ENVIS RESOURCE PARTNER ON ENVIRONMENTAL BIOTECHNOLOGY

SUPPORTED BY:

MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE

GOVERNMENT OF INDIA, NEW DELHI

ISSN : 0974 2476   Volume-33   Number-2, 2018

NEWS LETTER

ON

MEDICAL BIOTECHNOLOGY AND PUBLIC HEALTH

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ENVIS Resource Partner on Environmental Biotechnology publishes two volumes (4 Nos.) of news letter in a year (**ISSN: 0974 2476**). The articles in the news letter are related to the thematic area of the ENVIS Resource Partner (see the website: **http://deskuenvis.nic.in**).

<u>The format of the article as follows:</u>

1. Font should be Times New Roman and font size to be 12 in 1.5 spacing with maximum of 3-4 typed pages.
2. Figures and typed table should be in separate pages and provided with title and serial numbers.
3. The exact position for the placement of the figures and tables should be marked in the manuscript.

Articles should be sent to

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EDITORIAL

Medical biotechnology or red biotechnology is a part of the biotechnology that involves the production of vaccines and antibiotics, regenerative therapies, creation of artificial organs and treatment of diseases. Biotechnology has also offered modern medical devices for diagnostic and preventive purposes, which include diagnostic test kits, vaccines and radio-labeled biological therapeutics used for imaging and analysis. The medical biotechnology also helps in preparation of microbial pesticides, insect-resistant crops and environmental clean-up techniques. The advances of medical biotechnology in public health sector led to the development of various areas of sciences such as medicine, molecular medicines, microbiology, genetics, agriculture and livestock. In agricultural sector the application of biotechnology reduce or eliminate the exposure to pathogens or toxins of the food crops and generate more efficient and sustainable cultivation. The application of biotechnology also helps to improve food quality, inhibit food allergens, add nutritional value, remove anti nutrient substances of certain foods in health care sector.

(Ashis Kumar Panigrahi)

IN THIS ISSUE:

INTRODUCTION

Biotechnology is the technology that involves the use of living organisms or parts of living organisms, to develop new technologies and products.From new vaccines to prevent disease to genetically modified plants with resistance to pests; from replacement heart valves that are better accepted by the body; and from bacteria capable of cleaning up oil spills to environmentally friendly biofuels. It is applicable in various fields such as: Applications in human health & medicine, Veterinary sciences,Agriculture, Food processing & preservation, Bio-fuels & bio-energy, Chemical industry, Environmental management, Waste management, Aquaculture, Mining, Forestry, Soil conservation etc (Fig. 1).

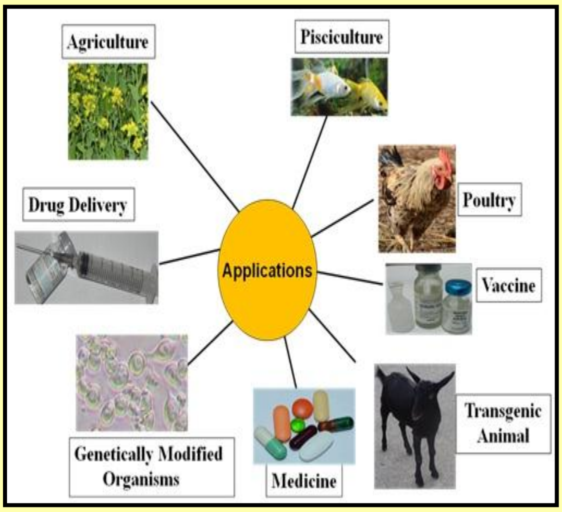

Figure: 1 Impact of Biotechnology on different fields & human life
Source: https://nptel.ac.in

Medical Biotechnology is a branch of the biotechnology which deals with modern medical devices for diagnostic and preventive purposes, *viz*. diagnostic test kits, vaccines and radio-labeled biological therapeutics used for imaging and analysis. The research and development of biotechnology in the field of medicine, agriculture and healthcare applicationia a global challenge now a days.

Human health is a major growing concern worldwide because of infectious diseases. Biotechnology has played a dynamic role in improving thechallenges regarding to human health as it has flexibility to reduce global health differences by the provision of promising technologies (Fig. 2).

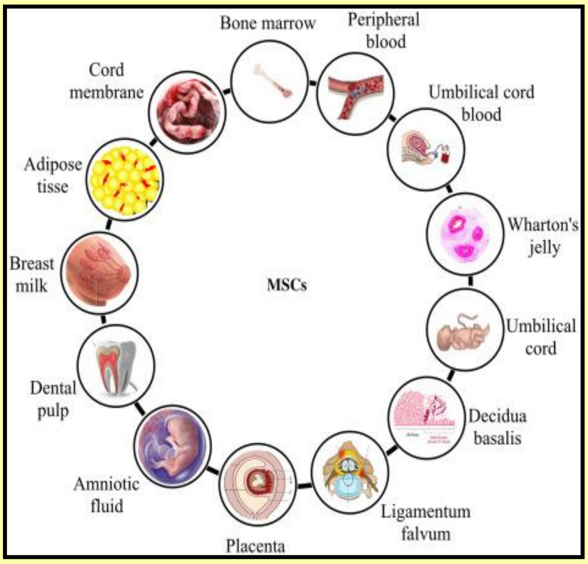

Figure: 2 Techniques and Applicationsof Medical Biotechnology
Source: https://www.sciencedirect.com

MEDICAL BIOTECH AND PUBLIC HEALTH

Today, the public iseven more excited by the developments in biotechnologythat promote health and prevent disease and dysfunction.Biotechnology health care products already on the market, *viz*. human growth hormones,human insulin, and hepatitis-B vaccine among others.

Public Health is the science of preventing disease, extending life and promoting health through the efforts and choices of societies, organizations, the public and private, communities and individuals. It utilizes all divisions of biotechnology, from the division in medicine to the agricultural components of biotechnology.

Many biotechnology companies are working on vaccines, therapeutics, and diagnostics that could be applied to both public health and safety. Vaccines exist for diseases such as anthrax, smallpox, plague, and tularemia as well as many other infectious diseases. The main concerns with vaccines though are safety, the ever changing strains of disease, as well as time needed to build immunity, and the ability to produce large quantities. Multiple generations of vaccines have been discovered to create a better understanding and all around better vaccine. These vaccines can be applied to general health but also as a defense precaution to bioterrorism (Fig. 3).

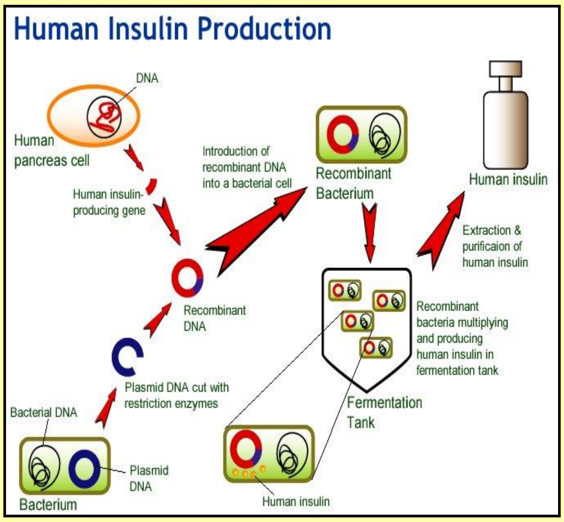

Figure: 3 Application of biotechnology in medicine

Source: https://www.hourlybook.com

GENE THERAPY

There are a number of diseases which can be caused by using specific biochemically synthesized medicine. The development of recombinant therapeutic biochemicals viz. insulin, interferon, somatotropin, somatostation, endorphin, human blood clotting factor, immunogenic proteins etc. have open new arena in human health care sector. In last two decades of nineteenth century there is remarkable advancement in recombinant DNA technology has developed and made possible to transfer genes for treatment of human diseases.

PHARMACOGENOMICS

Pharmacogenomics (pharmaco+genomics) is the study of the role of the genome in drug response. Pharmacogenomics analyzes how the genetic makeup of an individual affects his/her response to drugs.

BIOMEDICAL INNOVATIONS

A biomedical innovation is an innovation that specifically involves medicine or other ways of improving health.Biomedical innovations serve to maintain and improve the health of those that they affect.

- **Monoclonal Antibodies**

Monoclonal antibodies (mAb or moAb) are identical immunoglobulins, generated from a single B-cell clone. These antibodies recognize unique epitopes, or binding sites, on a single antigen. Derivation from a single B-cell clones and subsequent targeting of a single epitope is what differentiates monoclonal antibodies from polyclonal antibodies.

- **Viral Vector Manufacturing for Gene Therapies**

Viruses are infectious agents that can only replicate inside of living cells. This trait is used by molecular biologists for delivery of genetic materials into cells. Viral vectors are also explored for use in gene and cell therapy and as basis for prophylactic and therapeutic vaccines. In gene therapy, viral vectors can be used for delivery of functional genes to replace defective genes to cure genetic disorders.

APPLICATION OF MEDICAL BIOTECHNOLOGY

a. Diagnostic of diseases
b. Prevention of diseases
c. Treatment of diseases

a. Diagnostic diseases

Disease diagnosis refers to identification of the cause of the disease. Conventional methods include microscopy, culture of specimen and testing for sensitiveness, several immunological assays etc. But these conventional mechanisms often have negative aspects like being tedious; taking longer time etc. In order to overcome this, various biotechnological approaches has been developed.

➢ **Polymerase Chain Reaction (PCR)**

PCR is an efficient, simple and inexpensive tool used to amplify the desired sequence or sequences of DNA into billions of identical copies. It essentially employed for checking STRs, SNP in different breeds, parentage identification; genetic mutation, etc. The principal constituent of the PCR are the

DNA template, primers (forward and reverse), Taq polymerase enzyme, and the PCR machine (Thermocycler) which sustains the ideal temperature for each step in every cycle (Fig. 4).

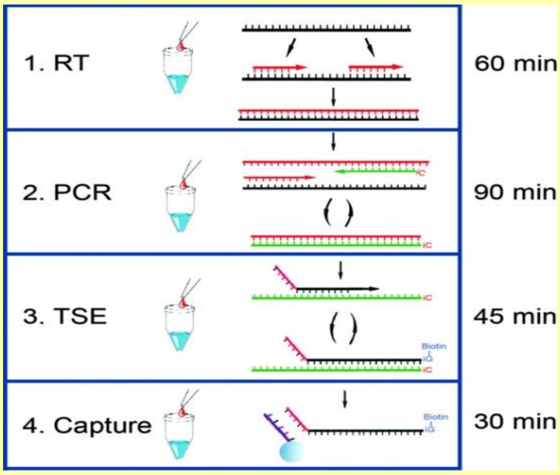

Figure: 4 Steps of Polymerase Chain Reaction
Source: https://jcm.asm.org

➢ Antigen-capture enzyme-linked immunosorbent assay (ELISA)

The antigen-capture enzyme-linked immunosorbent assay (ELISA) facilitates detection of antigen from pathogens directly from an animal prior to or during clinical disease. The ELISA commonly follows a sandwich assay format using capture and detecting antibodies (either specific MAbs or polyclonal antibodies). Antigen from the test sample is first captured by a specific MAb or polyclonal antibody bound to a solid-phase support and its presence is detected through use of a second MAb or polyclonal antibody, which may either be radio- or more generally, enzyme-labelled (conjugated) (Fig. 5).

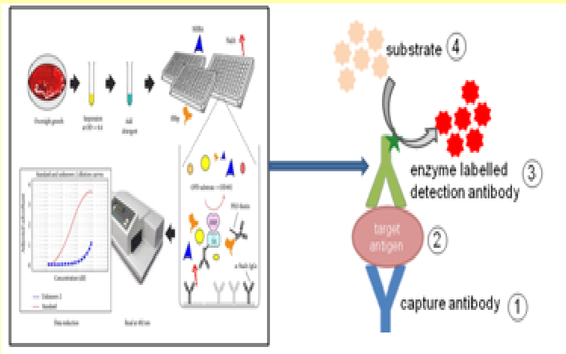

Figure: 5 Antigen-capture Enzyme-Linked Iimmunosorbent Assay (ELISA)

➢ In Situ Hybridisation

This technique involves tagging a single-stranded DNA or RNA with a radioactive molecule (probe). This then hybridizes with its complementary DNA in a clone of cells. On detection using autoradiography, the clone with the mutated gene will not appear on the photographic film because the probe is not complementary to the mutated gene.

➢ DNA Profiling/ finger printing

DNA is the master molecule of all life forms and constitutes the blue prints of every living forms and passed generation to generation. The technology that facilitates the identification of individuals at genetic level is known ad DNA fingerprinting of DNA profiling. This genetic analysis is based on identification of small conserved segments of the hereditary material which have the unique unaltered molecular signature. The DNA finger printing techniques has application in several areas like, (1) setting of genetic databank (ii) Reuniting of lost children (iii) solving disputed problem of parentage identify of criminals (iv) immigrant disput (v) Proper identification of fossilised species etc.

b. Prevention of diseases

Vaccines are used to stimulate immune system for a particular or group of disease disease through applying of avirulent strains of microorganisms or viruses. Modern techniques use specific genes of microorganisms cloned into vectors and mass-produced in bacteria to make large quantities of specific substances to stimulate the immune system. The substance is then used as a vaccine. In some cases, such as the H1N1 flu vaccine, genes cloned from the virus have been used to combat the constantly changing strains of this virus (Fig.6). The different types of vaccines are:-

- Whole organism vaccine: Live, attenuated vaccine

- Partial organism: Protein coat only
- Recombinant: Produced by genetic engineering.

Figure: 6 Different Vaccines

c. Treatment of diseases

✓ Stem cells

Stem cells are mother cells that have the potential to become any type of cells in the body. It can can become cells of the blood, heart, bones, skin, muscle, brain, etc. It also can can repair and replace tissue in human body. The easiest place to get stem cells is from an embryo.

Stem cells are introduced into a damaged area of the body where, under the right conditions, will replace the damaged area. Some timescells are grown in a lab first to ensure the right conditions and then placed into a sick person (Fig. 7).

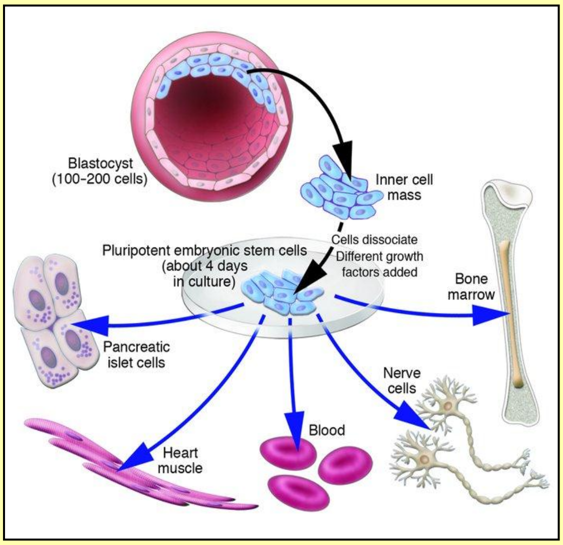

Figure: 7 Different stem cells
Source: https://www.jci.org

✓ Cloning

The term cloning describes a number of dif-ferent processes that can be used to produce genetically identical copies of a biological en-tity. The copied material, which has the same genetic makeup as the original, is referred to as a clone. Cloning in biotechnology refers to processes used to create copies of DNA frag-ments (molecular cloning), cells (cell cloning), or organisms (Fig. 8).

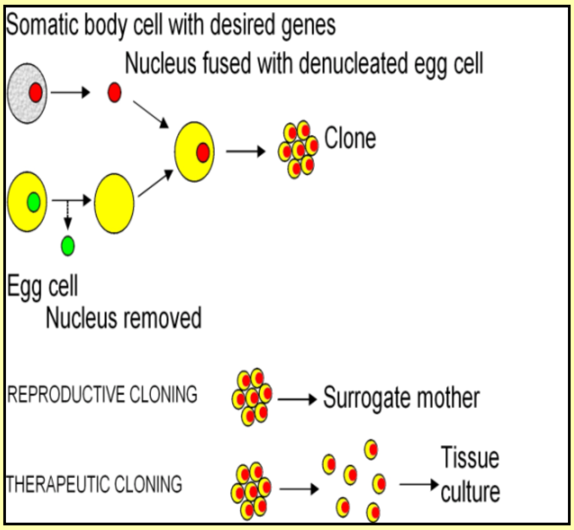

Figure: 8 Steps of cloning
Source: http://psychology.wikia.com

✓ Antibiotics

Antibiotics kill pathogenic microorganisms which are naturally produced by some other microorganisms, *viz.* the *Penicillium* fungi is well-known to produce penicillin antibiotics. Antibiotics are produced on a large scale by cultivating and manipulating fungal cells. The fungal cells have typically been genetically modified to improve the yields of the antibiotic compound (Fig. 9).

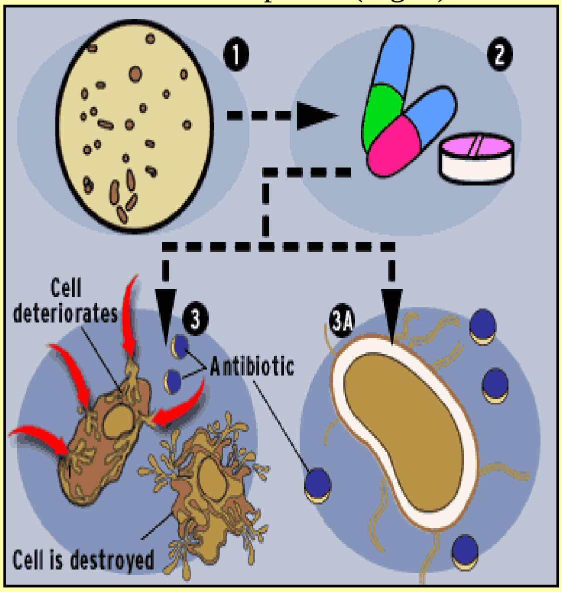

Figure: 9 preparation of antibiotics
Source: http://www.cbsnews.com/

INVITED ARTICLE - 1

PUBLIC HEALTH CONCERN OF BIOMDICAL WASTES AND ITS MANAGEMENT

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Waste generated during the diagnosis, treatment, or immunization of human beings or animal research activities or in the production or testing of biological or in health camps are grouped as Biomedical wastes (BMW) (Fig.1.1). Indiscriminate disposal of BMW or hospital waste and exposure to such waste possess serious threat to environment and to human health that requires specific treatment and management prior to its final disposal.Biomedical waste management has recently emerged as an issue of major concern not only to hospitals, nursing home authorities but also to the environment. The bio-medical wastes generated from health care units depend upon a number of factors such as waste management methods, type of health care units, occupancy of healthcare units, specialization of healthcare units, ratio of reusable items in use, availability of infrastructure and resources etc.The hazardous part of the waste presents physical, chemical, and/or microbiological risk to the general population and health-care workers associated with handling, treatment, and disposal of waste (Li and Jenq., 1993).

Figure: 1.1 Types of Biomedical Waste

The Biomedical wastes have many adverse and harmful effects to the environment including human beings, animals and birds.There are potential risks associated to individuals exposed to hazardous BMW directly or indirectly through careless management. The main groups exposed to risks are doctors, nurses, healthcare unit workers and maintenance staff; patients; visitors; workers in allied services example laundry, medical supplies store, waste handling and transportation and service workers dealing with waste treatment and disposal of health unit.

The proper management and disposal of biomedical wasted should be urgently required for environmental healthcare. A major issue related to current Bio-Medical waste management in many hospitals is that the implementation of Bio-waste regulation is unsatisfactory as some hospitals are disposing of waste in a haphazard, improper and indiscriminate manner. The unmanaged segregation of BMW and mixed with general municipality wastes through lack of expertise results the whole waste into hazardous and contaminated the environment. The problems of the waste disposal in the hospitals and other health-care institutions have become issues of increasing concern (Chandra, 1999). Inadequate Bio-Medical waste (Fig.1.2 & 1.3) management thus will cause environmental pollution, unpleasant smell, growth and multiplication of vectors like insects, rodents and worms and may lead to the transmission of diseases like typhoid, cholera, hepatitis and AIDS through injuries from syringes and needles contaminated with human (CEET., 2008). Rag pickers in the hospital, sorting out the garbage are at a risk of getting tetanus and HIV infections. The recycling of disposable syringes, needles, IV sets and other article like glass bottles without proper sterilization are responsible for Hepatitis, HIV, and other microbial diseases. It becomes primary responsibility of Health administrators to manage hospital waste in most safe and eco-friendly manner (CEET, 2008).

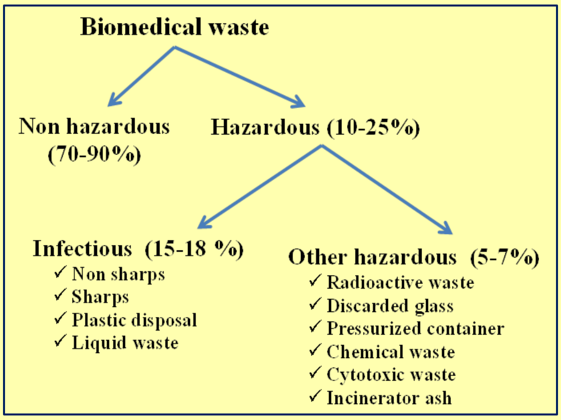

Figure: 1.2 Classification of Biomedical Waste

Types of biomedical wastes

- ✓ Human anatomical waste
- ✓ Animal waste
- ✓ Microbiology and biotechnology waste
- ✓ Waste sharps
- ✓ Discarded medicine and cytotoxic drugs
- ✓ Soiled waste
- ✓ Solid waste
- ✓ Liquid waste
- ✓ Incineration ash
- ✓ Chemical waste

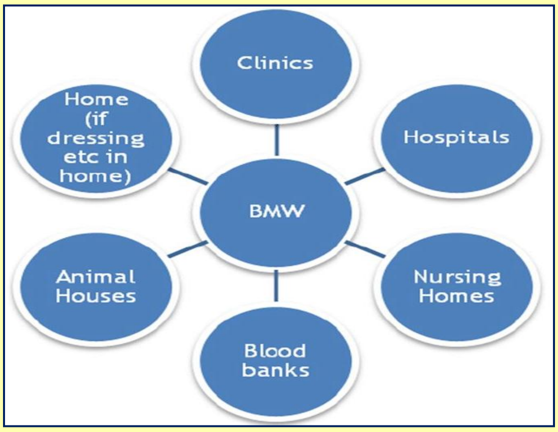

Figure: 1. 3 Source of biomedical Waste

Source:http://biomedjournal.com/wp-content/uploads/2015/02/Figure11.png

Biomedical waste management

There are five basic methods for biomedical waste processing and management.

i) **Incineration**: This was the method of choice for biomedical waste management in the 1990's and before. New EPA regulations have caused a shift to other methods, but it's still the only way to treat pathological waste like human tissue, blood, or body parts.

ii) **Autoclave:** Non-pathological waste can be rendered non-infectious through steam sterilization. Afterward, it can be taken to landfills as regular non-biomedical waste.

iii) **Microwave**: High-powered microwaves can neutralize non-pathological biomedical waste for disposal in solid waste landfills.

iv) **Chemical**: This method is largely reserved for treating chemical medical waste.

v) **Biological**: An experimental method treats some biomedical waste with enzymes, though it's still in the developmental phase.

The scientific management of biomedical waste has become a worldwide humanitarian topic today. The poor management of hazardous biomedical waste have aroused the concern world over, especially in the light of its far-reaching effects on human, health and the environment. The basic principle of good BMW practice is based on the concept of **3Rs**, *i.e.* **Reduce, Recycle** & **Reuse**. The best BMW management (BMWM) methods aim at avoiding generation of waste or recovering as much as waste as possible, rather than disposing. Medical care is vital for our life and health, but the waste generated from medical activities represents a real problem of living nature and human world. Improper management of waste generated in health care facilities causes a direct health impact on the community. Every day, relatively large amount of potentially infectious and hazardous waste are generated in the health care hospitals and facilities around the world. Therefore, the various methods of BMW disposal, according to their desirability, are prevented, reduce, reuse, recycle, recover, treat, and lastly dispose. Hence, the waste should be tackled at **source** rather than '**end of pipe approach**' (Chartier, et al., 2014). Only about 10%–

25% of BMW is hazardous, and the remaining 75%–95% is nonhazardous.

According to the Ministry of Environment Forest and Climate Change (MoEF& CC) the generation of BMW in India is 484 TPD (Tons/ day) from 1,68,869 healthcare facilities (HCF), out of which 447 TPD is treated, which means that almost 38 TPD of the waste is left untreated and not disposed finding its way in dumps or water bodies and re-enters our system.

In the World Health Organization (WHO) meeting at Geneva, in June 2007, core principles for achieving safe and sustainable management of health-care waste were developed. It was stressed that through right investment of resources and complete commitment, the harmful effects of health-care waste to the people and environment can be reduced. All stakeholders associated with financing and supporting health-care activities are morally and legally obliged to ensure the safety of others and therefore should share in the cost of proper management of BMW. In addition, it is the duty of manufacturer to produce environment-friendly medical devices to ensure its safe disposal. WHO reinforced that government should designate a part of the budget for creation, support, and maintenance of efficient health-care waste management system. These include novel and ingenious methods/devices to reduce the bulk and toxicity of health-care waste. Nongovernmental Organization should undertake program and activities that contribute in this incentive (WHO. 2004).

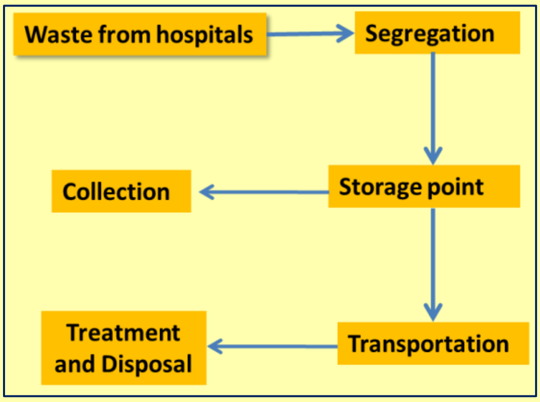

Figure: 1.4 Flow chart of BMW management

Salient Features of Bio-Medical Waste Management (Amendment) Rules, 2018:

- ✓ Bio-medical waste generators will have to phase out chlorinated plastic bags & gloves by March 27, 2019. Blood bags are exempted for phase-out, as per the amended BMW rules, 2018.
- ✓ All healthcare facilities shall make available the annual report on its website within a period of two years from the date of publication of Amended Rules 2018.
- ✓ Operators of common bio-medical waste treatment and disposal facilities shall establish bar coding and global positioning system for handling of bio-medical waste in accordance with guidelines issued by the Central Pollution Control Board by March 27, 2019.
- ✓ The State Pollution Control Boards have to compile, review and analyse the information received and send information to the Central Pollution Control Board in a new Form, which seeks detailed information regarding district-wise bio-medical waste generation, information on Health Care Facilities having captive treatment facilities, information on common bio-medical waste treatment and disposal facilities.
- ✓ Every occupier, *i.e.* a person having administrative control over the institution and the premises generating biomedical waste shall pre-treat the laboratory waste, microbiological waste, blood samples, and blood bags thru disinfection or sterilization on-site in the manner as prescribed by the WHO or guidelines on safe management of wastes from health care activities and WHO Blue Book 2014 and then sent to the Common bio-medical waste treatment facility for final disposal (Fig. 1.4).

Effect of BMWto the Environment

The improper management of bio-medical waste causes serious environmental problems in terms of air, water and land pollution. The pollutants are mainly classified into biological, chemical and radioactive. Environment problems can arise due to the generation of bio-medical waste from treatment and disposal. Indoor air pollutants like persistent of pathogens in the air of hospital/institution for a long period in the form of spores or as pathogens itself. The open burning and incinerators of BMW are the outdoor pollution causing sources.

Water pollution is another major threat from Bio-medical waste. The dumping of BMW in low-lying areas, or into lakes and water bodies, can cause severe water pollution in surface and ground water due to leaching of biological, chemicals or radioactive substances.Harmful chemicals present in biomedical waste such as heavy metals can also cause water pollution.

Land Pollution is caused by the final disposal of all bio-medical waste. Even liquid effluent after treatment is spread on land. Hence, pollution caused to land is inevitable. Open dumping of biomedical waste is the main cause for land pollution.

Conclusion

Biomedical wastes are highly hazardous and put people under risk of fatal diseases. The understanding of medical waste management and control techniques is mandatory for healthy humans and cleaner environment. Proper management of BMW through identification, segregation at the source of generation, collection in prescribed colored containers, safe transportation, appropriate treatment and environmentally sound disposal must be ensured. Hospital/institutes producing BMW must have adequate handling and disposal training to all categories of personnel with proper awareness. Awareness and training should be conducted in appropriate language/ medium and in an acceptable manner. All the medical professionals must be made aware of BMW new rules. The refuse disposal cannot be solved without public awareness education. Municipality and Government should pay importance to scientific and economically disposal of waste. Proper and safe management of BMW is a key issue to control and reduce infections inside a hospital and to ensure that the environment outside is well protected.

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INVITED ARTICLES - 2

IMPACT OF MEDICAL BIOTECHNOLOGY ON SOCIETAL ECONOMY- A CRITICAL NOTE

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Social economical structure, more precisely bio-econimocal structure relates to the innovation and applications of bio-products in the field of agriculture, medical, industrial sectors as well as different societal activities of the related population. As a whole biotechnology can support production of new-age bioproducts for economic growth, employment and change of societal approach for the application of health machineries. Past few decades of biotechnological innovations led to the development of modern thoughts of disease diagnosis based on molecular changes rather than mere symptomatical observation and treatment.

The emergence of this sector in mid 1970s configures the economy of scientific promise. It was previously thought to leave the ‘basic’ science to be proceeded towards the prediction of fulfillment of societal needs in long timeframe. But in late 1970s commercial development of new medicines, diagnostic services as well as commodities became identified as the matter of economic prospect of innovation based industrial emergence. In 1980s the biotechnology sector got its ground on completely novel form characterized by interlinking threads between basic science and market oriented research and development of new commodities for betterment of human health. In 1980s and 1990s rapid development in the technical aspect of molecular biology the scope in biotechnological promises got fulfilled basically focusing on recombinant DNA technologies. In mid 1980s mapping and cloning of rare gene disorders like Hungtington's disease or Duchenne Muscular dystrophy, Cystic fibrosis encouraged the biotechnologists to expand in common health problems including cancer and heart diseases. They were very much optimistic about the identification and cloning of related genes. In mid 1980s the commercial market analysis projected a huge growth of medical diagnostic market for the common diseases whereas in 1990s exceptional market prediction was made in the field of gene therapy. During this period a second wave of biotechnological investment done by many big pharmaceutical companies like Incyte pharmaceuticals, Human genome sciences, Millennium Pharmaceuticals, Celera Genomics etc emphasizing on commercialization of genomic discovery itself.

The academic genome research organizations were also benefitted in many ways by private as well as public funded projects. Human Genome project; International Haplotype Mapping projects as well as National biobanks showed remarkable convergence in private and public sector coalition in genome research. But those funding were obsessed with the rhetoric that overshadowed the public interest over the private profits. At the same time the genomic scientists raised the question on individual genomic differences and health risks and indicated the pave way towards the issue of personalized preventive measures. The science of pharmacogenomics prescribed the use of most suitable drugs for individual constitutions reducing the prescription of ineffective wasteful drugs leading to reduction of costs for drug reaction. So concept of "personalized medicine" contradicts many factors like distinctive alignment of personal health with the economic efficiency of profitable health care and pharmaceutical products. But it is not clear whether the new treatments through population stratification and "translational medicine" limits the assessment of agencies about cost effective business and the cumulative costs of such medicines poses a major challenge towards the resources of health system.

Medical biotechnology has tremendous power to generate knowledge and to solve the health and economic development issues in developing countries if we rise to the challenge. Although the need of developed vs developing countries are quite different on issues like health policy and review; relationship and implication of traditional medical practices; grave concern over government policies and ethical issues related guidelines; education of common people and finally the access of citizens to the knowledge of biotechnology. These developing countries have low biotechnological machineries with low capacity of solving biosafety issues. Considering the wide context of developing countries like India the research activities should be sharply focused on the ethical requirement of research that could concern with greater part of population. It is true in inner sense that there is fast growing weightage on interdependence of growing economy and scientific innovation more than any ethical concern. But any state should have reflection that globalization is the means of growth on the mountain base of social and human ethics.

FORTHCOMING EVENTS		
Events	**Date**	**Place & Correspondence**
25th Asia Pacific Biotechnology Congress	May 01-02nd, 2019	ANA Crowne Plaza Kyoto, Japan https://asiapacific.biotechnologycongress.com/
6th World Congress onSynthetic Biology and Advanced Biomaterials	May 13-14th, 2019	Melbourne, Australia https://syntheticbiology.conferenceseries.com/asiapacific/
637th International Conference on Environment and Natural Science (ICENS)	June 28 - 29th, 2019	Goa, India http://iastem.org/Conference2019/India/3/ICENS/
2nd Annual Biotechnology Congress	July 31-Aug 01, 2019	Chicago, USA https://annualbiotech.conferenceseries.com/

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