Dominant factors associated with biosafety facility and equipment in laboratories: an Indonesian 2011 study

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Abstrak

Latar belakang: *Ketersediaan fasilitas dan kelengkapan peralatan keamanan hayati di laboratorium adalah esensial dalam menciptakan lingkungan kerja yang aman bagi personel laboratorium. Tujuan dari penelitian ini adalah untuk mengidentifikasi faktor-faktor dominan berhubungan dengan kelengkapan alat pelindung diri (APD), ketersediaan biosafety cabinet, dan ketersediaan ruang sterilisasi di laboratorium.*

Metode: *Analisis data menggunakan sebagian data laboratorium klinik Rifaskes 2011. Cox regresi dipakai untuk mengidentifikasi faktor-faktor dominan yang terkait dengan kelengkapan alat pelindung diri (APD), ketersediaan biosafety cabinet, dan ketersediaan ruang sterilisasi.*

Hasil: *Dari 782 laboratorium, terdapat 769 laboratorium dengan data yang lengkap dan dapat dianalisis. Sangat sedikit (15%) laboratorium kelas utama dan laboratorium terakreditasi hanya 9,9%. Laboratorium kelas satu dibandingkan dengan laboratorium kelas madya dan pratama memiliki kesempatan yang lebih tinggi adanya alat pelindung diri (APD) lengkap, ketersediaan biosafety cabinet, dan ketersediaan ruang sterilisasi. Selain itu, laboratorium terakreditasi dibandingkan dengan yang tidak terakreditasi hampir 3 kali lipat mempunyai ketersediaan APD lengkap (RRa = 2,94; P = 0,000), hampir 4 kali memiliki biosafety cabinet (RRa = 3,94; P = 0,000), dan memiliki 37% kesempatan memiliki ruang sterilisasi (RRa = 1,37; P = 0,008).*

Kesimpulan: *Klasifikasi dan akreditasi laboratorium merupakan faktor dominan berhubungan dengan ketersediaan fasilitas dan kelengkapan peralatan biosafety di laboratorium.* ***(Health Science Indones 2013;1:1-6)***

Kata kunci: *akreditasi, biosafety, klasifikasi, laboratorium*

Abstract

Background: The availability of facility and completeness of equipments of biosafety in laboratories is esensial in creating safe working environment for laboratories personnel. The aim of this study was to identify the dominant factors related to completeness of personal protective equipment (PPE), availability of biosafety cabinet, and availability of sterilization room in laboratories.

Methods: Data analysis using a part of data of Rifaskes 2011 on clinical laboratories. Cox regression was conducted to identify the dominant factors related to completeness of personal protective equipment (PPE), availability of biosafety cabinet, and availability of sterilization room.

Results: From 782 laboratories, there were 769 laboratories with complete data and may be analyzed. We note that very few (15%) first class laboratories and accredited laboratories was 9.9% only. In term of laboratory classification, the first class compared with second and third class laboratories had higher chance having complete PPE, biosafety cabinet, and availability of sterilization room. In addition, the accredited laboratory compared with not accredited laboratory had almost 3 times having complete PPE (RRa = 2.94; P = 0.000), and had almost 4 times having biosafety cabinet (RRa = 3.94; P = 0.000), and had 37% more chance having sterilization room (RRa = 1.37; P = 0.008).

Conclusion: Laboratory classification and accreditation were dominant factors related to availability of facility and completeness of equipments of biosafety in laboratories. ***(Health Science Indones 2013;1:1-6)***

Keywords: accreditation, biosafety, classification, laboratories

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The National Health Facility Research (*Rifaskes*) 2011 conducted by the National Institute of Health Research and Development (NIHRD), Ministry of Health, Indonesia. *Rifaskes* aimed to provide a mapping of supplies availability of health care facilities in health institutions in Indonesia.[1]

Laboratory is one of the health care institutions that were covered in Rifaskes 2011 study. Biosafety in laboratory, according to World Health Organization (WHO), is defined as any containment efforts undertaken to prevent exposure of hazardous materials in laboratory.[2] Implementation of biosafety is very essential especially for laboratory with examination relating to hazardous biological materials.

Center for Diseases Control and Prevention (CDC) states that biosafety program includes safe methods, adequate facilities and equipments to handle infectious materials which are examined in laboratory. Biosafety facility and equipments in laboratory include personal protective equipment (PPE), biosafety cabinet, and sterilization room.[3]

Minister of Health's Decree number 411 states that all clinical laboratories must have 100% of biosafety facility and equipment. But, previous study reported that there still was laboratory in Indonesia with unavailable facility and equipment of biosafety.[4,5]

There are many factors that related to availability of facility and completeness of equipments of biosafety in laboratory. Therefore, this study aimed to identify the dominant factors that related to completeness of personal protective equipment, availability of biosafety cabinet, and availability of sterilization room in laboratories in Indonesia.

METHODS

This analysis used a part of *Rifaskes* laboratory study in Indonesia 2011. *Rifaskes* was a cross sectional study carried out in August - October 2010. The subjects of *Rifaskes* laboratory 2011 study were public as well as private clinical laboratories in 497 districts in 33 provinces in Indonesia, already operating before February 2010, and did not integrate with hospitals.

Data collected were human resources, facilities and infra structures, medicines and medical equipments, organization and essential management, health services, essential output, and other quality indicators data.

Data collected by special trained personnel for this study: students from schools of public health and health polytechnic, and health personnel from profesional organizations. Data were collected through interviews using special questionnaires for this study and observation.[1,6]

The outcomes of this analysis were the availability of facility and completeness of equipments of biosafety in laboratories: completeness of PPE, availability of biosafety cabinet, and availability of sterilization room.

The completeness of PPE was assessed from availability of four types of PPE, includes gloves, masks, aprons, and goggles, and divided into complete or incomplete. Laboratory had complete PPE if all four types of PPE (gloves, masks, aprons, and goggles) were available. Laboratory had incomplete PPE if one of four type of PPE (gloves, masks, aprons, or goggles) were not available.

The availability of biosafety cabinet was assessed from availability of biosafety cabinet class II in microbiological equipments, and was divided into available or not available.

The availability of sterilization room was assessed from availability of a room functioning for sterilization, either separated or merged with another room, and was divided into available or not available.

The related factors of this analysis were laboratory classi fication, regional, laboratory accreditation, occu pational accidents, and special examination programs.

Laboratory classification based on Minister of Health's Decree number 411 (third class, second class, and first class laboratory): (1) third class clinical laboratory is laboratory that carry out the inspection service clinical specimens with limited inspection force with a simple technique; (2) second class clinical laboratory is laboratories that carry out service on clinical specimens with clinical skills laboratory examination of the general level and immunological examination with simple techniques; (3) first class clinical laboratory is a laboratory that implement more complicated examination with automatic techniques.[4]

The region divided into Sumatera, Java-Bali, Kalimantan, Sulawesi, and other islands.

Laboratory accreditation in accordance with the laboratory accreditation held by the Committee on Laboratory Accreditation of Health every 5 (five) years, and was divided into accredited or not

accredited. Laboratory accreditation was assessed from the result of KALK (Committee on Laboratory Accreditation of Health), ISO (International Organization for Standardization) 15189, ISO 17025, and other accreditations. Laboratory only needs to pass one type of accreditation to be called as accredited laboratory, and not accredited laboratory if did not pass all types of accreditation.

Occupational accidents in laboratory were assessed from incidence of punctured sharp object, spilled hazardous chemical material, or spilled infectious material. Laboratory had occupational accident if one of three types of accidents were reported.

Special examination programs in laboratory were assessed from availability of examination of HIV/AIDS, pulmonary tuberculosis, malaria, or neonatal screening. Laboratory had special examination program if performed at least one of four types of examination.

Relative risk statistical analysis was performed using Stata released 9 to identify dominant factors related to completeness of personal protective equipment, availability of biosafety cabinet, and availability of sterilization room.

RESULTS

The number of clinical laboratories that met the inclusion criteria was 782 out of 902 clinical laboratories in Indonesia. For this analysis, the number of laboratories was 769 laboratories. The rests (13 laboratories) had incomplete data.

Table 1 shows 16% of laboratories had complete PPE. Availability of biosafety cabinet in laboratories was 12.5% and availability of sterilization room was 38%.

More than half of laboratories were located in Java-Bali islands (59,7%). However, only 9.9% of laboratories were accredited.

Occupational accident in laboratories was 18,2%. The occupational accidents were, among others, punctured sharp object, spilled hazardous chemical material, or spilled infectious material.

Amounted to 79.1% laboratories had at least one special examination programs such as examination of HIV/AIDS, pulmonary tuberculosis, malaria, or neonatal screening.

In addition, Table 1 shows that the first class laboratories, laboratories in Java-Bali and Sulawesi, accredited laboratories, laboratories which had occupational accident and special examination program more likely had complete availability of personal protective equipment and availability of biosafety cabinets. However, the first class laboratories, laboratories in Sulawesi and other islands, accredited laboratories, and laboratory which had special examination program were more likely had availability of sterilization room.

Table 2 reveals that first class compared with third class laboratories had 60% higher chance having complete personal protective equipment [adjusted relative risk (RRa = 1.60; P = 0.036]. However, the second class laboratories had 46% less chance having complete personal protective equipment (RRa = 0.64; P =0.187).

In term of laboratory accreditation, accredited laboratory compared with not accredited laboratory had almost 3 times having complete personal protective equipment (RRa = 2.94; P = 0.000).

In addition, laboratory which had at least one special examination program compared with did not have program had 60% more chance having complete personal protective equipment (RRa = 1.60; P = 0.083).

Table 3 shows that first class laboratories compared with third class laboratories was 3.8 times had biosafety cabinet (RRa = 3.82; P = 0.000). Whereas the second class laboratory was 2.3 times had biosafety cabinet (RRa = 2.32; P = 0.004). In term of accredited laboratories, the accredited compared with not accredited laboratory was almost 4 times had biosafety cabinet (RRa = 3.94; P = 0.000).

Table 4 shows that first class laboratories compared with third class laboratories had 83% more chance having sterilization room (RRa = 1.83; P = 0.000). Whereas, the second class laboratory had 24% more chance having sterilization room (RRa = 1.24; P = 0.122). In term of laboratory accreditation, the accredited compared with not accredited had 37% more chance having sterilization room (RRa = 1.37; P = 0.008).

DISCUSSION

This analysis had limitations, among others, some laboratories did not have complete data, and therefore they were not included in the data analysis. In addition we did not analyze management and financial matters.

Table 1. Description of personal protective equipment, biosafety cabinet, and sterilization room

	Completeness of personal protective equipment				Availability of biosafety cabinet				Availability of sterilization room			
	Incomplete (n=646)		Complete (n=123)		No (n=673)		Yes (n=96)		No (n=477)		Yes (n=292)	
	n	%	n	%	n	%	n	%	n	%	n	%
Laboratory classification												
Third class	482	87.3	70	12.7	521	94.4	31	5.6	377	68.3	175	31.7
Second class	92	91.1	9	8.9	87	86.1	14	13.9	61	60.4	40	39.6
First class	72	62.1	44	37.9	65	56.0	51	44.0	39	33.6	77	66.4
Region												
Sumatra	125	88.0	17	12.0	130	91.5	12	8.5	97	68.3	45	31.7
Java-Bali	375	81.7	84	18.3	393	85.6	66	14.4	271	59.0	188	41.0
Kalimantan	72	88.9	9	11.1	76	93.8	5	6.2	58	71.6	23	28.4
Sulawesi	25	80.6	6	19.4	24	77.4	7	22.6	18	58.1	13	41.9
Other islands	49	87.5	7	12.5	50	89.3	6	10.7	33	58.9	23	41.1
Laboratory accreditation												
No	609	87.9	84	12.1	642	92.6	51	7.4	452	65.2	241	34.8
Yes	37	48.7	39	51.3	31	40.8	45	59.2	25	32.9	51	67.1
Occupational accident												
No	510	85.3	88	14.7	532	89.0	66	11.0	369	61.7	229	38.3
Yes	110	78.6	30	21.4	116	82.9	24	17.1	90	64.3	50	35.7
Unknown	26	83.9	5	16.1	25	80.6	6	19.4	18	58.1	13	41.9
Special examination program												
No	147	91.3	14	8.7	153	95.0	8	5.0	108	67.1	53	32.9
Yes	499	82.1	109	17.9	520	85.5	88	14.5	369	60.7	239	39.3

Table 2. Dominant factors related to the completeness of personal protective equipments in laboratories

	Personal protective equipment						
	Incomplete (n=646)		Complete (n=123)		Adjusted relative risk	95% CI	p
	n	%	n	%			
Laboratory classification							
Third class	482	87.3	70	12.7	1.00	Reference	
Second class	92	91.1	9	8.9	0.64	0.34 – 1.24	0.187
First class	72	62.1	44	37.9	1.60	1.03 – 2.48	0.036
Laboratory accreditation							
No	609	87.9	84	12.1	1.00	Reference	
Yes	37	48.7	39	51.3	2.94	1.92 – 4.49	0.000
Special examination program							
No	147	91.3	14	8.7	1.00	Reference	
Yes	499	82.1	109	17.9	1.60	0.94 – 2.72	0.083

*Adjusted each other between risk factor listed on this Table

Table 3. Dominant factors related to the availability of biosafety cabinet in laboratories

	Biosafety cabinet						
	No (n=673)		Yes (n=96)		Adjusted relative risk	95% CI	p
	n	%	n	%			
Laboratory classification							
Third class	521	94.4	31	5.6	1.00	Reference	
Second class	87	86.1	14	13.9	2.32	1.32 – 4.10	0.004
First class	65	56.0	51	44.0	3.82	2.23 – 6.53	0.000
Laboratory accreditation							
No	642	92.6	51	7.4	1.00	Reference	
Yes	31	40.8	45	59.2	3.94	2.46 – 6.31	0.000

*Adjusted each other between risk factor listed on this Table

Table 4. Dominant factors related to the availability of sterilization room in laboratories

	Sterilization room						
	No (n=477)		Yes (n=292)		Adjusted relative risk	95% CI	p
	n	%	n	%			
Laboratory classification							
Third class	377	68,3	175	31.7	1.00	Reference	
Second class	61	60.4	40	39.6	1.24	0.94 – 1.62	0.122
First class	39	33.6	77	66.4	1.83	1.47 – 2.28	0.000
Laboratory accreditation							
No	452	65.2	241	34.8	1.00	Reference	
Yes	25	32.9	51	67.1	1.37	1.08 – 1.73	0.008

*Adjusted each other between risk factor listed on this Table

The study results showed that first class laboratories had more complete PPE than second and third class laboratories. First class laboratories as the highest classification carrying out more extensive examination than second and third class laboratories.[4] With more extensive examination, then the risk of the laboratories personnel will also increase for exposure to pathogenic agent such as blood, body liquids and other specimens that were collected from patients at risk of transmitting disease. The way to minimalized these risks was to provide complete PPE.[7] In accordance with this study results which proved that not all laboratories have complete PPE, another study also found the incompleteness of PPE in clinical laboratories in Ciptomangunkusumo Hospital Jakarta, even the incompleteness of PPE was major reason for health care worker to not use PPE in laboratories.[5]

Beside laboratory classification, laboratory accreditation was also proven as one of the dominant factors affecting the completeness of PPE. This was because one of the laboratory accreditation parameters was to have complete safety and security equipments, including PPE.[8]

Dominant factor that affected the availability of biosafety cabinet was classification and accreditation of laboratories. Minister of Health's Decree No.411 stated that any laboratory classification must have minimum capacity to carry out microbiology examination such as pulmonary tuberculosis/acid fast bacilli. For the laboratories performing acid fast bacilli examination, biosafety cabinet was the main equipment used to ward off the infectious droplets or aerosols resulting from the microbiological examination procedures. From this study results, first class laboratories have more biosafety cabinet than second and third class laboratories, it was because first class laboratories carrying out more complete microbiological examination, so that the availability of biosafety cabinet as security equipment was required.[3,4,9]

Supply of biosafety cabinet in laboratories for microbiology examination was also supported by Minister of Health's Decree No.298 and WHO. The decree stated that one of the laboratory accreditation parameters was the availability of safety working equipments in laboratories. WHO grouped laboratories carrying out microbiological examination into risk group 2 with

biosafety level 2 and biosafety cabinet class II was a required safety equipment to provide.[2,8]

Dominant factors affected the availability of sterilization room were classification and accreditation of laboratories. WHO defined sterilization as a process to kill or eliminate all microorganism and spores. From this definition, it can be concluded that availability of sterilization room was essential, especially for laboratories performing microbiological examination. In line with the result study stated that first class laboratories have more sterilization room than second and third class laboratories. This was due to higher classification of laboratory, more complete examination service were performed, resulting in risk of health care workers exposed to hazardous materials will also increase, so the need for the availability of safety and security facility such as sterilization room will also increase.[2,4] Availability of sterilization room was also required for laboratories performing microbiological examination for getting accreditation, because the function of sterilization room as occupational security facility.[8]

Laboratory accreditation was one of dominant factor related to completeness of PPE, availability of biosafety cabinet and sterilization room. Accredited laboratory will have more completed PPE, more available biosafety cabinet and sterilization room than non-accredited laboratory. With facility and equipment that are more available and complete, will support the implementation of biosafety in accredited laboratory. In accordance with Rif'ati study that stated accreditation of hospital related with calibrated slit-lamp as also supporting factor of biosafety in hospital.[10]

Conclusion

Laboratory classification and accreditation were domi nant factors related to availability of facility and completeness of equipments of biosafety in laboratories.

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