



Personalized Medicine: Need of an Hour in Global Healthcare

H. Y. Mahakalkar*¹, H. L. Tare², N. S. Deshmukh², S. R. Chaudhari³, R. A. Sawale³, B. V. Udugade⁴

1. Trimurti Shikshan Prasarak Mandal's Trimurti Institute of Pharmacy, Jalgaon, M.S., India.

2. Amrutvahini Sheti and Shikshan Vikas Sanstha's Amrutvahini College of Pharmacy, Sangamner, Savitribai Phule Pune University, M.S., India.

3. KJ's Educational Institute's Trinity College of Pharmacy, Pune, M.S., India.

4. Dnyanganga Education Society's Mandesh Institute of Pharmaceutical Science and Research Center, Mhaswad, Tal. Man, Dist. Satara, M.S., India.

Email- harshaltare51@gmail.com

ABSTRACT

Healthcare stakeholders providers, governments, payers, consumers, and other companies struggling to manage clinical, operational, and financial challenges envision a future in which new business and care delivery models, aided by digital technologies, may help to solve today's problems and to build as the sustainable foundation for affordable, accessible, high-quality healthcare. This article reviews the Healthcare facility, public health, social services, and other sectors typically function and are funded with different funding requirements and often incompatible data collection and information systems.

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INTRODUCTION

Growing health care costs, changing patient demographics, Evolving consumer expectations and complex health and technology ecosystems. The challenges before the global health care sector are plenty. But so are the opportunities. As health care sector stakeholders prepare their road map for the future, they need to have a panoramic view of what's working and what's not, what's redundant, and what's hot in their circles.[1-3]

FINANCIAL OPERATIONS AND PERFORMANCE IMPROVEMENT.

Many of the world's health systems are struggling financially due to an increasing number of people with chronic illnesses; expensive infrastructure and medical technology; rising labor costs and staff shortages; and other factors.

Care model innovation.

Pressures on health care's traditional break-fix model to change—to become more proactive, predictive, and focused on well-being—are coming from multiple directions, including a shift in attitudes and behaviors toward greater consumer engagement and empowerment. No longer are passive participants in their health care, consumers demanding transparency, convenience, access, and personalized products and services— similar to other aspects of their lives. It is, therefore, important for health systems to morph their strategies accordingly.

Presently, Healthcare has become one of India's largest sectors (in terms of revenue and employment). Indian healthcare delivery system is categorized into two major components:

(1) Public

(2) Private

1. Public sector

The Government, i.e. public healthcare system comprises limited secondary and tertiary care institutions in key cities and focuses on providing basic healthcare facilities in the form of primary healthcare centers (PHCs) in rural areas. [4-6]

2. Private sector

The private sector provides the majority of secondary, tertiary and quaternary care institutions with a major concentration in metros, Tier I and Tier-II cities. India's competitive advantage lies in its large pool of well-trained medical professionals. India is also cost\ competitive compared to its peers in Asia and Western countries. The cost of surgery in India is about one-tenth of that in the US or Western Europe.

Social determinants of health include factors like socioeconomic status, education, neighborhood and physical environment, employment, and social support networks, as well as access to health care, including income, education, and housing conditions. Addressing social determinants of health is important for improving health and reducing longstanding disparities in health and health care that are often rooted in social and economic disadvantages.[7-9]

CREATING FINANCIAL SUSTAINABILITY IN AN UNCERTAIN HEALTH ECONOMY

The emergence of personalized medicine, exponential technologies, disruptive competitors, expanded delivery sites, and revamped payment models are injecting uncertainty into the global health economy and increasing the urgency for organizations to plan when and how to make future moves as a market leader, fast follower, or niche player to remain relevant and financially viable.

Battling health system cost pressures

Global health care expenditures continue to escalate, shining a light on health systems' need to reduce costs and increase efficiency. Spending is projected to increase at an annual rate of 5.4 percent in 2017–2022, from USD 7.724 trillion to \$10.059 trillion (figure 3), although cost-containment efforts combined with faster economic growth should maintain the share of GDP devoted to health care at around 10.4 percent over the five years to 2022.

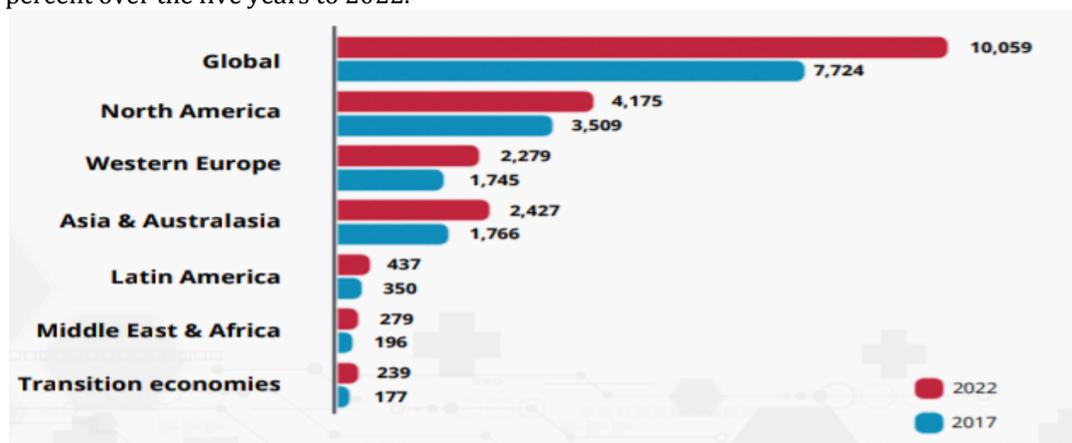


Fig. 1: Health care spending and CAGR 2017-2022

Similar to recent years, health care spending in 2019 will likely be driven by the shared factors of aging and growing populations, developing market expansion, clinical and technology advances, and rising labor costs. Still, the short-term outlook for health care spending is expected to vary by region:

- Population aging, rising wealth, and the expansion of China's health care system will likely drive increased spending in that country, as will the rollout of a new health insurance program in India.
- The United Kingdom's economy and health care spending could be dampened by its decision to leave the European Union (EU) in 2019.
- European Union health economies also may be negatively affected by "Brexit," as well as the long-running migration crisis. (32–34)

Competing with disruptive market entrants

Health care profits have been eroding over time and, in parallel, new entrants are threatening to redefine fundamental aspects of the health care business. The health technology sector is expected to reach \$280.25 billion by 2021, at a CAGR of 15.9 percent between 2016 and 2021-22 among initiatives by top technology companies to disrupt the health care sector.

Pursuing mergers, acquisitions, and partnering

Some health care organizations looking to optimize financial and operational performance continue to turn to mergers, acquisitions, and partnering to add capabilities and build scale. In other deals, Singapore-based Luye Medical Group, which owns 53 health care facilities across 26 cities in Singapore, Australia,

South Korea, and China, completed a majority equity investment in Singapore's Novena Heart Centre (NHC), which will enable Luye to cater to the rising demand for cardiovascular treatment. The search for alternative revenue sources is propelling vertical industry integration as well.

Stakeholder considerations

Shrinking margins and rising costs are driving public and private health systems to use technology innovations and other partnering arrangements to improve operational efficiencies and reduce expenses; however, doing so can be complicated by price controls, misaligned incentives, and disruptive market entrants. Yet there are ways to shape a more positive fiscal future. Governments that leverage private sector strengths in cost-efficient operations, through public-private partnerships and other collaborations, could help bolster underfunded and/or underperforming public health systems. Health plans that focus on affordability and create differentiation through innovation (i.e., member-focused digital service offerings) could reduce the cost of care provided to members and maintain strong margins. Health care providers that stress rigorous financial management, efficient operational performance, outcomes-based care, and innovative solutions development could improve care provision, reduce costs, counter declining margins.

Shifting health focus

Aging populations and the rise of non-communicable diseases are driving and industry shifts away from curing disease in the short term toward preventing and managing disease and promoting overall well-being in the long term. An important part of this approach is addressing the social determinants of health—the conditions in which people are born, grow, live, work, and age—because they often have a greater impact on health outcomes than does health care. Health care, public health, social services, and other sectors typically function and are funded in silos, with different funding requirements and often-incompatible data collection and information systems.

OUTPATIENT CARE

Ambulatory care or outpatient care is medical care provided on an outpatient basis, including diagnosis, observation, consultation, treatment, intervention, and rehabilitation services. This care can include advanced medical technology and procedures even when provided outside of hospitals.

Types of outpatient care

Emergency departments

Also known as emergency rooms which provide a broad range of emergency services to higher-acuity patients

Primary care clinics

These are settings where patients are seen by their primary care physicians (PCPs).

Retail clinics

Also known as convenient care clinics, these are walk-in clinics offering preventive health service and treatment for uncomplicated illnesses.

Typically offer primary care services to patients with limited access to health care, including homeless individuals or migrants, and patients with low income or no health insurance.

Urgent care centers

Facilities that provide medical services to patients needing immediate care for certain lower-acuity illnesses and injuries that do not require a trip to an emergency department

Ambulatory surgery centers (ASC)

Facilities that specialize in the same-day discharge of patients post-surgery and ASCs can be either hospital-associated or freestanding.

Specialized outpatient clinics

Facilities for providing care in specialty areas such as cardiology and urology, among others.

Imaging service facilities

Facilities where imaging services such as X-rays, MRIs, CT scans and ultrasounds are performed.[10-12]

There are six segments through which the Indian Healthcare market operates.

1. Hospitals
2. Pharmaceutical
3. Diagnostics
4. Medical Equipment & Supplies
5. Medical Insurance
6. Telemedicine

1. Hospitals

It consists of Government and Private Hospitals. Government hospitals: It includes healthcare centers, district hospitals, and general hospitals. Private hospitals – It includes nursing homes, and mid-tier and top-tier private hospitals.

2. Pharmaceutical.

Includes manufacturing, extraction, processing, purification and packaging of chemical materials for use as medications for humans or animals.

3. Diagnostics.

It comprises businesses and laboratories that offer analytical or diagnostic services, including body fluid analysis.

4. Medical Equipment & Supplies.

It includes the establishment's primarily manufacturing medical equipment and supplies, e.g. surgical, dental, orthopedic, ophthalmologic, laboratory instruments, etc.

5. Medical Insurance.

It includes health insurance and medical reimbursement facility, covering an individual's hospitalization expenses incurred due to sickness.

6. Telemedicine.

Telemedicine has enormous potential in meeting the challenges of healthcare delivery to rural and remote areas besides several other applications in education, training and management in the health sector. [13-14]

GLOBAL MORTALITY AND PERSONALIZED MEDICINE

The Global Burden of Disease (GBD) study, last conducted in 2015, regularly assesses mortality and disability from major diseases and external causes. It also assesses risk factors. A considerable number of personalized medicines are approved in the field of oncology. Cancers (malignant neoplasm) are among the top five causes of death worldwide (Figure 2). The only application of a PM drug affecting cardiovascular diseases, the leading cause of deaths in high and middle-income countries, is the use of lomitapide to treat homozygous familial hypercholesterolemia, a rare metabolic disorder that is an underlying cause of early cardiovascular death. No personalized medicines are used to treat infectious diseases, except for the HIV drugs abacavir and maraviroc. Before abacavir use, a companion test for a severe side-effect, the potentially life-threatening hypersensitivity reaction, is recommended in the drug label by the US Federal Drug Agency and required in Germany. Side-effects are expected in 48-61% of those who carry the HLA-B*5701 allele. The prevalence of the HLA-B*5701 allele genotype varies across ethnicities and appears to be low in some of the populations with a high HIV burden. WHO recommends abacavir as the preferred HIV treatment in children and, as hypersensitivity reaction remains rare, suggests that appropriately trained clinical staff should manage patients clinically where HLA-B*5701 screening is not feasible. Maraviroc, which may be used to treat a subgroup of people living with CCR5-tropic HIV, is not included in current WHO guidelines for treating and preventing HIV infection. Other major causes of death, as listed but not underlined in Figure 2, contain no indications for the drugs considered personalized medicines by the vfa. Concerning tuberculosis (TB), it is worth noting that individualizing drug therapy through drug-susceptibility testing plays a key role in large scale treatment of drug-resistant TB. Drug-susceptibility testing can, and increasingly does, involve genetic or molecular diagnostics of pathogens to better target drug therapies, but is not considered PM, in a narrow sense, because knowledge about the pathogen rather than about the person is used to improve health.

APPLICATIONS OF PERSONALIZED MEDICINE

- Personalizing treatment can help improve pharmacotherapy when the result of a biomarker test allows predicting treatment success.
- The occurrence of severe adverse drug effects with reasonable certainty.
- Based on the test result, a drug is then only given to the subgroup of patients for which it is expected to be beneficial.
- A biomarker test before drug use is currently either mandatory or recommended for 51 substances approved in Germany.
- The German Association of Research-based Pharmaceutical Companies (vfa) classifies drug substances, for which biomarker pre-testing is required or recommended in the German prescribing information or guidelines, as "personalized medicines"
- This group of substances is discussed throughout the article as there is no universal classification of personalized medicines
- More than three of four personalized medicines have applications in the field of oncology.

- Specific indications are breast cancer, lung cancer, leukemias, melanoma, colorectal cancer, stomach cancer, ovarian cancer, lymphoma and thyroid cancer.
- Other areas of PM applications are metabolic disorders, immunosuppression, and treatment of HIV or epilepsy.
- For 45 of the 51 PM drugs, the pre-tests examine biomarkers that correlate with a drug's efficacy.
- 5 of the 51 PM drugs, the pre-test examines a biomarker correlating with adverse drug effects.
- Testing for adverse drug effects is rarely mandatory (one of five PM drugs) whereas testing for drug efficacy usually is a required diagnostic step

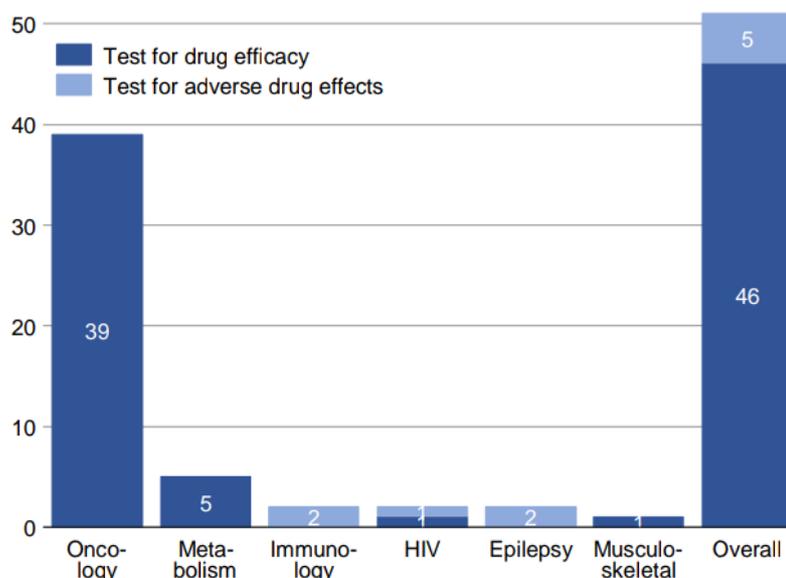


Fig. 2: Personalized medicines in Germany by area of application in 2017.

CONCLUSION

A complex approach combining the diverse biological levels DNA, RNA, and protein, maybe compulsory to functionally classify diseases. This appears to become a major challenge for diagnostic pathologists. Due to constant technological growth and new approaching into the high complication of a lot of diseases, molecular pathology is a quickly rising field fast middle phase in the clinical management of diseases as well as in the pharmaceutical development of new anti-cancer drugs. The application of novel compounds in clinical trials has revealed promising results; however, the current diagnostic procedures available for determining which patients will primarily benefit from rational tumor therapy are insufficient. To read a patient's tissue as "deeply" as possible, in the future, gaining information on the morphology and genetic, proteomic, and epigenetic alterations will be the upcoming task of surgical pathologists experienced in molecular diagnostics to provide the clinicians with information relevant for individualized medicine. This review will surely give an insight into aspects of personalized medicines.

REFERENCES

1. Ross J. (2020). The Growing Medication Problem: Perspective from Industry. In *Personalized and Precision Medicine Informatics*. (pp. 81-83). Springer, Cham.
2. Iyer A, Stein L, Franklin ES. (2020). Bettering healthcare outcomes through environmental design. In *Clinical Engineering Handbook*, 1 (pp. 852-857). Academic Press.
3. Alvarnas JC. (2020). Healthcare Perspective. In *Oncology in the Precision Medicine Era* (pp. 1-12). Springer, Cham.
4. Veet CA, Radomski TR, D'Avella C, Hernandez I, Wessel C, Swart EC, Shrank WH, Parekh N. (2020). Impact of Healthcare Delivery System Type on Clinical, Utilization, and Cost Outcomes of Patient-Centered Medical Homes: a Systematic Review. *Journal of General Internal Medicine*. 6:1-9.
5. Bahuguna P, Guinness L, Sharma S, Chauhan AS, Downey L, Prinja S. (2020). Estimating the Unit Costs of Healthcare Service Delivery in India: Addressing Information Gaps for Price Setting and Health Technology Assessment. *Applied Health Economics and Health Policy*. 14:1-3.
6. Kumar A, Vashist P.(2020). Indian community eye care in 2020: Achievements and challenges. *Indian Journal of Ophthalmology*. 68(2):291.
7. Alsaedi SA, Altalhi AA, Nabrawi MF, Aldainy AA, Wali RM. (2020). Prevalence and risk factors of gestational diabetes mellitus among pregnant patients visiting National Guard primary health care centers in Saudi Arabia.

- Saudi Medical Journal. 1;41(2):144-51.
8. Rao GN. (2020). Universal health care: Can Indian ophthalmologist community set an example?. *Indian Journal of Ophthalmology*. 68(2):281.
 9. Renovanz M, Hippler M, Voss M, Wehinger J, Keßler AF, Gempt J, Nadji-Ohl M, Lucas CW, Rapp M, Misch M, Coburger J. (2020). Study Protocol Glioma patients in outpatient care-Optimization of psychosocial care in neuro-oncological patients (GLIOPT): study protocol of a multicenter cluster randomized controlled trial. *Trials*, 434.
 10. Materniak S, Bland S, Margeson A, Webster D, Smyth D, O'Brien M.(2020). Differences among hepatitis C patients seen in community and specialist outpatient care settings. *Canadian Liver Journal*. 29:e20190003.
 11. Mehrotra A, Ray K, Brockmeyer DM, Barnett ML, Bender JA. (2020). Rapidly Converting to “Virtual Practices”: Outpatient Care in the Era of Covid-19. *NEJM Catalyst Innovations in Care Delivery*. 2020 1;1(2).
 12. Tian H, Yang W, Hu Y, Liu Z, Chen L, Lei L, Zhang F, Cai F, Xu H, Liu M, Guo C. (2020). Estimating cancer incidence based on claims data from medical insurance systems in two areas lacking cancer registries in China. *EclinicalMedicine*. ;20:100312.
 13. Ma M, Li Y, Wang N, Wu Q, Shan L, Jiao M, Fu X, Li H, Sun T, Yi B, Tian W. (2020). Does the medical insurance system really achieved the effect of poverty alleviation for the middle-aged and elderly people in China? Characteristics of vulnerable groups and failure links. *BMC Public Health*.20:1-5.
 14. Sidonio Jr RF, Zia A, Fallaize D. (2020). Potential Undiagnosed VWD Or Other Mucocutaneous Bleeding Disorder Cases Estimated From Private Medical Insurance Claims. *Journal of Blood Medicine*. 11:1.

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