

A case study: An Assessment of biosafety precautions at laboratories in selected government healthcare institutions in Colombo district, Sri Lanka

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ABSTRACT

Background: Laboratory services are an essential part of the entire health system and biosafety prevents unintentional exposure to pathogens and toxin which, paved the way for Sri Lanka to sign the Cartagena Protocol on Biosafety on 24th May, 2000.

Objectives: The objective of this study is to assess the biosafety precautions (BSP) in selected government healthcare institutions (SGHIs) in Colombo district, Sri Lanka.

Methods: A descriptive cross sectional study was performed in fourteen SGHIs in Colombo district, Sri Lanka. BSP level was assessed through a checklist based on direct observation by using adapted WHO laboratory assessment tool i.e. WHO, 2012. Accordingly, this consisted of developed and validated measurement criteria for BSP and the level of availability of BSP given values were 100% for fully availability, 50% for partial availability and 0% for non-availability.

Results: MRI had the highest BSP standard (89.3%) while the standard was poor at DMH (43.2%), IDH (43.8%), JAPR (46.3%), BHH (49.4%) and LRH (49.5%), respectively and the lowest was CSH (35.6%). Overall BSP level in Colombo district was 52.8%.

Conclusions and Recommendations: Six out of fourteen institutions showed very poor levels of BSP. Establishment of a biosafety committee, preparing standard operational practices (SOPs) and introduction of continuous professional development and surveillance systems, were identified as major recommendations for overall improvement.

Keywords: biosafety, precautions, laboratories, level, standard, practices

1. Introduction

The laboratory biosafety is defined by the World Health Organization (WHO) as “the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins or their accidental release” (Laboratory Biosafety Manual - Third Edition, 2015). Basic biosafety precaution in clinical laboratories is an important concern locally as well as internationally (WHO, 2004a) and a cross sectional study was done in Poland (Kozajda, Brodka and Szadkowska-Stanczyk, 2013) to evaluate the factors affecting biosafety in laboratories.

Officers in charge of the laboratory and hospital administration is responsible for job specific training programmes for all staff engaged with laboratory work (Chamberlain et al., 2009). A survey conducted in United States in 2008, suggested the need of consistent biosafety training for all categories of staff (Chamberlain et al., 2009) and the personal protective equipment (PPE) usage (i.e. gloves, gowns, lab coats etc.) in laboratories was 100% as confirmed by the United States Army Medical Research Unit, Kenya. Similarly in Sudan had written standard operation procedures (SOPs) for biosafety cabinet, autoclave, incinerator, sharp disposable containers, laboratories and conduct of biosafety officers as well as explicit procedures for the clean-up of spillages and hepatitis B vaccination programme (Elduma, 2012). An article in the Journal of the Dow University of Health Sciences Karachi, Pakistan revealed that, hand washing and decontamination of laboratory bench was 100%, PPE usage inside laboratories was 80%, disinfecting of working tables of the staff on a daily basis stood at 70%, staff training on biosafety was 60%, incidence reporting at 40%, distribution of biosafety handbook to staff remained at 20% and 10% of laboratories has eye wash station and emergency shower (Khan et al., 2014).

However, survey done by Medical Research Council and University of Karachi, Pakistan on laboratories showed that, 73.9% operated without written SOPs, 83.4% failed to maintain any accident records and 85% did not have any training in biosafety while a considerable amount of staff still practiced mouth pipetting, against the WHO guidelines (Khan et al., 2014).

An in depth, online survey conducted in 2005 in USA among 300 Asian based scientists studying infectious agents and/or toxins in their laboratories revealed that, majority (83%) used PPE along with the availability of biosafety cabinet (62%) and inventory on infectious agents and toxins (54%) but 25% of the laboratory technicians did not have biosafety manuals as well as 22%-33% did not have any protocol guidelines on biosafety (Gaudioso and Zemlo, 2007).

According to the Joint External Evaluation of International Health Regulations (JEEO IHR), Sri Lanka shows a low score towards biosafety and biosecurity measures, as stated in the Core Capacities mission report in 2017. Lack of research, training, national policies and legislation were also highlighted in this report and it can be reiterated that biosafety regulations in Sri Lanka have not been documented so far (WHO, 2011).

Western province occupies the highest density of population in the country and a large number of clinical laboratories are located in the Colombo district as reported in 2015 (Registrar General Department). Accordingly, this study is based on Colombo district which accounts for 18% of the entire bed strength of the country and the objective is to assess the biosafety precautions (BSPs) in selected government healthcare institutions (SGHIs) in the district.

2. Methodology

This is an institutional based descriptive cross sectional study intended to describe the availability of biosafety precautions at ten (10) line ministry hospitals and three (3) provincial hospitals at “base hospital” level and/or above. Medical Research Institute (MRI) is among the leading institutions handling the highest number of medical investigations in the Colombo district while, the role of the consultant microbiologist is crucial in leading and maintaining the “biosafety precautions” in the laboratory. Accordingly, fourteen (14) institutions were selected as the study setting namely, National Hospital (NHSL), Castle Street Hospital for Women(CSHW), De Zoysa Hospital for Women (DMH), Lady Ridgeway Hospital for Children(LRH), National Eye Hospital (EYE), National Institute of Infectious Diseases(IDH), Sri Jayewardenepura General Hospital (JAPR), Apeksha Hospital(APEK), Colombo South Teaching Hospital(CSTH), National Institute of Mental Health(NIMH), Base Hospital Mulleriyawa (BHM), Base Hospital Avissawella (BHA), Base Hospital Homagama (BHH)and the Medical Research Institute(MRI). Ethical clearance for this study was obtained from the Faculty of Medicine, University of Colombo.

Study period

The study was carried out from January to October 2018 and primary data collection was done by the principle investigator (PI) from 16th April to 30th August 2018.

Study population

All laboratories in selected fourteen (14) government healthcare institutions in the Colombo district, Sri Lanka were considered as the study population. Laboratories where consultant microbiologists were available, were considered under the inclusion criteria and under the exclusion criteria, TB and Malaria microscopic centres, blood banks and OPD laboratories were excluded.

Sample size

All laboratories fulfilling the inclusion and exclusion criteria were included without adopting a sampling strategy.

Study instrument

Availability of biosafety precautions were assessed using a checklist based on the direct observations by the principal investigator and was prepared by modifying the “WHO laboratory assessment tool” (WHO, 2012) to suit the local laboratory set up based on gold

standards of WHO guidelines (WHO Laboratory biosafety manual, 2004), (Sri Lanka College of Microbiologists, 2014), (Indian Council of Medical Research, 2008), (U.S. Department of Health and Human Services, 1999), (OSHA3404, 2011), (Frieden et al., 2012), (Baxter et al., 2008) and expert opinion. It consisted of two (2) main parts and was pretested before use. The first part consisted of date of observation, serial number, institution, biosafety level of laboratory and second consisted of biosafety related information such as infrastructure control, safety storage, maintain of laboratory equipment, personnel control, good housekeeping, waste and spill management, occupational safety, administrative control while, each subtopic contained multiple subunits as well. Expert opinion confirmed the content validity of the check list.

Quality of data

An extensive literature review was carried out, to obtain background information on related subtopics and other areas considered for this study, along with referencing of laboratory manuals from WHO, CDC, Canada, India and Sri Lanka.

Analysing data

The degree of biosafety precautions was explained as a percentage (%) and by colour coding, based on the calculation method obtained from the WHO laboratory assessment tool (WHO, 2012). Each sub unit check list was given four (4) responses with 100% for Yes; 50% for Partial; 0% percent for No and “X” for Not applicable which, was also excluded from consideration. Cumulative scores were calculated for each subtopic and laboratory as a percentage (%) and a particular colour code was assigned, to assess the level of biosafety precaution being maintained. Accordingly, for a cumulative score < 50%, it was red indicating a poor level, score of 50% - 79% in yellow indicating a moderate level and a score of > 80% in green indicating a good level.

3. Results

Overall analysis revealed, MRI having a high level (85.3%) coded in green and considered as good followed by DMH (43.2%), LRH (49.5%), IDH (43.76%), JAPR (46.3%) and BHH (49.42%) all of which, were coded in red indicating a poor level of biosafety precautions while, the lowest (35.57%) recorded by CSTH.

Table 1. Distribution of total availability of BSP-Infrastructure and safe storage

	NHSL	CSHW	DMH	LRH	EYE	IDH	JAPR	APEK	CSTH	NIMH	BHM	BHA	BHH	MRI	
1.Infrastructure															
1.Laboratory isolation	3	3	3	3	1	3	3	3	1	1	3	1	1	1	42.9
2.Biohazard warning symbol availability	3	3	3	2	1	3	3	3	3	3	3	1	2	1	21.4
3.All doors keeping closed	1	2	1	2	1	1	3	1	1	1	1	1	1	1	78.6
4.Rstriction to unauthorized people	1	2	1	2	1	1	3	1	1	1	2	1	1	1	82.1
5. Hand washing basins with Soap /disinfect	1	1	1	2	1	2	2	1	1	1	3	1	1	1	82.1
6 .Walls, ceilings and floors easily cleanable	2	1	2	1	1	1	2	2	1	2	1	1	1	1	82.1
7. Bench top resistant to alkali acid	1	1	1	1	1	1	2	1	1	1	1	1	1	1	96.4
8. Separate counter for receiving specimen	3	1	3	1	1	1	1	3	1	1	1	1	1	1	78.6
9. Changing room availability	2	3	3	3	3	3	3	3	3	1	3	3	1	1	25.0
10. Lunch room availability	1	3	1	1	1	1	1	3	1	3	1	1	1	3	71.4
11 .Adequate ventilation	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
12 .Adequate illumination.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
Total	66.7	58.3	62.5	66.7	91.7	70.8	45.8	54.2	83.3	79.2	62.5	91.7	95.8	91.7	73.0
11. Safe storage															
13.Storage arranged for sample safety	1	1	3	2	2	3	3	1	1	1	1	1	2	1	67.9
14.Additional storage availability	3	3	3	3	3	3	3	3	3	3	3	3	3	1	07.1

15.Accumulation of unwanted items	3	2	1	2	1	2	3	1	1	3	3	1	3	1	53.6
16.Freezers lock ability	1	3	3	2	3	3	3	1	3	1	3	3	1	1	39.3
17.No food/ drinks availability in refrigerator	3	3	1	1	3	3	1	1	3	1	1	3	3	3	42.9
18.separate storage of Laboratory cloths	3	3	3	3	3	3	3	3	3	3	3	3	3	2	03.6
Total	33.3	25.0	33.3	41.7	25.0	8.33	16.7	66.7	33.3	50.0	33.3	33.3	25.0	75.0	35.7

Table 2. Distribution of total availability of BSP- Maintain of laboratory equipment, Personal control over biosafety and Good housekeeping practices

	NHSL	CSHW	DMH	LRH	EYE	IDH	JAPR	APEK	CSTH	NIMH	BHM	BHA	BHH	MRI	
111.Maintain of laboratory equipment															
19.Biosafety cabinet availability	1	3	3	1	1	1	1	1	1	1	1	1	3	1	78.6
20.Availability of Autoclave	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
21.Availability Check lists for equipment's	1	2	3	2	1	1	1	1	3	3	3	1	1	1	64.3
22.Availability of Check lists fort cleaning	1	3	3	2	1	3	1	1	3	3	3	1	1	3	46.4
23.Availability of SOP's for equipment	3	3	3	1	1	1	1	1	1	1	1	1	1	1	78.6
24.Availability of recommended Service	3	1	3	3	3	3	3	3	3	3	3	3	3	3	07.1
25.Repairing by qualified person	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
Total	71.4	50.0	28.6	71.4	85.7	71.4	85.7	85.7	57.1	57.1	57.1	85.7	71.4	71.4	67.9
1V.Personal control over biosafety															
26.AVL of disposal gloves	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
27.Use sterile gloves for all procedures	3	3	3	2	3	3	3	3	3	3	3	3	3	3	03.6
28.Availability of gowns	2	1	2	2	1	3	1	3	3	2	3	3	1	1	50.0
29.Availability of aprons/Lab coats	2	1	2	2	3	3	1	3	3	3	3	3	1	1	39.3
30.Availability of goggles	3	3	3	3	3	3	3	3	3	3	3	3	1	1	14.3
31.Availability of Surgical masks	1	1	1	1	3	3	1	1	3	3	3	1	1	1	64.3
32.Availability of N95 masks	1	1	3	3	3	3	3	3	3	3	3	1	3	1	28.6
33.Availability of eye washing station	3	3	3	3	3	3	3	3	3	3	3	3	3	3	00.0
34.Availability of emergency shower	3	3	3	3	3	3	3	3	3	3	3	3	3	3	00.0

35.Not using open toed footwear	3	3	3	3	1	3	3	3	3	3	3	3	3	3	07.1
Total	40	50	30	35	30	10	40	20	10	15	10	30	50	60	30.7
V. Good housekeeping practices															
36.Check list available for cleaning	3	2	3	1	1	3	1	3	3	3	1	1	1	1	53.6
37.Covering of Biohazard waste	2	2	2	2	2	3	3	3	3	1	1	3	3	1	39.3
38.separate area coats, gowns and uniforms	3	1	3	3	3	3	3	3	3	3	3	3	3	1	14.3
39.Lab exposing to sunlight	3	1	3	1	1	3	3	3	3	1	1	1	3	1	50.0
40.Free of arthropods / rats	3	1	3	3	3	3	3	3	3	1	1	3	3	1	28.3
Total	10	80	10	50	50	0	20	0	0	60	80	40	20	100	37.1

Table 3. Distribution of total availability of BSP- Waste management and spill management and Occupational safety

	NHSL	CSHW	DMH	LRH	EYE	IDH	JAPR	APEK	CSTH	NIMH	BHM	BHA	BHH	MRI	
V1. Waste management and spill management															
41.Availability of Color code system	1	1	1	1	1	1	1	1	3	1	1	3	1	1	85.7
42.Daily waste removal	1	1	3	1	1	1	1	1	1	1	1	1	3	1	85.7
43.Daily checking the performance - autoclave	1	1	1	3	3	1	1	1	1	1	1	1	3	1	78.6
44.Availability - sealed bucket for centrifuges	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
45.Availability of puncture resistant bins	1	1	1	2	3	1	3	1	3	3	1	1	1	1	67.9
46.Availability of spill kit	2	1	3	3	3	3	1	3	3	3	3	3	3	1	25.0
Total	91.7	100	66.7	58.3	50.0	83.3	83.3	83.3	50.0	66.7	83.3	66.7	50.0	100	73.8
V11.Occupational safety															
47.Education of Lab workers for bio hazards	3	1	3	3	3	3	3	3	3	1	3	1	3	1	28.6
48.Warning for bio risk for childbearing age	1	3	1	1	1	1	3	3	3	1	3	2	1	1	60.7
49. Program for Hep B immunization	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0

50.Antibody checking for hepatitis B	1	1	1	2	1	1	1	1	3	1	1	1	1	1	89.3
51.Availability of First aid box	3	1	3	3	3	3	3	2	3	3	3	3	3	1	17.9
Total	60	80	60	50	60	60	40	50	20	80	40	70	60	100	59.3

	NHSL	CSHW	DMH	LRH	EYE	IDH	JAPR	APEK	CSTH	NIMH	BHM	BHA	BHH	MRI	
V111.Administrative control over laboratory															
52. Availability of training on biosafety.	3	3	3	3	3	1	3	3	3	3	3	1	3	1	21.4
53.Availability of biosafety manual available	3	1	3	3	3	3	3	3	3	1	3	3	3	1	21.4
54.Availability of record keeping	1	1	1	1	1	1	1	1	1	1	1	1	1	1	100.0
55.Availability of vaccination policy	1	1	2	1	1	1	1	1	1	1	1	1	1	1	100.0
56.Availability of SOPs	1	1	3	3	1	1	1	3	1	1	1	3	3	1	71.4
57.Available procedure for the cleaning spills	3	1	4	3	1	3	3	1	3	3	1	3	3	1	42.9
58.Availability of biosafety committee	3	1	3	3	3	3	3	3	3	3	3	3	3	1	14.3
59.Availability of Health surveillance	3	3	3	3	3	3	3	3	3	3	3	3	3	3	00.0
60. Standard protocol for procedures-available	1	1	1	3	1	1	1	1	3	3	3	3	3	1	57.1
61.Display standard protocol for procedures	3	1	3	3	3	3	3	1	3	3	3	3	3	1	21.4
62.Availability of standard protocol spill Mx	3	1	1	3	3	3	3	1	3	3	3	3	3	1	28.6
63.Displaying standard protocol for spill Mx	3	1	3	3	3	3	3	1	3	3	3	3	3	1	21.4
64.Accident and incident reporting system	1	1	1	1	1	1	3	3	1	1	1	1	1	1	85.7

Total	38.5	84.6	53.9	23.1	46.2	46.2	30.8	53.9	30.8	38.5	38.5	30.8	23.1	92.3	45.1
Grand Total (1-V111)	51.5	65.9	43.2	49.5	54.8	43.3	46.3	51.7	35.6	55.8	50.6	56.0	49.4	85.3	52.8 District Profile
Institution	NHSL	CSHW	DMH	LRH	EYE	IDH	JAPR	APEK	CSTH	NIMH	BHM	BHA	BHH	MRI	

Though the housekeeping and administrative controls are good in MRI (100%, 92.3%) and CSHW (80%, 84.6%), the levels of overall housekeeping (37.14%), administrative control (45.1%), storage safety (35.7%) and personnel control of laboratories on biosafety (30.7%) were poor. As a district, the overall biosafety level remained at a moderate level of 52.8 % for Colombo, as shown in yellow (Table 4).

4. Discussion

Laboratories are required to be located away from patient caring areas (WHO, 2004a) and only 42.9% (n=6) laboratories were isolated from heavy human traffic in hospitals which, was evident in a cross sectional study done in Nigeria using 80 diagnostic laboratories (Oladeinde et al., 2013) and remoteness was only 21.3%(n=80). Comparatively this study shows better isolation from human movement which, needs to be uplifted to 100% according to WHO recommendations.

Availability of biohazard signage was clearly visible in 21.4% (n=3) of the institutions and according to a study done in Karachi, Pakistan in 60 clinical laboratories in 2011, only 8.3% complied with this requirement (Qasmi, Khan and Maqbool, 2012) while, it was 3.8% in a research done in Nigeria, using 80 laboratories in 2013. Majority 78.6% (n=11) kept all doors closed for limited access, visibility of Alkali acid resistant laboratory bench tops was 96.4% (n=13) and 28 % (n=4) of laboratories had a changing room for staff use while, it was only 22.6 % (n=60), 71.5 % (n=80) and 15 % (n=80) respectively in the Nigerian study (Oladeinde et al., 2013).

Though, according to WHO guidelines (WHO, 2004a)) laboratories should be provided with additional long term storage space facility, in this study setting it was 7.1 % (n=1) and was available only at MRI. Cumulative value for usage of PPE was 30.7% but a study done in United States UN Army research unit (Juma et al., 2014) showed that, routine glove wear for procedures by the lab staff was 100% (n=203). Though, this study considered the cumulative total for assessing personal protection, the overall PPE usage remained inadequate as availability of items were as gowns (50%), aprons (39.3%), goggles (14.3%) and surgical masks (64.3%). However, a similar Sudanese study based on 190 laboratories indicated availability levels of laboratory coats 58.9 % (n=112) and gloves 61.6% (n=127), used during all laboratory procedures (Elduma, 2012). This variance could be attributed to the fact that Sudan survey includes both private (73%) and public (27%) laboratories while this study is focused only on selected government laboratories in the Colombo district. Further, there were no eye wash stations and emergency showers available even at MRI.

Though, the usage of sterile gloves for all procedures is considered as unnecessary the habit was prominent (96.4%) as seen in Table 2 and availability of the said item was 100%. Total maintenance score of laboratory equipment was at 67.9% in this survey (Table 2) but recommended level of periodical corrective maintenance service of instruments was at a low rate of 7.1%. This study indicated availability of biosafety cabinets 78.6% (n=11), autoclaves 100% (n=14), SOPs 78.6% (n=11) and check lists 46.4 % (n=7). Moreover, a study done in Italy among 537 laboratories in 2007 showed that, availability of biosafety cabinets was 81.8

%(n=139) (Moro, Nascetti and Morsillo, 2010). It should be noted that, in the local study setting majority of the biosafety cabinets were observed to be underutilised.

This survey revealed that, 71.4%, (n=10) of laboratories had rodents and arthropods while it was 98.94% (n=188) among the 190 laboratories considered for the Sudanese study (Elduma, 2012).

Waste management in specific was 100% at MRI and CSHW while overall total score was 73.8% which showed the need for prompt intervention. Overall in the laboratory setting, 32.1% (n=4) did not have puncture resistant bins and 14.3% were not removing waste daily while, a cross sectional survey done in 2011 among 60 laboratories in Pakistan showed that, 47% autoclaved waste generated daily (Qasmi, Khan and Maqbool, 2012).

Meanwhile, occupational safety of the whole sample total value score was 59.3% which requires intervention. Personal protection is not addressed adequately as only CSHW had a complete first aid box and similarly in Nigeria only 2.5% (n=80) of the laboratories had first aid boxes (Qasmi, Khan and Maqbool, 2012).

Training on BSP was provided only to 21.4% (n=3) of the institutions (Table 4) which, is at a very low percentage when, compared with 67% (n=315) of public laboratory staff undergoing training on BSP, as identified in a survey done in 2015 among 362 laboratory workers in Yemen (Al-Abhar N. et al, 2017)). Furthermore, availability of both bio safety manuals and SOPs also remained at low levels of 21.4% (n=3), in the selected labs. BS committees have been setup only at MRI and CSHW where, highest levels of BSP is witnessed at 85.3% and 65.9% respectively. Furthermore, administrative control over BSP (Table 4) was at high levels in both MRI (92.3%) and CSHW (84.6%) which, augments the formation of BS committees.

5. Conclusions and recommendations

Overall analysis indicated MRI adopting a good level (82.3%) of BSP, followed by CSHW (65.9%) and both had established BS committees. This outcome, substantiates the recommendation of setting up of BS committees for each and every institution as a measure of improving BSP. District score of 52.8% shows the urgent need of intervention while out of the 14 chosen laboratories, poor level of BSP was witnessed in six (6) while the lowest was CSTH (35.6%).

BS level of the institutions' storage, personnel protection, housekeeping, personnel and administrative controls were at a very low range of 30.7% - 45.1% and biosafety manuals as well as SOPs, should be made available for all laboratories. Furthermore, storage facilities too should be improved by incorporating required facilities, in the annual action plans of the institutions.

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