

Principles and practices of biosafety: Expanding and extending to food safety and food supply chain

Murli Manju, Amrita Ghosh¹, Ranabir Pal², Gabriel Alexander Quiñones-Ossa³, Rajashekar Mohan⁴, Amit Agrawal⁵

Department of Anatomy, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, ⁴Department of Surgery, K S Hegde Medical Academy of Nitte (Deemed to be University), Mangalore, Karnataka, ¹Department of Community Medicine, MGM Medical College and LSK Hospital, Kishanganj, Bihar, ²Department of Biochemistry, Medical College and Hospital, Kolkata, West Bengal, ⁵Department of Neurosurgery, All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India, ³Neurosurgery, Faculty of Medicine, Universidad El Bosque, Bogotá, Colombia

Abstract

The perception of biosafety on food and supply chains moves around the philosophical axis of “coping and living with occupational health hazards” to uphold the sustainable development of occupational safety. COVID-19 pandemic opened the “Pandora’s box” of prevailing lackadaisical attitude on the basic public health aspects principles that should apply to food safety and food supply chain. We must revamp the collaboration of food production and public health-care delivery system to save the community by containing the spread of highly infectious agent from known and unknown natural and artificial reservoirs. Equity of distribution of quality and quantity of the food and nutrition has to be ensured for the majority of the global population at this crossroads of socio-economic crisis which has pauperized en masse as the negative fallout of pandemic. Food safety should be an urgent agenda for comprehensive internalization and be supplemented with the mitigation plan to minimize psychosomatic stresses and revitalize emotional and psychosocial health by targeted interventions. There is dire need of translational research and holistic streamlining of biosafety program in the phase of the rising trend of the cases and sequels epidemiologic pandemic curve on ground. Needless to mention that apart from SARS-COV2, the holistic concept of the implementation of the biosafety programs can interrupt the transmission of innumerable infectious agents from the plant and animal resources. Biosafety models were reviewed for high laboratory standards in the real time “new normal” situation of containment and risk assessment in this unprecedented pandemic of new millennium.

Keywords: Agents, biosafety, COVID-19, equipment, food chain, food safety, protection

Address for correspondence:

Dr. Amit Agrawal,
Department of Neurosurgery, All India Institute of Medical Sciences, Saket
Nagar, Bhopal - 462 020, Madhya Pradesh, India.
E-mail: dramitagrawal@gmail.com

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INTRODUCTION

The basic conceptual framework and contextual design of biosafety is targeted on the safety precautions to reduce the risks of exposure to all the potentially infectious material,

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this finds ways and means to stop the transmission of gross reduction of the occupational hazards pave ways to improvement of the health of the community, the country, and the world.^[1] In addition, many laboratory facilities provide opportunities to handle highly infectious agents to halt spread of contamination, and also, various standards have been developed to safely handle these organisms such facilities. In this modern era, few regions have tried to create new threats of bioterrorism and to handle any untoward events, safety measures have been defined and protocols are formulated.^[1,2] Biosafety is a concept where regulatory systems and risk analysis protocols are implemented to ensure the safety of modern biotechnology in a holistic manner at international, regional, or national levels.^[2,3] The present pandemic of COVID-19 has created an era of uncertainty, changes, and challenges and created a high-risk scenario in the open world, safe handling of infectious material is a part of laboratory protocols,^[4] the current 2020 pandemic has provided a unique opportunity and responsibility for all of us to expand our experiences for the biosafety of the food and food supply chain. The concept of biosafety framework is improvement of the laboratories that process infectious agents, minimize all sorts of accidental threat to direct or indirect ways of acquisition of infections.^[1,5] Safe-food ensures minimization of modifiable physical, chemical, or microbial hazards for intended end-user and does not cause morbidity resulting from food paradigm, handling exercise, product differentiation, and acculturation among others.^[6] Even though we need stringent regulations in food supply chain to limit food-borne illness and food poisoning from toxins, chemicals, or other harmful elements, especially for high-risk population. This research group attempted to explore the additional hazards experienced in the midst of the COVID-19 pandemic, options, feasibility, and possibility of applying the biosafety standards inclusive of the vistas of holistic safety expanding and extending to food safety and food supply chain.

BIOSAFETY ISSUES AND CONCERNS

Biosafety concerns start from the production to the end user and direct or indirect interactions with environment, part of the challenge is the recognition of vulnerable points for potential contamination with harmful substances to human health and breach in the integrity of biosafety chain.^[7,8] Timely biosafety risk assessment shall help to reduce the exposure of harmful agents not only to the workers and users but also to the environments as well. This will further help in developing mitigations measures and will ensure the safety of supply chain.^[1] It is important to identify the potential sources of biologically active substances, their

concentration in which they can harm the human health. It is best possible by developing anticipatory strategies to develop methodologies to quantify and assess the risk and sharing the information in the real time with regulatory bodies.^[9]

PRINCIPLES OF BIOSAFETY

The principles of biosafety are typically visualized under containment and risk assessment. Basic concepts of containment are microbial practice, safeguard equipment and facility to shield laboratory personnel, ambience, and community from exposure to infectious laboratory microbes.^[10] Containment is conventionally of two major types: (a) Primary to protect laboratory workers and environment by mitigation technique, apt safety gears, and use of immunobiological for personal protection and (b) Secondary to protect the external environment from spillage of contagious resources by the pooled effects of design and operational aspects of process and logistics.^[2] Containment has three elements, namely^[2,11] Laboratory Office Practice by stringent practice of standard techniques, capacity building by implementing tailor-made biosafety standard office procedures for risk reduction,^[12] Standard Microbiological Practice include personal protection including consistent and correct use and disposal of good quality laboratory dress, gloves and follow other protective logistics of do's and do not's earmarked for the specific job responsibilities,^[2] Technical procedures include correct use of pipettes and other technical procedures involving hypodermic needles and syringes, routine recording and reporting of factual and potential exposures to infective materials with cleanup, decontamination, and other acts. Safety equipment include biological safety cabinet with laboratory coats dress, gloves, protective eyewear for anticipated splatter of microbes, and other hazardous materials facility designs facilitate smooth working by correct and cleanable hand washing area and workstation, nonerodible to supply water, and acid-alkali-solvent-heat resistant lab-tops. Risk assessment: The crucial factors of containment depend on risk mitigation based on infectivity of agent, severity of disease, and nature of laboratory works. Risk assessment entails correct system approach of microbial handling, equipment, and safeguards to prevent laboratory-acquired transmission, namely limited access or restricted entry when work in progress, only allowing authorized personnel, banning trespassers to laboratory working zones, especially for kids.^[13]

EMERGING AND RE-EMERGING INFECTIONS

New infections agents continue to emerge as a phenomenon in the last century; on the other hand,

old microbial agents resurface after they have been on a significant decline globally or regionally depending on the considerable change of epidemiological triad in favor of the agents to become health problems for a noteworthy segment of the population.^[14,15] All these emerging and re-emerging infections interact in their permutations and combinations to finally pose great threat to the existence of human and animal populations for which there is relentless research and development on the natural history of diseases and mankind continues to find out solutions to the outbreak interventions.^[16,17] The emerging and reemerging infectious diseases are posing challenges to the basic researches. The changes in world paradigm lead to emergence of many vector borne infectious diseases in spite of our best possible effort to encounter insect vector (c. f. Lyme disease) or rodent host (c. f. Hantavirus pulmonary syndrome and Lassa fever). Further, emergence of infectious diseases from technological advancements, namely air conditioning systems (Legionnaire disease) and mass food production (hemolytic uremic syndrome). The well-known protozoan disease Malaria was successfully eliminated for many years with integrated vector control mechanism and sensitive drugs in the many parts of the world. In recent decades, *Plasmodium* species have shown resurgence/re-emergence due to global warming on one hand and parasitic resistance to the drugs as well as vector resistance to insecticide posing real threat to human civilization with illimitable morbidity and mortality.^[18,19]

HISTORY DO TELL TALES

In 1941 Meyer and Eddie^[20] published their manuscript, a research works on a series of 74 laboratory-associated Brucellosis cases which were reported from the United States. Their study concluded that the hazards to handle the cultures, specimens, or even inhalation of the dusts from the laboratory that contain *Brucella* sp. organisms are exceedingly dangerous to the laboratory personnel. The research group, however, attributed among others, the careless behaviors of the laboratory workers and practice of poor techniques in a good number of cases while managing the potentially infectious materials.^[20] Sulkin and Pike^[21] in 1949 published for the first time a case series of laboratory-associated 222 viral infections. Of these individuals with reported viral infections, 21 were reported to have deceased later. However, the documentation was poor and only 27 (12%) of the reported cases were recorded as known accidents.^[21] Hanson et al.^[22] in 1967 reported 428 evident infections with *arbovirus* that were sourced and accepted as acquired from the laboratory. Is important to recall that the first biological safety conference

was organized under the aegis of the Center for Disease Control that could have classifies four different levels of bio-containment from biosafety level (BSL) 1-4.^[23]

ROUTES OF TRANSMISSION

The hazards of exposure of laboratory personnel to potentially infectious materials (i.e., the reservoirs of agents to the susceptible hosts) leading to morbidity, mortality, and disability can be prevented by the barriers of infections in the macro and microenvironments. We need to cultivate the knowledge of well-known routes of exposure and concept of spread of infection (which are always present in clinical, laboratory, and experimental settings) can be extended to the food and supply chain as well (with modifications risk of exposure versus chances of infection, relative concentration and virulence of organisms). These routes include oral infection (either ingestion or hand to mouth transmission), parenteral inoculation (pricks and punctures), direct skin contact or mucosal exposure, inhalation of infectious aerosols, sharing contaminated fomites (e.g., door-knobs, handles, railings, elevators, cell-phones, packaging, etc.), spillage of potentially infected material, and many more. The realistic implementation of the paradigm of safety as the primary welfare issues concern from the awareness of the stakeholders and personnel of all workplace levels to combat the crisis in addition to health-care perspectives.^[24-26]

LEVELS OF BIOSAFETY

The level of biosafety in the laboratory settings are determined by the volume and concertation of the virulent organisms, anticipated virulence, pathogenetic potential, antimicrobial resistance pattern, availability of treatment, or immunobiological against the organism (most of the a known one).^[2,8,11,27] Depending on these and many other parameters, BSLs can vary from BSL 1 to BSL 4 [Table 1].^[27] The key element of biosafety is the development and adoption of a standard protocol and strict adherence to the standard practices and techniques microbiological principals.^[12] To make sure the safety in laboratory with a good knowledge potential hazards and safe operations in the laboratory settings and who knows specific entry and exits needs to the entire functioning, the vulnerable points and personnel can be identified, and it can be anticipated to ensure the necessary measure to maintain the integrity of the safety during the entire chain of food supply. Based on the concept regular surveillance, audit and training these steps in food supply can be monitored and the safety of food supply chain can be assured.^[28]

Table 1: Safety practices - Few examples from laboratory environment

Safety level	Recommendations
Biosafety level 1	<p>Provides guidelines to practice in training and teaching laboratory facility</p> <p>Involves handling of viable microorganisms which are not known to cause disease in healthy adult humans consistently (vaccine strains excluded)</p> <p>However very young, aged, and immunodeficient individuals and immunosuppressed individuals are at risk</p> <p>Standard microbiological protocol</p> <p>Standard hand washing</p>
Biosafety level 2	<p>Special primary or secondary barriers not recommended</p> <p>Handling of the broad spectrum of indigenous moderate-risk agents</p> <p>Associated with varying severity of human diseases</p> <p>Handling persons are prone for exposure by accidental percutaneous exposure or mucous membrane exposures</p> <p>Need to extreme precautions while handling contaminated needles or any sharp instruments</p> <p>Need to use personal protective equipment's (i.e., splash shields, face protection masks, gowns, and gloves)</p> <p>Facilities for hand washing and waste decontamination are required</p>
Biosafety level 3	<p>Applies to facilities where microorganisms have potential for respiratory transmission and has the potential to cause serious and lethal infections</p> <p>There is a risk of autoinoculation, ingestion, and or exposure to aerosols containing infectious material</p> <p>These facilities need primary and secondary barriers to prevent biohazards including a gas-tight aerosol generation facility</p> <p>Controlled access required to minimize release of infectious aerosols</p>
Biosafety level 4	<p>Working with agents which has a high individual risk of life-threatening disease that may be transmitted via the aerosol route</p> <p>Nonavailability of vaccine or therapy</p> <p>Protection aimed to completely isolate from aerosolized infectious materials</p>

HANDLING AND TRANSPORT: PRODUCTION TO USE

As for any other packaged material, the food and food supply can be at risk of contamination starting from the source to the end user and thus to ensure the biosafety there will be a need of standard guidelines and identification of vulnerable points to the last man on the road.^[7,29] The use of dedicated transport mechanisms and equipment for food items is needed to maintain the safety of the food materials from site of production to the actual consumer (c. f. concept of cold chain in vogue for immunization practice in the whole world from). In addition to the identification of vulnerable points, we need to identify the protective way to be implemented with reasonable effort and in global perspective, transporting of food materials can be outside the buildings, inside the buildings, in the vehicles (may be air transport or may be sea transport) and may need manual handle to reach the end user,^[26] for example, liquids as well as solids need to be transported in leak-proof packing, to be kept separately and this should be able to protect possible breakage and spillage of the contents.^[30] In addition to safe transportation

and handling, there is a need to maintain the quality, flavor, texture and biosafety of the food from farm to the plate through collection, storage, processing, transportation, and retail chain of business to reach the end user actual customers in different point of the world.^[31]

In the wake of the COVID-19 pandemic, when “over the counter” exchanges are being gradually replaced by the “online” paradigm, the research groups are working on their how long can SARS-COV-2 virus can survive on difference surfaces, namely metal (doorknobs, jewellery, and silverware)-5 days; stainless steel (refrigerator, pot, pan, sinks, and water bottle): 2–3 days; copper (pennies, teakettles, and cookware): 4 h; aluminum (soda can, tinfoil, and water bottle): 2–8 h; glass (drinking glasses, measuring cups, mirrors, and windows) – up to 5 days; ceramics (dish, pottery, and mug): 5 days; cardboard (shipping box): 24 h; Wood (furniture, decking): 4 days; Plastics (milk container, bottle, public place seats, backpacks, and elevator buttons): 2–3 days; Paper (mail and newspaper): up to 5 days. We have known that SARS-COV-2 usually survive for shorter time in higher temperatures and humidity levels; won't survive the shipping time; SARS-COV-2 transmission is higher from the delivery personnel whose status of positivity remain largely unknown; leaving packages in open spaces and/or spray them with a disinfectant for a few hours and washing/sanitizing hands after handling mail or a package may limit transmission. Further, for food (takeout, produce) and water: Feco-oral spread has been hypothesized not proved; fabrics (cloth and linen), shoes, skin, and hair: Disputed till date.^[32] However, we don't know the precise quantum of virus to initiate pathogenesis and all this knowledge is crippled with the recent global consensus research findings that airborne transmission may be the main reason for devastating COVID-19 pandemic.^[33]

BIOSAFETY MEASURES

Depending on the biosafety concerns, the concept of safety in laboratory practice consists of preventive protocols, primary and secondary barriers, and personal protective equipment (PPE). safety measures can be further categorized engineering controls (air filters, ventilation devices, safe containers, particularly for sharp objects, safe places for eating, and drinking with frequent maintenance of these facilities,^[4,7] also, is important to have a written well-defined safety plan with clear objective encompassing the details safety protocols to be followed in routine as well in emergency, details of personnel's to be contacted in emergency circumstances and a system to co-ordinate safe communication.^[7] Preventive protocols will include

simple measures such as adequate ventilation, frequent hand washing, maintain safe distance, and eye washing.^[7] The biosafety protocol should be well documented in the understandable language of the workmen; it should be tailor-made and frequently updated with the introduction of new technology and logistics as a routine practice. The biosafety system should have drills and audit at regular intervals to optimize the required implementation by the personnel and optimum functioning of the infrastructure in emergent situations.^[7] As per standards clean, disposable PPE kits can be supplemented in high risk areas consisting of caps, gloves, gowns, shields to protect face, goggles for eye protection, shoe, and/or shoe coverings.^[26]

BIOLOGICAL SAFETY (BIOSAFETY) CABINETS

Biosafety in Microbiological and Biomedical Laboratories has rapidly become an integral part of the practice and policy in the United States since 1984.^[2] Biological safety (biosafety) cabinets (BSCs) are primarily meant for containing potentially infectious microbes to ensure safety of the lab personnel, BSCs are dedicated devices to enclose a workstation to provide barriers to aerosol exposure between worker and infective material.^[26] Most BSCs use i.e., high efficiency particulate air (HEPA), made from paper thin sheets of borosilicate medium, filters in exhaust and supply systems and able to arrest penetrating particle sizes of 0.3 μm with the efficiency of minimum 99.97% and removes bacteria and spores. Laminar air flow cleans aseptic rooms using air through HEPA filters. BSCs provide protection to workmen (handling infectious materials), environments (by straining microbes), and products (in handling cell cultures). Functional operation and integrity of BSC are certified during installation and minimum, annually thereupon.^[2]

BIOSAFETY AND BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

We are living in an era of uncertainty and change in the epidemiological transition pattern during incessant global warming, newer challenges of emerging, and re-emerging infections amid erratic human risk-taking behaviors. Day-to-day operation of the laboratory works with the infective materials and agents in the public and private research works and health practices, regular clinical and diagnostic services, and veterinary health-care facilities is expanding. Recent Covid-19 pandemic has been providing us a great lesson that current global practices of health-care delivery system and supportive laboratory services need a paradigm shift. As Covid-19 may or may not be part of threats of bioterrorism, the organizations and laboratory services around the world with international

health-care advisory groups are mitigating by evaluation of current strengths, weakness, opportunity and threats to ensure effectiveness of the biosafety issues, capacity building programs, improving infrastructure logistics, and revamping of systems approach to provide optimum biosafety. Individual laboratory personnel working with pathogenic microbes must learn the science and art of safety and security of manipulation of potentially infective materials. Optimum mix of updated knowledge, apposite techniques, and suitable equipment can ensure safety of the laboratory medicine community from individual, laboratory, and ambient exposure to hazards.^[2]

NEED OF BIOSAFETY LEGISLATION

The spectrum of biotechnology added our ability to exchange genetic materials across the living organisms overcoming physiological barriers by the recombinant DNA technology. Thus biotechnology has provided us with options and choices to explore probabilities to use agricultural and industrial forestry produces by cultivation of Genetically Modified (GM) crops; the research scientists are not unanimous in futuristic vision with the GM crops with potential hazards on human health namely antibiotic resistance, allergenic quality, altered nutritional pattern, and toxicity. Biosafety legislation in Food Technology is needed to avoid unintended hazards to human health and environment. Mandatory labelling of GM food products should be declared as the rights of consumers and must be respected along with periodic assessments of impacts by independent testing for overall safety including preservation of the environmental. Many nations promulgated regulatory laws to assess impact of hazards on three levels, namely Agricultural genetics and preservation of biodiversity, safety of food in terms of allergy and toxicity, and environmental changes include nontarget organisms with the concepts of microbial thriving and production of toxin under three conditions nutrients, moisture, and warmth (40-140°F).^[34] Essential elements in the biosafety guidelines are to assess and identify bio-risk with specific measures and code of practice, physical plant namely laboratory design and facility, purchase and maintain equipment, medical surveillance, capacity building, infrastructural safety from chemicals, fire, radiation, electricity, etc., commissioning and certification guidelines should suffice.^[12]

GLOBAL INITIATIVES FOR FOOD SAFETY

Two major international protocols address GM debate viz. Cartagena Protocol^[8] and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the

Cartagena Protocol on Biosafety-the Supplementary Protocol,^[35] both attached to the Convention on Biological Diversity of 1993. These efforts culminated eventually to Intergovernmental Committee for the Cartagena Protocol on Biosafety. They formulated guidelines and legal frameworks for produce, handle, and consumption of GM foods and thereby protect both biological diversity and human life from any adverse effects of technology modified organisms. Biosafety was important central to protect global health and our environment from the negative impacts of modern biotechnology. The Protocol provides the international regulatory outline for reconciliation of trade and environmental protection needs to meet budding global biotechnology industry. The precautionary principle of the protocol for uncertain situations was from the Rio Declaration on Environment and Development (1992) that threats of grave damage to human and continuing hazardous outcome to the environment not acceptable on the excuse of paucity of scientific development. The protocol also included the concept of unintentional transboundary transmission and sharing of information, specifies handling, packaging, safe movement during transport with supportive documentations. Basic principle of the Supplementary Protocol was that the polluters have to pay compensation for the damages and also explicitly declared that it does not encroach on the rights and obligations of States under the general international law regarding their responsibility of international wrongful activities and allows additional domestic laws.

BIOSAFETY CAPACITY BUILDING WITH RESEARCH AND DEVELOPMENT

The basics of biosafety teaching-learning, even in the UG and PG curriculum of the health-care teaching in our country, is not taken up seriously as expected from the filling the lacunae of safety issue.^[7] We need to prepare a system of biosafety capacity building in all branches of science. Further, continuous upgrading in the period of explosion of biotechnology needs basic and translational research. In addition to the scientific approach, there shall be a need for a strong legal support to ensure the safety and integrity of biosafety food supply and food chain, while planning the safety protocols we need to keep biosafety of human and health, address the ecological concerns, safeguard environment, monitor public attitudes, and consider socio economic and ethical aspects.^[36,37]

CONCLUSIONS

This interprofessional research group felt emergent exploration of the hazard risk with options, feasibility and

possibility to apply during the pandemic going up to food safety and food supply chain in the real open world and in the community. The concept of biosafety should be ingrained in the mindset of the personnel working in the field of food and nutrition. The extension of the biosafety conceptual design to the ignored mammoth food supply chain can only ensure safety of human and animal health. This shall include, but will not be limited to source of production, storage, transport, supply chain, and the environment but also extension approach to have regular impact assessments. Biosafety can be achieved by taking into consideration the safety principles of laboratory biosafety such as personnel hygiene, judicious use of personnel protective equipment's, developing practical guidelines, regular monitoring, training and frequent auditing, sharing details of any untoward events to all parts of food production from farming of raw materials to reach the plate of the end-user global citizen to keep them hale and hearty.

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