



The Changing Face of Therapeutics- The Relevance

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Editorial

Change is the law of life. The landscape of disease management in India has been undergoing significant changes due to various factors, including technological advancements, policy initiatives, and the evolving nature of health challenges.

Changing Spectrum of Diseases

The spectrum of diseases is changing significantly due to various factors such as climate change, global mobility, and shifts in socioeconomic conditions. Climate change is a critical factor driving the spread of infectious diseases. Rising temperatures and changing precipitation patterns are expanding the habitats of vectors like mosquitoes, which transmit diseases such as malaria, dengue, and Zika. Increased international travel and trade facilitate the rapid spread of diseases across borders. Urbanization and migration also play roles in altering disease dynamics, as dense populations and poor living conditions in urban areas can exacerbate the spread of infectious diseases. Economic development and changes in social conditions can impact disease patterns. Improved healthcare access and vaccination programs have reduced the incidence of some infectious diseases. New diseases continue to emerge due to factors such as deforestation, wildlife trade, and climate change. Moreover, previously controlled diseases are re-emerging in new areas.

Several diseases have been eradicated or are on the verge of eradication, thanks to extensive global health initiatives and advancements in medicine. Smallpox is the only human disease that has been completely eradicated. The World

Health Organization (WHO) declared smallpox eradicated worldwide. This success was achieved through a global vaccination campaign. Polio has been eradicated from most parts of the world, including the Americas, Europe, Southeast Asia, and the Western Pacific. The development of the polio vaccine in the 1950s played a crucial role in controlling the disease.

The emergence of new diseases continues to be a significant public health concern, driven by various factors such as environmental changes, human behavior, and microbial evolution. Lifestyle diseases are becoming more common.

The Changing Face of Therapeutics

Diagnosis, prevention, management and treatment of acute and chronic medical conditions have improved with technological advancements in terms of scalability, efficacy, access, and personalized approach [1].

The pharmaceutical and biotechnology industries spend billions on cutting - edge research and development (R & D), clinical trials and marketing to introduce drugs to market. However, fewer than 1 in 50 drug discovery projects or may be less results in the delivery of a drug to market, and the average time from concept to market is around 10-15 years, at a cost of nearly a billion dollars per drug.

Emphasis is always on discovering more and more safe and effective drugs. Several drugs have become obsolete or discontinued in recent years due to various reasons, including advancements in medical research, safety concerns, and availability of more effective treatments. Few examples:

Boceprevir: This drug, used for treating hepatitis C, was discontinued as more effective treatments became available. (Initially approved for use in 2012, it was withdrawn in 2015) [2].

Abciximab: A platelet aggregation inhibitor used in certain cardiac procedures, its use is reduced due to the development of newer antiplatelet agents like clopidogrel, ticagrelor, Cangrelor etc.

Cimetidine: Used for treating ulcers and gastroesophageal reflux disease (GERD), it has been replaced by newer proton pump inhibitors (rabeprazole, pantoprazole etc.) with better safety profiles.

Several drugs are withdrawn from market due to safety reasons. Rofecoxib (Vioxx) 2004, withdrawn due to risk of myocardial infarction, Avandia (rosiglitazone) was an oral antidiabetic medication used to treat type 2 diabetes. It came under scrutiny due to safety concerns related to an increased risk of cardiovascular events. Propulsid (cisapride) was a medication used to treat gastrointestinal disorders such as gastroesophageal reflux disease (GERD). It was withdrawn from the market in 2000 due to safety concerns regarding serious cardiac arrhythmias [3]. Nimesulide is used to treat pain and dysmenorrhea. Due to concerns about the risk of liver toxicity, nimesulide has been withdrawn from the market in several countries such as Mexico, Spain, Finland, Belgium, and Ireland. Nimesulide in the US is available for adult use only.

Need for Newer and Newer Drugs

Despite of huge advances and achievements of last 100 years in drug development, the need to discover drugs which are more safe and effective drugs for existing and evolving disease has also increased. This is primarily due to

1. Most of the time treatment only leads to symptomatic relief and may associated with undesirable side effects.
2. In infectious disease due to irrational usage of drug may lead to development of resistance, making existing drugs ineffective.
3. Appearance of newer infections like SARS COVID, N1N1, newer variants of existing infections.
4. Changing environmental factors, increasing sedentary lifestyle, increased lifespan and emergence of psychosocial disorders.
5. Nutritional deficiencies due to change in eating patterns and more consumption of preserved food.
6. Increasing knowledge about patho-physiology of disease enabling discovery of more selective and less toxic drugs.
7. Progress in molecular biology helps in understanding new targets that may lead to discovery of highly selective and efficacious medicine.

8. Health care spending is also increased.
9. Changing market dynamics.
10. Availability of newer technologies on drug discovery such as pharmacogenomics & toxicogenomic, proteomics, bioinformatics and data-mining technologist, combinational chemistry and high-throughput screening, structured base drug design, virtual screening, NMR, X Ray and mass spectroscopic techniques.

Approval of Newer Drugs

Many new drugs were approved by regulatory agencies like USFDA, EMA, DCGI which are safe and effective. In 2023, CDER approved 55 new drugs never before approved or marketed in the U.S. examples sotagliflozin (approved to treat heart failure), lecanemab-irmb (To treat Alzheimer's disease), bexagliflozin (To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise), daprodustat (To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months), zavegepant (To treat migraine), perfluorhexyloctane (To treat signs and symptoms of dry eye disease). Many drugs under verge of approval, many are in the pipeline [4]. In 2024, USFDA approved several drugs, deuruxolitinib for severe alopecia areata, ensifentrine for chronic obstructive pulmonary disease, elafibranor for primary biliary cholangitis in combination with ursodeoxycholic acid.

Dramatic Change in Management Various Disease Example to Quote Diabetes

In management of diabetes, lots of new drugs are entre into market with better safety and efficacy profile. The advent of two new classes of anti-hyperglycemic agents, the sodium-glucose cotransporter-2 inhibitors (SGLT2-i) and the glucagon-like peptide-1 receptor agonists (GLP-1 RA), and their respective large cardiovascular outcome trials, has led to a paradigm shift in how cardiologists and health care practitioners conceptualize T2D treatment. Introduction on once-a-week GLP1 agonist, once a week DPP4Is, once a week insulin, oral insulin, inhalation insulin continuously changing the dynamics of diabetes management [5]. Similar changes are occurring in various therapeutic areas like cardiovascular segment, neuropsychiatry, oncology, respiratory, Gastrointestinal, ophthalmology and immunology.

Conclusion

The landscape of drug development and clinical trials has undergone significant transformations in recent years, driven by advances in technology, regulatory changes, changing disease patterns, evolving healthcare needs. More and more safe and effective drugs are available for treatment. The usage of certain drugs like digoxin, Crystalline Penicillin, Sulfa

group of antibiotics were reduced drastically. Development of new vaccines to control various infectious disease totally change the landscape. Introduction artificial Intelligence and machine Learning in drug discovery, Genomics and Personalized Medicine will play a key role in the Changing Face of Therapeutics [6-10].

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