

SOME ETHICAL PERSPECTIVES IN THE DISCIPLINE OF MICROBIOLOGY

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Abstract

Ethics are of vital importance in microbiology. No new scientific or technological development can claim immunity from ethical scrutiny. More specifically, moral & ethical concerns are of considerable importance in influencing public attitudes towards microbiology. In addition to the biosafety and biosecurity in microbiological research, it is necessary to emphasize the prevention of the techniques and published knowledge from being misused.

The ethical issues of microbiological characterization techniques in controlling the infectious diseases and avoiding the spreading include both individuals and public at large. Professional ethics is the moral bond that links a profession, the people it serves, and society. The patient's welfare is paramount in clinical research and healthcare ethics. The ethical issues we display influence the kind of people who choose to work in our profession and determine who choose to seek for our services.

This article addresses ethical issues concerning biosecurity, ethical issues in molecular techniques in epidemics, antibiotic restriction and some ethical aspects in clinical laboratory.

Keywords: Ethical issues, microbiology, biosecurity, misuse of microbial research.

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Introduction

Antony Von Leeuwenhoek, a famous name in the microbial world helped in two remarkable professions i.e. medicine and science. Later the scientific achievements of Louis Pasteur and Rudolf Virchow helped in modeling the role of microbes in the development of modern medical profession. The advancements in pathophysiology of infectious disease and development of therapeutics to treat such infections could have offered comfort and cure. The contributions of Alexander Fleming's Penicillin

and Jonas Salk polio vaccine also cannot be overlooked.

The HIV virus has shattered the concept of health, illness and infectious disease in general and particularly the physicians. The ethical issues involving the transmission and communication of the disease were highlighted with the emergence of AIDS. This leads to the emphasis on the concept of a patient as a victim and vector. Since then, bioethics

has recognized the relevance of remarkable characters of infectious diseases.

Microbes and bioweapons

After the attacks on the World Trade Center in New York City, when the envelopes loaded with *Bacillus anthracis* spores were mailed to various government officials and media personalities. Many people contracted anthrax from the envelopes. Few persons died, and some survived, only after long illnesses.

It is acknowledged that balancing bioterrorism needs scientific and medical advancement. A group of scientists catalyzed responses to bioterrorism and wanted to do something for public interest. Scientists helped in identifying the source of the anthrax attacks and recommended new guidelines on publishing research to limit the terrorists' access to advanced microbial research that might be used for bioweapons development. This has led to the development of new field of microbial forensics. The research publications are providing detailed information for making infectious agents more dangerous from available sources. This leads to debates to keep away the terrorists from obtaining information that they could use in developing bioweapons.

Micro-organisms intrinsically carry a 'dual-use' potential and therefore most microbiologists are more or less affected by dual-use issues.

Responsibilities in microbiology require on the one hand scientific openness to widen knowledge and improve public health and on the other a demand for security to avoid antisocial attacks or heinous actions (1). Both are prerequisites for scientific work.

The American Society for Microbiology (ASM) has raised both the issues of defending scientific commitments to openness in publication and insisting scientists take an active role in stopping bioterrorism(2). The International Union of Microbiological Societies (IUMS) is having a target:

- 1) To promote the microbiological sciences studies internationally.
- 2) To commence, expedite and coordinate research and other scientific activities involving international cooperation.
- 3) To safeguard the dialogue or reviews and circulation of the results of international conferences, symposia and aid in their reports publication.

Above all the main objective is to constantly advance the knowledge of the microbiological sciences in order to always enhance human well-being (3).

Biosecurity and culture collection units

The advances in the field improve understanding in microbiology through research on infection mechanisms & microbial communities interactions. The introduction of working practices to protect laboratory personals, and the environment further improves quality assurance and management. The need for centers of expertise in microbial culture isolation, identification and maintenance to conserve microbial gene pool had been realized internationally or globally for future study (4).

All the culture collection units' requires approved standards of operation for globally harmonized process, since; they are also institutions, performing fundamental or applied research often in international co-operation.

The culture collection center requires having highly standardized processes for biosafety and biosecurity because of holding the pathogenic strains.

Biosecurity is governed by the non-proliferation approach of the Biological and Toxin Weapons Convention (BTWC). Two other globally important fundamental for biosecurity includes: the World Health Organization (WHO) Laboratory Biosecurity Guidance of 2006 (WHO/CDS/EPR/2006.6) (WHO, 2006) and the International Union of Microbiological Societies (IUMS) and Code of Ethics (IUMS, 2006).

The other codes of conduct also includes: the Dutch Code of Conduct for Biosecurity (Royal Netherlands Academy of Arts and Sciences, 2008) and the DFG Code of Conduct on work with highly pathogenic micro-organisms and toxins (German Research Foundation, 2013). These codes are based upon the essential demands of the documents to furnish Principles Theater relevant and useful for all the institutions related to microbial work.

The biosecurity guidance for culture collections has been developed by Organization for Economic Co-operation and Development (OECD) in 2001 (5).

The OECD biosecurity best practice guidelines cover some of the following important aspects:

- Assessing biosecurity risks of biological material.

- Biosecurity risk management practices.
- Security management of personnel & visitors.
- Incident response plan.
- Staff training and developing a biosecurity-conscious culture.
- Material control and accountability.
- Supply of material.
- Transport security
- Security of information.

The aim is to prevent microbial Biological Resource Centers (BRCs) from directly or indirectly contributing to the malicious misuse of biological agents and toxins, including the development or production of biological weapons.

There are different codes of conduct. Three different types of codes can be distinguished.

- a) Aspirational (codes of ethics)
- b) Educational/Advisory (codes of conduct)
- c) Enforceable (codes of practice)

However, the key aim of a code is prevention. The conclusion was that BRCs needed a binding code of conduct specific to their needs. The Code of Conduct on Biosecurity for BRCs is concise, simple, and clear and addresses all laboratories holding dangerous organisms.

Bio-riskassessment difficulties

Several factors may hamper biosecurity risk assessment, such as: Difficulty of risk quantification, inadequate necessary data, complications/difficulties in stabilizing causality in biological systems and multiple risk factors (dose of a pathogen intake and uncertainty of dose-response predictions) (6).

The difficulties of risk assessment in microbiology include four elements: Hazard identification & Exposure assessment, Dose-response relationship & Risk characterization.

Ethical issues in molecular techniques in epidemics

The microorganism's molecular characterization open up new opportunities to understand their pathogenicity, evolution and their spread as human pathogens, but it also helps in understanding the epidemiology of the diseases. The advancements achieved by molecular characterization helped in tracing the contacts in outbreaks and has a

promising prospects for infectious disease control. There are certain operational issues in molecular characterization techniques that need to be resolved (7).

The use of characterization techniques in infectious disease control raises ethical issues, in which individual interests and needs must be weighed against those of the public at large (8). Due to recent scientific and technological advances in molecular microbial characterization, the need for ethical guidance has now gained a new sense of urgency (9). The ethical difficulties related to the use of microbial characterization techniques in public health also need to be addressed.

Ethical / moral obligation to avoid disease spreading

The molecular techniques can provide very clear information regarding different microbial relational patterns in an outbreak (10),(11),(12). Despite the fact that the results of such techniques must be understood in the context of traditional epidemiological information but even then, the most probable route of transmission is rarely the only one possible. The more certainty/validity on the microbial relational patterns by molecular techniques found in an outbreak introduces an ethical debate that needs to be resolved (13),(14).

The discussions about who is responsible for infection or outbreaks are complex with no simple or single conclusions; however, it is tempting to jump from information about 'who infected whom' to judgments about responsibility for infection. However, it is ethically problematic to attribute the responsibility to individuals for outbreaks of infectious diseases, even with the most sophisticated microbial molecular typing techniques.

This is because molecular microbial typing methods can help to elucidate potential transmission pathways, yet additional conditions are required before moral responsibility can be attributed to individuals for the spread of infection. Most advanced molecular technology (in combination with epidemiological information) may be able to visualize certain transmission patterns in an outbreak, but does not necessarily lead to valid conclusions or outcome on the disease cause. Transmission of a microbe, for instance, may lead to colonization, but colonization may not necessarily

lead to infection or subsequent disease. But even if we assume that transmission leads to disease, this does not make the source or actor *morally* responsible(15). Therefore, ethical guidelines are very important in sample collection, transportation and laboratory procedures as little contamination can give false results.

Re-emerging diseases, resistance and antibiotic restriction

We are also facing the new emerging diseases as Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS) or avian influenza apart from AIDS or re-emerging disease such as Ebola or Methicillin Resistant Staphylococcus aureus (MRSA) or drug resistant tuberculosis.

We turn our attention to questions on a social scale raised by infectious disease. Let us compare the successes and failures in combating tuberculosis, a disease that was once treatable but is now considered a re-emerging threat due to development of drug resistant strains. Two well settled examples are the reemergence of tuberculosis and sepsis due to MRSA.

The first real pride in medicine may be treating infectious disease, but antibiotics notwithstanding, neither the clinical nor the ethical challenges posed by such infections have diminished. As physicians, as a profession, and as a society the balance between safeguarding the public and protecting the rights of the patient must constantly be evaluated. In our roles as individual patient or physician, we remain part of a global community: emerging infections challenge us to remember both.

Antibiotic constraints present difficult choices for physicians and patients. The physicians must choose between the welfare of the patient and the directive of healthcare systems for restricting antibiotics prescribing. The patient expects best care, but remains often unaware of antibiotic restriction policies and is therefore not fully informed about treatment (16).

The physician's dilemma is responsibility towards patient and need to preserve antibiotic for future use. So the relationship among these roles creates ethical tensions. The risks of treating or not treating the patient with antibiotics are complex. The best therapy will result in cure without a need for return visit for follow up medication.

The substandard therapy, that fails to eliminate the bacterial disease, results in a poor outcome and detrimental events and also broadens the risk of antimicrobial resistance. It is also ethically unacceptable.

It is necessary to identify those patients who need optimal antibiotic therapy to achieve the quick bacterial and clinical cure (17).

In some cases reducing antibiotic prescribing is an easy way for health care system to reduce cost rather than to improve healthcare for patient or manage resistance.

Ethics in clinical microbiology laboratory

The medical laboratory professionals are an integral part in diagnosing the infectious disease, susceptibility to treatment, monitoring surveillance programmes and research response. The personnel of laboratories working in clinical and /or research are bound by the ethical codes of their respective profession. Laboratories must comply with the ethical code of conduct prescribed by international and national statutory bodies and address the ethical, social and legal aspects in biomedical science. Laboratories shall not involve in practices restricted by law and should uphold their profession reputation.

Ethical practice can be considered as an excellent practice accompanied by proper technical behavioral attitudes. The major three classes, all medical laboratories have answerability to others include patients, colleagues, profession and the society (18). The specialists engaged in the clinical laboratory also have the duty to devote to the well-being of the society. They should adhere to the applicable laws and regulations relevant to their professions. The medical field is bound to great standard of responsibility and practice, and should aim to affect those that do not meet these standards.

Laboratories must assemble ample information to analyze specimens and patients. The clinical information must be sufficient to enable the test to be performed and interpreted correctly.

The informed compliance or authorization is required for all the procedures to be carried out on competent patients. The tests must be carried out to an appropriate specification which should be

determined in detail by professional institutions or regulatory administrative authorities. The microbiology laboratories performing HIV testing must have to follow National AIDS Control Organization (NACO) guidelines, which include pre-test and posttest counseling. All the laboratory tasks must be carried out with the high level of expertise and proficiency expected of the scientific, medical and allied health fields.

All the tests results are private or confidential unless disclosure is authorized.

The laboratory must assure that data is stored. There must be reasonable security against loss, illegal approach, and tampering or other data misuse(19).

So, microbiology as a discipline has a commitment to society and the community it serves. In other words, the end results of the microbial work can be better used for the service of the community (20).

It is therefore important that professionals i.e. microbiologists are well prepared to meet these issues and reflect on ethical implications of using the techniques in outbreak management. This requires awareness about the existing ethical guidelines in India and around the world in order to be able to formulate the conditions under which they may be applied in public health practice.

Some of the important guidelines are as follows:
ICMR GUIDELINES FOR GOOD CLINICAL LABORATORY PRACTICES (20)&WHO HANDBOOK FOR GOOD LABORATORY PRACTICE (20)

The handbook covers each and every aspect of laboratory procedures. It endorses some laboratory practices that are scientifically and ethically relevant and have worldwide acceptance. The ethical issues mentioned broadly in the processing of microbial work outlines the following:

Ethical Issues in the definition of test design and parameters, Ethical issues in documentation & environmental variables, Ethical issues with quality assurance, Ethical issues with evaluation and reporting of results, Ethical issues with use of stored of biological material&Research Ethics.

Conclusion

To enhance biosafety, microbiologists need to build a culture of responsibility across the scientific community and embrace the premise that the misuse of science is absolutely wrong. Responsibilities in the microbiological science require on the one hand scientific openness and on the other a demand for security.

The response to emerging infectious disease must also involve public policy. The policy forum, must acknowledge that balancing bioterrorism preparedness with scientific and medical advancement.

The Code of Conduct on biosecurity is concise, simple, and clear and addresses all laboratories holding dangerous organisms.

However, we are only now beginning to understand the downstream consequences of restricting antibiotics on outcomes and costs. We are hampered by the lack of a universal ethical framework and information on outcomes. In addition, the concept of 'effective' or 'best' therapy will vary among different groups.

The reputation of the discipline in the field of microbiology could be enhanced and maintained by considering the standard of ethics. High standard of ethics would lead to a positive attitude in public. Code of ethics for designing microbial work, research and publications would certainly benefit the subject as a discipline and the public at large which it serves.

Conflict of Interest

None

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