Pharmacoinformatics and Drug Discovery Technologies:

Theories and Applications

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Chapter 18

Pharmaco-EcoMicrobiology and Its Potential Role in Medical and Environmental Sciences

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ABSTRACT

Despite the call of the World Health Organization (WHO) for "Pharmacovigilance," i.e. the monitoring, detection, assessment, and prevention of any adverse reactions, poor attention has been given to identify the long term and short term Adverse Effects (ADEs) of antimicrobial agents on the environment. It is obvious that most of the health sectors across the globe are occupied by infectious diseases (e.g. tuberculosis, HIV, and hepatitis), and to combat such threats, the pharmaceutical industries are pouring tons of drugs and reagents into a market worth billions of dollars. The discharge of these products into the ecosystem is potentially a threat to the environment and human health. In this chapter, the authors depicted a recently described terminology, "Pharmaco-EcoMicrobiology" (PEcM), that could cover these problems and their possible solutions on medical and environmental aspects. In this regard, the role of pharmacoinformatics could also be crucial, since it can provide swift information for implementation and use of information technologies for the discovery and development of drugs as well as in pharmacy education and also the detection and combat of adverse drug effects.

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INTRODUCTION

The World Health Organization (WHO) defined ‘‘Pharmacovigilance’’ activities as the monitoring, detection, assessment, understanding and prevention of any adverse reactions to drugs at therapeutic concentration on animals and humans (Mann & Andrew, 2002). Inadequate attention has been given to identifying the long term and short term Adverse Effects (ADEs) of antimicrobial agents on the environment (given at therapeutic doses). Furthermore, the continuous spread of various infectious diseases such as MDR, XDR, sputum positive pulmonary tuberculosis, avian influenza, H1N1, NDM-1, hepatitis, and also bird flu, along with other veterinary microbial/viral diseases (or drug based animal pandemics), could be attributed to the interactions called Pharmaco-EcoMicrobiology (i.e. the interaction between therapeutic wastes with environment). The severity of these interactions could have various grades of consequences, which varies from milder form to irreversible environmental damage disturbing the homeostasis of the ecosystem. These changes could result into the evolution of new drugs and antibiotic resistant species of various flora and fauna, which have the potential to alter the disposition of pre-existing interactions called *k* and *r*-selections.

In this chapter, we tried to depict a more elaborative terminology that can cover the entire problem and its possible solutions in medical aspects. In this regard, the role of pharmacoinformatics is crucial, since it can provide swift information for implementation and use of information technologies for the discovery and development of drugs as well as in pharmacy education. A great effort has been made by Rahman et al. (2007) to enunciate the new term “Pharmacoenviromentology,” which covers the environmental impact of drugs given to humans and animals at therapeutic doses (Rahman, Khan, Gupta, & Uddin, 2007). However, we found at the same time that this is partial towards environmental damage, not describing in detail the more important aspect of infectious- and resistant- diseases. Hence, there is an urgent need to elaborate the relation of Pharmacology and Medical Microbiology keeping in view the importance of Ecological balance, since the outbreak of recent epidemics and their association with contamination of environment by pharmaceutical metabolite (discharge) have come to light. In the existing literature, the terminology “Pharmaco-EcoMicrobiology” has been given as a broad spectrum platform that defines the interplay between antimicrobial pharmacological agents and animate microbial ecology (Mann & Andrew, 2002; Shahid, Khardori, Tripathi, & Bergman, 2010). This new domain, ‘‘Pharmaco-EcoMicrobiology,’’ has been derived by the aggregation of three important branches of life science, i.e. pharmacology, ecology, and microbiology, which would be responsible for studying the Adverse Drug Effects (ADEs) due to antimicrobial drugs disposed in the environment due to human negligence (Mann & Andrew, 2002). The role of PEcM is important in dealing with the issues of harm associated with the use of given medications and assists in avoiding the hazards of adverse drug reactions. The lack of information and infrastructure for educating pharmacists and medical practitioners about the potential risk of dosage of drugs, which invariably affects the health of the patient, is of major concern in medical community. Pharmaco-EcoMicrobiology (PEcM) can provide an indispensable support for carefully monitoring adverse drug events and their potential danger in damaging the environment.

Keeping in view of the already available literature focusing on the association of pharmaceutical discharges to the environmental damage, the present hypothesis elaborates the association of these discharges on the spread of infectious diseases, drug resistant microbes/virus, and their effect on human health and environment. There is an urgent need to elaborate the more important relationship of infectious microbes and their resistant strains with pharmaceutical waste disposal in environment. Thus, the management of infectious diseases (which are emerging as a big challenge for mankind) and its exacerbation by environmental damage due to chemical and pharmaceutical discharges are opening a new window for researchers to strike a balance between Pharmacology and Medical Microbiology, keeping the safety of the environment at the helm. The safety board for regulating drug therapies and supervising the damage control to the environment by hazardous medical discharge usually do not have any associative linkage, which could carefully monitor the whole setup of drug development and their downstream effect after their discharge into the environment. During the development of new drugs, often the more specific sites and targets are under consideration, ignoring the deteriorating effect of these new therapies on environment. These issues are essential in view of increasing toxicity by air and water pollution, which is increasingly becoming a major health problem in many cities across the world.

INTERRELATION AMONG PHARMACOLOGY, MICROBIOLOGY, AND ECOLOGY, AND THEIR IMPLICATIONS IN MEDICAL SCIENCE

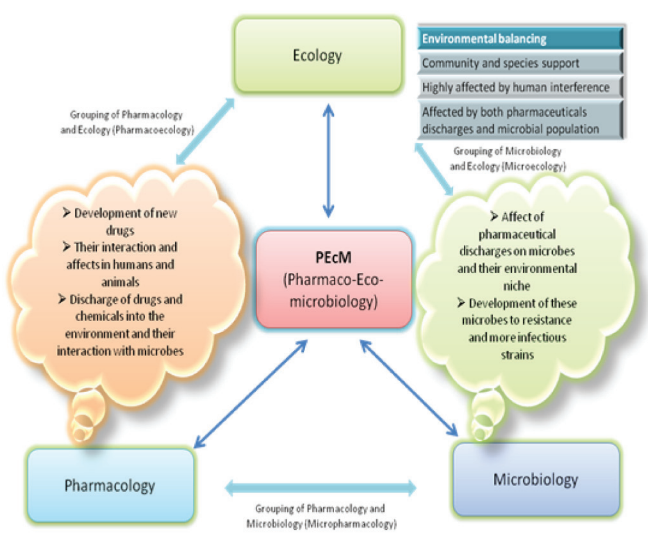
For the sake of defining Pharmaco-EcoMicrobiology (PEcM) it is quite obvious to dig down all the three branches of life science so that the requirement of such terminology can be explained (Figure 1). As already described, Pharmacology is the study of drugs and their effects on humans and animals (Vallance & Smart, 2006). Even though drugs play a crucial role in fighting diseases in humans and animals, they also pose major health hazards when their degraded discharge contaminates our environment (water, sewage, and air) and imbalances the ecological system. Major risks of pharmacological waste need not to be from drugs and antibiotics, but they may be in the form of any other chemicals that are released from household and personal care products (i.e. shampoos, conditioners, perfumes, etc.) (Shahid, Tripathi, Sobia, Singh, Malik, & Khan, 2008). The rapid growth of the world wide web as a tool for global connectivity has affected the way in which health-related information is distributed and accessed over the internet. Many informatics and internet applications are now available for use by both health-care professionals and patients, with many people using the internet to search for drug-related and other health-related information. The practice of pharmaceutical care aims to ensure optimum medication-related therapeutic outcomes in patients, and involves identifying, solving, and preventing potential or actual Drug-Related Problems (DRPs) with regards to a patient's drug therapy. Pharmacoinformatics involves the use of informatics, the internet, and interactive technologies to solve DRPs, with a focus on providing optimum pharmaceutical care and improved patient safety. This chapter highlights the different pharmacoinformatics channels that have been used in the provision of pharmaceutical care (http://linkinghub.elsevier.com/retrieve/pii/S1470204509701044). Hazardous waste is the waste that is dangerous or potentially harmful to our health or the environment. They can be liquids, solids, gases, or sludge. They can be discarded as commercial products, like drugs or pesticides, or the by-products of manufacturing processes (EPA, 2011a). The present method employed for waste management is not ideal to deal with such issues. If we look from a microbiological point of view, the medical waste from hospitals and research facilities are suspected to affect the growth and transmission of many microbes. Even the metabolized or degraded form of these drugs is supposed to cause resistant in some microbes, making the transmission incurable by current therapeutic treatments (EPA, 2011b). Ecological projection on this issue is always being ignored, and there is an urgent need to formulate strategic guidelines before the conditions become unmanageable.

These waste products, as we mentioned, affect adversely on human health and are responsible for the damage of local flora fauna and aquatic life. Altogether, the discharge of pharmacological and medical wastes is needed to be kept under strong check to avoid the mutilation of ecology and danger of more challenging infections. Thus, covering of all these three major projections (as indicated by the terminology of PEcM) is indeed a vital issue for policy makers.

APPLICATION OF PEcM IN APPLIED MEDICINE

Most of the health sectors across the globe are completely occupied by the infectious diseases (e.g. tuberculosis, HIV, and hepatitis). The pharmaceutical industries are pouring tons of drugs and reagents into a market that is worth billions of dollars. The discharge of these products into the ecosystem is potentially a threat to the environment and human health. We do examine the threat of these chemical discharges to human health, but more often we ignore their detrimental effects on aquatic life and local flora-fauna, which poses substantial danger to the ecosystem as a whole. Being an important member in the chain of ecosystem, humans hold the responsibilities to look forward to the safety and benefit of the other species too (which is to our own benefit). The WHO has suggested environmental pharmacology that deals with standard operating procedures for hospitals and research facilities waste disposal (Rahman, Khan, Gupta, & Uddin, 2007; Rahman & Khan, 2006). But regulatory authorities are not strictly following these Standard Operating Procedures (SOPs) to check the discharge of harmful chemicals into the water and air, which could cause a drastic condition for other species as well as for humans. Many incidents of tons of discharge into the environment have come across in developed countries and now these incidences are growing day by day in developing nations also (Hindu, 2010; Dean, 2007). Medical sciences have not yet developed single step drugs for tuberculosis, which means the patient is subjected to a combinational therapy of 4 to 5 antibiotics for a time period of 6 to 9 months, which ultimately increases the cost of treatment along with production of tons of

Figure 1. Different projection including work that can be carried out in all three different branches, i.e. pharmacology, ecology, and microbiology



antibiotics (which are less effective alone) every year. Such a high scale production is likely to ultimately get discharged into the environment, posing a threat to human health and other communities of the ecosystem (Science Daily, 2010).

Furthermore, the emergence of resistant strains of tuberculosis and other diseases along with epidemics and seasonal flus, which claim hundreds of thousands of human lives every year are responsible for enormous drugs production. These drugs, after their utilization, get discharged into the environment. Though WHO has given the specific guidelines for the disposal of waste and sterilization of environment (WHO, 2011), mere guidelines will not suffice the urgent need of environmental safety, as specified by a number of incidences, especially in developing (also in developed countries) countries, where these guidelines are just pieces of paper. Since we are losing human and animal lives, the PEcM should not be taken as a terminology but rather it should be a matter of immediate attention well above all the disputes of all the countries of the world.

RELATION OF PHARMACO-ECOMICROBIOLOGY (PEcM) WITH PHARMACOINFORMATICS

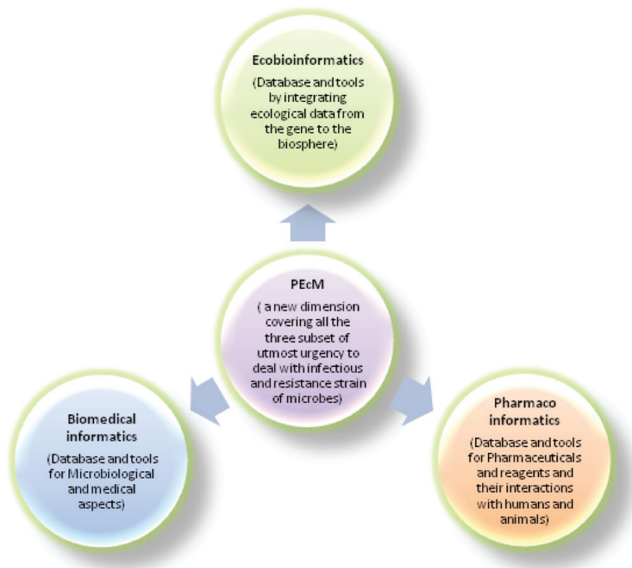
Bioinformatics covers the creation and advancement of databases, algorithms, computational and statistical techniques, and theory to solve formal and practical problems arising from the management and analysis of biological data (Bioinformatics, 2011). Bioinformatics is emerging as a source of scientific hub that provides the storage and establishment of relationships between the experimental hypotheses and outcomes. Common activities in bioinformatics include mapping and analyzing DNA and protein sequences, aligning different DNA and protein sequences to compare them and creating, and viewing 3-D models of protein structures. Currently Bioinformatics is used as follows (Whittaker, 2003):

- In drug target identification and validation
- In the development of biomarkers
- In toxicogenomic and pharmacogenomic tools to maximize the therapeutic benefit of drugs.

The tools for bioinformatics need to be improved to save and analyze the data for drug interaction with environment (especially interaction to communities of the ecology other than humans) and its role in drug resistant strains of infectious microbes. In that scenario, Pharmacoinformatics could provide an extra edge to the regulatory authorities around the globe that are responsible for managing the contamination rate of the environment by hazardous Pharmacological and Medical wastes. With the advent of terminologies like Ecoinformatics and pharmacoinformatics, it is well established that the role of computer science and informatics are very useful for scrutinizing the dosage of drugs and their related adverse effect. Ecoinformatics is actually a new bioinformatics integrating ecological data from the gene to the biosphere; on the other hand, biomedical informatics seeks to combine classic bioinformatics with healthcare and clinical information. PEcM, as an immediate issue of high concern, can be only dealt with effectively by using the tools of bioinformatics for establishing the well-built bond between all three subsets of PEcM (Figure 2).

In a nutshell, apart from improving tools of sterilization and sanitation, new treatment regimens and therapies need to be improved. One of the remedies for this draconian problem of environmental terror by pharmacobiological waste could be the development of more target specific genomic medicines and small nanotechnology drugs. Such kinds of drugs may discontinue the high dose current therapy format, which subse-

Figure 2. Relation of PEcM with the advent of terminologies of bioinformatics



quently reduces the risk of environmental pollution by post treatment discharge into the ecosystem. Not only medicines but eco-friendly pesticides, fertilizers, and personal care products should be used in general practice to avoid environmental damage and the danger of microbial resistance.

ROLE OF DRUG ADULTERATION AND UNQUALIFIED MEDICAL PRACTITIONERS IN RURAL AREAS OF DEVELOPING NATIONS AND THEIR DETRIMENTAL EFFECTS ON HUMAN HEALTH AND ECOSYSTEM

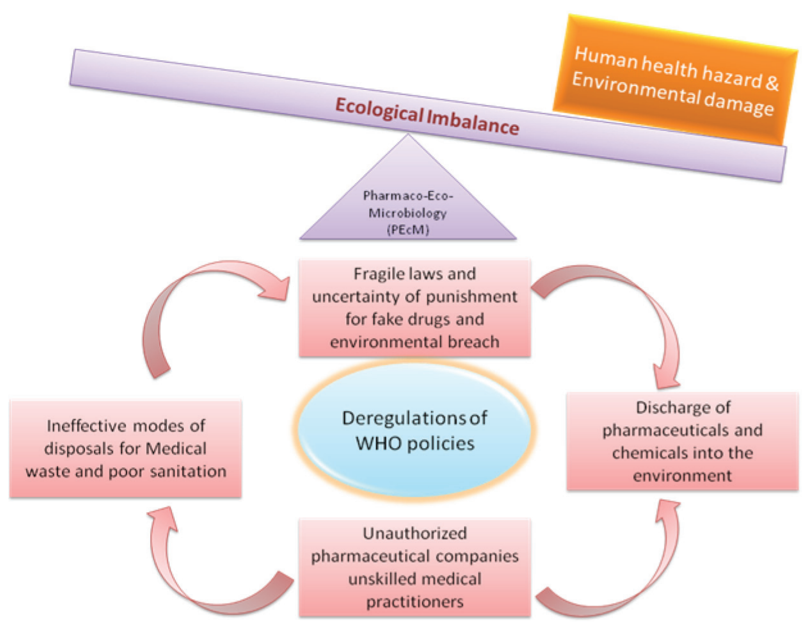
Drug adulteration could be major source of development of resistance in microbes that cause infection. Many such cases of heaps of adulterated drugs, which are caught by administrations, have come to light in many cities across India in year 2009-2010 (Reuters, 2010). Such pharmaceutical forgery not only increases the chances of health problems by ineffective regimen but may also increase the chances of more severe to resistant diseases. The outbreak of XDR (Extreme Drug Resistance) in Tugela-Ferry and Kiletcha provinces of South Africa (African Liberty, 2009) amazed the whole world. Lack of stringent laws and uncertainty of punishments are the main reasons for drug forgery and environmental breach. These emergent and vibrant issues where human lives are at stake completely ignores the environmental damage by discharge of these fake drugs into the water and air, initiating the bigger crisis. On the other hand, one of the prominent fears persisting in densely populated developing nations is that of unauthorized pharmaceutical companies and unqualified medical practitioners. The doctor to patient ratios in these countries are high, and to an extension to that, in resource limited settings often unqualified medical professionals can do the incorrect diagnosis leading to a detrimental effect on the patient's health (Figure 3). In this view, medical agencies should disseminate skills to the unskilled workers so that incorrect diagnoses can be avoided, and the use of adulterated drugs can be discontinued. While in resource limited settings especially the rural and remote areas, medicinal herbs, homeopathy, ayurved, and unani medicines can be used as an alternative to allopathic medicines. Such therapies are effective, have less side effects, and are environment friendly. Unless there is a question of emergency medicines, the aforementioned therapies can be used as cost effective measures and are also environment friendly.

DETRIMENTAL EFFECT OF CHEMICALS ON THE ENVIRONMENT AND LIVING ORGANISMS

What is Acid Rain, and what are Its Effects?

Several industries and emissions from vehicles give rise to an increase of SO_2 and nitrogen oxides in the air. These emissions change into sulphates and nitrates under the influence of sunlight and moisture, and get converted into sulphuric acid and nitric acid, which come down as acid rain. Acid rain was first noticed during the 19th century, when people observed the effects of industrialization on plants and animals. In 1872, the Scottish chemist, Angus Robert Smith used the term "Acid Rain" in his book *Air and Rain: The Beginnings of Chemical Climatology,* and the name has stuck. In the 1960s, fishermen noticed a severe problem of sharp reduction in the quantity of fish in lakes of North America and Europe. It is believed that around 50% of the acid rain that occurs in Canada is due to pollution caused in the United States of America, and the effect of polluting industries in England can be felt in Norway. Natural rainfall has a pH of around 6.0. This is because of the effect of Carbon dioxide in the air, which combines with water to form carbonic acid. The effect of this is negligible, as it is neutralized in the soil by alkaline materials like limestone. However, the other emissions cause the pH of the rain water to drop below 5.5, and at this level, it is considered to be acid rain. The soil cannot neutralize the acidity of the rain water. In some places the acidification is so severe that the pH drops to around 4.0. Rare

Figure 3. Relation PEcM and ecological balance, and deregulation of WHO policies and their detrimental effects on human health and ecosystem

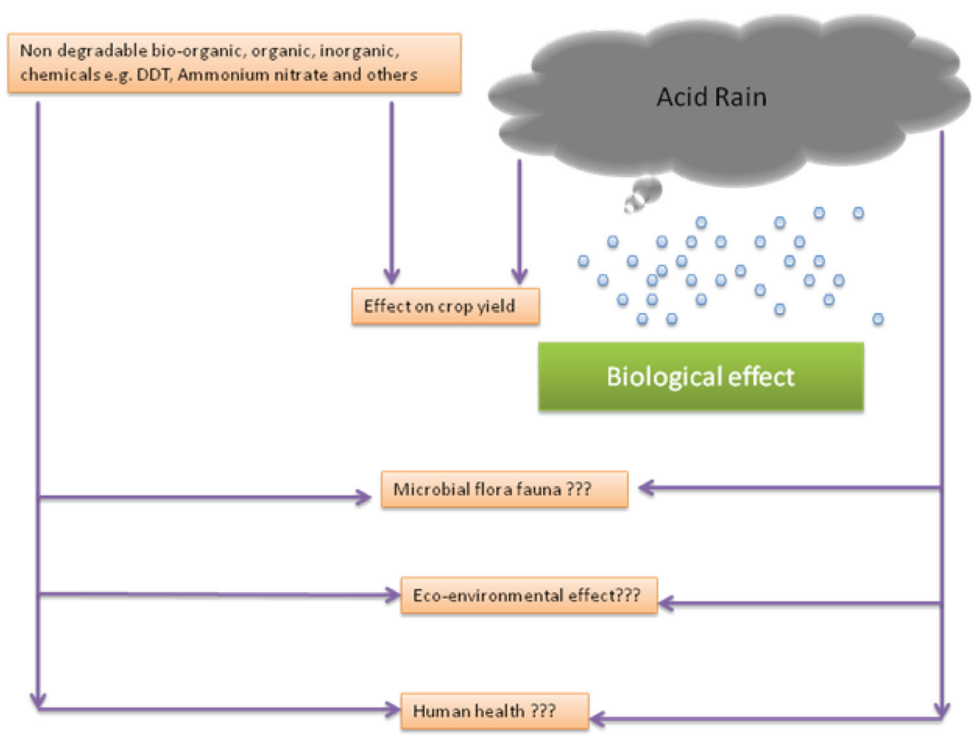


cases have been reported of acid rain having pH of around 2 - 2.5 (Essortment, 2011). Thus, acid rain is very harmful to plant life, aquatic life, and also to human beings (Figure 4).

Effect of Pesticides

Several researchers are in the process of expanding their study to investigate the role of specific types of bacteria in the ecosystem to better understand why certain bacteria are so directly impacted by acidity while others appear relatively unaffected. The pesticides and related chemicals originating from human activity or agricultural farming are discharged directly or indirectly into the receiving waters. The presence of these chemicals in the environment has become a global issue. Field studies have shown that the reproduction, growth, and development of wildlife species, including invertebrates, amphibians, reptiles, fish, birds, and mammals may have been affected by chemicals that interact with the endocrine system. Pesticides at low concentrations may act as blockers of sex hormones, causing abnormal sexual development, abnormal sex ratios, and unusual mating behavior. Pesticides can also interfere with other hormonal processes, such as the thyroid, and its influence on bone development (Ewing, 1999). Chemicals are capable of blocking the action of hormones in fish, amphibians, and reptiles and causing reproductive dysfunction and abnormal development. They act on target tissues through hormone receptors or nonreceptors, may influence hormone secretion or its clearance from the body. In the last years, a number of deformed frogs have been found in the eastern US and Canada. The cause of mass deformities of transforming frogs remains elusive, but various factors have been implicated, including pesticides and related chemicals. The role of pesticides and related chemicals in amphibian malformations may be of concern due to the high deformity rates as-

Figure 4. Schematic sketch showing effects of chemicals on the ecosystem and environmental factors



sociated with sites where agricultural chemicals have been used. These chemicals can be a major threat to fish, amphibians, and reptiles, and the aquatic environment by reducing productivity and fecundity. Further research is needed to assess the effectiveness of alternative pesticides and related chemicals to diminish the effects on fish, amphibian, and reptilian populations. Studies need to simultaneously consider the benefits to both agricultural and conservation communities; scientists from both communities should provide input to make realistic and informed decisions about the protection and conservation of aquatic biodiversity within agricultural landscapes (Khan & Law, 2005) (Figure 4).

Effects of DDT

Dichlorodiphenyltrichloroethane (DDT) was discovered by the Swiss scientist Paul Müller in 1942. It is a mixture of isomers, principally p,p'-DDT, with lesser amounts of o,p'-DDT. Also, small amounts of the breakdown products DDD and DDE can be found in its formulation. DDT was used during World War II to control typhus which was spread by the body louse. Since then it has been used to control mosquito borne malaria, and was also used as a general agricultural insecticide and pesticide (Pan-UK, 2011). Initially DDT was spectacularly successful particularly in the control of malaria, as well as against agricultural pests. But by the 1950s, resistant problems developed, and during the 1960s, a number of severe environmental problems were recognized leading to wide-ranging restrictions on its use. Recently several studies have shown that DDT and its breakdown products have widespread persistence in the environment, and a high potential for bioaccumulation because of its non-biodegradable disposition (Pan-UK, 2011). It has a reported half-life of 2-15 years in most of the soils. In addition to that, DDT has got a strong affinity towards adipocyte tissues and is difficult to eliminate once it enters the human body. It enters into human body through the edible flora and fauna surviving in a DDT rich environment. Best example is a fish surviving in a pond having high concentration of DDT. The level of DDT in this fish would be higher, which will directly be transfered to the human consuming this fish (Pan-UK, 2011; Working Party on Pesticides Residues, 1996). Many governmental and inter-governmental organisations regard DDT as a major hazard to the environment (Pan-UK, 2011). A documented world survey of 1984 showed that 233 species, mostly insects, were resistant to DDT (Metcalf, 1989). Hence, in present days with cross resistance to various insecticides, it is difficult to obtain accurate figures of resistant species against DDT. It causes several acute and chronic toxic effects in humans as well as animals. Moreover, some studies have demonstrated that DDT is a potent carcinogen, primarily affecting the liver and lungs which has been experimentally proven in animals such as rats, mice, and hamsters (Cornell University, 1994). In addition to that, the US Department of Health and Human Services has also determined that "DDT may reasonably be anticipated to be a human carcinogen" (Working Party on Pesticides Residues, 1996). Considering all these facts, there is a requirement to phase out the use of DDT for any purpose in the environment. In addition to that, appropriate measures should be taken on the diplomatic and scientific levels to neutralize the concentration of pre-existing DDT in the environment. Due to significant increase in the prevalence of cancer in the world, the U.S. Federal government has declared a war against cancer. However, the underestimation of the impact of a pollutant like DDT (e.g. arsenic, lead, etc.) on the prevalence of cancer could further exacerbate the condition. Furthermore, research should be done to categorize such kinds of chemicals as risk factors, confounders, and effect modifiers, which could further help in formulating preventive strategies against such kinds of deadly diseases. The procrastination in the assessment of the effect of these chemicals on the ecosystem and on the prevalence of various diseases could result in irreversible damage to the environment as well as the uncontrolled spread of various fatal diseases, resulting in the increasing morbidity of various flora and fauna and serious adverse impacts on the environment.

Effect of Mutagens on the Environment

Mutations are one of the important components of evolution, which facilitates natural selection of certain species over others by increasing their fitness levels (survival of the fittest). It acts on both intraspecies and interspecies levels. As time passes, only superior species (or individuals of the same species) remain. However, humans, due to their increased brain capacity, thinking, documentation skills, and division of labor, challenge the harmful mutations. The increased survival rate of patients with thalassemia, diabetes, asthma, cardiovascular diseases, several infectious diseases, and various autoimmune diseases are phenomenal. However, the leakage of various mutagens in the environment increases the onus on the management section which could be avoided easily if we follow appropriate precautions. The disposal of various non-biodegradable pesticides, herbicides, radiological wastes, pharmaceutical wastes, and medical wastes are the commonest to increase the levels of mutagens in the environment. Another commonly seen mutagenic chemical is charcoal which is commonly used to build roads where workers boil it for their own ease (commonly observed in developing countries). Some of these mutagens are carcinogens, which act by incorporating mutations in the various proto-oncogenes and/or other quintessential genes of the cell cycle (gatekeeper, caretaker, and cell cycle checkpoints). Only limited tests are available so far for the categorization of these chemicals as mutagens. Ames test is one of them, which requires highly skilled personnel and equipment for the detection. Therefore, there is a need to build a handy and cost effective kit for the detection of mutagens in the environment, which will significantly help in formulating preventive strategies against exposure from harmful chemicals. This approach could help in lowering the prevalence of cancer and various other diseases.

DISASTER MANAGEMENT AND BIOLOGICAL WARFARE

History has witnessed the impact of human made disasters on earth. The nuclear bomb explosions on Hiroshima and Nagasaki and its aftermath is one of the examples among many where all the forms of life were exposed to radioactivity and their progenies are still paying the price. Similarly, the Bhopal gas tragedy (Bhopal Disaster, 2011), Chernobyl tragedy (Chernobyl Tragedy, 2011), and various other accidental radioactive leakages and spillage are the examples of how acute the consequences could be after their exposure. However, the subtle effects of harmful chemicals could be even more damaging because their impacts are not perceptible during the short duration in which they are actively engaged in transforming some ecological homeostasis and which ultimately results in disaster. The green house effect and global warming are the best examples of this. In addition to that, the resistance in the various strains of virulent and non-virulent micro-organisms could be involved in shifting the disposition of ecological temperament, which is solely due to the various forms of pollution generated by humans. Therefore, effective measures should be taken in assessing the homeostatic balance of the ecology for which a thorough knowledge of flaura and fauna in certain ecosystem is desired. Any shift in these life forms should be scrutinized to see its ultimate effect on the environment, and preventive measures should be adopted in time to avoid any disasters.

CONCLUSION

Pharmacoinformatics is an applied discipline dealing with the application of IT and computer science in the field of drug discovery as well as patient care with special emphasis on various aspects regarding drugs. There are no clear cut boundaries defined for Pharmacoinformatics. It integrates diverse disciplines like bioinformatics and chemoinformatics, along with other well-developed pharmaceutical disciplines like pharmacology. By utilizing pharmacoinformatics, a swifter and strategically accurate approach can be carried out to solve the hazards of inaccurate drug dosage and its affect on environment causing slow and long damage to food chain and different species. We propose PEcM as a new branch in life sciences to study the interaction of drugs with different species and ecosystems, and the guidelines that should be adopted to avoid their harmful effects. It is a connecting link between the significant branches of life sciences. The necessity of PEcM cannot be ruled out in view of increasing incidents of infectious diseases and environmental pollution. When combined with applied medical and biological sciences, it could be a topic of urgent discussion. It covers the causes of epidemics and infections, their fatal effects on environment including human health hazards and environmental pollution. To minimize or to eradicate these harmful effects, PEcM can be an imperative tool for applied medicine and life sciences to discuss the present guidelines for dealing with infectious diseases and/or designing new ones for better treatment so that an environmental balance could be maintained. There is an urgent need for Pharmacologists, Microbiologists, Ecologists, Environmentalogists, Biochemists, Physiologists, and Epidemiologists to come on a single platform and discuss this burning issue to find better solutions with applicable guidelines and to develop new tools for laboratories.

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