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Research Article

Evaluation of compliance with biosafety standards in a tertiary care clinical laboratory

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Abstract

In the field of science and research, clinical laboratories play an essential role in the advancement of medicine and the understanding of target diseases. Evaluate compliance with biosafety standards in a tertiary care clinical laboratory. Method. An observational, descriptive study was carried out in the first quarter of the year 2024 in a clinical laboratory of the third level of care, as an instrument an observation guide made up of 19 items was used: aimed at the 7 clinical laboratory professionals and one assistant. health services N=8. The observation was carried out by three professionals, two Masters in Biological Safety and one Master in infectious diseases, in a direct, open, non-participatory manner and for 45 minutes. To measure the level of agreement between observers, the Fleiss Kappa statistical method was used. Root cause analysis methodology or Ishikawa diagram was used to visualize the aspect of greatest non-compliance with biosafety standards. Results. There was a 14.2% non-compliance rate related to food intake in the laboratory and non-use of gloves. Waste management is the aspect of greatest non-compliance in the laboratory. Conclusion. The observation guide made it possible to identify the aspects that favor non-compliance with biosafety standards and the Ishikawa Diagram facilitated the vision of the possible causes of poor waste management in search of improvement actions.

Keywords: biosecurity; clinical laboratory; standards

Introduction

In the field of science and research, clinical laboratories play an essential role in the advancement of medicine and the understanding of diseases. In these work spaces, analyzes and tests of biological samples are carried out, which allows obtaining valuable information for the diagnosis, treatment and monitoring of various conditions [1].

This is why it is timely to explore compliance with biosafety standards and the practices that must be managed in clinical laboratories for the handling of biological samples with infectious potential, minimizing the risk of accidents, exposures and the spread of diseases. thus protecting laboratory personnel, the community and the environment [2,3].

According to Escalante [4] in the year 2022, risk is linked to the human being from its very conception, remains inherent to social activity and has evolved together with the species. Its absolute elimination is unattainable; Therefore, although no effort is spared to mitigate or eradicate some causal elements, circumstances arise that lead to the emergence of new risks. This vision is consistent with the way risk is addressed in clinical laboratories.

The World Health Organization (WHO) recognizes that the morbidity attributable to occupational exposure is 40% in the case of hepatitis B and C; and 2.5% in the case of HIV-AIDS. Latin America has the highest prevalence of hepatitis B virus (HBV) transmission in healthcare workers; The percentage of infections attributable to occupational causes is 52% for this virus, 65% for hepatitis C virus (HCV) and 7% for human immunodeficiency virus (HIV/AIDS) [5].

Laboratory-acquired infections (LAB) are presented as a problem associated with the manipulation of infectious biological agents. These infections are caused by biological pathogens in the handling of materials and samples, hence the presence of biosafety and its development, which is related to the evolution of microbiology [6].

With the COVID-19 pandemic, biosafety concerns increased. In 2020, China enacts a new comprehensive biosafety law that comes into force in April 2021. In February 2022, the United Kingdom held a public consultation to provide an update on its biosafety strategy. In that same month, the United States publishes a review on the scope and effectiveness of national biosafety policy frameworks for research into pathogens with pandemic potential [7].

In Cuba, biosafety has its highest expression in Decree-Law 190 of 1999 on Biological Safety, where the basic principles of this discipline are conceived in its contribution to sustainable development and this document defines Biological Safety as "a set of measures scientific and organizational, among which are the human and engineering techniques, which include the physical, aimed at protecting the worker in the facility, the community and the environment, from the risks associated with working with biological agents or the release of organisms to the environment"[8].

Due to the importance this represents, the objective of this research is to evaluate compliance with biosafety standards in a third level of care clinical laboratory.

Material and method

An observational, descriptive study was carried out in the first quarter of 2024 in a clinical laboratory at the third level of care. The observation guide was used as an instrument: aimed at seven graduates in health technology and a health services assistant N=8 who constitute the research sample, with the purpose of evaluating compliance with biosafety standards.

The observation was carried out in a direct, open and non-participatory manner, in the laboratory for 45 minutes, indiscriminately by three nursing professionals, two Masters in Biological Safety and one Master in infectious diseases (evaluators) with experience in the subject.

For the interpretation of the observation guide, the first step was the evaluation of agreement. This measures the agreement between observers, from which the Fleiss Kappa index is obtained, particularly those cases in which the number of observers involved is greater than two [4,9].

Subsequently, a pilot test was carried out on 15 clinical laboratory professionals who carry out similar activities, to measure the level of agreement between observers through the Fleiss Kappa statistical method.

According to the Altman 1991 scale, the coefficients register values between 0 and 1, with 0 being the value where there is greatest disagreement between researchers and 1 being the point where there is greatest agreement. Their classification indicates that Kappas can be Poor (0 to 0.20), Weak (0.21 to 0.40), Moderate (0.41 to 0.60), Good (0.61 to 0.80) and Very good (0.81 to 1.00) [4,9].

To represent the aspects of greatest non-compliance with biosafety standards in a visual way, the root cause analysis methodology or Ishikawa diagram was used where the problem represents the "head of the fish", from which a central spine emerges. From there the major causes or large thorns are derived. In turn, large thorns can be made up of smaller thorns, also called minor causes [10,11].

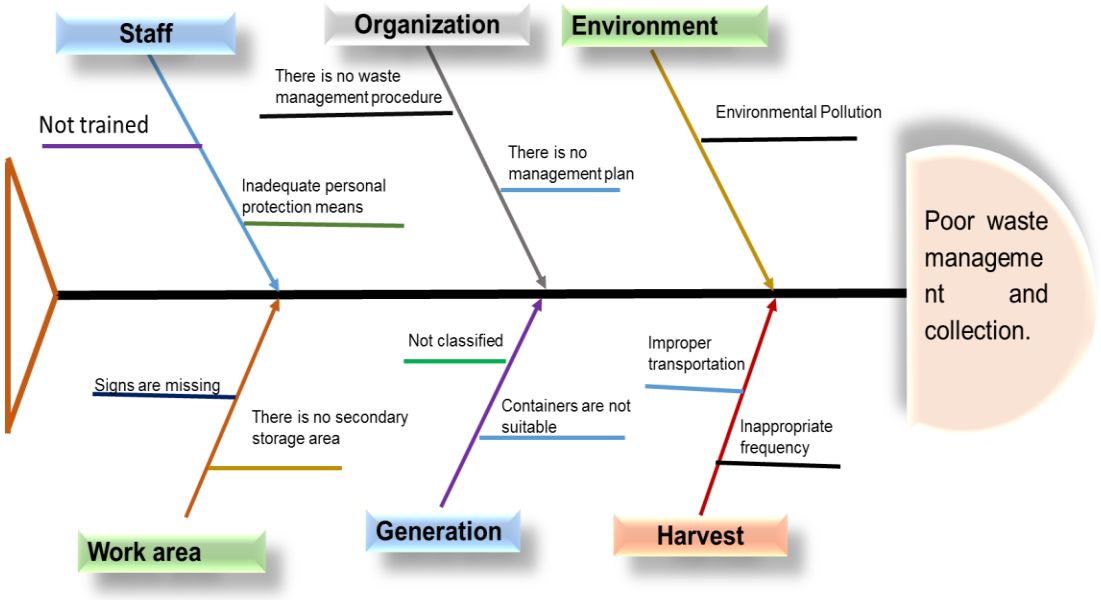
Results

The Fleiss Kappa (Annex 2) of the observation guide turned out to be 0.871. To calculate the reliability or internal consistency of the instrument, Cronbach's alpha was used and the value reached was 1.0000.

The sample is made up of 7 graduates in health technology and 1 health services assistant, 100% of whom are female. The observation allowed the visualization of adherence to compliance with biosafety standards in the daily activities of the clinical laboratory staff and it was found that there are no vulnerabilities related to item 1 related to the signaling of risk areas. Non-compliance with item 2 related to the use of personal protective equipment, specifically gloves, was observed in 14.2%, by the health service assistant. However, there are no non-compliances in items 3 and 4 related to the accident report and the accessibility of these records. Regarding the observation of item 5 linked to hand washing made up of sections a, b, c, it was found that the staff has the material resources and structure in the area to carry out hand washing. Subsequently, the observation of item 6 related to eating, drinking or smoking in the area, it was detected that a worker ate food in the laboratory, which represents 14.2% of the sample. On the contrary, when observing item 7, related to the decontamination of the work surface with an appropriate disinfectant, it was found that the procedure is 100% complied with. Regarding item 8 related to the prohibition of the use of the refrigerator to store food, it was identified that 100% of the sample complies with the provisions. In the same way, items 9 and 10 are met, the first related to the entry of non-laboratory personnel and the second, related to periodic medical examinations according to the work activity carried out. On the contrary, the observation of items 11, 12, 13, 14, 15, 16 and 17, related to the temporary storage of waste, classification, transportation, state of the containers and classification, allowed us to verify that there is poor management and waste collection. The evaluators agree that it is not observed that the conditions related to internal and external transportation are created; the internal one refers to the transfer of dangerous biological waste within the institution and the external one, related to the final destination of the dangerous biological waste and, in relation to the temporary storage of dangerous biological waste, there are containers intended for sharps and hospital waste that do not meet the established requirements.

In the observation of item [18] related to knowledge about biosafety standards, a lack of knowledge related to waste management was identified; however, it was found that laboratory cleaning is carried out correctly, items [19].

Aspects of greatest incidence in non-compliance with biosafety standards



Discussion

The result of the interpretation of the observation guide made it easier to verify compliance or non-compliance with the regulations and regulated procedures. The range of agreement reached in the present research according to the Altman scale is very good, coinciding with those achieved by Escalante [4] in the year 2022, in his research titled biological risk management as a self-care action of the Nursing professional, it also coincides with Sisalema [9] and collaborators in their study evaluating agreement between doctors on medical emergency priorities using Fleiss's kappa coefficient. The characterization of the sample corresponds to what is described for the health sector in Cuba, where women constitute the main workforce [3]. Regarding area signage, recent evidence on the subject suggests that it is essential in a laboratory environment to identify those areas that may indicate a danger to our health [13]. Aspect that is fulfilled in the present investigation and when compared with other investigations coincides with the results achieved by Ramos [14] and collaborators in the investigation evaluation of biological risk in Quality Control laboratories of the Finlay Institute, in which the signaling was observed in the areas of Limited Access and Biological Risk and differ from those published by Valdes [15] and collaborators in their study of biosafety in primary health care clinical laboratories.

The percentage of compliance with biosafety standards to prevent and control the risks to which the personnel of the laboratories under study are exposed, related to items 2, 3, 4, 5, 6, 7, 8, 9 and 10, demonstrate knowledge, control and organization in matters of safety and health at work and monitoring compliance with correct practices and techniques, the use of protective means, control of compliance with individual protection measures, universal precautions and measures biosafety in the laboratory. Similar findings were published by Ramos and Puentes [16] in the educational intervention on biosafety at the Aracelio Rodríguez Castellón University Polyclinic in the municipality of Cumanayagua, where a high level of compliance with biosafety standards was found. The research titled, compliance with biosafety measures in the outpatient surgery surgical unit of Camagüey, differs from the results found in the present study, in which it was found that 36.0% of the nursing staff always applies biosafety measures, 31.0% sometimes use them and 33.0% never apply them [17]. The observation allowed vulnerabilities related to waste management to be identified in the laboratory.

Similar results are published in Peru, in a quasi-experimental study with pre- and post-test design, to evaluate compliance with solid waste management. In this, it is confirmed that the segregation, primary, intermediate and final storage, in addition to internal and external transportation, treatment and collection of waste are deficient [18]. The results found in this research coincide with the study by Ocampo and Arena [19]in Lima, Peru, where vulnerabilities in the following items: intermediate and final storage of solid waste, treatment and management of laboratory waste. The management of waste from health institutions has great importance and interest in recent years, because it is a management tool that guarantees health and environmental safety, which begins from the source of generation, to continue its management. in the different areas of the institution, until ensuring that it reaches its final destination outside the establishment, for treatment or adequate disposal [20].

The WHO recommends three basic principles: the reduction of unnecessary waste, the separation between ordinary and hazardous waste and its appropriate treatment in order to reduce risks. The link between human health and the environment has long been recognized. Without a doubt it depends on the will and capacity of a society to improve the interaction between human activity and the chemical, physical and biological environment [20]. In general, the results regarding training reveal a deficiency in knowledge regarding waste management, although the cleaning procedure in the laboratory is adequate, which coincides with the results of two investigations prior to the study carried out; the first, carried out by Escalante4 in 2022 and the second by Valdés3 in 2023, in which poor waste management and little knowledge of the personnel related to this process and an adequate cleaning procedure were found.

Conclusions

The observation guide made it possible to identify the aspects that favor non-compliance with biosafety standards and the Ishikawa Diagram facilitated the vision of the possible causes of poor waste management in search of improvement actions.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Authors' contribution

Miriam Virginia Valdés Fernández. Conceptualization, data curation, formal analysis, investigation, methodology, supervision, validation, visualization, writing the original draft, and review and editing.

Floriano José Valdés Fernández. Conceptualization, data curation, formal analysis, investigation, methodology, supervision, validation, visualization, writing the original draft, and review and editing.

Anays Arredondo Ramírez. Conceptualization, supervision, validation, visualization, writing, review and editing.

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Annex

Annex 1. Observation guide

Guide to observing biosafety standards				
Director:				
Name and surname and position of the interviewee:				
Inspector:				
Date:				
	Aspects to check	State		Observaciones
		Yes (1)	No (0)	
Biological safety structure and management				
1	Biological risk areas are marked			
2	Staff use personal protective equipment.			
3	There are accident records			
4	These records are accessible			
Appropriate practices and procedures				
5	Staff have the material resources for hand washing.			

a	Soap or other detergent agent.			
b	Towel or paper for drying.			
c	Running water available .			
6	Staff are prohibited from eating, drinking or smoking in the area.			
7	appropriate disinfectant (when finishing work, when spills, or other incidents occur).			
8	Staff use the refrigerator to store food			

Annex 1. Observation guide

Guide to observing biosafety standards				
Director:				
Name and surname and position of the interviewee:				
Inspector:				
Date:				
	Aspects to check	State		Observaciones
		Yes (1)	No (0)	
9	The entry of personnel from outside the laboratory is prohibited.			
10	Periodic medical examinations are carried out according to the work activity carried out.			
Handling of contaminated waste				
11	Is there a temporary storage area for waste?			
12	Is waste moved safely from the temporary storage site to the treatment or final disposal site?			
13	Are the containers for waste collection appropriate? Are they kept with a lid?			
14	Properly separate waste according to its classification by category?			
15	Do you prevent the accumulation of infectious material removed in laboratory areas?			

Annex 1. Observation guide

Guide to observing biosafety standards				
Director:				
Name and surname and position of the interviewee:				
Inspector:				
Date:				
	Aspects to check	State		Observaciones
		Yes (1)	No (0)	
16	Is waste treated properly?			
17	Are there adequate means of transportation to transport waste?			
18	Do they show knowledge of biosafety standards through the execution of procedures?			
19	Is laboratory cleaning carried out from the highest risk area to the lowest risk area?			

compliance with biosafety standards													
							N						En2ij -n
	1	2	3	C2	C3	n*(n-1)	judges		2	3	neij	n2ij-n	n*(n-1)
1	3	3	3	0	3	6	3	1	0	3	9	6	1.00
2	3	3	3	0	3	6	3	2	0	3	9	6	1.00
3	3	3	2	1	2	6	3	3	1	2	5	2	0.33
4	3	3	3	0	3	6	3	4	0	3	9	6	1.00
5	3	3	3	0	3	6	3	5	0	3	9	6	1.00
6	3	3	3	0	3	6	3	6	0	3	9	6	1.00
7	3	2	3	1	2	6	3	7	1	2	5	2	0.33
8	3	3	3	0	3	6	3	8	0	3	9	6	1.00

9	3	3	3	0	3	6	3	9	0	3	9	6	1.00
10	3	3	3	0	3	6	3	10	0	3	9	6	1.00
11	3	3	3	0	3	6	3	11	0	3	9	6	1.00
12	3	3	3	0	3	6	3	12	0	3	9	6	1.00
13	3	3	3	0	3	6	3	13	0	3	9	6	1.00
14	3	3	3	0	3	6	3	14	0	3	9	6	1.00
15	1	3	3	0	2	6	3	16	0	2	4	1	0.17
16	3	3	3	0	3	6	3	21	0	3	9	6	1.00
17	3	3	3	0	3	6	3	22	0	3	9	6	1.00
18	3	3	3	0	3	6	3	23	0	3	9	6	1.00
19	3	3	3	0	3	6	3	23	0	3	9	6	1.00
								total	**2**	**54**	**158**		16.83
							Pj=T/	343	0.012	0.341	0.354		0.89 po
							Pe-PJ		0.00016	0.116	0.116	Pe	
						n	Proportion of agreement with expectations (po)						
						n-1	**K=Po-Pe0.87**						
						n*(n-1)	**Coherence 1-Pe**						

Annex 2: Calculation of the reliability or internal consistency of the observation guide related to compliance with biosafety standards

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