**Materials and Methods:** Interview with the researchers of the center and the use of the methodology for evaluating biological risks designed for Cobos, 2009.

**Results:** Fifty-three biological risks were identified and evaluated, 32 as moderated, 18 as tolerable and 3 as trivial. Such classification are crucial to establish its management priorities and represent a way of surveillance in Biosafety field.

**Conclusion:** The results of this research represent an essential factor for the Biosafety documentation development adapted to the Center and according to the legal basis in terms of biological safety in Cuba.

*Med Segur Trab (Internet) 2014; 60 (237) 620-626*

**Key words:** Biological risk; Biosafety; Methodology; Evaluation

## Resumen

**Introducción:** El Centro para la Investigación y Rehabilitación de las Ataxias Hereditarias presenta riesgo biológico, sin embargo no tiene implementado un sistema de bioseguridad.

**Objetivo:** Aplicar la metodología para evaluar este tipo de riesgo.

**Materiales y Métodos:** Entrevistas con los trabajadores del centro y el empleo de la metodología diseñada por Cobos, 2009.

**Resultados:** Cincuenta y tres riesgos biológicos fueron identificados y evaluados, de ellos 32 moderados, 18 tolerables y 3 triviales. Esta clasificación es muy importante para establecer prioridades para su gestión, además representa una manera de establecer vigilancia en bioseguridad.

**Conclusión:** Los resultados de esta investigación representan un factor esencial para el desarrollo de la documentación de bioseguridad ajustada a las características de la entidad de acuerdo a la base legal en materia de seguridad biológica en Cuba.

*Med Segur Trab (Internet) 2014; 60 (237) 620-626*

**Palabras clave:** *Riesgo biológico, bioseguridad, metodología, evaluación.*

## INTRODUCTION

The work with pathogenic microorganism in Microbiology Laboratory is development in special environment that damaged the health of the workers and it has negatives consequences for the environment. The main features of them take a place for the biological aspect, mainly microorganism and their metabolism's products and the other hand biological samples that can present biological agents. The development of the genetically engineer, the study of the infection diseases and the production of the biological product need laboratories with systems of safety, specific equipment and rooms with specific constructive features to decrease biological risk. This kind of risk represent la probability of appearance and the level of consequences of a negative event relationship with the work with biological agents that affecting to men, their community and environment<sup>1</sup>. When the people keep touch with biological agents, they must know the process to management biological risks. Inside of this process take place the evaluation risks as scientific methods. The main activity can change. It could apply to technological process as biopharmaceutical industry, chemical, mechanical and others.

On the other hand, the Center for Research and Rehabilitation of Hereditary Ataxias, institution of science and technological innovation belongs to health sector in Holguin province. It makes researches in the field of the hereditary ataxias directed to looking for a therapy to modify the evolutive course and the severity of the illness, beside it provide medical assistance for improving the quality of life in families with ataxias. The laboratory personnel handle blood, saliva, amniotic fluid of patients to perform the molecular diagnosis of hereditary ataxias and other neurodegenerative disorders and controlled clinic trials for this illness and neurological tissues due to the research projects. Nevertheless, this Center must design its Biosafety's system to management biological risk to an acceptable level.

Nowadays, there are different methods for evaluating biological risk, one of them is Biogaval Method that it brings prevention and practical value for evaluating the biorisk<sup>2,3</sup>. This method can apply in many activities of any country but it uses the list of biological agents of Spain, vaccine program and other own elements of Spain. As a result of that, a methodology to evaluate biological risk was designed according to the Cuban legal bases of Biosafety and it applied with excellent results during 2009 in Immunology and blood by product Center. This methodology analyze the biological risks for process and biological material, of all them examine elements for determining consequences and probabilities and finally the join of this results permit to get a level for the risk.

In spite of both institutions have different social object, there are biological risks. As a matter of fact, the main goal of this research is to apply the same methodology in the Center for Research and Rehabilitation of Hereditary Ataxias to provide qualitative and quantitative dates for improving the perception, management and control of biological risk. This result will be the pedestal for strategic decisions making, prevention and program planning and Biosafety standards.

## METHODS

### Obtaining information

Interview to specialists were realized to define the processes with biological risks.

## METHODOLOGY

The methodology to evaluate biological risk was proposed by<sup>4</sup> and it is available in *Revista Electrónica «Ciencias Holguín»*. Vol. XV (4), diciembre 2009. <http://www.ciencias.holguin.cu>, but this tool proposes:

- Step I: Identification of the process with biological risk.
  - Step II: Name of manipulated biological material.
  - Step III: Classification of biological agents that can appear in the biological material.
  - Step IV: Classification of biosafety level of the area according to the Resolution 38/2006<sup>5</sup> and Resolution 8/ 2002.
  - Step V: Verifying the fulfillment of biosafety main principles according to the biosafety level defined in Resolution 103/2002<sup>6</sup>.
  - Step VI: Identification of biohazard.
  - Step VII: Valuation of Consequences.
  - Step VIII: Valuation of Probabilities.
  - Step IX: Determination of the magnitude of the biological risk.
- Is very important say that the magnitude of the biological risk was determined for the matrix of working risk evaluation, 2004 (See [table 1](#)).

**Table 1. Determining the magnitude of the risk**

	CONSEQUENCES			
	Low	Average	High	
<b>P</b>	<b>Low</b>	Trivial (TR)	Tolerated (TO)	Moderated (MO)
<b>R</b>		Tolerated	Moderated	Important (IM)
<b>O</b>		Moderated	Important	Severe (SE)
<b>B</b>	<b>Average</b>	Trivial (TR)	Tolerated (TO)	Moderated (MO)
<b>A</b>		Tolerated	Moderated	Important (IM)
<b>B</b>		Moderated	Important	Severe (SE)
<b>I</b>	<b>High</b>	Trivial (TR)	Tolerated (TO)	Moderated (MO)
<b>L</b>		Tolerated	Moderated	Important (IM)
<b>I</b>		Moderated	Important	Severe (SE)
<b>T</b>				
<b>I</b>				
<b>E</b>				
<b>S</b>				

## RESULTS

The methodology allowed the identifying of dangers for process and biological materials.

The Center for Research and Rehabilitation of Hereditary Ataxias contain two areas with biological areas: Neurophysiology and Neuropathology.

Neurophysiology has a Biosafety level 2 to small scale with one process with biological risk: Electromiography: analyze the state of the muscles in patients with ataxia SCA 2.

On the other hand, Neuropathology has a Biosafety level 2 to small scale with four processes with biological risk:

Take of sample: methods for obtaining samples for molecular studies.

Handling of deoxyribonucleic acid (DNA): purification's methods of DNA for molecular studies. Transportation of biological material: transfer of biological material (amniotic fluid, DNA, blood and neurological tissue) to analytical laboratory.

Neurological study: working these samples as a result of research project that executed in the Center.

Fifty-three risks were identified and evaluated. They were classified in 32 moderated with 60 %, 18 tolerable with 34 % and three trivial with 6 % for obtaining a better management of them (See table 2). The main biological risks were: puncture with syringe, cutting with broken glasses, handling of human nervous tissues and exposition to droplet of air.

**Table 2. Quantity of identified biological risks and their classifications**

Classification	Quantity	Percent
Moderated	32	60
Tolerated	18	34
Trivial	3	6
Total	53	100

## DISCUSSION

The analysis of evaluation risk by means of percent showed the risk classified as moderated with the highest value because the institution doesn't have any activity planned of Biosafety and it represents the first step in this subject. Also, there are not risks evaluated as important and severe because the Center presents some knowledge about Biosafety due to the academic formation of some workers and they have some resources to management the Biosafety, as a matter of fact there has not been any accident due to biological risks. Something risks are mentioned: splash and shedding of infectious liquids, exposition to aerosols, puncture with needle, manipulated tissues.

On the other hand, about the principles that were analyzed, the design of the installation and the protection equipment were the most critical because the Center doesn't have investments overlooking constructive remodeling process. As a matter of fact according to the resolution number 103 in 2002, the Center has promote the organization in their process, people and materials, beside they must increase the management of shopping of protection equipment. Experts responsible for the activity itself should implement documentation Biological Safety on current legal base in the country.

The main biological agents according to the handle biological material are:

Hepatitis B virus.

Hepatitis C virus.

Human immunodeficiency virus.

These biological agents belong to Biosafety's level 1 and 2 that affecting to the men and they were described by Bermúdez, 2011 in the dental activities and others institution of health<sup>7</sup>. The main features, survive conditions, reservoir, zoonoses, vectors, treatments, control measurements of each one of identified biological agents were exposed. These results are very important for choosing of specific disinfectant, making kit specific antibiotic for fighting against them and other actions that the Center will realize about Biosafety.

This methodology allowed defining consequences and probabilities for determining the magnitude of the risk, therefore arrangement the work for management and decreasing biological risks to acceptable level.

The results represented the bases of Biosafety system and they are the principal results for developing the process of take decisions up the scientific knowledge and current information according<sup>8-11</sup>.

This risk's evaluation will be useful to the projection and the improvement of management of health and safety and particularly Biosafety. Its results are the bases in the Center to Research and Rehabilitation of Hereditary Ataxias for:

- Definition of requirements of aptitude of the personal for the work or process.
- Making rules's of safety and Biosafety, others rules and instructions.
- Designe of formation's plans.
- Inclusion of safety's requirements as a parameter's quality in the new projects of construction, methods of work and others activities.
- Making standard rules.
- Specific Prevention programs specific for the Center.
- To join of Safety and Health Management System with Quality and Protection of the Environment.
- Applying the internal controls for verifying the fulfillment of requirements.
- Making safety authorizations for different levels.

These aspects defined by<sup>12,13</sup> are the most important for the specialists that will be responsible to control the fulfillment about Biosafety in the Center for Research and Rehabilitation of Hereditary Ataxias. They shape a document defined as Biosafety Program that will be the next activity for applying in this Center.

These results had a similar behavior with the study realized in Immunology and blood by product center due to:

There are not risks classified like severe and the identified biological agents belonged to first and second level, nevertheless in this study were found more virus that bacterias in comparison with the other research because of the samples manipulates in the Center for Research and Rehabilitation of Hereditary Ataxias.

On the other had the quantity of risks in this research was lower than the other study because the Center for Research and Rehabilitation of Hereditary Ataxias presents fewer processes with biological risks.

It is important to mention that research reveals the value of the evaluation of risks as described the Specification of common management system requirements as a framework for integration when expresses: the risk assessment is the main driving force of the systems management of health and safety at work and the others, and probably that it appears in future standars of systems management (PAS 90: 2008)<sup>14,15</sup>.

## CONCLUSIONS

The application of the methodology to evaluate biological risks in the Center for Research and Rehabilitation of Hereditary Ataxias allowed the identification of the areas and processes with biological risks. In addition, 53 biological risks were evaluated as: 32 risks moderated, 18 tolerable and three trivial according to the process and materials handles. These results are the bases for designing the next activities about Biosafety for management the biological risks and they showed that this methodology can be applied in different situations where the biological risk is there.

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