Summer Internship Report
At

Ernst & Young

(April 18th to June 17th, 2022)

A
Report

By

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PGDM (Hospital and Health Management)

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International Institute of Health Management Research, New Delhi

FEEDBACK FORM

Name of the Student: Anindya Mukherjee

Summer Internship Institution: EY India

Area of internship: Government & Public Sector – Strategy & Transactions; Healthcare Infrastructure Consulting

Attendance: 2 months

Objectives met:

- Exposure to Healthcare infrastructure advisory sector
- Understanding of health infrastructure project conceptualization (technical feasibility)
- Interaction with various stakeholders in the public sector & private sector for overall understanding of project implementation including public private partnership

Deliverables:

Worked on 3 projects on the following tasks:

- Data collection and secondary research
- Compilation of data
- Market Outreach

Strengths:

- Quick to grasp fundamental concepts and accurately apply learnings to deliverables

- Extremely pro-active, diligent and punctual with delivery
- Inquisitive, enthusiastic about learning across sub-sectors within the health domain
- Analytical approach towards project delivery
- Good team player

Suggestions for Improvement:

- Should work on improving technical skills such as storytelling through data for further well-rounded development as a professional

Signature of the Officer-in-Charge (Internship)

Date: 15th June 2022

Place: Delhi, India

Certificate of Approval

The Summer Internship Project of titled **"Conceptual Design of Greenfield Biocontainment Research Laboratory and Small Animal Testing Facility intended by Gujarat Biotechnology Research Centre"** at **"Ernst & Young India''** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed, or conclusion drawn therein but approve the report only for the purpose it is submitted.

Dr. Anandhi Ramachandran

Senior faculty & Associate Professor

IIHMR, Delhi

ACKNOWLEDGEMENT

I would really like to express my appreciation and gratefulness to my mentor **Ms. Supriya Swarup** for correctly assisting me to complete this report. I would love to provide my special way to my college faculty mentor Dr. Anandhi Ramachandran whose assist, stimulating pointers and encouragement helped me in all time of fabrication system and in scripting this report. I also definitely thanks for the time spent proofreading and correcting my many errors. I could also want to acknowledge with tons appreciation the crucial position of the relaxation of the people who guided me in one of a kind tasks at some stage in my internship. Many thanks visit the supervisors who've given their complete effort in guiding the crew in achieving the intention as well as their encouragement to preserve our progress in track.

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Abbreviations

EY = Ernst & Young

NMC = National Medical Council

CAPFIMS = Central Armed Police Forces Institute of Medical Sciences

IPD = In-patient department

GBRC = Gujarat Biotechnology Research Centre

BSL = Bio-safety level

ABSL = Animal Bio-safety level

JNPAH = Jaharlal Nehru Port Authority Hospital

SARS = Severe Acute Respiratory Syndrome

RG4 = RNA G-quadruplex

GMP = Good Manufacturing Practice

GLP = Good Laboratory Practice

PPE = Personal Protective Equipment

BSAT = Biological Select Agents and Toxins

MCC = Microbial Containment Complex

NIHSAD = National Institute of High Security Animal Diseases

Observational learning

Introduction

EY is considered to be one of the most important professional services networks in the world. It exists to create a better working environment, to help create long-term value for customers, individuals and communities and to build trust in the larger markets. Empowered by data and technology, various EY teams in more than 150 countries offer a secure level of confidence and help customers grow, transform and operate. By working on all assurance, consultation, law, strategy, taxes and duties, EY teams are asking better questions to find new answers to the complex problems facing our world today. There are special activities offered by EY; Some of those activities include advice, assurance, taxation, transactions, auditing, financial services, accounting, consultation etc. EY consultation creates a better working environment by seeing business transformation through human power, technology, and innovation. EY consultation does more than provide details. Speed and curiosity help clients navigate uncertain times by embracing change and mobilizing others to seek the answers they need today and in the future.

Objectives

- Building a higher operating world
- Provide quality information and services to help build trust and confidence in the financial market.
- Enabling reliable information to clients
- Enabling better business performance
- Work with stakeholders to identify biggest and most relevant area of impact

- Engage investors with value strategy and understand the opportunity

Mode of data collection

The mode of data collection was from various official documents, records, and official websites. The data which was collected was quantitative, and secondary. The link of the official websites was provided. A few of those links contained official documents. On contemplating various documents and websites, the reliable data was then taken from those official documents as well as official websites and then put into the excel sheet or word file. The entire content or data of the internship is related to medical colleges, nursing colleges, bio-containment labs and hospitals. For collecting data of the colleges, website like National Medical Council (NMC) was visited which contains the name of the colleges (private as well as government) for each state and union territory, number of courses it provides and number of seats each college offers for a particular course. A few of the college's (information of which was not present in NMC) official website was visited to collect data with regard to the specialization it provides and to know the number of seats it offers for each course (related to the medical and paramedical field).

For the level 4 bio-containment labs, data was taken from official link which contained details of all the 59 level 4 bio-containment labs operating currently across the world. A few of the official documents also contained information about the labs.

For collecting data of the hospitals, the official website of the hospitals (Government and private) was visited which contained the specialties each hospital provides for patient care.

General findings

The first program /project was related to CAPFIMS (Central Armed Police Forces Institute of Medical Sciences) where medical, paramedical colleges and various hospitals within the radius of 10-15 kilometer of CAPFIMS was marked using the google earth application and then put into excel sheet according to the marking numbers. The hospitals and medical colleges which were present in the radius of 10-15 Km, the official website of those medical colleges and hospitals were visited and data was withdrawn with regard to the specialties a hospital provides, bed capacity of a hospital, operator of the hospital (private/government), and courses / specialization a medical or paramedical college provides and then it was put into the excel sheet for analysis.

Data regarding international inflow of patient in few of the hospitals in Delhi was also taken and the comparison was done between international patient inflow and total IPD; bed occupancy was also estimated.

An overview of medical education was also done to see the increase in number of medical colleges, medical admissions (MBBS, MD, MS) over the period of time. For reference, states which were taken was Delhi, Haryana, Rajasthan and Uttar Pradesh. For these particular states Doctor to patient ratio and nurse to patient ratio was also measured. Medical workforce per 1000 population was measured.

The learning or observation from the data indicates that the state Uttar Pradesh has the highest number of medical colleges (65) in India. Total number of medical colleges (private as well as government) has been increased over the period of time (approximately 120% increase in 8 years according to the data). Total number of MBBS seats and PG seats have also been increased (approximately 1.5 times and 1.2 times in 8 years according to the

data). Total number of paramedical seats, nursing seats has been increased as well. As per the second project or (GBRC) is concerned, the number of level 4 bio-containment labs were counted. The observation was that there are 59 bio-containment labs across the countries. However, in India there are only 2 level-4 biocontainment labs (which is significantly less in number). BSL-4 laboratories are used to study infectious agents or substances that pose a high chance of aerosol-transmitted laboratory infections and life-threatening diseases for which no vaccine or remedy is available. In order to strengthen the public health system of India the importance of establishing these labs is utmost. Henceforth the Gujarat government came up with establishing greenfield research facility and small animal testing facility with biocontainment concept to handle infectious agents in a secured manner.

The third project was related to Jaharlal Nehru Port Authority Hospital (operated by Jaharlal Nehru Port Trust). The hospital wanted to expand its bed capacity from 50-100 and therefore it was looking for a hospital to do business (public-private partnership). The learning was that eventually how many hospitals attended consultation meeting with regard to the same and sought interest in doing business with JNPAH. A total of 152 hospitals (mostly private) were approached across the country among only 21 sought interest which is 13.8%.

Project Report

On

Importance of Greenfield Biocontainment Research Laboratory (BSL4) and Small Animal Testing Facility (ABSL-3)

intended by

GBRC (Gujarat Biotechnology Research Centre)

Abstract

A unique and important part of the national bio-economy is concerned with biodefense and the health risks posed by the most threatening contagious diseases caused by viruses such as Ebola virus, Corona virus and antibiotic-resistant viruses. Dangerous viruses are categorized according to the severity of the diseases they cause, their way of transmission, and the availability of antimicrobials and antiretroviral drugs to treat those infected. Bacteria are classified as high-risk biological (BSL) 2, 3, or 4, and BSL-4 are associated with the viruses that have no active treatment or vaccine available. The BSL-3 Lab has slightly weaker infrastructure requirements than the BSL-4 labs and treats viruses such as plague and anthrax. The BSL-4 Lab is specially designed to protect the well-being of research & development employees and ensure the safety of the surrounding community and environment in the event of a potential release due to an obstacle breach. The number of these laboratories in medical research is well known.

Introduction

Globally, biotechnology applications have seen a phenomenal advancement over the last few decades. Accordingly, biosafety and biosecurity practices pertaining to the secured handling and confinement of contagious pathogens, emerging and re-emerging microorganisms along with hazardous biological materials are of utmost concern, as inadvertent or deliberate usage in addition to laboratory associated infections may have fatal Consequences.[1] The reason behind the occurrence of occupational infections is the presence of wide variety of bacteria, viruses, fungi, and parasites.[2] Although the exact risk of infection after exposure remains unclear, laboratory studies suggest that Brucella species, Salmonella, Mycobacterium species are the most common causes.[2] Infections caused by bacteria (hepatitis B virus, hepatitis C virus, as well as human immunodeficiency virus) are still the most common reported disease, and dimorphic fungi accounts for a much larger number of fungal infections.[2] Due to the concern to the role of the laboratory in preparing for tackling biological terrorism, discussions about the risk of infection found in the laboratory by rare agents become highly important.[2] Doctors who have concern towards a sick laboratory worker would be expected to consider the likelihood of a laboratory acquired infection while advising exposed laboratory workers about postexposure prevention.[2] Laboratory staff are often infected unintentionally because of transmission patterns that are unknown to them. This was exemplified by the first case of a highly severe acute respiratory syndrome (SARS) laboratory coronavirus, which occurred approximately 4 months after the end of the SARS epidemic.[2]This necessitates the institution of code of conduct, ethics and biosafety practices and adherence to globally harmonized regulations

and guidelines, ultimately for ensuring the protection of public health and the environment.[1] In India, all activities related to Biotechnologically Engineered organisms or cells and hazardous microorganisms and products are regulated as per the "Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, Rules, 1989" (Rules, 1989) notified by the Ministry of Environment, Forest and Climate Change (MoEF & CC), Government of India under the Environment (Protection) Act, 1986 (EPA 1986).[1]

Biosafety level (BSL) is a set of safeguards which are referred to some autoclave related activities performed in a particular biological laboratory.[3] These are individual safeguards which are implemented to provide protection to laboratory personnel, the environment, and the surrounding community. The selection of bio-safety (level 1level 4) laboratories is based on the compound or organism being studied in a particular laboratory environment. For example, a basic laboratory environment dedicated to the study of non-lethal substances that minimizes potential threats to laboratory staff is generally referred to as BSL-1 (lowest laboratory biosafety level) due to the lower risk of transmission or severity. A specialized laboratory for investigating potentially lethal contagious agents such as Ebola is labeled BSL-4 due to higher risk of transmission or severity. This is the highest and toughest laboratory level and required for research and diagnostic purposes.

A BSL-3 laboratory typically incorporates studies of native or exotic microorganisms that can cause serious or potentially fatal illness by inhalation. Examples of microorganisms used in BSL-3 include yellow fever, West Nile virus, and the bacteria that cause tuberculosis.[3] Microbes are extremely dangerous, so work is often tightly controlled and

registered with the appropriate government agency. Laboratory staff are also under medical supervision and may be immunized by the microorganisms they work with.[3]

The BSL-4 Lab represents the highest level of biocontainment and provides unmatched protection for users, samples, and the environment. Currently, more than 50 of the largest and safest facilities in neighboring countries are treating some of the world's deadliest microorganisms for research purposes.[4] Most of the WHO regions holds BSL-4 laboratories. Most are in North America or Western Europe, but some are built in Asia, and some construction projects are ongoing in China, Japan and sub-Saharan Africa, increasing sustainability issue for lower-income countries.[4]The containment lab shares many issues related to training opportunities, maintenance, and trust building. Many regional initiatives and limited international efforts have made the global forum believe in identifying best practices, standards and opportunities for collaboration.[4]

A BSL-4 laboratory is built in an isolated area—often located in a separate building or in an isolated and restricted zone of the building. The laboratory also has its own air supply and exhaust, vacuum lines and decontamination system.[3]

Animal biosafety level 3 (ABSL 3) includes native or exotic pathogens, pathogens that lead to potential aerosol-mediated infections, and laboratory animals infected with pathogens that cause serious or potentially lethal contagious diseases.[5] ABSL-3 Labs have special structural and design features. ABSL 3 is designed considering the ABSL2 standard practices, procedures, containment equipment, and facility requirements. [5]

As per as India is concerned there are only 2 labs among 59 BSL-4 labs in the whole world.[6]

In order to strengthen the public health system and bio safety system of India, Gujarat Biotechnology Research Centre (GBRC) is planning to establish Greenfield research facility and small animal testing facility with biocontainment concept to handle infectious agents in a secured manner as Government of Gujarat has recognized the importance of the science of biotechnology and its potentiality.[7] Realizing that biotechnology has the potential to provide solutions to threat of pandemics and crippling diseases of humans as well as animals, GBRC is planning to expand research horizon so that the lethal disease-causing microorganisms can be studied and any hope of cure can be established.[7]

The containment labs should be designed in such a way that it handles different microorganisms without any cross-contamination issues. There are some microorganisms (RG4) that require BSL-4 facility for handling. Small animal testing facility is also designed to handle RG4 group microorganisms with ABSL 3 Plus biocontainment arrangement.

Objectives

- BSL labs' main intention is to work for prophylaxis and control for newly emerging contagious diseases through research and diagnostic activities.
- To protect users, sample and environment.
- To handle deadliest virus and toxins.
- To signify the progress of science and fight against deadly pathogens.

- To provide research and novel diagnostic tests in the environment that can be carried out on the actual target agents of disease and not surrogates.
- To characterize newly emerging pathogens.
- To provide global benefits through safe and secure response to deadliest pathogens.
- Assess the options to handle multiple organisms simultaneously in BSL-4 biocontainment facility.
- Flexibility to handle microorganisms causing serious human and animal diseases.
- Compliance with National and International biocontainment regulations.
- To handle multiple organisms at the same time in different laboratory modules.
- Abide by the cGMP and GLP guidelines.
- Compatibility with internal and external health and safety regulations.

Study Objectives

- To enumerate the continent wise global distribution and ownership status of BSL-4 laboratories.
- To determine the distribution of BSL-4 labs in Asia and compare the status of India in terms of holding high level bio-containment labs with other countries.

Mode of data collection

Study Design: Descriptive

Data Type: Secondary data (Quantitative)

Sample size: 59

Sampling method: Exhaustive sampling

Literature Review

A study was done by Jim.K on September 9, 2020 on careful performance of staff and researchers dealing dangerous microbes in different biosafety level laboratories.[8] The findings were that pathogens are studied in different biocontainment labs according to its requirement of containment. The labs are categorized from BSL 1 to BSL 4. The pathogens which do not consistently cause any disease can be studied in BSL 1 lab.[8] BSL 2 lab works with moderately hazardous agents. An example of a moderately hazardous agent would be Staphylococcus aureus. In BSL 2 labs, there is a minimum use of PPE but the work happens behind self-closing doors.[8] BSL-3 centers are designed to residence potentially deadly, airborne microbes. Sets of doorways isolate a BSL-3 lab. BSL-4 centers are reserved for retailers with a high fatality charge, consisting of Ebola.[8] They require complete body positive pressure suits, decontamination of all substances, and a shower upon exiting the lab. Even as running in those labs inadequate PPE or different failures ought to lead to publicity.[8] The dangerous procedures involve direct handling of a biological agent in a high concentration such as challenging an animal with syringe or nebulizer.[8] The work surroundings in a BSL 3 or BSL 4 facility requires special sort of man or woman who've already worked in BSL 2 labs and demonstrated proficiency.[8] Another study was done by Amy.P, Kelly.F on July 01, 2014.[9] The study found that the ability to respond to public health emergencies which involves infectious diseases as well as the ability to adequately prepare for that is not yet known or recognized.[9] The investigation of emerging infectious diseases needs to be carried out in suitable places. To ensure that the laboratory workers are protected from the consequences safe conduct of such investigations should be done.[9]

Therefore, special containment facilities are designed and constructed.[9]

Another study on establishment of biosafety level labs by Devendra.T.M, Pragya.D. Y in August 2014 was done.[10] The study found that India has made significant progress in establishing and organizing different levels of biosafety labs to deal with deadly pathogenic diseases.[10] Outbreaks occur due to the microorganisms which spread very rapidly and also due to poor handling of those microorganisms in laboratories[10] As India, progressing rapidly towards technology and science, a few of the laboratories are also either in the planning phase or operational phase to deal with biosafety issues involved in handling deadly agents which are also needed for research and diagnosis.[10]

Another study by Amy.C. S, Nicole.G discussed on impact of regulation and safety consideration at maximum biocontainment.[11] Studies have shown that limitations in level 4 biosafety level research (BSL-4) could have a significant impact on the number and size of research projects investigating biodefense biological pathogens.[11] Detection, use, storage, and transmission of selected biological and toxic agents (BSAT) is highly regulated because it can lead to significant hazard to public health and safety.[11] All state, federal, city, and local laws must be complied with it for obtaining and maintaining registration for the institution to conduct research involving BSAT.[11] Safety considerations are especially important in BSL-4 laboratories. In order to perform both invitro and in vivo tests, a pressure encapsulating suit is required even though it imposes strict physical limits on the researcher.[11]

Data Variables

In this study the number of labs was counted on basis of continents and sub-continents, the status of the bio-containment labs was reviewed; for example, whether one particular lab is operational, the design of the lab has been planned or it has been newly constructed, information about research subject - for example, whether one lab takes human as subject or animal as subject or both as subject was scrutinized, and ownership of the labs (government owned, university owned, bio-defense owned or privately owned), size and cost of the lab were discussed.

The design or framework of the labs had been documented and GMP and GLP guidelines were also discussed.

Analysis

The overall distribution of BSL-4 labs across the globe is mentioned below in Figure number 1. Among all the continents, Europe possesses the highest number of BSL-4 containment labs (25), whereas the continent of Africa possesses the lowest number of BSL-4 containment labs (3). As per India is concerned, it comes under the Asia continent and holds only 2 BSL-4 labs (operational), distribution of which is being mentioned in Figure number 2.

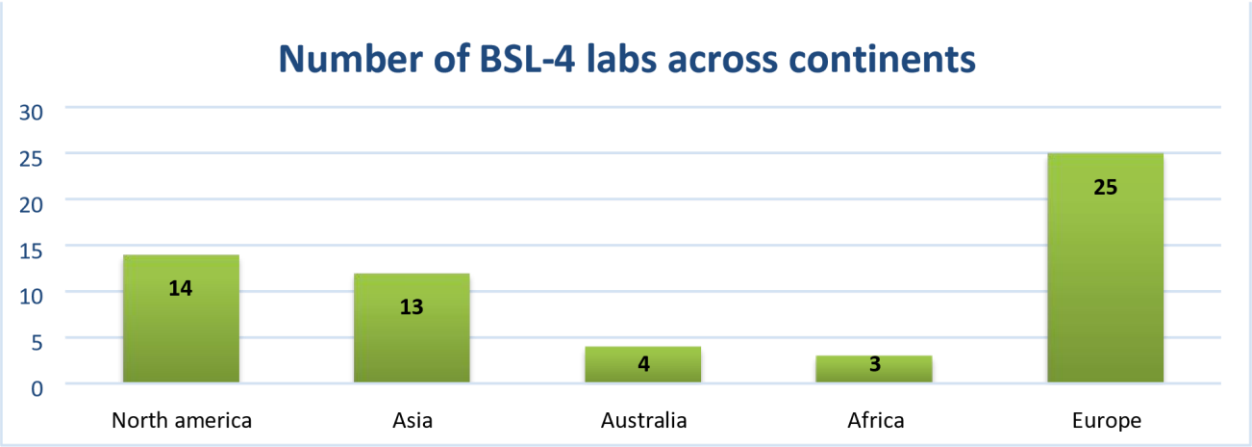

Figure - 1

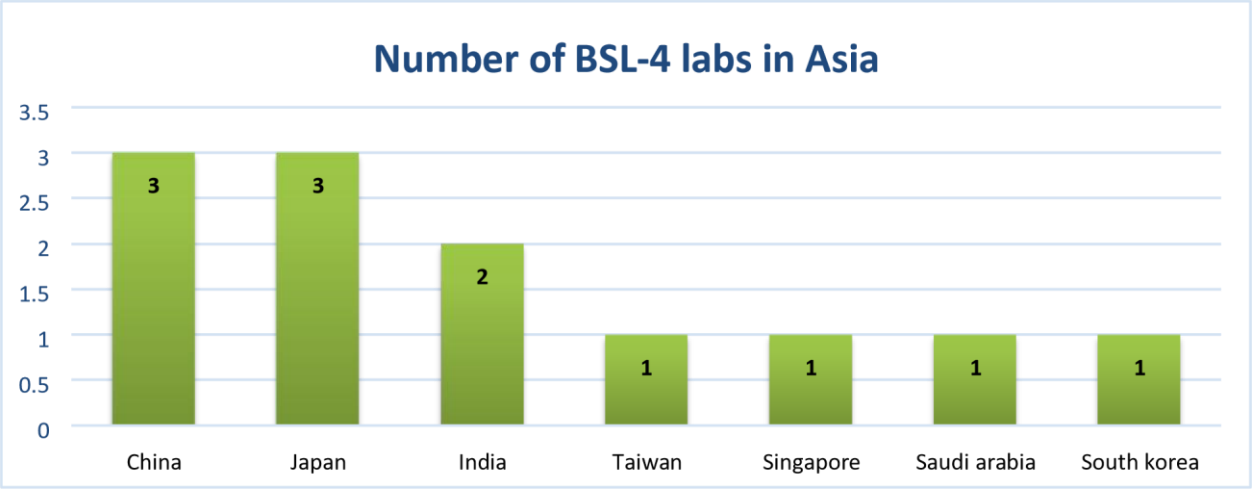

Figure – 2

Microbial containment complex (MCC), situated in Pune, Maharashtra and National Institute of High Security Animal Diseases (NIHSAD) in Bhopal, Madhya Pradesh are the only 2 containment labs which are operational in India. These both labs are Government owned or operated. The size of MCC is 848 square meters whereas the size of NIHSAD was not disclosed. Speaking of the experiment subjects MCC takes human being as subject whereas NIHSAD takes animal as subject. The cost of establishing both labs caused the Indian government 15 and 18 crores respectively.

The MCC does Investigation of outbreak of highly infectious diseases such as Severe Acute Respiratory Syndrome (SARS), Avian and pandemic Swine Influenza, Nipah virus, Crimean Congo hemorrhagic fever virus and Kyasanur forest disease virus.

The NIHSAD does all the research, diagnosis and control of exotic and emerging animal diseases.

Among all the BSL-4 labs (59) across the world, 60% (36/59) of all BSL-4 labs are government run public health institutions, 20% (10/59) labs are run by universities, approximately 20% (11/59) labs are run by biodefence agencies and only 3% (2/59) labs are privately owned which are mentioned in Figure 3.

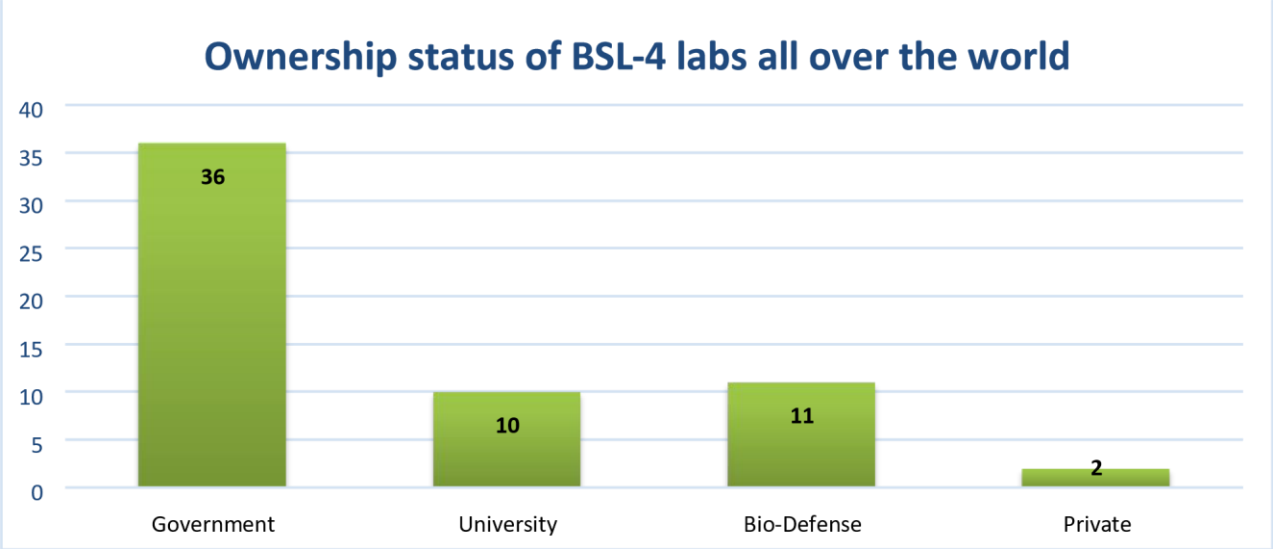

Figure - 3

BSL4 labs range in size from 28 m2 to 4084 m2. Area information of only 44 BSL-4 labs among 59 is reported which has been mentioned below in Figure 4.

No. of labs	Size (Sqm)
11	>1000 Sqm
11	200-1000 Sqm
22	<200 Sqm

Figure - 4

Area information of BSL-4 labs

Guidelines of BSL-4 labs

Guidelines	High Containment Laboratory (HCL)
Facility is located in a separate building (isolation of facility)	Yes
An efficient primary containment system	Yes
Presence of cabinet room and suit laboratory	Yes
An arrangement of interlocked autoclave or fumigation chamber	Yes
Controlled air system	Yes
Negative pressure is maintained in the facility	Yes
Tested HEPA filters	Yes
Different design of ventilating system for cabinet room and suit laboratory	Yes
Emergency lighting and communication systems inside and outside of the facility	Yes
Safety equipment	Yes
Flexible-film isolators for separation of works	Yes

Personal Protective Equipment (One-piece positive pressure suit)	Yes
Access is strictly limited.	Yes
Supplies and materials should come through a double-door autoclave or fumigation chamber	Yes
Laboratory monitoring	Same as BSL-3 Lab
Hazardous biomaterials are strictly decontaminated within facility within 24 hours	Yes
Health and medical surveillance	Same as BSL-3 Lab
Emergency procedures	Yes

Discussion

Globally, there is a strong view that studies on microbial agents require extra care and vigilance to avoid health risks for laboratory and community workers.[12] Emerging diseases caused by known and unknown viruses occur unexpectedly around the world. This often occurs in epidemic ways and is very difficult to diagnose and to control. [12] It is important to have research facilities with high levels of protection and procedures to deal with such threats. Institutions authorized to investigate such outbreaks need to be prepared.[12] It is also imperative that the storage of these germs be carried out in appropriate biosafety laboratories. The most important public health problems around the world are being addressed by building a global network of well-equipped laboratories and trained staff, and there is a growing need for transport facilities.[12] Protective resources are also needed to improve international capacity for diagnostics and policies. Biosafety policies and procedures are designed to protect employees and the environment from harmful biological hazards and compliance with regulatory requirements.[12] Content science has emerged as an important branch of science in recent times. There were no national guidelines for establishing, operating and maintaining care, auditing and verifying laboratory containers.[12] Therefore, the more initial establishment of such facilities, the more responsible it is to manage the laboratory and the limited knowledge to make such projects is a major obstacle. In many developing countries, awareness of bio-containment has

increased but planning, design, construction and laboratory laboratories require constant review and clear definitions of vulnerable groups and their management.[12] All countries around the world try to focus on strengthening BSL 4 Labs. As the countries face with this epidemic, countries are more inclined to build their own public health system; for example, a high-level bio-safety laboratory in Wuhan is a perfect evidence of how China is strengthening its public health system and bio safety management system following an epidemic or outbreak of SARS. As India is concerned, there are only 2 labs out of 59 BSL4 labs worldwide. In order to strengthen the public health system and bio security system of India, the BSL-4 community as a whole must improve the public image and improve the safety and security record. The recent outbreak of the Corona virus has revealed that there is a lack of infrastructure to deal with deadly viruses in the country. With a view to a strategic future, the GBRC is considering establishing a high-level biocontainment platform in Gujarat to address future challenges.[7] The facility should be instrumental in rehabilitating large banks and cells and viruses and producing clinical grade material in accordance with cGMP guidelines.[7]

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Annexure

S. No	Name of the Project	Date(s) of Visit	% of Time Spent	Interacted with (Name and Designation)
1	Biocontainment BSL-4 research facility (Establishment intended by GBRC)	18-04-2022 to 14-5-2022	45%	Mr. Divyanshu Bhatt (Manager at EY)
2	Central Armed Police Forces Institute of Medical Sciences (CAPFIMS)	15-05-2022 to 02-06-2022	30%	Ms. Komal Aggarwal (Associate in strategy & transactions at EY)
3	Jaharlal Nehru Port Authority Hospital (operated by JNPT)	02-06-2022 to 17-06-2022	25%	Mr. Hitesh Pandit (Executive at EY)