A study about importance of biosafety and biosecurity on aspect of Good Laboratory Practice (GLP) in a Quality Control (QC) laboratory of Bangladesh

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The Quality Control (QC) laboratory, Chittagong is basically designed to analysis the biological and chemical characteristics of fish and fishery products in view of sustaining Bangladesh export performance in world seafood markets through integration of qualified personnel, standard methods, appropriate equipment and quality assurance system are in place for necessary testing and interpretation of tested results. We describe herein, facilities on microbiological test at biosafety level 2 (BSL-2) containment laboratories, with regard to biosecurity regulations, safety considerations, necessary space, and physical aids in executing ISO standards. These competences can positive impact the number of testing samples investigating microbial pathogens of biodefense concern. Acquisition, use, storage and transfer of microbiological pathogenic bacteria such as reference strains are highly regulated due to their potential to pose a severe threat to export of fish and fishery products. All federal, state, city, and local regulations must be followed to obtain and maintain registration for the institution to conduct research involving pathogens. These include continuous monitoring of personnel, controlled access to containment laboratories, accurate and current pathogens inventory records. Safety considerations are paramount in BSL-2 containment laboratories while considering these types of research tools, workflow and time required for conducting both qualitative and quantitative microbiological test parameters in limited space.

Keywords: Biosafety, Biosecurity, Biosafety Level, Quality Control.

INTRODUCTION

Shrimp and prawn are one of the leading exportable products in Bangladesh. Bangladesh is earning about 500 million of foreign currency yearly by exporting shrimp and contributing 3.78% in Gross Domestic Product (GDP). To gauge the prospects of shrimp farming, the south-western region of Bangladesh has been considered as the core farming areas. Shrimps and Prawns are the main exportable items which earn a substantial amount as Bangladeshi Taka (BDT) 2744.12 cr. against 50368 ton of product with demandable variation in 2007-2008 (DoF, 2012) and in 2009-2010 the earnings come to BDT 3408.52 cr. (DoF, 2012). Production of shrimp by culture and capture fisheries increased to a great extent in the beginning of 1980’s in Bangladesh.
In 2007-2008, 217,877.05 hectar have been brought under shrimp culture (DoF, 2012). Although shrimp farming has had a significant impact on the economy of Bangladesh, it is generally agreed. Major export items from Bangladesh are raw shrimp block frozen, Individually Quick Frozen (IQF) Shrimp and prawn, consumer pack of raw frozen shrimp, dry, salted and dehydrated fish and a little quantity of value added shrimp products. 63% of frozen shrimp exported to the European countries and 34% to USA and middle-east counties from Bangladesh (DoF, 2012).

Due to insufficient attention toward standard of hygiene and quality of the product, reasonable numbers of seafood products have gone out of business. As a result, the export of shrimp products has suffered considerable losses in rejection from 1975 to 1978 and the country was placed under automatic detention by United State Food and Drug Authority USFDA. In October 1979, Bangladesh was black listed along with other countries by USFDA for having the evidence of Salmonella, filth, flies, cockroach and other insects in frozen shrimps frog legs. It faced heavy loss in the form of rejection and of relatively low price offered by the foreign buyers for fish products from Bangladesh. So, Government then felt necessity of establishing Fish inspection and quality control (FIQC) service in the country to regulate the sanitation status of the factory and the quality of fish and shrimps meant to export. Under this scheme, two testing laboratories were established in Chittagong and Khulna. In the year 1994, the existing processing of Bangladesh was filtered as per FIQC act and EU (European Union) regulations. On July 30, 1997, the EU imposed ban on imports of fishery products from Bangladesh as a result of EU inspections of Bangladesh’s seafood processing plants. Inspections found serious deficiencies in the infrastructure and hygiene in processing establishments and insufficient guarantees of quality control by Bangladeshi government inspectors. The ban was estimated to cost the Bangladesh shrimp processing sector nearly US$15 million revenue loss from August to December 1997. In order to lift the ban, the Bangladesh shrimp processing industry had invested US$17.6 million in plant upgrades, the government had invested US$382,000 in laboratory and personnel upgrades and outside partners had invested US$72,000 in training programs in Bangladesh in 1997 (Cato and Subasinge, 2003).

After successful upgradeation by July 1998, a total of 11 plants were approved for export to the EU. Now 62 plants had EU approval out of 65 plants licensed for export by the government. The government promulgated Fish and Fish Products (Inspection and Quality Control) Rules in December 1997 to implement the program. The EU experts subsequently visited Bangladesh to inspect the arrangement made by government. The experts were satisfied by the government efforts in this respect and the EU ban on import of frozen fish from Bangladesh was lifted in 1998. At present, FIQC Laboratory, Chittagong is accredited by BAB (Bangladesh Accreditation Board) in May, 2014. The laboratory is basically designed to analyze the biological and chemical characteristics of fish and fishery products in view of sustaining Bangladesh export performance in world seafood markets through integration of qualified personnel, standard methods, appropriate equipment and quality assurance system are in place for necessary testing and interpretation of tested results. Microbiological testing parameter such as Aerobic Plate Count (APC), Total Coliforms, Presumptive E.coli, E.coli, Vibrio cholerae, Vibrio para-haemolyticus, Salmonella spp, Staphylococcus aureus, Listeria monocytogenes, Shigella spp etc. are available in this laboratory.

Biosafety is a discipline that focuses on the safe handling and containment of infectious microorganisms and hazardous biological materials. Recently, research on infectious pathogens has been on the rise due to the emergence of new and re-emergence of previously identified infectious agents and diseases, some of which could be used as weapons of bioterrorism. Laboratory biosafety is of the utmost importance when working with any potentially infectious pathogenic organism. On the other hand, the term quality control covers that part of quality assurance, which primarily concerns the control of errors in the performance of tests and verification of test results. QC must cover all aspects of every procedure within the department. It must be practical, achievable, and affordable. All materials, equipment and procedures must be adequately controlled. The United States Department of Health and Human Services (DHHS) has published guidelines recommending best practices for working safely with microbial pathogens by classifying organisms, designating biosafety levels (BSL) for use, elaborating on risks associated with handling various microbial agents, engineering controls to mitigate risks, and appropriate personal protection equipment (PPE) needed for laboratorians conducting scientific research in biocontainment laboratories (CDC, 2009). Biosafety levels (BSLs) ascribe the proper microbiological practices, engineering controls, and safety practices required for a biocontainment laboratory, and the microbiological agents which can be handled safely within. Biosafety level 1 (BSL-1) confers the basic level of protection and is appropriate for microbial agents not known to cause disease in healthy humans. BSL-1 laboratories are often utilized for teaching and training of new laboratory personnel. Biosafety level 2 (BSL-2) laboratories contain moderate-risk agents that can cause human disease, albeit moderately, with variable disease course dependent on route of exposure. Most clinical,
diagnostic, and teaching laboratories, where blood or blood products may be handled are BSL-2 laboratories. Agents handled at Biosafety level 3 (BSL-3) are known to cause potentially lethal infections and severe disease in humans. These agents pose a risk of disease through potential aerosol transmission and can be indigenous or exotic. In contrast, pathogens handled at biosafety level 4 (BSL-4) pose a high risk of severe disease and have a higher potential for fatality.

But studies on laboratory biosafety and biosecurity in Bangladesh are uncommon. This study is important for Quality Control Laboratory, Chittagong because this organization are not solely responsible for confirming the export of good quality fish and fisheries product in USA, Canada, Australia, EU country, Japan, Middle-East Country etc for help to earn foreign currency which participate to national GDP of Bangladesh, also help to maintain good food safety and public health related issues. So the main objective of the current investigation was to have better understanding about importance of biosafety and biosecurity on aspect of Good Laboratory Practice in QC laboratory especially microbiological unit of Chittagong.

**MATERIALS AND METHODS**

**Study area selection and target group**

Microbiological unit of QC laboratory, Chittagong was selected for the study. Because good laboratory practices of biosafety and biosecurity are heavily concentrated in this area. Various national and international laboratory experts have been working with lab personnel to sustainable increase of biological characteristics analysis of fish and fishery products in view of sustaining Bangladesh export performance in world seafood markets through integration of qualified personnel, standard methods, appropriate equipment and quality assurance system by following biosafety and biosecurity properties. For that, study data were collected during January to June 2016. The target population included analysts, laboratory stuffs and contracted persons.

**Questionnaire design and implementation**

The questionnaire was comprised of two parts: demographic questions and general biosafety and biosecurity questions. Questions raised in our questionnaire were based on standards stipulated in international laboratory biosafety manuals such as the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition and the Laboratory Biosafety Manual (3rd Edition) developed by the World Health Organization (2014). In this study, questions indicative of respondents’ general knowledge of laboratory biosafety, including issues such as biosecurity, biocontainment, decontamination protocols, biosafety levels and cabinets, standard operating procedures (SOPs), PPE, biohazard transport and disposal, pest control, and other topics were asked. Also, respondents were asked about the availability and use of biosafety devices (such as facilities with the appropriate biosafety level and biosafety
cabinets) and PPE. On PPE, we asked the respondents to list up to five of the basic PPE (for instance, Lab coat, hand gloves, nose mask, hair net, face mask/safety goggles) they use when working with pathogens.

All lab personnel were further asked about their awareness of national laws regulating biosafety and select agents, as well as biosafety and biosecurity-related terms and regulatory associations both in Bangladesh and globally.

**Data management and statistical analysis**

Data were processed and finally analyzed with Microsoft Excel 2013. A dependent/outcome variable was created for the following specific objectives that were used to determine the status of biosafety and biosecurity in Bangladesh fisheries research facilities: 1. General knowledge of laboratory biosafety and biosecurity; 2. Availability and proper use of biosafety devices and personal protective equipment (PPE); 3. Management knowledge of biological safety; 4. Breakdown of laboratory biosecurity; 5. Attitude and adherence to standard laboratory practices; and 6. Biosafety awareness level among researchers. A numeric scoring system was developed to assess general biosafety knowledge, the proper use of biosafety devices and PPE, the attitude of researchers and their adherence to standard laboratory practices, and the level of biosafety awareness.

**RESULTS**

**Response rate**

Biosafety and biosecurity related set questions/per person were distributed among 13 participants including three categories (Table 1). In addition, per set question consist of 10 individual questions. Average response rate was 75% (Table 1).

**Demographic information**

The demographic information for the respondents is presented in Figure 1, 2 and 3. Respondents were
Table 1. Different category of participant with their response rate

<table>
<thead>
<tr>
<th>Category</th>
<th>Person Attended</th>
<th>Person Response</th>
<th>Response Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyst</td>
<td>05</td>
<td>05</td>
<td>100</td>
</tr>
<tr>
<td>Lab staff</td>
<td>04</td>
<td>03</td>
<td>75</td>
</tr>
<tr>
<td>Contacted Person</td>
<td>04</td>
<td>02</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total Participant</strong></td>
<td><strong>13</strong></td>
<td><strong>Average Response Rate</strong></td>
<td><strong>75</strong></td>
</tr>
</tbody>
</table>

Figure 1. Response rate in different category

Figure 2. Age distribution in lab personnel

predominantly male (54.0%) than female (46%) (Figure 2) – had a mean age of 35.7 ± 6.9 years. The highest numbers were within the ages 36 to 46 years old at 46.15%. Followed by out of the total were 31% belonged to 25 to 35 years, 23.07% in 47 to 57 years (Figure 1). The majority of respondents (46.15%) had less than 10
years of experience in microbiology laboratory (Figure 3).

**General knowledge of laboratory biosafety and biosecurity**

A majority (85%) of the respondents had satisfactory knowledge scores and (15%) had poor knowledge score (Figure 4).

**Availability and proper use of biosafety devices and personal protective equipment**

About 77.0% of the respondents reported that these devices were readily available and used appropriately. Most of the respondents (77%) reported the use of PPE, though (15.38%) had no knowledge of biosafety level; 31.0% used BSL-1, 39% used BSL-2, and 15.38% (two
Knowledge of Lab biosafety and biosecurity

![Knowledge of Lab biosafety and biosecurity](image)

Figure 5. Knowledge of Lab biosafety and biosecurity

Availability and proper use of biosafety devices and personal protective equipment

![Availability and proper use of biosafety devices and personal protective equipment](image)

Figure 6: Availability and proper use of biosafety devices and personal protective equipment

respondents) used BSL-3 facilities (Figure 5).

Management knowledge of biological safety

Well above three quarters of the respondents (84.75%) received satisfactory scores (Figure 6). Of the 13 respondents, fewer than half (35.9%) had undergone training in laboratory biosafety, 69% had laboratory decontamination protocols in place, 47.3% had SOPs in use in their laboratories, 18.9% had their SOPs updated yearly.

Breakdown of laboratory biosecurity

Approximately three-quarters of respondents (69.23%) reported no occurrence of breakdown or failure of laboratory biosafety (Figure 7). Of the respondents who reported the occurrence of biosafety breakdown, 70.0% cited the presence of laboratory biohazards associated with pathogenic agents.

Attitude and adherence to standard laboratory practices

About 77.0% of the respondents reported a good attitude relating to standard laboratory practices (Figure 8). The majority of respondents (68.9%) reported decontaminating or removing PPE upon exit from the research facility. Substantially fewer respondents (21.6%) reported showering when exiting areas of the laboratory containing infectious material. Only 39.2% reported decontaminating equipment before removal from the
research facility. Approximately half of the respondents (54.1%) reported autoclaving laboratory bio-waste. A similar proportion (52.7%) were unaware of how biohazardous waste is transported for disposal, though 32.4% and 14.9% of respondents, respectively, reported the use of dedicated vehicles and/or vendors and wheelbarrows for disposal of waste. Half of the respondents (50.0%) reported incinerating biohazardous waste, while 31.1% reported disposing biohazardous waste in the general waste dumps.

**Biosafety awareness among analyst**

Overall, the biosafety awareness level is very much satisfactory. The percentage of respondents having high awareness level is 100% (Figure 9).

**Discussion**

This study revealed the level of low negligence of laboratory biosafety and biosecurity in Chittagong microbiology laboratory facilities. We found that the majority of lab personnel have good laboratory biosafety general knowledge, most report acceptable usage of biosafety devices and PPE, and good access to BSL-1 to 3 facilities, including BSCs. Analyst continue to work with pathogens at all risk levels (1 to 3) except BSL-4. The overall awareness level of lab personnel regarding national and international laws and bodies pertaining to laboratory biosafety is satisfactory. We also found that most of the lab personnel have good laboratory biosafety scores. To our knowledge, this survey is the first in Chittagong to evaluate laboratory biosafety in Chittagong microbiology laboratory facilities. Though the survey average response rate of 75% is higher, not having a reasonable response rate may be due to inadequate motivation on the part of the lab personnel, which could also be indicative of the level of attention attached to laboratory biosafety. In a survey of laboratory biosafety in India, Goswami et al. (2011) discovered that paramedical staff displays a high level of biosafety knowledge. However, the majority of lab personnel reported that

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**Figure 7.** Management knowledge of biological safety

<table>
<thead>
<tr>
<th>Satisfactory knowledge</th>
<th>Poor knowledge</th>
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<tbody>
<tr>
<td>84.75%</td>
<td>15.25%</td>
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</table>

**Figure 8.** Breakdown of laboratory biosecurity

<table>
<thead>
<tr>
<th>Had not occurred</th>
<th>Had occurred</th>
</tr>
</thead>
<tbody>
<tr>
<td>69.23%</td>
<td>31.00%</td>
</tr>
</tbody>
</table>
Attitude and adherence to standard laboratory practices

![Pie chart showing 77.00% Good and 23.07% Poor]

**Figure 9.** Attitude and adherence to standard laboratory practices

Biosafety awareness among analyst

![Pie chart showing 100% High and 0.00% Low]

**Figure 10.** Biosafety awareness among analyst

there are no lacks of the use of PPE upto biosafety level (1 to 3) except BSL-4. But Oladeinde et al. (2013) reported that most public and private human diagnostic laboratories in Africa have lacks of the use of PPE upto biosafety level (1 to 3) except BSL-4.

Management and administrative control of biological safety are integral parts of an effective biosafety program (Astuto-gribble LM et al., 2009). The most of lab personnel received satisfactory scores in the category of laboratory biosafety management provides good biosafety and biosecurity knowledge in microbiology laboratory in Chittagong. It is noteworthy that some lab personnel had completed laboratory biosafety training and this laboratory had established decontamination protocols and SOPs including updating of SOPs. Gaudioso et al. (2006) found that biosafety training is routine in the US bioscience community. The importance of training laboratory researchers in biosafety and biosecurity (Heckert RA et al., 2011) was emphasized in studies conducted by Goswami et al. (2011), Hakim et al. (2012) and Qasmi et al. (2012) in developing countries. Biosafety training and proper use of PPE also key guard of GLP (Rusnak JM et al., 2004).
The majority of the lab personnel to our survey described having a good attitude related to standard laboratory practices. Wearing PPE was reported to be the most routinely used biosafety practice in a survey of research laboratories in various parts of the world (Astuto-gribble LM et al., 2009). Encouragingly, the majority of lab personnel in our study reported routine use of PPE. A good percentage of lab personnel reported routinely decontaminating or removing PPE upon exit from their lab area. There is no a lack of awareness of how biohazardous waste generated in laboratories is transported for disposal. Our findings are comparable to results obtained from a survey of the laboratories of 250 community health workers in Pakistan (Hakim et al., 2012) where 30% of laboratory researchers reported use of PPE when carrying out microbiological work, 85.2% reported washing hands during laboratory procedures, 32.2% of laboratories reported having policies for the safe handling of sharps and 70% of the labs routinely decontaminated work surfaces and had pest control programs. The good awareness level of lab personnel concerning national and global laws guiding biosafety, select agents, and other terms and associations (BBAB, ICDDRB) related to biosafety and biosecurity point of laboratory biosafety knowledge in Bangladesh.

The results of our multivariate logistic regression analysis revealed that good knowledge of laboratory biosafety in Chittagong microbiology laboratory is more likely to be associated with male lab personnel. The observation that male lab personnel demonstrated high knowledge scores is expected as more male respondents had received training on laboratory biosafety than females but not had work experience greater than 10 years than female that participated in the study. Our results also show that lab personnel working in microbiology laboratory demonstrate greater biosafety knowledge. Greater biosafety knowledge is reflected in the observation that lab personnel are also predictive factors associated with adequacy and proper usage of biosafety devices and PPE, a good attitude towards biosafety, and adherence to standard laboratory practices.

CONCLUSION

Current knowledge of laboratory biosafety and biosecurity are satisfactory for analyst rather than laboratory stuff and contracted person. It is necessary to give more attention to the quality and safety aspects of fish and fisheries products related to the harvesting, handling, processing and packaging. Now-a-days, the shrimp is creating a good market as a safe product and good taste to the consumer. This exportable product has a great chance to earn a lot from international market. Lack of proper knowledge of biosafety and biosecurity, negligence about sanitation and quality related factors at different stages of handling, transportation and processing results low graded frozen shrimp and huge qualitative and quantitative losses. So, we should concern about the quality and safety aspects of fish and fisheries products. Low quality fish and fisheries products are not only a great concern of food security and public health but also of serious national economic loss. If the defects and hazards of fish and fisheries products are controlled then export of Bangladesh would be increased.

Conflict of Interest

We declare no conflict of interest.

Acknowledgments

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